# Michigan Medicaid Clinical and PDL Criteria

**Version: May 1, 2025v3**

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## ACCUTANE® (*ISOTRETINOIN*)

**Length of Authorization:** As determined by diagnosis

- **For qualifying diagnoses related to acne**: Maximum of 2 months; renewal for a total of five consecutive months of treatment / manufacturer, off for 2 months.
- **For all other qualifying diagnoses**: 6 months.

### DIAGNOSIS TO APPROVE

- Severe disfiguring cystic acne unresponsive to other covered treatments
- Severe acne unresponsive to other covered treatment
- Darier – White disease (keratosis follicularis)
- Neuroblastoma – adrenal, cancer, lesions
- Psoriasis – unresponsive to other covered treatment, must be prescribed by dermatologist
- Lamellar ichthyosis
- Epidermolysis bullosa
- Pityriasis rubra pilaris
- Keratosis palmaris et plantaris
- Rosacea
- Mycosis fungoides
- Leukoplakia

## ACZONE® (*DAPSONE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Six-week trial on a benzoyl peroxide or retinoid product; **OR**
- Allergy/adverse reaction to benzoyl peroxide or retinoid

## ALLERGY: ANTIHISTAMINES – 2ND GENERATION

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure on one preferred second-generation antihistamine or clinical rationale why they cannot be tried

## ALLERGY: LEUKOTRIENE INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one month with one preferred medication

#### **MONTELUKAST** (SINGULAIR®)

- Clinical rationale why the (swallow) tablet dosage form is inappropriate for the following age limits:
  - 4mg chew tabs – prior authorization (PA) required for patients > 5
  - 5mg chew tabs – PA required for patients > 14
  - Granules – PA required for patients >5; Requests for granules for patients <5 years may bypass PDL criteria if the patient is unable to chew or swallow a tablet.

## ALLERGY: NASAL ANTIHISTAMINES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure on one preferred medication

## ALLERGY: NASAL CORTICOSTEROIDS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with a preferred medication

#### XHANCE® (FLUTICASONE)

- Diagnosis of chronic rhinosinusitis with or without nasal polyps in adults; **AND**
- Therapeutic failure with a three-month trial with a preferred medication

## ALLERGY: COMBINATION NASAL SPRAYS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- 1 month trial and failure of one preferred nasal antihistamine; **AND**
- 1 month trial and failure of one preferred nasal corticosteroid

## ALPHA-1-PROTEINASE INHIBITORS

**Length of Authorization:** According to the prescribing physician's length of treatment; maximum 12 months

### DIAGNOSIS TO APPROVE

- Congenital alpha-1-antitrypsin deficiency

## ALVAIZ® (ELTROMBOPAG)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Diagnosis of persistent or chronic immune thrombocytopenia (ITP); **AND**
  - Patient is 6 years of age or older; **AND**
  - Prescriber attests that patient had an insufficient response to corticosteroids, immunoglobulins, or splenectomy; AND
  - Must be prescribed by or in consultation with a hematologist or oncologist; **OR**
- Diagnosis of chronic hepatitis C-associated thrombocytopenia; **AND**
  - Patient is 18 years of age or older; AND
  - Prescriber attests that patient is unable to start or maintain interferon-based therapy due to thrombocytopenia; AND
  - Must be prescribed by or in consultation with prescriber specializing in infectious disease, gastroenterology, or hepatology; **OR**
- Diagnosis of severe aplastic anemia; **AND**
  - Patient is 18 years of age or older; **AND**
  - Prescriber attests that patient had an insufficient response to immunosuppressive therapy; **AND**
  - Must be prescribed by or in consultation with a hematologist or oncologist

#### RENEWAL REQUESTS

- Prescriber attests that the patient is demonstrating a beneficial clinical response

## AMONDYS 45® *(CASIMERSEN)*

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for home administration will require MDHHS review and must specifically indicate that the medication will be home infused (versus being infused in an office/clinic/infusion center setting).
- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## AMZEEQ® (*MINOCYCLINE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age: ≥9 years of age; **AND**
- Patient has diagnosis of non-nodular moderate to severe acne vulgaris

## ANADROL® (OXYMETHOLONE)

**Length of Authorization:** Initial = 3 months; renewals = 1 year

### DIAGNOSIS TO APPROVE

- Anemias caused by deficient red cell production, acquired or congenital; **OR**
- Aplastic anemia; **OR**
- Myelofibrosis; **OR**
- Hypoplastic anemias; **OR**
- Hereditary angioedema; **OR**
- Metastatic breast cancer

## ANALGESICS: OPIOIDS - LONG ACTING

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 6 months for Zohydro® ER; 1 year for all other medications

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**

  Therapeutic failure of one week with one preferred medication
- See additional medication-specific criteria below:

#### BELBUCA® (BUPRENORPHINE FILMS)

- Diagnosis of moderate to severe chronic pain requiring around the clock opioid analgesia; **AND**
- Patient ≥ 18 years old

#### TRAMADOL-CONTAINING PRODUCTS – MINIMUM AGE 12 YEARS

- Effective 11/1/2022, claims submitted for tramadol-containing products for patients less than 12 years of age will deny for prior authorization.

### QUANTITY LIMITS

| | |
|---|---|
| Belbuca® *(buprenorphine)* | 60 per 30 days |
| Oxycontin® ER 10mg *(oxycodone-controlled release tab)* | 180 per 30 days |
| Oxycontin® ER 15mg (*oxycodone-controlled release tab*) | 120 per 30 days |
| Oxycontin®ER 20 mg (*oxycodone-controlled release tab*) | 90 per 30 days |
| Oxycontin®ER 30mg (*oxycodone-controlled release tab*) | 60 per 30 days |
| Oxycontin® ER 40mg (*oxycodone-controlled release tab*) | 45 per 30 days |
| Oxycontin® ER 60mg (*oxycodone-controlled release tab*) | 30 per 30 days |
| Oxycontin® ER 80mg (*oxycodone-controlled release tab*) | 22 per 30 days |

## ANALGESICS: OPIOIDS - SHORT AND INTERMEDIATE ACTING

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 14 days for Adapaz®; 1 year for all other medications |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**

  Therapeutic failure of one week each with two preferred medications
- See additional medication-specific criteria below:

#### SHORT ACTING NARCOTIC 7-DAY LIMIT

- Effective 9/5/18, claims submitted for short acting narcotics for more than a 7-day supply for opioid naïve patients (i.e., those with no claim for an opioid medication within the past 180 days) will deny for prior authorization.

#### CODEINE-CONTAINING AND TRAMADOL-CONTAINING PRODUCTS – MINIMUM AGE 12 YEARS

- Effective 11/1/2022, claims submitted for codeine-containing and tramadol-containing products for patients less than 12 years of age will deny for prior authorization.

#### FENTANYL – ORAL *(ACTIQ®, FENTORA®)*

- Management of breakthrough cancer pain in patients established on immediate release and long-acting opioid therapy; **AND**
- Requests for controlled substances must be under the name and ID of the prescribing physician; **AND**
  - 18 years of age; **AND**
- Medication must be prescribed by a physician who is experienced in the use of Schedule II opioids; **AND**
- Current dosage regimen of the long acting and regularly prescribed immediate release narcotics must be maximally optimized; **AND**
- No concomitant use of other inducers of cytochrome P450; **AND**
- No concomitant use of other inhibitors of cytochrome P450

#### ROXYBOND® *(OXYCODONE)* TABLETS

- PDL criteria may be bypassed to allow coverage if an abuse deterrent formulation is needed

#### TRAMADOL ORAL SOLUTION *(QDOLO®)*

- Patient age is 12 years and older; **AND**
- Allow if patient has difficulty swallowing tablets
- Quantity limit = 80 ml per day (400mg/day)

## QUANTITY LIMITS

| | |
|---|---|
| ACTIQ – all strengths | 120 units per 30 days |
| BUTORPHANOL 10MG/ML NASAL SPRAY | 15 mL per 30 days |
| CODEINE SULFATE 15 MG TAB | 180 per 30 days |
| CODEINE SULFATE 30MG TAB | 180 per 30 days |
| CODEINE SULFATE 30 MG/5ML SOLN | 240ml per 30 days |
| CODEINE SULFATE 60 MG TAB | 180 per 30 days |
| FENTORA – all strengths | 120 every 24 days |
| HYDROMORPHONE HCL 1 MG/ML ORAL CONC | 120ml per 30 days |
| HYDROMORPHONE HCL 2MG TAB | 180 per 30 days |
| HYDROMORPHONE HCL 4MG TAB | 165 per 30 days |
| HYDROMORPHONE HCL 8MG TAB | 84 per 30 days |
| MEPERIDINE HCL 50MG TAB | 120 per 30 days |
| MEPERIDINE HCL 50 MG/5ML SOLN | 240ml per 30 days |
| MORPHINE SULFATE 10 MG /5ML SOLN | 240ml per 30 days |
| MORPHINE SULFATE 100 MG/5ML SOLN | 120 per 30 days |
| MORPHINE SULFATE 100 MG/5ML ORAL SYRINGE | 120 per 30 days |
| MORPHINE SULFATE 15 MG TAB | 180 per 30 days |
| MORPHINE SULFATE 20 MG/5ML SOLN | 240ml per 30 days |
| MORPHINE SULFATE 30 MG TAB | 90 per 30 days |
| OXYCODONE HCL 5 MG CAP | 90 per 30 days |
| OXYCODONE HCL 5MG TAB | 90 per 30 days |
| OXYCODONE HCL 5MG/5ML SOLN | 240ml per 30 days |
| OXYCODONE HCL 20MG/ML SOLN | 90ml per 30 days |
| OXYCODONE HCL 10MG TAB | 90 per 30 days |
| OXYCODONE HCL 15 MG TAB | 90 per 30 days |
| OXYCODONE HCL 20 MG TAB | 90 per 30 days |
| OXYCODONE HCL 30 MG TAB | 60 per 30 days |
| OXYMORPHONE HCL 5MG TAB | 120 per 30 days |
| OXYMORPHONE HCL 10MG TAB | 90 per 30 days |

# ANALGESICS: OPIOIDS - TRANSDERMAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

## CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one week with the preferred medication

## QUANTITY LIMITS

| | |
|---|---|
| Butrans® *(buprenorphine patch)* | 6 per 28 days |
| fentanyl patch (Duragesic®) | 10 per fill |

## ANALGESICS: CHRONIC OPIOID MANAGEMENT WITH HIGH MME

| | |
|---|---|
| **Length of Authorization:** | Date-of-service (to allow for 7-day supply) for pharmacy requests; 1 year if criteria met) or to be determined by MDHHS for prescriber requests |

**General Instructions:**
Michigan Medicaid recognizes that certain patients will require chronic opioid use at doses higher than the CDC recommendation. In an effort to improve opioid prescribing practices to the Michigan Medicaid population, requests for chronic high dose opioids must be submitted with documentation that supports a chronic pain (pain lasting longer than three months) diagnosis that requires continued use of opioid medications. It is important that all practitioners follow best practices for prescribing chronic opioids. NOTE: A taper to reduce high MME is not always clinically appropriate.

**Best Practices for Opioid Prescribing:**

- **Multifaceted approach** to pain management which includes**:**
  - Assess patient's opioid abuse/addiction potential utilizing a validated risk assessment tool (multiple validated tools such as the Opioid Risk Tool (ORT) are available, and any template is acceptable)
  - Use of non-opioid pharmacologic treatments
  - Use of adjuvant, non-pharmacologic therapies such as weight loss, physical therapy (PT), occupational therapy (OT), and behavioral therapy
- **MAPS report** before every controlled substance prescription
- **Toxicology screens (urine or blood) at appropriate intervals**
- **Comprehensive Treatment Plan** with:
  - Discussion of possibility of tapering from high dose opioids (optimize opioids at the lowest dose for pain management while maximizing patient's ability to function)
  - Explanation of risks and benefits of long-term opioid use
  - Pain agreement that includes an informed consent, signed by patient
- Recording any **Overdose History** (prescription or illicit drugs) and the outcome
- Making **Narcan® (naloxone)** opioid overdose recovery medication available to all chronic opioid patients along with instructions on how and when to use.
  - Naloxone covered for all Michigan Medicaid beneficiaries without a prior authorization
  - Prescriptions obtained from practitioner directly or under the State of Michigan Naloxone Standing order at a participating pharmacy
  - Information about Michigan's Standing Order is available online at either www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79678---,00.html or www.michigan.gov/documents/mdhhs/Standing_Order_571880_7.pdf
- The SUPPORT for Patients and Communities Act requires state Medicaid programs to monitor concurrent prescribing of opioids and other drugs when prescribed at the same time, such as benzodiazepines.
  - Information about the CMS guidance to promote proper use of prescription opioids is available at https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf

**Submitted documentation must include:**

- Current **History and Physical with explanation of medical necessity of high MME**
- **Medication List** complete with *all* current medications including over-the-counter
- **Identification of the total daily MME of all combined opioid medications and the date that the high MME dosing regimen was initiated**
- ***Pregnant* patients** on opioids are considered high-risk patients and need to be followed by an OB/GYN whose name must be submitted with request

**References:** K. Kroenke, MD, et al. Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report. Pain Medicine, 20(4), 2019;724-735, January 2019
https://academic.oup.com/painmedicine/article/20/4/724/5301726

## CRITERIA TO APPROVE

**Initial Request:**

1. Patient has current cancer-related pain; **OR**
2. Patient has pain related to sickle cell disease; **OR**
3. Patient is in hospice or palliative care; **OR**
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS).

**If answered "Yes" to any of the above questions 1 - 4, no further information is required.**
**If answered "No" to all of the above, responses to questions 5 – 12 and supporting documentation for items 13 -17 are required.**

5. A risk assessment has been performed.
6. A Pain Medication Agreement with informed consent has been reviewed with, completed, and signed by the patient.
7. The MAPS/NarxCare report has been reviewed by the prescriber in the last 30 days. (Please ***do not*** submit the MAPS report.)
8. Concurrently-prescribed drugs have been reviewed, and based on the prescriber's assessment, the drugs and doses are deemed safe for the patient.
9. Non-opioid pain interventions have been recommended and utilized including but not limited to non-opioid medications and adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss.
10. A toxicology screen (urine or blood) from either an onsite UDS or a commercial lab has been performed at appropriate intervals and showed expected results.
11. The patient has been counseled on obtaining a Narcan (naloxone) kit and on appropriate utilization.
12. If applicable, the patient has been counseled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines, sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).
13. Submit current pain-related history and physical(s) including clinical justification supporting need for exceeding high MME.
14. Submit list of all recent non-opioid medications utilized for pain management (if none utilized, then document rationale explaining why these cannot be used).
15. Submit list of all current opioid medications (long and short-acting) and document the date that the current high MME dosing regimen was initiated. _____
16. Document the combined total daily Morphine Milligram Equivalent (MME) of all current opioid medications.
    _____MME/day
    (NOTE: Values above 90 MME trigger this high MME prior authorization).
    - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at:
        - CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR
17. If patient is currently pregnant, document the name of the OB services provider following this high-risk pregnancy.

**Renewal Requests for Continuation of Therapy if answered "No" to all of questions 1 -4:**

1. The patient must continue to meet high MME criteria
2. All required documentation must be submitted
3. Documentation of taper plan or rationale why taper is not appropriate is required

## ANALGESICS: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS) AND COX II INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | For the duration of the prescription up to 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month each with two preferred medications
- See additional medication-specific criteria below:

#### CELEBREX® (CELECOXIB)

- Therapeutic failure of a 30-day trial with two or more preferred NSAIDs and the preferred agent in the COX II Inhibitor class

#### KETOROLAC TROMETHAMINE NASAL SPRAY

- Contraindication to oral dosage forms (i.e., inability to swallow)
- Length of authorization – 30 days.

#### VIMOVO® (NAPROXEN/ESOMEPRAZOLE) AND DUEXIS®(IBUPROFEN/FAMOTIDINE)

- History of or active GI bleed/ulcer; **OR**
- Risk for bleed/ulcer; **AND**
  Therapeutic failure with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| Celebrex® *(celecoxib)* capsules | 2 per day |
| Toradol® (*ketorolac)* tablets | 21 per fill |

## ANALGESICS: OPIOID USE DISORDER TREATMENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 12 months |

### CRITERIA TO APPROVE

- Allergy to a preferred medication in this class; **OR**
- Contraindication to a preferred medication in this class; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure after a one-month trial with one of the preferred medications.

### QUANTITY LIMITS

- Oral buprenorphine maximum dose must not exceed 32 mg per day across all strengths and products
- The prescriber must provide a written explanation citing the clinical basis for the need for the higher dose.

## ANALGESICS: OPIOID WITHDRAWAL SYMPTOM MANAGEMENT

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

## ANTIBIOTICS / ANTI-INFECTIVES: ANTIFUNGALS - ORAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | For the duration of the prescription up to 6 months |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one month with one preferred medication; **OR**
- Serious illness resulting immunocompromised status; **OR**
- See additional medication-specific criteria below:

#### BREXAFEMME® (IBREXAFUNGERP)

- Diagnosis of vulvovaginal candidiasis; **OR**
- Diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VCC) in a 12-month period; **AND**
- Patient is a post-menarchal female
- Quantity Limit: Treatment = 4 tablets; Maintenance = 24 tablets
- Length of approval: Treatment = one time; Maintenance = 6 months

#### CRESEMBA® (ISAVUCONAZONIUM)

- Diagnosis of aspergillosis; **AND**
- Patient is 18 years or older; **AND**
- Trial on voriconazole/Vfend or amphotericin B - approve without trials if intolerant to prerequisite meds or renal dysfunction

#### NOXAFIL® (*POSACONAZOLE*) 300 MG SUSPENSION PACKETS

- Maximum patient age = 17 years

#### SPORANOX® (ITRACONAZOLE)

- Onychomycosis with previous failure on or contraindication to terbinafine: length of approval - toenails 12 weeks; fingernails - 6 weeks.
- Below diagnoses without previous trial:
  - Aspergillosis
  - Blastomycosis
  - Febrile neutropenia
  - Histoplasmosis

#### VFEND® (VORICONAZOLE)

- Aspergillosis – no trial/failure required

#### VIVJOA® (OTESECONAZOLE)

- Patient has diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period; **AND**
- Patient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); **AND**

- Patient has tried and failed or has a contraindication or intolerance to maintenance antifungal therapy with oral fluconazole.
- Length of approval: one time

### QUANTITY LIMITS

| | |
|---|---|
| Brexafemme® 150 mg tab *(ibrexfungerp)* | Treatment: 4 tablets<br>Maintenance: 24 tablets |
| Diflucan® 150 mg tab *(fluconazole)* | 2 per fill |
| fluconazole 150 mg tabs *(Diflucan®)* | 2 per fill |
| Lamisil® tabs *(terbinafine)* | 84 per fill |
| Sporanox® *(itraconazole) – brand & generic* | 100 mg – 100 per 30 days<br>250 mg kit – 34 per fill<br>Solution – 840 per fill |
| terbinafine tabs *(Lamisil®)* | 84 per fill |
| Vivjoa® (oteseconazole) | 18 per treatment course |

## ANTIBIOTICS / ANTI-INFECTIVES: ANTIFUNGALS TOPICAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | For the duration of the prescription up to 6 months |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with two weeks with two preferred medications; **OR**
- Organism resistant to the preferred medications
- See additional medication-specific criteria below:

#### CICLOPIROX SHAMPOO

- Bypass trial and failure of two preferred medications and instead allow a trial and failure of one preferred shampoo medication

#### JUBLIA® *(EFINACONAZOLE)*

- Diagnosis of toenail onychomycosis; and patient aged 6 years or older; and trial and failure on ciclopirox or allergy to ciclopirox

#### TAVABOROLE

- Diagnosis of toenail onychomycosis; and patient must be 6 years or older; and documented trial and failure on ciclopirox or allergy to ciclopirox

#### VUSION® *(MICONAZOLE NITRATE/ZINC OXIDE/PETROLATUM)*

- Maximum patient age = 16 years

## ANTIBIOTICS / ANTI-INFECTIVES: ANTIVIRALS - HERPES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | For the duration of the prescription up to 6 months |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure on ten days of two preferred medications

## ANTIBIOTICS / ANTI-INFECTIVES: ANTIVIRALS - INFLUENZA

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | For the duration of the prescription up to 6 months |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a five-day trial with two preferred medications

### QUANTITY LIMITS

| | |
|---|---|
| Tamiflu® and solution *(oseltamivir) – brand & generic* | Capsules – 14 per fill<br>12 mg/mL solution – 50 mL per fill<br>6 mg/mL – 120 mL per fill |

## ANTIBIOTICS / ANTI-INFECTIVES: ANTIVIRALS - TOPICAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

## ANTIBIOTICS / ANTI-INFECTIVES: CEPHALOSPORINS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Date of service

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection caused by an organism resistant to the preferred cephalosporins; **OR**
- Therapeutic failure (duration = 3 days) with any two preferred cephalosporins medications

### QUANTITY LIMITS

| | |
|---|---|
| cefaclor caps *(Ceclor®)* | 42 per fill |
| cefaclor ER tabs *(Ceclor CD®)* | 42 per fill |
| cefadroxil caps/tabs *(Duricef®)* | 28 per fill |
| cefdinir tabs *(Omnicef®)* | 28 per ill |
| cefpodoxime tabs *(Vantin®)* | 28 per fill |
| cefprozil tabs *(Cefzil®)* | 28 per fill |
| ceftibuten caps *(Cedax®)* | 14 per fill |
| cefuroxime tabs *(Ceftin®)* | 42 per fill |

## ANTIBIOTICS / ANTI-INFECTIVES: GASTROINTESTINAL ANTIBIOTICS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication
- See additional medication-specific criteria below:

#### AEMCOLO® (RIFAMYCIN) – *PDL CRITERIA DO NOT APPLY*

- Travelers' diarrhea caused by noninvasive strains of *E. coli* and age ≥ 18 years of age; **AND**
- The patient has had an inadequate response, intolerance or contraindication to azithromycin or a fluoroquinolone.
- Quantity Limit: 12 tablets
- Length of approval: 3 days

#### DIFICID® (*FIDAXOMICIN*) 40 MG/ML ORAL SUSPENSION

- Maximum patient age = 17 years

#### LIKMEZ® (METRONIDAZOLE)

- PDL criteria may be bypassed if patient is less than 12 years of age or unable to swallow tablets
- Quantity limit: 400 mL per 10 days

#### NITAZOXANIDE (ALINIA®) – *PDL CRITERIA DO NOT APPLY*

- Tablets:
  - For treatment of diarrhea caused by Cryptosporidium parvum or Giardia lamblia; AND
  - The patient has had a trial on metronidazole or a clinical reason why it cannot be tried;
  - Length of authorization = 1 month
  - Quantity limit = 6 tablets per rolling 30 days

#### XIFAXAN® (RIFAXIMIN)

- 200 mg tabs:
  - Travelers' diarrhea caused by noninvasive strains of *E. coli* and age ≥ 12 years of age (PDL criteria do not apply)
- 550 mg tabs:
  - Reduction in risk of overt hepatic encephalopathy recurrence in patients ≥ 18 years of age (PDL criteria do not apply); **OR**
  - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) in patients ≥18 years of age (PDL criteria do not apply)

## ANTIBIOTICS / ANTI-INFECTIVES: HEPATITIS C - DIRECT ACTING ANTIVIRALS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | Up to 16 weeks |

### CRITERIA TO APPROVE

- Patient is allergic to preferred medication; **OR**
- Patient had unacceptable side effects from previous trial of preferred medication; **OR**
- Patient has a contraindication to the use of preferred medication; **OR**
- Patient is on another medication that may cause a drug interaction with preferred medication; **OR**
- Patient failed on a previous course of preferred medication; **OR**
- American Association for the Study of Liver Diseases (AASLD) treatment guidelines recommend use of this PDL non-preferred drug regimen due to the patient's clinical presentation.

## ANTIBIOTICS / ANTI-INFECTIVES: HEPATITIS C INTERFERONS AND RIBAVIRIN

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication

## ANTIBIOTICS / ANTI-INFECTIVES: INHALED

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one month with one preferred medication

## ANTIBIOTICS / ANTI-INFECTIVES: MACROLIDES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | Date of service |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection caused by an organism resistant to the preferred macrolide medications; **OR**
- Therapeutic failure (duration = 3 days) with two preferred medications

### QUANTITY LIMITS

| | |
|---|---|
| azithromycin (*Zithromax®*) | 500mg – 3 per fill<br>600mg – 12 per fill<br>1g packet - 2 per fill |
| clarithromycin tabs *(Biaxin®)* | 28 per fill |

## ANTIBIOTICS / ANTI-INFECTIVES: OTIC ANTIBIOTICS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 30 days for ciprofloxacin/fluocinolone (Otovel®); 1 year for all other medications |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure (duration = 3 days) with one preferred medication

## ANTIBIOTICS / ANTI-INFECTIVES: OXAZOLIDINONES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 2 months

### CRITERIA TO APPROVE

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- See additional medication-specific criteria below:

#### SIVEXTRO® (TEDIZOLID)

For diagnosis of non-purulent cellulitis

- Trial, failure or intolerance to first line beta lactam therapy **and**
- Trial, failure or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (SMZ/TMP), tetracycline (minocycline or doxycycline) **or**
- Culture and *sensitivity* results demonstrate resistance to first line agents **or**
- Contraindication or intolerance to all other treatment options

For diagnosis of purulent cellulitis, abscess, or wound infection:

- Trial, failure or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (smx/tmp), tetracycline (minocycline or doxycycline) **or**
- Culture and sensitivity results demonstrate resistance to first line agents **or**
- Contraindication or intolerance to all other treatment options

### QUANTITY LIMITS

| | |
|---|---|
| linezolid tabs *(Zyvox®)* | 28 per fill |
| tedizolid (Sivextro®) | 14 per fill |

## ANTIBIOTICS / ANTI-INFECTIVES: QUINOLONES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | Date of service; If needed, longer lengths may be approved for transplant recipients |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection is caused by an organism that is resistant to the NO PA REQUIRED quinolone medications; **OR**
- Trial/failure (duration = 3 days) of any two preferred quinolone medications; **OR**
- Antibiotic therapy initiated in hospital
- See additional medication-specific criteria:

### MOXIFLOXACIN

- PDL criteria and quantity limit do not apply when used for the treatment of active drug-susceptible pulmonary tuberculosis for patients ≥12 years of age.
- Length of approval = 17 weeks when used for the treatment of active drug-susceptible pulmonary tuberculosis

### QUANTITY LIMITS

| | |
|---|---|
| ciprofloxacin tabs (Cipro®) | 42 per fill |
| ciprofloxacin XR (Cipro XR®) | 14 per fill |
| levofloxacin tabs (Levaquin®) | 500mg - 14 per fill<br>750mg - 28 per fill |
| moxifloxacin (Avelox®) | 14 per fill |

## ANTIBIOTICS / ANTI-INFECTIVES: TOPICAL ANTIBIOTICS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 1 year |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one month with one preferred medication; **OR**
- See additional medication-specific criteria below:

#### XEPI® *(OZENOXACIN)*

- Quantity limit = 2 tubes per month
- Length of authorization = 1 month

## ANTIBIOTICS / ANTI-INFECTIVES: VAGINAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 6 months |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication
- See additional medication-specific criteria below:

#### XACIATO® (*CLINDAMYCIN) VAGINAL GEL*

- Patient age is 12 years or older

## ANTIHEMOPHILIC FACTORS

| | |
|---|---|
| **Length of Authorization:** | • Medicare Co-pay Requests: Date of service<br>• Regular / Non-emergency Hemophilia Program Requests: Date Range = Start Date (generally the day that the request was received) + 6 days not to exceed the total number of days' supply approved<br>• Emergency Hemophilia Program Requests: Date Range = Date of Service only |

### HEMOPHILIA PROGRAM REQUESTS

- All regular / non-emergency requests must be submitted using the MDHHS – Hemophilia Case Review Form.
- A diagnosis is required to be marked by the pharmacy.
- A copy of the prescriber's order is required to be included with the care review/fax form.
- See additional medication-specific criteria below:

#### HEMLIBRA® *(EMICIZUMAB)*

- Diagnosis of Hemophilia A (congenital factor VIII disorder)
- Treatment is initiated at 3 mg/kg once weekly for 4 weeks followed by one of the following maintenance dose regimens:
    - 1.5 mg/kg weekly; **OR**
    - 3 mg/kg once every two weeks; **OR**
    - 6 mg/kg once every four weeks
- **Length of authorization = 1 year**

## ARCALYST® (*RILONACEPT*)

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Auto-Inflammatory Syndrome (FACS) and Muckle-Wells Syndrome (MWS); **OR**
- Deficiency of Interleukin-1 Receptor Antagonist; **OR**
- Pericarditis

## ARGININE

| | |
|---|---|
| **Length of Authorization:** | • U6W powder NDC submitted as a MIC claim (with approvable diagnosis): 1 year |

### DIAGNOSIS TO APPROVE

#### ARGININE DEFICIENCY

- If not compounded, then clinical rationale why the med is not being compounded AND the above diagnosis is required.

## ASPRUZYO® (*RANOLAZINE*)

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Patient is ≥18 years of age; **AND**
- Diagnosis of chronic angina; **AND**
- Therapeutic failure of generic ranolazine tablets; **OR**
- Patient has swallowing difficulties
- Quantity Limit: 60 per 30 days

## ASTHMA / COPD: ANTICHOLINERGICS – SHORT ACTING

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

### QUANTITY LIMITS

| | |
|---|---|
| Atrovent HFA (ipratropium) | 6 inhalers per 90 days |

## ASTHMA / COPD: ANTICHOLINERGICS – LONG ACTING

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 1 year |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| Incruse Ellipta (umeclidinium) | 3 inhalers per 90 days |
| Spiriva Handihaler (tiotropium) – pkg size = 5 | 1 inhaler per 5 days |
| Spiriva Handihaler (tiotropium) – pkg size = 30 | 1 inhaler per 30 days |
| Spiriva Handihaler (tiotropium) – pkg size = 90 | 1 inhaler per 90 days |
| Spiriva Respimat 1.25mcg, 2.5 mcg | 3 inhalers per 90 days |

## ASTHMA / COPD: BETA ADRENERGIC AND ANTICHOLINERGIC COMBINATIONS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 1 year |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| Combivent Respimat (ipratropium/albuterol) | 5 inhalers per 90 days |
| Anoro Ellipta (umeclidinium/vilanterol) | 3 inhalers per 90 days |
| Stiolto Respimat (tiotropium/olodaterol) | 3 inhalers per 90 days |
| Bevespi Aerosphere (glycopyrrolate/formoterol) | 3 inhalers per 90 days |

## ASTHMA / COPD: BETA ADRENERGIC/ANTICHOLINERGIC/CORTICOSTEROID COMBINATIONS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 1 year |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| TRELEGY ELLIPTA 100-62.5-25 (fluticasone/umeclidinium/vilanterol) | 3 inhalers per 90 days |
| TRELEGY ELLIPTA 200-62.5-25 (fluticasone/umeclidinium/vilanterol) | 3 inhalers per 90 days |
| BREZTRI AEROSPHERE INHALER (budesonide/glycopyrrolate/formoterol) | 3 inhalers per 90 days |

## ASTHMA / COPD: BETA ADRENERGICS – SHORT ACTING

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| **Length of Authorization:** | 1 year |
|---|---|

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| Albuterol HFA 90 mcg Inhaler (albuterol) | 6 inhalers per 90 days |
| ProAir RespiClick (albuterol) | 3 inhalers per 90 days |
| Ventolin HFA 90 mcg Inhaler (albuterol) | 6 inhalers per 90 days |
| Xopenex HFA 45 mcg Inhaler (levalbuterol) | 6 inhalers per 90 days |

## ASTHMA / COPD: BETA ADRENERGICS – LONG ACTING

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a two-week trial with one preferred medication
- See additional medication-specific criteria below:

#### BROVANA® (ARFORMOTEROL) NEBULIZER SOLUTION

- Bypass PDL if patient requires long-acting beta-adrenergic medication and cannot use a dry powder inhaler

#### PERFOROMIST® (FORMOTEROL) NEBULIZER SOLUTION

- Bypass PDL if patient requires long-acting beta-adrenergic medication and cannot use a dry powder inhaler

#### STRIVERDI RESPIMAT® (OLODATEROL) INHALER

- Diagnosis of COPD (must not be used for asthma or acute exacerbations) inhaler

### QUANTITY LIMITS

| | |
|---|---|
| Serevent Diskus (salmeterol) | 3 inhalers per 90 days |

## ASTHMA / COPD: BETA ADRENERGIC/CORTICOSTEROID COMBINATIONS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| Advair Diskus (fluticasone/salmeterol) | 3 inhalers per 90 days |
| Advair HFA (fluticasone/salmeterol) | 3 inhalers per 90 days |
| Airduo Digihaler(fluticasone/salmeterol) | 3 inhalers per 90 days |
| Airsupra (albuterol/budesonide) | 6 inhalers per 90 days |
| Breo Ellipta (fluticasone/vilanterol) | 3 inhalers per 90 days |
| Breyna (budesonide/formoterol) | 6 inhalers per 90 days |
| Dulera (mometasone/formoterol) | 3 inhaler per 90 days |
| Symbicort (budesonide/formoterol) | 6 inhalers per 90 days |
| Wixela (fluticasone/salmeterol) | 3 inhalers per 90 days |

### MAXIMUM AGE LIMITS

| | |
|---|---|
| Breo Ellipta (fluticasone/vilanterol) 50-25 mcg | 11 years |
| Dulera (mometasone/formoterol) 50 mcg/5mcg | 11 years |

## ASTHMA / COPD: PHOSPHODIESTERASE-4 (PDE-4) INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### DALIRESP® *(ROFLUMILAST)*

- Severe COPD associated with chronic bronchitis and a history of exacerbations; **AND**
- Trial/failure on at least one first-line or second-line agent; **AND**
- Adjunctive therapy (Daliresp® (roflumilast) must be used in conjunction with first-line or second-line agent

## ASTHMA / COPD: INHALED GLUCOCORTICOIDS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a two-week trial with one preferred medication; **OR**
- For children less than 13 years of age or a patient with a significant disability: inability to use the inhaler on preferred medications, or non-compliance because of taste, dry mouth
- See additional medication-specific criteria below:

#### ASMANEX® HFA *(MOMETASONE)*

- Requests submitted referencing exception due to compatibility with spacer/chamber will require trial only on fluticasone HFA

#### ASMANEX® TWISTHALER 110 MCG *(MOMETASONE)*

- Requests submitted to exceed the age limit of 11 years may be approved if a lower dose is needed and the dose requested does not exceed 1 inhaler per 30 days

### QUANTITY LIMITS

| | |
|---|---|
| Asmanex (mometasone) HFA | 3 inhalers per 90 days |
| Asmanex (mometasone) Twisthaler | 1 inhaler per fill |
| fluticasone HFA 110mcg | 3 inhalers per 90 days |
| fluticasone HFA 220mcg | 6 inhalers per 90 days |
| fluticasone HFA 44mcg | 3 inhalers per 90 days |
| Pulmicort 90mcg Flexhaler (budesonide) | 3 inhaler per 90 days |
| Pulmicort 180mcg Flexhaler (budesonide) | 6 inhalers per 90 days |
| Pulmicort 1 mg/2 ml Respules (budesonide) | 2 respules per day |

### MAXIMUM AGE LIMITS

| | |
|---|---|
| Arnuity Ellipta (fluticasone) 50 mcg | 11 years |
| Asmanex (mometasone) HFA 50 mcg | 12 years |
| Asmanex (mometasone) Twisthaler 110 mcg | 11 years |
| Pulmicort 0.25 mg/2 ml Respules (budesonide) | 8 years |
| Pulmicort 0.5 mg/2 ml Respules (budesonide) | 8 years |
| Pulmicort 1 mg/2 ml Respules (budesonide) | 8 years |

## ARAZLO® *(TAZAROTENE)* LOTION

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Patient age: ≥9 years of age; **AND**
- Patient has diagnosis of acne vulgaris

## ARIKAYCE® (AMIKACIN LIPOSOMAL)

| | |
|---|---|
| **Length of Authorization:** | 6 months |

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Diagnosis of Mycobacterium avium complex (MAC) lung disease as determined by the following (attestation only required):
  - Chest radiography or high-resolution computed tomography (HRCT) scan; **AND**
  - At least two positive sputum cultures; **AND**
  - Other conditions such as tuberculosis and lung malignancy have been ruled out; **AND**
- Attestation that the patient has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin), rifampin and ethambutol (Note: Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of six months); **AND**
- Attestation that the patient has failed or is intolerant to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator; **AND**
- Attestation that the requested medication will be prescribed in conjunction with a multi-drug antimycobacterial regimen

## AUSTEDO® / AUSTEDO XR (*DEUTETRABENAZINE*)

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Diagnosis of chorea associated with Huntington's disease **OR** tardive dyskinesia secondary to use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.); **AND**
- For tardive dyskinesia, attestation that a baseline AIMS test has been completed; **AND**
- Patient ≥ 18 years of age; **AND**
- Prescribed by or in consultation with a neurologist or psychiatrist

#### RENEWAL REQUESTS

- Attestation of patient's improvement in symptoms associated with their condition; **AND**
- For tardive dyskinesia, attestation that a follow-up AIMS test has been completed and there has been a positive response to therapy

## AZELEX® (AZELAIC ACID)

| | |
|---|---|
| **Length of Authorization:** | For the duration of the prescription up to 1 year |

### CRITERIA TO APPROVE

- Acne unresponsive to a tretinoin product or clinical rationale why tretinoin product not appropriate; **OR**
- Mild to moderate rosacea unresponsive to standard first line treatments or clinical rationale why 1st line treatments not appropriate

## BAL IN OIL® (*DIMERCAPROL*)

| | |
|---|---|
| **Length of Authorization:** | 1 month maximum |

### DIAGNOSIS TO APPROVE

- Treatment of poisonings due to any of the following:
  - Arsenic
  - Gold
  - Mercury
  - Lead

## BEYFORTUS (NIRSEVIMAB-ALIP)

| **Length of Authorization:** | 1 dose; Except for planned cardiac surgery with cardiopulmonary bypass – 2 doses |
|---|---|

### CRITERIA TO APPROVE

- Mother did not receive vaccination against RSV in the 2nd or 3rd trimester; **AND**
- Patient is < 8 months of age and born during (or entering) their first respiratory syncytial virus (RSV) season; **OR**
- Patient is up to 24 months of age entering their second RSV season and is at increased risk of severe RSV disease such as but not limited to:
  - Patient has chronic lung disease (CLD) and they required medical support during the 6-month period before the start of the second RSV season; **OR**
  - Patient has congenital heart disease (CHD); **OR**
  - Patient is immunocompromised; **OR**
  - Patient has neuromuscular disorder; **OR**
  - Patient has cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight for length < 10th percentile; **OR**
  - Patient is Alaska Native; **OR**
  - Patient is American Indian; **AND**
- Patient has *not* received 5 doses of palivizumab (Synagis®) for the current RSV season;

**Length of approval:**

- Planned cardiac surgery with cardiopulmonary bypass: 2 doses, to include 1 dose before surgery and 1 dose after surgery
- All other requests: 1 dose

## BENLYSTA® (*BELIMUMAB*)

| **Length of Authorization:** | 6 months |
|---|---|

### CRITERIA TO APPROVE

- Diagnosis of active systemic lupus erythematosus (SLE); **OR**
- Diagnosis of active lupus nephritis; **AND**
- Patient ≥ 5 years old; **AND**
- Must be prescribed by, or in consultation with, a rheumatologist or nephrologist; **AND**
- Patient is currently taking standard therapy for systemic lupus (i.e., corticosteroids, antimalarials or immunosuppressives)

## BENZNIDAZOLE

**Length of Authorization:** 60 days

### CRITERIA TO APPROVE

- Diagnosis of Chagas Disease; **AND**
- Patient is between the age(s) of 2 years old and 12 years old; **AND**
- Must be prescribed by an infectious disease specialist

## BILTRICIDE® (*PRAZIQUANTEL*)

**Length of Authorization:** 1-day treatment

### DIAGNOSIS TO APPROVE

#### LIVER FLUKES

- *All Schistosoma species*

#### CLONORCHIASIS AND OPISTHORCHIASIS

- *Clonorchis sinensis, opisthorchis viverrini*

#### NEUROCYSTICERCOSIS AND TISSUE FLUKES

- *Opisthorchis felineus, paragonimus westermani, fasciola hepatica, heterophytes, fasciolopsis buski, diphyllobothrium latum, taenia saginata, taenia solium, dipylidium caninum, hymenolepis nana*

## BIJUVA® (ESTRADIOL/PROGRESTERONE)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Patient has diagnosis of moderate to severe vasomotor symptoms due to menopause

## BONJESTA® (DOXYLAMINE SUCCINATE AND PYRIDOXINE HYDROCHLORIDE)

| | |
|---|---|
| **Length of Authorization:** | 3 months |

### DIAGNOSIS TO APPROVE

- Patient age is 18 years of age or older; **AND**
- Diagnosis of pregnancy with nausea/vomiting that has not been controlled through conservative measures such as eating smaller meals, eating low-fat bland foods and avoiding trigger odors

## BRONCHITOL® (*MANNITOL*)

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Patient is ≥ 18 years; **AND**
- Patient has a diagnosis of cystic fibrosis (CF); **AND**
- Prescriber attestation that the Bronchitol Tolerance Test (BTT) will be prescribed and performed using the Bronchitol package size of 10 capsules to confirm the patient is suitable for Bronchitol therapy. Once confirmed, the larger Bronchitol package size should be used for treatment; **AND**
- Bronchitol will be used as add-on maintenance therapy to improve pulmonary function; **AND**
- Prescribed by or in consultation with a pulmonologist.
- Quantity limit: 560 per 28 days

## BYLVAY® (*ODEVIXIBAT*)

| | |
|---|---|
| **Length of Authorization:** | Initial = 6 months; Renewal = 1 year |

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is ≥ 3 months of age; **AND**
- Patient is diagnosed with progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2, confirmed by a genetic test; **AND**
- Patient has elevated serum bile acid concentration; **AND**
- Patient experiences persistent moderate to severe pruritus; **AND**
- Prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist); **OR**
- Patient is diagnosed with Alagille syndrome (ALGS); **AND**
  - Patient is ≥12 months of age; AND
  - Patient has evidence of cholestasis, as evidenced by ≥ 1 of the following:
    - Serum bile acid > 3 times upper limit of normal (ULN) for age; **OR**
    - Conjugated bilirubin > 1 mg/dL; **OR**
    - Gamma glutamyl transferase (GGT) > 3 times ULN for age; **OR**
    - Fat soluble vitamin deficiency not otherwise explained; **OR**
    - Intractable pruritus only explained by liver disease; **AND**
  - Patient experiences persistent moderate to severe pruritus; **AND**
  - Prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist)

#### RENEWAL REQUESTS

- Patient has experienced a reduction in serum bile acid concentration; **AND**
- Patient has experience improvement in pruritis

## BYNFEZIA® (*OCTREOTIDE*)

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Patient ≥ 18 years of age; **AND**
- Patient must have ONE of the following diagnoses:
- Acromegaly with an inadequate response to **ALL** of the following:
  - surgical resection
  - pituitary irradiation
  - bromocriptine mesylate at maximally tolerated doses; **OR**
- Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors; **OR**
- Profuse watery diarrhea associated with VIP-secreting tumors

## CABLIVI® SUBCUTANEOUS INJECTION *(CAPLACIZUMAB-YHDP)*

| | |
|---|---|
| **Length of Authorization:** | 60 days from date of last plasma exchange |

### CRITERIA TO APPROVE

- Maintenance of abstinence from alcohol with a history of alcohol abuse and **is abstinent at the initiation of treatment with Campral®; AND**
- No other active substance abuse; **AND**
- Females: Rule out pregnancy; **AND**
- Rule out significant renal disease; **AND**
- Provide details of the treatment program.
- Extensions of authorization require a detailed update on compliance with counseling and medication.

## CAMZYOS® (*MAVACAMTEN*)

| | |
|---|---|
| **Length of Authorization:** | Initial = 6 months; Renewal = 1 year |

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥18 years of age; **AND**
- Diagnosis of symptomatic New York Heart Association (NYHA) class 2 to class 3 obstructive hypertrophic cardiomyopathy (HCM); **AND**
- Must be prescribed by a cardiologist; **OR**
- Prescribed in consultation with a cardiologist: Identify the cardiologist name and NPI_____; **AND**
- Patient has documented left ventricular ejection fraction (LVEF) ≥ 55%; **AND**
- Prescriber attests that the member will not be prescribed disopyramide, ranolazine, or combination therapy of beta blocker and calcium channel blocker, while the member is receiving Camzyos; **AND**
- For females of childbearing potential, a pregnancy test is performed and is negative before starting therapy; **AND**
- Attestation provided of patient, provider, and pharmacy enrollment in Camzyos Risk Evaluation and Mitigation Strategy (REMS) Program
- Quantity Limit: 30 per 30 days

#### RENEWAL REQUEST

- Must be prescribed by a cardiologist; **OR**
- Prescribed in consultation with a cardiologist: Identify the cardiologist name and NPI_____; **AND**
- Prescriber attests to positive clinical response or stable disease; **AND**
- Prescriber attests that the member will not be prescribed disopyramide, ranolazine, or combination therapy of beta blocker and calcium channel blocker, while the member is receiving Camzyos; **AND**
- Prescriber attests that the member is not pregnant; **AND**
- LVEF is ≥50%

## CARDIAC MEDICATIONS: ACE INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure on one preferred medication
- See additional medication-specific criteria below:

#### EPANED® (ENALAPRIL)

- PDL criteria may be bypassed if patient unable to swallow tablets.

#### QBRELIS® (LISINOPRIL)

- PDL criteria may be bypassed if patient is unable to swallow tablets.

## CARDIAC MEDICATIONS: ALPHA ADRENERGIC AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on one preferred medication

## CARDIAC MEDICATIONS: ANGIOTENSIN RECEPTOR ANTAGONISTS (ARB)

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure on one preferred medication

## CARDIAC MEDICATIONS: ANGIOTENSIN II RECEPTOR NEPRILYSIN INHIBITORS (ANRI)

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on one preferred medication
- See additional medication-specific criteria below:

#### ENTRESTO® (SACUBITRIL-VALSARTAN) SPRINKLES

- PDL criteria may be bypassed if patient is unable to swallow tablets.
- Quantity Limit: 60 tablets per 30 days

#### ENTRESTO® (SACUBITRIL-VALSARTAN) TABLETS

- Quantity Limit: 60 tablets per 30 days

## CARDIAC MEDICATIONS: DIRECT RENIN INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

#### TEKTURNA® (ALISKIREN)

- Therapeutic failure on an ACE inhibitor or ARB

## CARDIAC MEDICATIONS: ANTIHYPERTENSIVE COMBINATIONS: ACEI & ARB

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication

## CARDIAC MEDICATIONS: BETA BLOCKERS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- See additional medication-specific criteria below:

#### HEMANGEOL® *(PROPRANOLOL)* ORAL SOLUTION

- Patients is <1 year of age

## CARDIAC MEDICATIONS: CALCIUM CHANNEL BLOCKERS (CCBS)

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- See additional medication-specific criteria below:

#### NORLIQVA® *(AMLODIPINE)* ORAL SOLUTION

- Patients is ≥6 years of age; **AND**
- Allow if patient has swallowing difficulties

## CARDIAC MEDICATIONS: DIRECT RENIN INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Trial/failure on an ACE inhibitor or an ARB or clinical rationale why neither is appropriate.

## CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: FIBRIC ACID DERIVATIVES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication

## CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: BILE ACID SEQUESTRANTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication

## CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: STATINS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- Quantity limit (all products) = one per day
- See additional medication-specific criteria below:

### ATORVALIQ® (*ATORVASTATIN*)

- Patient cannot swallow whole tablets
- Quantity limit = 20 mL per day

### EZALLOR® SPRINKLE (*ROSUVASTATIN*)

- Patient cannot swallow whole tablets

## CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: NIACIN DERIVATIVES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication

## CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: OTHER

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- See additional medication-specific criteria below:

#### ICOSAPENT ETHYL – *PDL CRITERIA DO NOT APPLY*

- Adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia; **OR**
- Adjunct to maximally tolerated statin therapy in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and one of the following:
  - Established cardiovascular disease; **OR**
  - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease (i.e., men >55 years and women >65 years, cigarette smoker or stopped smoking within the past 3 months, hypertension (pretreatment blood pressure >140mmHg systolic or >90mmHg diastolic))

#### OMEGA-3 ACID ETHYL ESTERS – *PDL CRITERIA DO NOT APPLY*

- Adjunct to diet to reduce severe triglyceride (TG) levels (hypertriglyceridemia) in adult patients; **AND**
- Triglyceride levels ≥500 mg/dL

#### NEXLETOL® (*BEMPEDOIC ACID*), NEXLIZET® (*BEMPEDOIC ACID/EZETIMIBE) – PDL CRITERIA DO NOT APPLY*

- Patient is ≥ 18 years of age; **AND**
- Established atherosclerotic cardiovascular disease (ASCVD) or Heterozygous familial hypercholesterolemia; **AND**
- Failure to achieve target LDL-C on maximally-tolerated doses of statins; **AND**
- Therapy will used in conjunction with maximally-tolerated doses of a statin

## CARDIAC MEDICATIONS: LIPID LOWERING AGENTS: PCSK9 INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

#### CLINICAL PA CRITERIA FOR PCSK-9 INHIBITORS

- Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR**
- Diagnosis of heterozygous familial hypercholesterolemia (HeFH); **OR**
- Diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
- A treatment failure despite high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin) for at least 8 weeks. If intolerant to statins, this must be supported by submitted chart notes/labs.; **AND**
- A treatment failure of ezetimibe, alone or with either a high intensity or maximally tolerated dose statin (atorvastatin or rosuvastatin); **AND**
- Patient has failed to reach target LDL-C levels (document lab values):
    - ASCVD at very high risk (including those with FH), LDL-C goal <55 mg/dL.
    - ASCVD not at very high risk (not including FH), LDL-C goal <70 mg/dL with the option to target <55 mg/dL.
    - HeFH or HoFH: No LDL-C value required

## CARDIAC MEDICATIONS: ANTICOAGULANTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | Current prescription up to 6 months |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on one preferred medication
- See additional medication-specific criteria below:

#### PRADAXA ORAL PELLETS® (DABIGATRAN)

- Patient must be ≤11 years; **AND**
- When used for VTE treatment, attestation that parenteral anticoagulation has been used for at least 5 days

### QUANTITY LIMITS

| | |
|---|---|
| Eliquis (apixaban) 2.5 mg tablets | 2 per day |
| Eliquis (apixaban) 5 mg tablets | 218 per 102 days |
| Eliquis Starter Pack tablets | 74 per 30 days |
| Pradaxa (dabigatran) 75 mg capsules | 2 per day |
| Pradaxa (dabigatran) 110 mg capsules | 4 per day |
| Pradaxa (dabigatran) 150 mg capsules | 2 per day |
| Xarelto (rivaroxaban) 1 mg/mL suspension | 20 mL per day |
| Xarelto (rivaroxaban) 2.5 mg tablets | 2 per day |
| Xarelto (rivaroxaban) 10 mg tablets | 1 per day |
| Xarelto (rivaroxaban) 15 mg tablets | 102 per 102 days |
| Xarelto (rivaroxaban) 20 mg tablets | 1 per day |
| Xarelto (rivaroxaban) Starter Pack tablets | 51 per 30 days |

## CARDIAC MEDICATIONS: PLATELET AGGREGATION INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- See additional medication-specific criteria below:

#### CLOPIDOGREL 75MG

- Quantity limit = 1 tablet per day

#### CLOPIDOGREL 300MG

Quantity limit = 2 tablets per 30 days

#### EFFIENT® (PRASUGREL)

- Due to a black box warning related to increase in risk of bleeds in patients > 75
- PDL criteria must be met, and the MD will need to document medical necessity or clinical rationale for consideration.

#### ZONTIVITY® (VORAPAXAR)

- Diagnosis of history of myocardial infarction (MI) or peripheral artery disease (PAD) without a history of stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS), GI bleed or peptic ulcer **AND**
- Concurrent use of aspirin and/or clopidogrel **AND**
- Written by (or in collaboration with) a cardiologist or vascular surgeon

## CARDIAC MEDICATIONS: PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Diagnosis of pulmonary hypertension; **AND**
- Must be prescribed by or in consultation with a cardiologist or pulmonologist; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- See additional medication-specific criteria below:

#### OPSYNVI (MACITENTAN/TADALAFIL)

- Patient is ≥18 years of age; AND
- Quantity limit = 1 tablet per day

#### TADLIQ (TADALAFIL) ORAL SUSPENSION

- Patient is ≥18 years of age

#### WINREVAIR (SOTATERCEPT-CSRK)

- Diagnosis of PAH WHO group 1, functional class II or III; **AND**
- Documented trial and failure of, or contraindication to, at least 2 months of combination therapy including one PDE-5 inhibitor AND one ERA; **AND**
- Winrevair is being used as add on therapy to standard care; **AND**
- Platelet count of > 50,000/mm3 (> (>50x$10^9$/L), acceptable hemoglobin levels, and other labs in accordance with the product label; **AND**
- Counseling has occurred regarding the need for effective contraception due to risk of embryo-fetal toxicity, and the risk of impaired fertility with use of this medication

## CARNITOR® INJECTABLE (L-CARNITINE; LEVOCARNITINE)

| | |
|---|---|
| **Length of Authorization:** | Up to 1 year |

### DIAGNOSIS TO APPROVE

- Diagnosis of epilepsy and the patient is on valproic acid
- Short chain acetylcholine dehydrogenase deficiency (SCAD)
- Inborn errors of metabolism with low carnitine levels prescribed by an endocrinologist

## CAROSPIR® *(SPIRONOLACTONE)* SUSPENSION

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### DIAGNOSIS TO APPROVE

- Clinical reason why spironolactone tablets are not appropriate for use.

## CASGEVY® (EXAGAMGLOGENE AUTOTEMCEL)

| | |
|---|---|
| **Length of Authorization:** | Determined by MDHHS |

### CRITERIA TO APPROVE

- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## CENTRAL NERVOUS SYSTEM DRUGS: ALZHEIMER'S DEMENTIA

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication

## CENTRAL NERVOUS SYSTEM DRUGS: ANTIANXIETY - GENERAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | Duration of the prescription up to 1 year |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month each with two preferred medications
- See additional medication-specific criteria below:

#### ALPRAZOLAM INTENSOL

- PDL criteria may be bypassed for documented swallowing difficulty.

#### DIAZEPAM INTENSOL

- PDL criteria may be bypassed for diagnoses related to seizure disorder or for documented swallowing difficulty.

#### LORAZEPAM INTENSOL

- PDL criteria may be bypassed for diagnoses related to seizure disorder or for documented swallowing difficulty.

#### ALPRAZOLAM ODT (NIRAVAM)®

- PDL criteria may be bypassed for documented swallowing difficulty.

## CENTRAL NERVOUS SYSTEM DRUGS: ANTIMIGRAINE AGENTS, ACUTE TREATMENT-TRIPTANS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with treatment with use of two of the preferred agents

### QUANTITY LIMITS

| | |
|---|---|
| almotriptan (Axert) | 9 per fill |
| Axert® (almotriptan) | 9 per fill |
| Frova® (frovatriptan) | 18 per fill |
| Imitrex® (sumatriptan) | 18 per fill |
| Imitrex Injection® (sumatriptan) | Vial – 2 mL per fill<br>Kit and Injection – 4 per fill |
| Imitrex® Nasal Spray (sumatriptan) | 6 per fill |
| Maxalt®/ Maxalt MLT® (rizatriptan) | 18 per fill |
| naratriptan (Amerge®) | 9 per fill |
| Relpax® (eletriptan) | 12 per fill |
| rizatriptan (Maxalt®/ Maxalt MLT®) | 18 per fill |
| sumatriptan (Imitrex®) | 18 per fill |
| sumatriptan Injection (Imitrex®) | Vial – 2 mL per fill<br>Injection – 4 per fill |
| sumatriptan Spray, Nasal (Imitrex®, Tosymra®) | 6 per fill |
| zolmitriptan (Zomig®) | 12 per fill |
| Zomig® (zolmitriptan) | 12 per fill |

# CENTRAL NERVOUS SYSTEM DRUGS: ANTIMIGRAINE AGENTS, ACUTE TREATMENT - OTHER

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

## CRITERIA TO APPROVE

### CLINICAL PA CRITERIA FOR PREFERRED ACUTE MIGRAINE AGENT

- Patient has a diagnosis of migraine with or without aura; **AND**
- Patient is ≥18 years of age; **AND**
- Patient must have tried and failed, or have contraindication to, one preferred triptan medication

### NON-PREFERRED AGENT PA CRITERIA

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial of the preferred agent

## QUANTITY LIMITS

| | |
|---|---|
| Elyxyb® (celecoxib) | 14 doses per 30 days |
| Nurtec ODT® (rimegepant) | 54 tablets per 90 days |
| Reyvow® (lasmiditan) | 8 tablets per 30 days |
| Ubrelvy® (ubrogepant) | 16 tablets per 30 days |
| Zavzpret® (zavegepant) | 8 nasal spray devices per 30 days |

## CENTRAL NERVOUS SYSTEM DRUGS: ANTIMIGRAINE AGENTS, PREVENTIVE TREATMENT

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 6 months; Renewal = 12 months |

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication

#### INITIAL REQUESTS

- Patient has a diagnosis of migraine with or without aura; **AND**
- Patient age ≥18 years of age; **AND**
- Patient has ≥ four migraine days per month for at least three months; **AND**
- Patient has tried and failed ≥ one-month trial of any two of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol)
  - Anti-epileptics (e.g., valproate, topiramate)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan); **OR**
- Diagnosis of cluster headaches (Emgality only)

#### RENEWAL REQUESTS

- Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches

### QUANTITY LIMITS

| | |
|---|---|
| Aimovig® (erenumab-aooe) 140 mg/mL Autoinjector | 3 mL per 90 days |
| Aimovig® (erenumab-aooe) 70 mg/mL Autoinjector | 6 mL per 90 days |
| Ajovy® (fremanezumab-vfrm) 225 mg/1.5 mL Autoinjector, Syringe | 4.5 mL per 90 days |
| Emgality 300 mg Dose (3 x 100 mg/mL syringes) | 9 mL per 90 days |
| Emgality® (galcanezumab-gnlm) 120 mg/mL Pen, Syringe | 3 mL per 90 days |
| Nurtec ODT® (rimegepant) | 54 tablets per 90 days |
| Qulipta (atogepant) | 90 tablets per 90 days |

Preventive migraine treatments added to maintenance medication list.

An override will be approved for requests which demonstrate that the prescribed loading dose will exceed the maintenance quantity limit in table above.

## CENTRAL NERVOUS SYSTEM DRUGS: ANTIPARKINSON'S AGENTS: DOPAMINE AGONISTS & OTHER

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Up to 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication; **OR**
- Patients using bromocriptine for indications other than Parkinson's do not need to meet non-preferred agent criteria
- See additional medication-specific criteria below:

#### AZILECT® (*RASAGILINE*)

- Patient is 18 years of age or older

#### CREXONT® (*CARBIDOPA/LEVODOPA*)

- Patient is 18 years or older; **AND**
- Prescribed by or in consultation with a neurologist

#### GOCOVRI® (*AMANTADINE EXTENDED-RELEASE*)

- Diagnosis of dyskinesia associated with Parkinson's disease; **AND**
- The patient is receiving concomitant levodopa-based therapy; **AND**
- Patient has failure, contraindication or intolerance to immediate-release amantadine; **OR**
- Patient is experiencing 'off' time on levodopa/carbidopa therapy

#### INBRIJA® (*LEVODOPA INHALATION*)

- Prescribed by or in consultation with a neurologist; AND
- Medication will be used concomitantly with levodopa/carbidopa

#### NEUPRO® (*ROTIGOTINE*)

- Quantity Limit (all strengths): 30 patches per 30 days

#### ONGENTYS® (*OPICAPONE*)

- Patient has a diagnosis of Parkinson's Disease; **AND**
- Patient is experiencing 'off' time on levodopa/carbidopa therapy; **AND**
- Attestation that medication will be used concomitantly with levodopa/carbidopa and will not be used as monotherapy.

#### RYTARY® (*CARBIDOPA/LEVODOPA*)

- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with a neurologist

### VYALEV® (*FOSLEVODOPA/FOSCARBIDOPA*)

- Patient is 18 years of age or older; **AND**
- Diagnosis of Parkinson's disease that is levodopa-responsive; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Prescriber attests that the patient is experiencing persistent motor fluctuations with a minimum of 2.5 hours of "off" time per day despite optimized carbidopa/levodopa therapy

### XADAGO® (*SAFINAMIDE*)

- Patient must be 18 years or older
- Patient is experiencing 'off' time on levodopa/carbidopa therapy; **AND**
- Medication will be used concomitantly with levodopa/carbidopa and will not be used as monotherapy.

## CENTRAL NERVOUS SYSTEM DRUGS: DRUGS FOR ATTENTION DEFICIT HYPERACTIVITY DISORDERS (ADHD) – AMPHETAMINES AND PSEUDOAMPHETAMINES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 6 months for fatigue with chemo/radiation; 1 year for all other diagnoses |

### CRITERIA TO APPROVE (PDL NON-PREFERRED)

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication; **OR**
- Allow PDL non-preferred liquid formulations to be approved if patient has swallowing difficulties; AND
- Utilization of urine or saliva toxicology screening is strongly encouraged for initial and renewal requests requiring prior authorization; **AND**
- See additional criteria below:

### TOXICOLOGY SCREENING REQUIREMENTS

- Submission of urine or saliva toxicology screening results within the last 2 months may be required if MDHHS MAPS review indicates multiple controlled substances and/or multiple providers; **AND**
- Submission of current toxicology screening results (within 2 months of request) will be required for requests for doses that exceed FDA approved dosages.

### DIAGNOSES TO APPROVE

**ADD / ADHD (PDL criteria apply):**

- **Under age 4:** ADD / ADHD confirmed by a child and adolescent psychiatrist, developmental and behavioral pediatrician, or pediatric neurologist; **AND**
  - MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results
- **Ages 4–5:** ADD / ADHD confirmed by a comprehensive evaluation and/or standard assessment tool; **AND**
  - MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results

- **Ages 6–17:** No PA required
- **Ages ≥ 18 (continuation of *un*interrupted therapy – < 6-month lapse):** ADD / ADHD; **AND**
    - MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results
- **Ages ≥ 18 (new onset adult ADD / ADHD or continuation of interrupted therapy - >6 month lapse):** ADD / ADHD confirmed by a behavioral health provider after turning 18 years old; **OR**
    - Score of 14 or greater on the Adult ADHD Self-Report Screening Scale for DSM-5 (ASRS-5): **OR**
    - Score of 46 or greater on the Wender Utah Rating Scale; **AND**
    - MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results

## QUANTITY LIMITS

| | |
|---|---|
| Adderall (amphetamine salts combo) immediate-release caps | 5mg, 7.5mg, 10mg, 12.5mg, 15mg – 4 per day<br>20mg – 3 per day<br>30mg – 2 per day |
| Adderall XR® (amphetamine salts combo) extended-release caps | 5mg, 10mg, 15mg, 25mg, 30mg – 2 per day<br>20mg – 3 per day |
| Vyvanse® *(lisdexamfetamine)* | 80 mg per day |

## METHAMPHETAMINE

**Requests will require MDHHS review for patient-specific medical necessity according to the following criteria:**

## INITIAL REQUESTS

- Patient must be 6 years of age or older; **AND**
- Patient has a diagnosis of attention-deficit hyperactivity disorder (ADHD); **AND**
- Prescribed by or in consultation with a psychiatrist; **AND**
- Medical necessity is demonstrated through submission of medical records/documentation that **contains specific documentation of each of the following**:
    - Diagnostic justification for ADHD, including use of standardized criteria; **AND**
    - Patient has tried and failed immediate-release AND extended-release methylphenidate; **AND**
    - Patient has tried and failed immediate-release AND extended-release amphetamine; **AND**
    - Patient has tried and failed immediate-release AND extended-release mixed amphetamine salts (amphetamine/dextroamphetamine); **AND**
    - Patient has tried and failed immediate-release AND extended release dextroamphetamine; **AND**
    - Patient has tried and failed immediate-release AND extended release dexmethylphenidate; **AND**
    - Patient has tried and failed serdexmethylphenidate/dexmethylphenidate; **AND**
    - Patient has tried and failed lisdexamfetamine; **AND**
    - Patient has tried and failed atomoxetine; **AND**
    - Patient has tried and failed viloxazine; **AND**
    - Patient has tried and failed extended-release clonidine; **AND**
    - Patient has tried and failed extended release guanfacine; **AND**
    - Results of clinical evaluation for stimulant use disorder; **AND**
    - Specific justification for use of methamphetamine at the requested dosage, including any relevant dosage titration schedule/plan and accompanying rationale in light of treatment history; **AND**

    - Current clinical notes outlining all diagnoses, current medications, description of patient symptoms and treatment plan; **AND**
    - Broad panel urine toxicology screening results (within 2 months of request); **AND**
    - Detailed description of MAPS review and reconciliation with prescribed drugs and current toxicology screening results
- Notes:
    - Exceptions will not be considered for diagnoses other than ADHD.
    - If two or more active controlled substances have been prescribed for the patient within the past year and methamphetamine is being requested, all controlled substances must be written by the same prescriber or a detailed justification provided for different prescribers.
- **Quantity limit (5 mg tabs):** 150 tablets per 30 days
- **Length of authorization:** 12 months

### RENEWAL REQUESTS

- Submission of current clinical notes including vital signs, detailed description of benefit from therapy, treatment plan, rationale for continuation with current input from psychiatrist, and detailed description of MAPS review and reconciliation with prescribed drugs and current toxicology screening results
- Submission of urine toxicology screening results (within 2 months of request)

## CENTRAL NERVOUS SYSTEM DRUGS: MULTIPLE SCLEROSIS AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with two preferred medications
- See additional medication-specific criteria below:

#### AVONEX® *(INTERFERON BETA-1A)*

- Quantity limit = 4 per 34 days

#### BAFIERTAM® (*MONOMETHYL FUMARATE)*

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Attestation that Bafiertam will be used as single agent monotherapy
- Quantity limit: 120 per 30 days
- Initial length of authorization: 6 months
- Renewal criteria:
    - Attestation of tolerance to maintenance dose; **AND**
    - Attestation of a CBC, including lymphocyte count, serum aminotransferase, ALP, and total bilirubin levels

MAVENCLAD® *(CLADRIBINE)*

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include relapsing-remitting disease and active secondary progressive disease; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Therapeutic failure on one month trial of at least two preferred medications

MAYZENT® *(SIPONIMOD)*

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient CYP2C9 variant status has been tested to determine genotyping (required for dosing); **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- Patient has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Therapeutic failure on one month trial of at least two preferred medications

PLEGRIDY® *(PEGINTERFERON BETA-1A)*

- Therapeutic failure on one month trial of at least two preferred medications

PONVORY® *(PONESIMOD)*

- Patient age between 18 year and 55 years; **AND**
- Patient has a diagnosis of a relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) or active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Prescriber attestation that first-dose monitoring, as clinically indicated, will occur; **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Prescriber attestation that ponesimod will NOT be used in combination with anti-neoplastic, immunosuppressive, or immune-modulating therapies, or, if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications; **AND**
- Therapeutic failure on one month trial of at least two preferred medications

TASCENSO® (*FINGOLIMOD)*

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Patient age ≥10 years; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient is unable to use generic fingolimod capsules or brand Gilenya capsules due to swallowing difficulties.

### VUMERITY® *(DIROXIMEL FUMARATE)*

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**

Therapeutic failure on one month trial of at least two preferred medications

### ZEPOSIA® *(OZANIMOD)*

- Patient is 18 years of age or older; **AND**
- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist;
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, has been performed before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months; **AND**
- For MS, therapeutic failure on one month trial of at least two preferred medications.

## CENTRAL NERVOUS SYSTEM DRUGS: NEUROPATHIC PAIN

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year unless otherwise specified |

### LYRICA (*PREGABALIN*) DOSAGE LIMIT

- Maximum daily dosage limit = 600 mg across all strengths
- Length of authorization: determined by MDHHS

### QUANTITY LIMITS

| Drug Name | Quantity Limit |
|---|---|
| Lyrica® (pregabalin) 25mg, 50mg, 75mg, 100mg, 150mg, 200mg | 3 caps per day |
| Lyrica® (pregabalin) 225mg, 300mg | 2 caps per day |
| Lyrica® (pregabalin) 20mg/ml solution | 20 ml per day |

## CENTRAL NERVOUS SYSTEM DRUGS: SEDATIVE HYPNOTIC NON-BARBITURATES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** For the duration of the prescription up to 12 months

### CRITERIA TO APPROVE

- Allergy to the preferred medications in this class; **OR**
- Contraindication or drug to drug interaction with all preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication
- For medications requiring prior authorization for patients over age 65 years, the patient must have failed **zaleplon** or **zolpidem** and one other preferred, age-appropriate agent
- See additional medication-specific criteria below:

#### EDLUAR® *(ZOLPIDEM)*

- Patient has difficulty swallowing

### AGE EDITS

| **Generic Name (*Brand*)** | **Prior Authorization Required for ages:** |
|---|---|
| temazepam (*Restoril*) | <18 years and ≥65 years |
| triazolam (*Halcion*) | <18 years and ≥65 years |
| daridorexant (Quviviq) | <18 years |
| estazolam (*Prosom*) | <18 years |
| zolpidem (*Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist*) | <18 years |
| suvorexant (*Belsomra*) | <18 years |
| tasimelteon (*Hetlioz*) | <18 years |
| eszopiclone (*Lunesta*) | <18 years |
| doxepin (*Silenor*) | <18 years |
| ramelteon (*Rozarem*) | <18 years |
| flurazepam (*Dalmane*) | < 15 years and ≥65 years |

### QUANTITY LIMITS

| | |
|---|---|
| temazepam (Restoril®) | 7.5 mg caps 34 per 34 days |
| triazolam (Halcion®) | 10 per 30 days |
| zolpidem (Ambien®, Ambien CR®) tablets | 5mg, 6.25mg – 2 per day<br>10mg, 12.5mg – 1 per day |
| zolpidem (Edular®) SL tablets | 5mg – 2 per day<br>10mg – 1 per day |
| zolpidem (Intermezzo®) SL tablets | 1.75mg – 2 per day<br>3.5mg – 1 per day |
| zolpidem capsules | 7.5mg – 1 per day |

## CENTRAL NERVOUS SYSTEM DRUGS: SKELETAL MUSCLE RELAXANTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with two preferred medications
- Non-preferred criteria do not apply to dantrolene if diagnosis is cerebral palsy
- See additional medication-specific criteria below:

#### FLEQSUVY® *(BACLOFEN)*

- Allow if patient has had a trial and failure with baclofen oral solution

#### LYVISPAH® *(BACLOFEN)*

- Allow if patient has had a trial and failure with baclofen oral solution

## CERDELGA® (*ELIGLUSTAT*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of Gaucher disease Type 1; **AND**
- Verification patient is not receiving concomitant enzyme replacement therapy with imiglucerase (Cerezyme®), velaglucerase (VPRIV®) or taliglucerase (ELELYSO®).

## CHOLBAM® (*CHOLIC ACID*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is at least 3 weeks old; **AND**
- Must be prescribed by a hepatologist or pediatric gastroenterologist; **AND**
- Diagnosis of bile acid synthesis due to single enzyme defect or peroxisomal biogenesis disorder

## CUVPOSA® *(GLYCOPYRROLATE)*

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Patient must be ≤ 16 years of age

## CUVRIOR® (TRIENTINE TETRAHYDROCHLORIDE)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥18 years of age; **AND**
- Patient has a diagnosis of Wilson's disease; **AND**
- Patient is de-coppered [i.e., serum non-ceruloplasmin copper (NCC) level ≥ 25 and ≤ 150 mcg/L]; **AND**
- Patient has been treated with penicillamine for at least one year and was tolerant to penicillamine; **AND**
- Patient will discontinue penicillamine before starting therapy with Cuvrior; **AND**
- Prescribed by or in consultation with a gastroenterologist, hepatologist or neurologist
- Quantity limit = 10 tabs per day

#### RENEWAL REQUEST

- Patient must continue to meet the above criteria; **AND**
- Patient continues to respond positively to therapy

## CYCLOSET® *(BROMOCRIPTINE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Therapeutic failure with a one-month trial of any two preferred diabetic medications

## CYKLOKAPRON/LYSTEDA® *(TRANEXAMIC ACID)*

**Length of Authorization:** Maximum of 2 months per request. If extension is requested, then medical rationale is needed to continue treatment.

### DIAGNOSIS TO APPROVE

#### CYKLOKAPRON

- Short term treatment of hemorrhage in hemophilia patients (e.g., dental extractions)
- Bleeding after surgery
- Prevent rebleeding of subarachnoid hemorrhage
- Menorrhagia
- Epistaxis
- Hereditary angioedema

#### LYSTEDA®

- Menorrhagia

## CYSTADANE® (*BETAINE POWDER*)

**Length of Authorization:** For the duration of the current prescription up to one year

### DIAGNOSIS TO APPROVE

- Homocystinuria
- Criteria specifically applies to Betaine powders in HIC3 C7D

## CORLANOR® *(IVABRADINE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is at least 6 months and older **AND**
- Currently symptomatic or has a history of symptoms related to heart failure (dyspnea, fatigue, fluid retention) AND
- No current acute decompensated heart failure **AND**
- Left ventricular ejection fraction (LVEF) < 35% **AND**
- Sinus rhythm with resting heart rate > 70 bpm **AND**
- Patient is receiving maximally tolerated doses of bisoprolol, carvedilol or metoprolol succinate extended release

## CYSTARAN®/CYSTADROPS (*CYSTEAMINE*)

**Length of Authorization:** 1 year

## DIAGNOSIS TO APPROVE

- Cystinosis

# CYSTIC FIBROSIS AGENTS

**Length of Authorization:** 1 year

## CRITERIA TO APPROVE

### KALYDECO® *(IVAKAFTOR)*

- Diagnosis of cystic fibrosis; **AND**
- Presence of one mutation in the CFTR gene that is responsive to ivacaftor, based on in vitro data and/or clinical data (97 mutations as of 12/2020); **AND**
- Patient is ≥ 1 months old; **AND**
- For 5.8mg granules and 13.4mg granules, patient age is ≤ 1 year; **OR**
- For 25mg granules, 50 mg granules and 75 mg granules, patient age is ≤ 5 years; **AND**
- Must be prescribed by a pulmonologist experienced with the treatment of Cystic Fibrosis
- For renewal requests, attestation of continued therapeutic effectiveness.

### ORKAMBI® *(LUMACAFTOR/IVACAFTOR)*

- Diagnosis of cystic fibrosis **AND**
- Presence of a *F508del* genetic mutation confirmed by genetic testing (copy of test results must be faxed) **AND**
- Patient is ≥ 12 years old for 200 mg-125 mg tabs; 6-11 years old for 100 mg-125 mg tabs; 2-5 years old for 100 mg-125 mg granules and 150 mg-188 mg granules; or 1-2 years for 75mg-94mg granules, 100mg-125mg granules and 150mg-188 mg granules; **AND**
- Baseline FEV1 and BMI measurements have been obtained or attempted; **AND**
- Must be prescribed by a pulmonologist experienced with the treatment of Cystic Fibrosis
- For renewal requests, attestation of continued therapeutic effectiveness.

### SYMDEKO® *(TEZACAFTOR/IVACAFTOR)*

- Patient has a diagnosis of cystic fibrosis (CF); **AND**
- Patient has a homozygous *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene detected by an FDA cleared test (copy of test results must be faxed); **OR**
- Patient has at least one copy of a mutation in the CFTR gene responsive to tezacaftor/ivacaftor, based on clinical and/or in vitro assay data (154 mutations as of 12/2020) (copy of test results must be faxed); **AND**
- Patient is 6 years of age or older; **AND**
- For 50 mg/75 mg tablets; patient is ≤ 16 years of age; **AND**
- Baseline FEV1 and BMI measurements obtained or attempted (measurements must be documented); **AND**
- Must be prescribed by a pulmonologist experienced with the treatment of Cystic Fibrosis
- For renewal, attestation of continued therapeutic effectiveness.

### TRIKAFTA® *(ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)*

- Patient has a diagnosis of cystic fibrosis; **AND**
- Presence of at least one F508del genetic mutation confirmed by genetic testing (copy of test results must be faxed); **OR**
- Presence of at least one mutation in the CFTR gene that is responsive based on in vitro data (copy of test results must be faxed); **AND**

- Patient is ≥ 2 years old; **AND**
- For 80-40-60 mg granules, patient age is ≤ 5 years; **OR**
- For 50-25-37.5 mg tablets and 100-50-75mg granules, patient age is ≤ 11 years; **AND**
- Baseline FEV1 and BMI measurements obtained or attempted (measurements must be documented); **AND**
- Must be prescribed by a pulmonologist experienced with the treatment of Cystic Fibrosis; **AND**
- Prescriber will be adherent to the following FDA guidelines for prescribing including:
  - Perform baseline liver function tests and routine monitoring; **AND**
  - Adjust Trikafta dose and evaluate risk/benefits of continued Trikafta use in patients with hepatic impairment per FDA recommendations **AND**
  - Perform baseline ophthalmic assessment for cataracts in pediatric patients and yearly follow-up.
- For renewal, attestation of continued therapeutic effectiveness.

## DARTISLA ODT® (*SPARSENTAN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of peptic ulcer; **AND**
- Dartisla ODT will be used as an adjunct to treatment of peptic ulcer to reduce symptoms as it must not be used as monotherapy; **AND**
- Patient must have experienced therapeutic failure, contraindication or intolerance to generic glycopyrrolate tablets

## DAYBUE® (*TROFINETIDE*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 2 years of age; **AND**
- Prescribed by or in consultation with a neurologist, developmental pediatrician, medical geneticist or physical medicine and rehab (PM&R) physicians; **AND**
- Patient has a diagnosis of Rett Syndrome; **AND**
- Prescriber obtained a baseline assessment using a standardized tool (Rett Clinical Severity Scale, Clinical Global Impression Scale for Rett Syndrome, or other appropriate tool)

#### RENEWAL REQUEST

- Submission of most recent (within 6 months of request) clinical notes and repeat testing (Rett Clinical Severity Scale, Clinical Global Impression Scale for Rett Syndrome, or other appropriate tool) that demonstrate a response to therapy.

## DERMATOLOGIC AGENTS: ACNE AGENTS: COMBINATION BENZOYL PEROXIDE AND CLINDAMYCIN

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication

## DERMATOLOGIC AGENTS: TOPICAL STEROIDS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** For the duration of the prescription up to 6 months

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure of 14 days with **one** of the preferred medications in the same subclass

## DIABETES: AMYLIN ANALOGS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

# DIABETES: INCRETIN MIMETICS AND COMBINATIONS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

## CRITERIA TO APPROVE

### CLINICAL PA CRITERIA FOR PREFERRED AGENTS

- Diagnosis of type 2 diabetes; **AND**
- Discontinuation of other GLP-1 agonists; **AND**
- Discontinuation of DPP-4 inhibitors

### NON-PREFERRED AGENT PA CRITERIA

- Diagnosis of type 2 diabetes; **AND**
- Discontinuation of other GLP-1 agonists; **AND**
- Discontinuation of DPP-4 inhibitors; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one preferred medication within same subgroup
- See additional medication-specific criteria below:

#### SOLIQUA® *(INSULIN GLARGINE/LIXISENATIDE)*

- One-month trial and failure with one of the preferred medications in each subgroup of the components (basal insulin and GLP-1 agonist)

#### XULTOPHY® *(INSULIN DEGLUDEC/LIRAGLUTIDE)*

- One-month trial and failure with one of the preferred medications in each subgroup of the components (basal insulin and GLP-1 agonist)

## QUANTITY LIMITS

| Drug name | Quantity limitation |
|---|---|
| Bydureon Bcise® (exenatide) | 12 pens per 84 days |
| Byetta® (exenatide) | 3 pens per 90 days |
| Mounjaro® (tirzepatide) | 12 pens per 84 days |
| Ozempic® (semaglutide) | 3 pens per 84 days |
| Rybelsus® (semaglutide) | 1 tab per day |
| Soliqua® (insulin glargine/lixisenatide) | 20 pens per 100 days |
| Trulicity® (dulaglutide) | 12 pens per 84 days |
| Victoza® 2-Pak (liraglutide) | 6 pens per 90 days |
| Victoza® 3-Pak (liraglutide) | 9 pens per 90 days |
| Xultophy® (insulin degludec/liraglutide) | 15 pens per 90 days |

## DIABETES: INSULINS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication within same subgroup; **OR**
- Patient is clinically stable and switching would cause a deterioration in clinical condition
- Quantity Limits:
  - Injections: 90 mL per fill
  - Inhalation cartridges: 180 per fill
- See additional medication-specific criteria below:

TOUJEO SOLOSTAR® *(INSULIN GLARGINE)*

- Trial and failure on both preferred medications in this class

## DIABETES: ORAL HYPOGLYCEMICS – ALPHA GLUCOSIDASE INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

## DIABETES: ORAL HYPOGLYCEMICS – BIGUANIDES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with a preferred medication

## DIABETES: ORAL HYPOGLYCEMICS – COMBINATIONS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

| | |
|---|---|
| **Length of Authorization:** | 1 year |

### CRITERIA TO APPROVE

#### CLINICAL PA CRITERIA FOR PREFERRED AGENTS THAT CONTAIN A DPP-4 INHIBITOR

- Discontinuation of GLP-1 agonists

#### NON-PREFERRED AGENT PA CRITERIA

- Discontinuation of GLP-1 agonists (Only applies to products that contain a DPP-4 inhibitor); **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

### QUANTITY LIMITS

| | |
|---|---|
| Janumet® (sitagliptin / metformin) | 2 tabs per day |

## DIABETES: ORAL HYPOGLYCEMICS – DPP4 INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

#### CLINICAL PA CRITERIA FOR PREFERRED AGENTS

- Discontinuation of GLP-1 agonists

#### NON-PREFERRED AGENT PA CRITERIA

- Discontinuation of GLP-1 agonists; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

### QUANTITY LIMITS

| | |
|---|---|
| Januvia® (sitagliptin phosphate) | 100mg/day max daily dose limit; qty limit of 1 tab - any strength - per day] |

## DIABETES: ORAL HYPOGLYCEMICS – MEGLITINIDES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

## DIABETES: ORAL HYPOGLYCEMICS – 2ND GENERATION SULFONYLUREAS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

## DIABETES: ORAL HYPOGLYCEMICS – SGLT2 INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

## DIABETES: ORAL HYPOGLYCEMICS – THIAZOLIDINEDIONES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with a preferred medication

## DIABETES: GLUCAGON AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a trial with one preferred medication

## DIABETES: INSULIN SUPPRESSANTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a trial with one preferred medication

## DICLEGIS® (DOXYLAMINE/PYRIDOXINE)

**Length of Authorization:** 3 months

### CRITERIA TO APPROVE

- Pregnancy with nausea/vomiting that has not been controlled through conservative measures

## DIFFERIN® (*ADAPALENE*)

**Length of Authorization:** For the duration of the prescription up to 1 year

### CRITERIA TO APPROVE

- Acne unresponsive to a tretinoin product or clinical rationale why tretinoin product not appropriate

## DOJOLVI® (TRIHEPTANOIN)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient has a diagnosis of a molecularly confirmed long-chain fatty acid oxidation disorder; AND
- Prescribed by, or in consultation with, a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders.

## DOPTELET® (*AVATROMBOPAG*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Platelet count < 50 x 109/L (document date of lab and level); **AND**
- Diagnosis of chronic liver disease and scheduled to undergo a procedure; **OR**
- Diagnosis of chronic immune thrombocytopenia and has had an insufficient response to a previous treatment

## DUAVEE® (ESTROGEN, CONJUGATED/BAZEDOXIFENE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Clinical rationale why other products used to treat menopause are not appropriate.

## DUOBRII® (HALOBETASOL/TAZAROTENE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Patient has a diagnosis of plaque psoriasis; **AND**
- Female patients of reproductive potential have had a negative pregnancy test within 2 weeks prior to initiating therapy; **AND**
- Female patients of reproductive potential have been counseled to use effective contraception; **AND**
- Patient had a failure of at least a two-month trial on any high potency topical steroid (i.e., clobetasol, halobetasol)

## DUVYZAT® (*GIVINOSTAT*)

**Length of Authorization:** Initial = 1 year; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 6 years of age or older; **AND**
- Diagnosis of Duchenne muscular dystrophy (DMD) that has been confirmed by the presence of a mutation in the DMD gene; **AND**
- Prescribed by or in consultation with a neurologist or physiatrist (physical medicine or rehabilitation);

#### RENEWAL REQUESTS

- Prescriber attests that the patient has demonstrated a beneficial response to therapy

## EGATEN® (TRICLABENDAZOLE)

**Length of Authorization:** 4 weeks

### CRITERIA TO APPROVE

- Patient ≥ 6 years old; **AND**
- Patient has a diagnosis of fascioliasis; **AND**
- Prescribed by or in consultation with an infectious disease specialist or gastroenterologist

**Special Instructions from Novartis for prescribers and pharmacies on how to obtain Egaten® (only available directly from the manufacturer, Novartis):**

**Prescriber process**

- Prescriber will write a prescription and give it to the patient or e-prescribe to the patient's desired pharmacy
- Prescriber will contact Novartis at 1-888-669-6682 to begin the shipping process to the pharmacy
- Choose Prompt 1 for "Medical Professional"
- Choose Prompt 2 for "questions regarding product quality" → call will be routed to the Customer Interaction Center
- Novartis will ask for information (patient name, patient DOB, pharmacy name and pharmacy phone number)
- Novartis will arrange for shipment to the pharmacy at no charge to the patient

  NOTE: The pharmacy MUST have the prescription on hand in order to accept shipment of the medication

**Pharmacy process**

- Egaten® is only available through Novartis and is not available from wholesalers
- The patient or their prescriber will send the prescription to the pharmacy
- Pharmacy will contact Novartis at 888-669-6682 to begin the shipping process to the pharmacy
- Choose Prompt 1 for "Medical Professional"
- Choose Prompt 2 for "questions regarding product quality" → call will be routed to the Customer Interaction Center
- Novartis will require information (patient name, patient DOB, pharmacy name, pharmacy phone number)
- Novartis will contact coordinate shipment to the pharmacy at no charge to the patient
- Shipment will be received (by the pharmacy) the next day

NOTE: The pharmacy MUST have the prescription on hand in order to accept shipment of the medication and MAY NOT bill the patient, provider, or any insurer for this product

## EGRIFTA® (TESAMORELIN ACETATE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Human immunodeficiency virus (HIV) infection **AND**
- Patient is currently being treated with either a protease inhibitor (PI) or a nucleoside reverse transcription inhibitor (NRTI) **AND**
- Abdominal lipodystrophy as defined by the following:
  - Males: Waist circumference of at least 95 cm (37.4 in) and waist-to-hip ratio of at least 0.94.
  - Females: Waist circumference of at least 94 cm (37 in) and waist-to-hip ratio of at least 0.88.

### RENEWAL REQUESTS

- Absence of unacceptable toxicity from the drug and
- Decrease in waist circumference from baseline

## ELEVIDYS® (DELANDISTROGENE MOXEPARVC-ROKL)

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## EMPAVELI® (PEGCETACOPLAN)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is ≥18 years of age: **AND**
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); **AND**
- Prescribed by or in consultation with a hematologist; **AND**
- Patient has laboratory evidence of significant intravascular hemolysis (e.g., serum lactate dehydrogenase (LDH) ≥ 1.5 times the upper limit of normal [ULN]) plus ≥ 1 of the following:
  - Presence of a thrombotic event; **OR**
  - Presence of organ damage secondary to chronic hemolysis (e.g., renal insufficiency, pulmonary insufficiency, or hypertension); **OR**
  - Patient is pregnant and potential benefit outweighs potential fetal risk; **OR**
  - Patient has symptomatic anemia (regardless of transfusion dependence); **OR**
  - Patient has abdominal pain requiring admission or opioid analgesia; **AND**
- Patient must have been vaccinated against encapsulated bacteria (*Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae type B*). If patient has not been previously vaccinated, then the patient must be vaccinated at least 2 weeks prior to initiation of therapy and revaccinated according to current medical guidelines for vaccine use.

#### RENEWAL REQUESTS

- Patient has documented beneficial disease response compared to pre-PNH treatment baseline, as demonstrated by ≥ 1 of the following:
  - Decrease in serum LDH; **OR**
  - Stabilization/increase in hemoglobin level; **OR**
  - Decrease in packed RBC transfusion requirement; **OR**
  - Reduction in thromboembolic events

## ENSPRYNG (SATRALIZUMAB-MWGE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Patient has been diagnosed with neuromyelitis optica spectrum disorder (NMOSD); **AND**
- Patient must be anti-aquaporin-4 (AQP4) antibody positive; **AND**
- The prescribing physician must be a neurologist or ophthalmologist; **AND**
- Attestation that there is no evidence of active or untreated latent tuberculosis prior to initiating therapy; **AND**
- Attestation that baseline liver transaminase and neutrophil count was performed prior to treatment; **AND**
- Attestation that patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Attestation that patient has NOT received any vaccinations in the 4-weeks prior to the start of therapy
- Quantity limit: 1 mL (120mg) every 4 weeks

## ENSTILAR® FOAM (CALCIPOTRIENE/BETAMETHASONE)

**Length of Authorization:** 4 weeks

### CRITERIA TO APPROVE

- Diagnosis of plaque psoriasis; **AND**
- Patient ≥ 18 years old; **AND**
- Must be prescribed by a dermatologist; **AND**
- Clinical reason why covered topical steroids cannot be used
- Quantity limit = 420 gm per 28 days

## EOHILIA® (*BUDESONIDE*)

**Length of Authorization:** 12 weeks

### CRITERIA TO APPROVE

- Patient ≥11 years old; **AND**
- Diagnosis of eosinophilic esophagitis (EoE); **AND**
- Prescribed by or consultation with an allergist or gastroenterologist; **AND**
- Patient did not respond clinically (e.g., a 1-month trial) to treatment with a topical (inhaled) glucocorticosteroid **or** proton pump inhibitor
- Quantity Limit: 20ml/day

## EPIDUO® (ADAPALENE/BENZOYL PEROXIDE) GEL

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of acne **and** a two-month trial on benzoyl peroxide or Differin®.

## ESBRIET® (*PIRFENIDONE*)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Idiopathic pulmonary fibrosis

## EVAMIST® *(ESTRADIOL)* TRANSDERMAL SPRAY

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Clinical rationale why covered topical estradiol products that do not require PA are inappropriate.

## EVRYSDI® *(RISDIPLAM)* ORAL SOLUTION AND TABLETS

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

**Requests will require MDHHS review and must include the following:**

#### INITIAL REQUESTS (ALL CRITERIA MUST BE MET)

- Submission of genetic testing confirming mutation of SMN1 and SMN2; **AND**
- Must be prescribed by a neurologist or physiatrist (physical medicine and rehab) who specializes in SMA (spinal muscular atrophy); **AND**
- Patient weight; **AND**
- Confirmation that patient has been counseled on potential fertility risks and risks of potential embryo fetal toxicity; **AND**
- Documentation of physical exam and scoring (i.e., HINE, CHOP Intend, Upper Limb Module) validating age-appropriate motor assessments.

#### RENEWAL REQUESTS (ALL CRITERIA MUST BE MET)

- Must be prescribed by a neurologist or physiatrist (physical medicine and rehab) who specializes in spinal muscular atrophy; **AND**
- Submission of most recent progress notes and current repeat ambulatory testing (i.e., HINE, CHOP Intend, Upper Limb Module) that demonstrates a response to therapy.

## EXSERVAN® *(RILUZOLE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Diagnosis of amyotrophic lateral sclerosis (ALS); **AND**
- Patient has diagnosis of dysphagia; **AND**
- Prescribed by or in consultation with a neurologist

## EXONDYS 51® *(ETEPLIRSEN)*

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for home administration will require MDHHS review and must specifically indicate that the medication will be home infused (versus being infused in an office/clinic/infusion center setting).
- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## FABIOR® (*TAZAROTENE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of acne vulgaris; **AND**
- Therapeutic failure of at least two preferred topical acne products

## FABHALTA® (*IPTACOPAN*)

**Length of Authorization:** Initial = 6 months (PNH and C3G); 9 months (IgAN); Renewal = 1 year (each diagnosis)

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is ≥18 years of age: **AND**
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); **AND**
- Prescribed by or in consultation with a hematologist; **AND**
- Patient has a mean hemoglobin level <10 g/dL; **AND**
- Patient has an LDH level of 1.5 times the upper limit of the normal range; **OR**
- The patient is transitioning from another complement inhibitor approved for the diagnosis of PNH**; OR**
- Diagnosis of immunoglobulin A nephropathy (IgAN); **OR**
- Diagnosis of complement 3 glomerulopathy (C3G); **AND**
- Prescribed by or in consultation with a nephrologist; **AND**
  - Patient has a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g; **AND**
  - Patient's eGFR is ≥ 30 mL/min/1.73 $m^2$; **AND**
  - Patient is on a stable dose of maximally-tolerated renin-angiotensin system (RAS) inhibitor therapy [e.g. ACE inhibitor (e.g. captopril, enalapril), angiotensin II receptor blocker (ARB) (e.g. candesartan, valsartan)]; **AND**

- Patient must have been vaccinated against encapsulated bacteria (*Haemophilus influenzae* type b, *Streptococcus pneumoniae and Neisseria meningitidis*) at least 2 weeks prior to initiation of therapy and revaccinated according to current medical guidelines for vaccine use.

### RENEWAL REQUESTS

- Patient has documented beneficial disease response compared to pre-PNH treatment baseline, as demonstrated by ≥ 1 of the following:
  - Decrease in serum LDH; **OR**
  - Stabilization/increase in hemoglobin level; **OR**
  - Decrease in packed RBC transfusion requirement; **OR**
- Patient has documented beneficial disease response compared to pre-IgAN or pre-C3G baseline as demonstrated by a reduction in proteinuria.

## FEMTRACE® (ESTRADIOL ACETATE)

**Length of Authorization:** For the current prescription up to one year

### CRITERIA TO APPROVE

- Documented therapeutic failure on a generic estradiol product **and/or**
- Clinical rationale requiring this particular strength

## FENSOLVI® (*LEUPROLIDE ACETATE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age between 2 years and 16 years of age; **AND**
- Diagnosis of central precocious puberty (CPP); **AND**
- Therapeutic failure with Lupron Depot-Ped (leuprolide)

## FILSUVEZ® (BIRCH BARK EXTRACT)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient age ≥ 6 months; **AND**
- Diagnosis of dystrophic or junctional epidermolysis bullosa (EB) as confirmed by one of the following:
  - Immunofluorescence mapping (IFM); **OR**
  - Transmission electron microscopy (TEM); **OR**
  - Genetic testing; **AND**
- Prescribed by or in consultation with a dermatologist or geneticist
- **Quantity Limit:** 30 tubes (25ml containing 23.4 grams of gel per tube) per 30 days

#### RENEWAL REQUESTS

- Patient is demonstrating clinical benefit with use

## FILSPARI® (*SPARSENTAN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥18 years of age; **AND**
- Patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; **AND**
- Must be prescribed by, or in consultation with, a nephrologist; **AND**
- Prescriber must be certified in and patient must be enrolled in the Filspari Risk Evaluation and Mitigation Strategies (REMS) program; **AND**
- Prescriber has confirmed aminotransferases (ALT, AST) are < 3x upper limit of normal (ULN) and will measure aminotransferase levels and total bilirubin monthly for the first 12 months after initiation, then every 3 months for the duration of treatment; **AND**
- Prescriber will confirm negative pregnancy test prior to initiating therapy, once monthly during treatment, and one month after discontinuation for patients of reproductive potential.

## FINACEA® (*AZELAIC ACID*)

**Length of Authorization:** For the duration of the prescription up to 1 year

### CRITERIA TO APPROVE

- Mild to moderate rosacea that is unresponsive to standard first line treatments or clinical rationale why 1st line treatments not appropriate

## FIRAZYR® (*ICATIBANT*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Diagnosis of hereditary angioedema

## FIRDAPSE® (AMIFAMPRIDINE)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS); **AND**
- Patient does not have a history of seizures; **AND**
- Prescribed by a neurologist

## FULYZAQ® (*CROFELEMER*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Current therapy with antiretroviral meds; **AND**
- Therapeutic failure on any anti-diarrheal medication

## FUROSCIX® (*FUROSEMIDE*)

**Length of Authorization:** 1 month

### CRITERIA TO APPROVE

- Patient is 18 years or older; **AND**
- Diagnosis of chronic heart failure (CHF); **OR**
- Diagnosis of chronic kidney disease (CKD), including nephrotic syndrome; **AND**
- Prescribed by or in consultation with a cardiologist or nephrologist; **AND**
- Provider attestation that member is showing signs of extracellular volume expansion due to CHF or kidney disease; **AND**
- Provider attestation that member does not have anuria, hepatic cirrhosis, ascites, or hypersensitivity to furosemide or adhesive; **AND**
- Provider attestation that member will use Furoscix for short-term use only and will be transitioned to oral diuretics as soon as practical
- Quantity Limit: 8 kits per 30 days

## GALAFOLD® (*MIGALASTAT*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Diagnosis of Fabry disease; **AND**
- Patient had an amenable galactosidase alpha gene (GLA) variant based on an in vitro assay; **AND**
- Patient will not use in combination with agalsidase beta (Fabrazyme); **AND**
- Prescribed by or in consultation with a specialist in genetic disorders
- Quantity limit = 14 caps per 28 days

## GASTROINTESTINAL: ANTIEMETICS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Up to 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Therapeutic failure with 48-hour trial with one preferred medication
- See additional medication-specific criteria below:

#### AKYNZEO®

- May only be approved for highly emetogenic regimens or regimens including anthracyclines and cyclophosphamide that are not considered highly emetogenic and
- Therapeutic failure on a preferred 5-HT3 receptor antagonist (granisetron, ondansetron) and a preferred substance P receptor agonist (Emend)

### QUANTITY LIMITS

| | |
|---|---|
| Akynzeo® (netupitant/palonosetron) | 1 per fill |
| Emend® (aprepitant) 125mg/80mg dose pack | 3 tablets per claim – billed by the tablet, not by the pack |
| Emend® (aprepitant) 40mg, 125mg tablet | 1 tablet per claim |
| Emend® (aprepitant) 80mg tablet | 2 tablets per claim |
| granisetron (Kytril®) 1mg tab | 15 per fill |
| granisetron (Kytril®) 1mg/5ml oral soln | 150 mL per fill |
| ondansetron (Zofran®) 4mg, 8mg tablet, ODT | 60 per 30 days |
| Ondansetron (Zofran®) 16mg tablet, ODT | 30 per 30 days |
| ondansetron (Zofran®) 4mg/5ml oral solution | 75mL per fill |
| Sancuso® (granisetron) transdermal patch | 1 patch every 5 days |

## GASTROINTESTINAL: BILE SALTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Up to 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on a one-month trial of one preferred medication

## GASTROINTESTINAL: CHRONIC GI MOTILITY

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Up to 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication within the same subclass
- See additional medication-specific criteria below:

#### AMITIZA® *(LUBIPROSTONE)*

- Patients is ≥18 years of age; **AND**
- Quantity limit of 2 tablets/day

#### IBSRELA® *(TENAPANOR)*

- Patients is ≥18 years of age; **AND**
- Diagnosis of irritable bowel syndrome with constipation (IBS-C); **AND**
- Therapeutic failure after one-month trial of one preferred agent of IBS-C; **AND**
- Quantity limit of 2 tablets/day

#### LINZESS® *(LINACLOTIDE)*

- Patients is ≥6 years of age; **AND**
- Quantity limit of 1 tablet/day

#### LOTRONEX® *(ALOSETRON)*

- Patient is female; **AND**
- Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Therapeutic failure after one-month trial of diphenoxylate/atropine or loperamide

#### MOTEGRITY® *(PRUCALOPRIDE)*

- Diagnosis of chronic idiopathic constipation (CIC); **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Therapeutic failure after one-month trial of one preferred agent for CIC

#### RELISTOR® *(METHYLNALTREXONE)*

- Diagnosis of opioid induced constipation (OIC); **AND**
- Therapeutic failure after one-month trial of one preferred agent for OIC

#### SYMPROIC® *(NALDEMEDINE TOSYLATE)*

- Diagnosis of opioid induced constipation (OIC); **AND**
- Therapeutic failure after one-month trial of one preferred agent for OIC

#### TRULANCE® *(PLECANATIDE)*

- Diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C); **AND**

- Therapeutic failure after one-month trial of one preferred agent for CIC or IBS-C

VIBERZI® *(ELUXADOLINE)*

- Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Therapeutic failure after one-month trial of diphenoxylate/atropine or loperamide
- Quantity limit = 60 tabs per 30 days

## GASTROINTESTINAL: H. PYLORI TREATMENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one course (e.g. 10-14 days) trial of the preferred agent

## GASTROINTESTINAL: PANCREATIC ENZYMES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Therapeutic failure after one-month trial of one preferred agent
- See additional medication-specific criteria below:

CREON®, ZENPEP® *(LIPASE/PROTEASE/AMYLASE)*

- Cystic fibrosis or chronic pancreatic insufficiency.

PERTZYE®, VIOKACE® *(LIPASE/PROTEASE/AMYLASE)*

- Must meet both PDL (trial on preferred medication) and clinical criteria

## GASTROINTESTINAL: PROGESTINS FOR CACHEXIA

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial of one preferred agent

## GASTROINTESTINAL: PROTON PUMP INHIBITORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial with one preferred medication

### QUANTITY LIMITS

| | |
|---|---|
| Omeprazole 20 mg capsule | 2 per day |
| Omeprazole 10 mg capsule | 2 per day |
| Omeprazole 40 mg capsule | 2 per day |
| Nexium 20 mg packet (esomeprazole) | 2 per day |
| Nexium 40 mg packet (esomeprazole) | 2 per day |
| Nexium 10 mg packet (esomeprazole) | 2 per day |
| Nexium 2.5 mg packet (esomeprazole) | 2 per day |
| Nexium 5 mg packet (esomeprazole) | 2 per day |
| Protonix 20 mg tablet (pantoprazole) | 2 per day |
| Protonix 40 mg tablet (pantoprazole) | 2 per day |
| Protonix 40 mg suspension (pantoprazole) | 2 per day |

## GASTROINTESTINAL: ULCERATIVE COLITIS – ORAL

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial with one preferred medication

## GATTEX® (*TEDUGLUTIDE*)

**Length of Authorization:** 1 year

### DIAGNOSES TO APPROVE

- Short bowel syndrome

## GIMOTI® (*METOCLOPRAMIDE*) NASAL SPRAY

**Length of Authorization:** 12 weeks

### CRITERIA TO APPROVE

- Patient age ≥18 years; **AND**
- Patient has a diagnosis of diabetic gastroparesis with acute or recurrent symptoms; **AND**
- Patient has had a trial and failure to an oral metoclopramide dosage form; **OR**
- Patient is unable to ingest oral dosage forms due to one of the following:
  - Oral/motor difficulties; **OR**
  - Dysphagia

## GLUTAMINE

**Length of Authorization:** 1 year

### DIAGNOSES TO APPROVE

- History of transplant
- Currently receiving chemotherapy
- Currently receiving immunosuppressant therapy
- Short gut syndrome

## GLYCOPYRROLATE INJECTION – USED ORALLY

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Indicated use to reduce secretions

## GONITRO® SUBLINGUAL POWDER *(NITROGLYCERIN)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Clinical reason why patient cannot use sublingual nitroglycerin tablets

## HAEGARDA® (C1 ESTERASE INHIBITOR)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Patient has a history of ONE of the following criteria for long-term hereditary angioedema (HAE) prophylaxis:
  - History of 2 or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes) **OR**
  - Patient is disabled more than 5 days per month by HAE **OR**
  - History of recurrent laryngeal attacks caused by HAE; **AND**
- Patient is 6 years of age or older; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology or medical genetics; **AND**
- Treatment with 'on demand' therapy (i.e., Kalbitor, Firazyr, Ruconest, Berinert) did not provide satisfactory control (i.e., treatment for acute attacks was unsuccessful); **AND**
- Therapeutic failure, intolerance or contraindication to attenuated (17 alpha-alkylated) androgens (i.e., danazol) for HAE prophylaxis

## HORMONE THERAPY FOR GENDER DYSPHORIA

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient has had an initial evaluation completed by a health care provider experienced in gender dysphoria that specializes in treatment and evaluation of gender disorders (including health history, physical exam, desired treatment goals and relevant lab testing); **AND**
- Persistent well documented gender dysphoria; **AND**
- Patient has the ability to make a fully informed decision and consent of treatment; **AND**
- Prior consent for treatment including potential adverse health effects, expected benefits/effects including future body image changes and potential effects on fertility; **AND**
- No significant medical or mental health concerns and, if so, they been addressed and been deemed to not be a contraindication to therapy

#### RENEWAL REQUEST

- Patient has had ongoing follow-up and monitoring following standard guidelines including addressing mental health concerns (for example, Version 7 WPATH Standards of Care or 2017 Clinical Practice Guideline, Endocrine Society https://doi.org/10.1210/jc.2017-01658

## HYFTOR® (*SIROLIMUS*) GEL

**Length of Authorization:** Initial = 3 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 6 years old; **AND**
- Patient has a documented diagnosis of facial angiofibroma associated with tuberous sclerosis; **AND**
- Prescribed by, or in consultation with, a dermatologist or a neurologist
- Quantity Limit:
  - Ages 6 -11 years: Up to 2 tubes (20 grams) per 30 days
  - Age 12 years and older: Up to 3 tubes (30 grams) per 30 days

#### RENEWAL REQUEST

- Prescriber attests to positive symptom improvement based on size and redness of facial angiofibroma

## IMCIVREE (SETMELANOTIDE)

**Length of Authorization:** Initial requests 16 weeks; renewal up to 12 months.

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 2 years of age; **AND**
- Genetic testing demonstrates homozygous or compound heterozygous mutations in one of the
- following genes: POMC, PCSK1, or LEPR; **AND**
- The genetic variant is interpreted as pathogenic, likely pathogenic, or of uncertain significance; **OR**
- Patient has a diagnosis of Bardet-Biedl Syndrome; **AND**
- If patient ≥ 18 years of age: body mass index (BMI) ≥ 30 kg/m2; **OR**
- If patient is 2 to 17 years of age: BMI ≥ 95th percentile for age and sex; **AND**
- Prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders.

#### RENEWAL REQUEST

- Patient has achieved a weight loss of ≥5% of baseline weight; **OR**
- Patient has achieved at least a 5% reduction in baseline BMI for patients with continued growth potential.

## IMMUNOGLOBULIN GAMMA

**Length of Authorization:** According to prescribing physician's recommendations related to patient's condition – 1 month, 3 months, 6 months or 1 year

### DIAGNOSIS TO APPROVE

- Immunodeficiency syndrome
- Idiopathic thrombocytopenia purpura
- B-cell chronic lymphocytic leukemia
- Kawasaki syndrome
- Bone marrow transplant patients
- Pediatric HIV infection
- Chronic fatigue syndrome
- Myasthenia gravis
- Chronic inflammatory demyelinating polyneuropathy (CIDP)

## IMVEXXY® (*ESTRADIOL*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Patient has diagnosis of moderate to severe dyspareunia

## INCRELEX® AND IPLEX® (MECASERMIN RINFABATE [RDNA ORIGIN])

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE FOR CHILDREN ONLY

- Severe primary IGF-1 deficiency (Primary IGFD) defined by:
  - Height standard deviation score < -3.0: **AND**
  - Basal IGF-1 below normal: **AND**
  - Normal or elevated growth hormone; **AND**
- Growth hormone gene deletion in patients who have developed neutralizing antibodies to Growth Hormone; **AND**
- Patient is 2 years of age or older; **AND**
- For Increlex 40 mg/4 mL vials, patient must be ≤17 years of age; **AND**
- Prescriber must be a pediatric endocrinologist; **AND**
- Patient has open epiphyses

## INFUVITE® PEDIATRIC VIALS (MULTIVIT INFUSION, PEDI 1,VIT K)

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Patient must be ≤ 11 years of age

## INGREZZA® (*VALBENAZINE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Diagnosis of chorea associated with Huntington's disease **OR** tardive dyskinesia secondary to use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.); **AND**
- For tardive dyskinesia, attestation that a baseline AIMS test has been completed; **AND**
- Patient ≥ 18 years of age; **AND**
- Prescribed by or in consultation with a neurologist or psychiatrist

#### RENEWAL REQUESTS

- Attestation of patient's improvement in symptoms associated with their condition; **AND**
- For tardive dyskinesia, attestation that a follow-up AIMS test has been completed and there has been a positive response to therapy

## INTRAROSA® (*PRASTERONE*)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Post-menopausal female with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy; **AND**
- One-month trial on a vaginal estrogen product (i.e., Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem)

## INVELTYS® *(LOTEPREDNOL ETABONATE)* OPHTHALMIC DROPS

**Length of Authorization:** 3 months

### CRITERIA TO APPROVE

- Therapeutic failure on a generic ophthalmic prednisolone, dexamethasone, fluorometholone or loteprednol drops; **OR**
- Contraindication, allergy or history of unacceptable side effects to the afore-mentioned generic products

## IQIRVO® (ELAFIBRANOR)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 18 years of age or older; **AND**
- Diagnosis of primary biliary cholangitis (PBC) confirmed by two or more of the following:
  - Alkaline phosphatase (ALP) is elevated above the upper limit of normal as defined by normal laboratory reference values
  - Presence of antimitochondrial antibody (AMA), or other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
  - Histologic evidence of PBC seen on biopsy; **AND**
- Patient had inadequate response for at least 12 months to ursodeoxycholic acid (UDCA/ursodiol) or intolerance to UDCA/ursodiol; **AND**
- Patient does not have decompensated cirrhosis; **AND**
- Prescribed by or in consultation with a gastroenterologist or hepatologist; **AND**
- Will not be used in combination with Ocaliva (obeticholic acid) or Livdelzi (seladelpar)

#### RENEWAL REQUESTS

- Prescriber attests that the patient has achieved or maintained a clinical benefit from therapy; **AND**
- Patient has not progressed to decompensated cirrhosis

## ISTURISA® *(OSILODROSTAT)* TABLETS

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Diagnosis of Cushing's disease; **AND**
- Pituitary surgery is not an option; **AND**
- Prescribed by, or in consultation with, an endocrinologist.

## IVERMECTIN TABLETS *(STROMECTOL®)*

**Length of Authorization:** Date of service

### QUANTITY LIMIT

- Quantity limit = 10 tablets per 30 days

## JATENZO® (TESTOSTERONE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); **AND**
- Patient is 18 years of age or older; **AND**
- Serum testosterone < 300 ng/dL
- For requests submitted for gender dysphoria, please refer to the **Hormone Therapy for Gender Dysphoria criteria**

## JOENJA® (*LENIOLISIB*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 12 years of age; **AND**
- Patient has a genetic phosphoinositide 3-kinase delta (PI3Kδ) mutation with a variant in PIK3CD and/or PIK3R1 genes; **AND**
- Prescriber obtained a baseline assessment of symptoms, signs, and manifestations of APDS; **AND**
- If applicable, prescriber has verified non-pregnant status and counseled patient on use of highly effective contraception during and for 1 week after last use; **AND**
- Prescribed by or in consultation with an immunologist, pulmonologist, allergist, hematologist, oncologist, gastroenterologist, or a physician who specializes in the treatment of APDS.
- **Quantity Limit:** 2 tabs per day

#### RENEWAL REQUEST

- Submission of most recent (within 6 months of request) clinical notes that demonstrate a response to therapy.

## JUXTAPID® (*LOMITAPIDE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Homozygous familial hypercholesterolemia; **AND**
- Qualifying prescriber specialty (endocrinologist, lipidologist, or cardiologist with lipodology experience); **AND**
- Confirmation that prescriber is REM certified

## JYNARQUE® (*TOLVAPTAN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age ≥ 18 years; **AND**
- Diagnosis of autosomal dominant polycystic kidney disease (ADPKD); **AND**
- Prescribed by a nephrologist; **AND**
- Baseline ALT, AST, and bilirubin tests within normal limits (copy of test results not required)
- For renewal, lab results must continue to be within normal limits

## KARBINAL® ER SUSPENSION *(CARBINOXAMINE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Clinical rationale why carbinoxamine immediate release is not appropriate for use.

## KERENDIA® (*FINERENONE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 year of age; **AND**
- Patient has a diagnosis of type 2 diabetes; **AND**
- Patient has a diagnosis of chronic kidney disease (CKD); **AND**
- Patient is currently receiving a maximally tolerated dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or has a contraindication to ACE or ARB; **AND**
- Patient is not taking any strong CYP3A4 inhibitors; **AND**
- Patient has eGFR ≥ 25 mL/min/1.73 m2; **AND**
- Serum potassium is ≤ 5 mEq/L.

## KRINTAFEL® (TAFENOQUINE SUCCINATE)

**Length of Authorization:** One-time fill

### CRITERIA TO APPROVE

- Diagnosis of Plasmodium vivax malaria; **AND**
- Prescribed by or in consultation with an infectious disease specialist; **AND**
- Patient ≥ 16 years old; **AND**
- Patient must be negative for G6PD deficiency (attestation that the patient has been tested is required); **AND**
- If female, patient must not be pregnant; **AND**
- Prescribed in combination with an appropriate antimalarial therapy (i.e., chloroquine); **AND**
- Dose does not exceed 300mg (two-150mg tablets) as a single dose

## KORLYM® (MIFEPRISTONE)

**Length of Authorization:** 6 months

### DIAGNOSIS TO APPROVE

- Hyperglycemia associated with type 2 diabetes secondary to Cushing's syndrome

## LAMPIT® (*NIFURTIMOX*)

**Length of Authorization:** 60 days

### CRITERIA TO APPROVE:

- Patient must be < 18 years of age; AND
- Patient must weigh ≥ 2.5 kg; AND
- Patient has a diagnosis of Chagas disease cause by Trypanosoma cruzi confirmed by serologic testing.

## LEUPROLIDE ACETATE INJECTION

**Length of Authorization:** For the duration of the prescription up to 1 year

### DIAGNOSIS TO APPROVE:

- Endometriosis
- Prostate cancer
- Precocious puberty
- Fibroids (uterine leiomyomata)

## LICE AND SCABIES TREATMENT

**Length of Authorization:** Date-of-service

NATROBA® *(SPINOSAD)*

- Patient is ≥6 months of age

SKLICE® *(IVERMECTIN)*

- Patient is ≥6 months of age

OVIDE® *(MALATHION)*

- Patient is ≥2 years of age

## LIDODERM® PATCH *(LIDOCAINE)*

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Quantity limit = 30 patches per 30 days
- Quantity limit exception for postherpetic neuralgia

## LIDOTRAL® 3.88% CREAM *(LIDOCAINE)*

**Length of Authorization:** date of service

### CRITERIA TO APPROVE

- A one-month trial/failure of generic lidocaine cream or ointment is required

## LITFULO® (RITLECITINIB)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 12 years of age; **AND**
- Diagnosis of severe alopecia areata
- Quantity limit: 1 capsule per day

## LIVDELZI® (*SELADELPAR*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 18 years of age or older; **AND**
- Diagnosis of primary biliary cholangitis (PBC) confirmed by two or more of the following:
  - Alkaline phosphatase (ALP) is elevated above the upper limit of normal as defined by normal laboratory reference values
  - Presence of antimitochondrial antibody (AMA), or other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
  - Histologic evidence of PBC seen on biopsy; **AND**
- Patient had inadequate response for at least 12 months to ursodeoxycholic acid (UDCA/ursodiol) or intolerance to UDCA/ursodiol; **AND**
- Patient does not have decompensated cirrhosis; **AND**
- Prescribed by or in consultation with a gastroenterologist or hepatologist; **AND**
- Will not be used in combination with Ocaliva (obeticholic acid) or Iqirvo (elafibranor)

#### RENEWAL REQUESTS

- Prescriber attests that the patient has achieved or maintained a clinical benefit from therapy; **AND**
- Patient has not progressed to decompensated cirrhosis

## LIVMARLI® (*MARALIXIBAT*)

**Length of Authorization:** initial = 6 months; renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is ≥ 3 months of age; **AND**
- Patient is diagnosed with Alagille syndrome; **AND**
- Patient has evidence of cholestasis, as evidenced by ≥ 1 of the following:
  - Serum bile acid > 3 times upper limit of normal (ULN) for age; **OR**
  - Conjugated bilirubin > 1 mg/dL; **OR**
  - Gamma glutamyl transferase (GGT) > 3 times ULN for age; **OR**
  - Fat soluble vitamin deficiency not otherwise explained; **OR**
  - Intractable pruritus only explained by liver disease; **AND**
  - Patient experiences persistent moderate to severe pruritus; **AND**
  - Prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist); **OR**
- Patient is diagnosed with progressive familial intrahepatic cholestasis (PFIC); **AND**
  - Patient is ≥12 months of age; **AND**
  - Patient has elevated serum bile acid concentration; **AND**
  - Patient experiences persistent moderate to severe pruritus; **AND**
  - Prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist)

#### RENEWAL REQUESTS

- Patient has experienced a reduction in serum bile acid concentration; AND
- Patient has experience improvement in pruritis

## LODOCO® (*COLCHICINE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Patient has one of the following conditions or diagnoses:
  - A previous myocardial infarction or a history of an acute coronary syndrome; **OR**
  - Angina (stable or unstable); **OR**
  - A past history of stroke or transient ischemic attack; **OR**
  - Coronary artery disease; **OR**
  - Peripheral arterial disease; **OR**
  - Patient has undergone a coronary or other arterial revascularization procedure in the past; **AND**
- Patient does not have severe hepatic impairment; **AND**
- Patient does not have renal failure (e.g. creatine clearance < 15ml/min); **AND**
- Patient does not have pre-existing blood dyscrasias
- Quantity Limit: 1 tablet per day

## LUMIZYME® (ALGLUCOSIDASE ALFA)

**Length of Authorization:** 1 year

- Requests for clinical prior authorization for office/clinic/infusion center administration for FFS patients should be referred to the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.
- Requests for clinical prior authorization for office/clinic/infusion center administration for Health Plan patients should be referred to the Health Plan.
- Requests for FFS patients submitted for home administration will require MDHHS review and must specifically indicate that the medication will be home infused (versus being infused in an office/clinic/infusion center setting).

## LUPANETA® (LEUPROLIDE/NORETHINDRONE)

**Length of Authorization:** 1 year

- Clinical rationale why the individual components (injectable leuprolide and oral norethindrone) are not appropriate for use.

## LUPKYNIS® (*VOCLOSPORIN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age ≥18 years; **AND**
- Diagnosis of lupus nephritis; **AND**
- Prescribed by or in consultation with a rheumatologist or nephrologist; **AND**
- Patient must concomitantly receive background immunosuppressive therapy (mycophenolate mofetil (MMF) and corticosteroids), with the exception of cyclophosphamide.

## LYFGENIA® (LOVOTIBEGLOGENE AUTOTEMCEL)

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## MALARONE® (ATOVAQUONE/PROGUANIL)

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- For Malarone 62.5/25 mg pediatric tablets, patient must be ≤ 16 years of age.

## METOCLOPRAMIDE ODT *(METOZOLV ODT®)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Clinical rationale why generic Reglan (metoclopramide) is inappropriate (i.e., swallowing difficulty)

## MIDAZOLAM INJECTABLE

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- **Intranasal** use for diagnosis of uncontrolled or partially controlled epilepsy
- Quantity limit (per fill) = 4 kits

## MIFEPREX® (*MIFEPRISTONE*)

**Length of Authorization:** 1 fill

### CRITERIA TO APPROVE

- Prescriber attests or pharmacy reports an allowed ICD-10 diagnosis from the prescription order on the submitted pharmacy claim.
- The allowed diagnoses, listed below, ensure that the medication is prescribed in accordance with the American College of Obstetricians and Gynecologists (ACOG) recommendations for miscarriage management in the patient's home. (Updated Mifepristone REMS Requirements | ACOG)
- *NOTE: When physician administered and billed by the practitioner office as a medical benefit to the Department's CHAMPS, this product is covered without prior authorization.*

### ALLOWED DIAGNOSES FOR MISCARRIAGE

| ICD10 | Diagnosis |
|---|---|
| O02.1 | Missed Abortion |
| O20.0 | Threatened Abortion |
| O03.0 | Genital tract and pelvic infection fol incmpl spon abortion |
| O03.1 | Delayed or excessive hemor following incmpl spon abortion |
| O03.2 | Embolism following incomplete spontaneous abortion |
| O03.30 | Unsp complication following incomplete spontaneous abortion |
| O03.31 | Shock following incomplete spontaneous abortion |
| O03.32 | Renal failure following incomplete spontaneous abortion |
| O03.33 | Metabolic disorder following incomplete spontaneous abortion |
| O03.34 | Damage to pelvic organs following incomplete spon abortion |
| O03.35 | Oth venous comp following incomplete spontaneous abortion |
| O03.36 | Cardiac arrest following incomplete spontaneous abortion |
| O03.37 | Sepsis following incomplete spontaneous abortion |
| O03.38 | Urinary tract infection following incomplete spon abortion |
| O03.39 | Incomplete spontaneous abortion with other complications |
| O03.4 | Incomplete spontaneous abortion without complication |
| O03.5 | Genital tract and pelvic infct fol complete or unsp spon abort |
| O03.6 | Delayed or excess hemor fol complete or unsp spon abortion |
| O03.7 | Embolism following complete or unsp spontaneous abortion |
| O03.80 | Unsp comp following complete or unsp spontaneous abortion |
| O03.81 | Shock following complete or unspecified spontaneous abortion |
| O03.82 | Renal failure following complete or unsp spon abortion |
| O03.83 | Metabolic disorder following complete or unsp spon abortion |
| O03.84 | Damage to pelvic organs fol complete or unsp spon abortion |
| O03.85 | Oth venous comp following complete or unsp spon abortion |
| O03.86 | Cardiac arrest following complete or unsp spon abortion |
| O03.87 | Sepsis following complete or unsp spontaneous abortion |
| O03.88 | Urinary tract infection fol complete or unsp spon abortion |
| O03.89 | Complete or unsp spontaneous abortion with oth complications |
| O03.9 | Complete or unsp spontaneous abortion without complication |

## MINOLIRA® (*MINOCYCLINE*) EXTENDED-RELEASE TABLETS

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of acne vulgaris; **AND**
- Patient is 12 years of age or older; **AND**
- Clinical reason why (covered) generic minocycline cannot be used

## MIPLYFFA® (*ARIMOCLOMOL*)

**Length of Authorization:** initial = 1 year; renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 2 years of age or older; **AND**
- Patient weighs at least 8 kg; **AND**
- Diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating biallelic pathogenic variants in either the NPC1 gene or NPC2 gene; **AND**
- At least one neurological sign of Niemann-Pick disease type C (e.g. loss of motor function, swallowing, and speech and cognitive impairment); **AND**
- Patient has the ability to walk independently or with assistance; **AND**
- Patient will use Miplyffa concurrently with miglustat; **AND**
- Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C.

#### RENEWAL REQUESTS

- Prescriber attests that the patient demonstrates positive clinical response to therapy (e.g. slowing of disease progression, improvement in neurological symptoms of disease)

## MIRVASO® (*BRIMONIDONE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- ≥ 18 years old **AND**
- Diagnosis of rosacea **AND**
- Documented trial/failure (or clinical inappropriateness) of topical metronidazole, retinoids and oral antibiotics

## MISCELLANEOUS: ANDROGENIC AGENTS (TOPICAL)

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Serum testosterone < 300 ng/dL
- Trial and failure with one preferred medication
- For requests submitted for gender dysphoria, please refer to the **Hormone Therapy for Gender Dysphoria criteria**
- For renewals, confirm that testosterone levels are being monitored annually.
- Contraindications:
  - Severe renal or cardiac diseases
  - Benign prostatic hyperplasia with obstruction
  - Prostate cancer
  - Undiagnosed genital bleeding
  - Breast cancer
  - Pregnancy

## MISCELLANEOUS: ANTIHYPERURICEMIC AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial of one preferred agent
- See additional medication-specific criteria below:

#### GLOPERBA® *(COLCHICINE)* ORAL SOLUTION

- Allow if patient has difficulty swallowing tablets or has enteral tube feeding.

## MISCELLANEOUS: ANTI-OBESITY AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Initial = 6 months; Renewal = 6 months

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Prescriber attests that the patient will not use more than one weight loss medication in this drug class concurrently; **AND**
- Prescriber attests that the patient will not use an anti-obesity GLP-1 agonist (Wegovy, Saxenda or Zepbound) concurrently with a medication that contains a DPP-4 inhibitor (alogliptin, linagliptin, saxagliptin or sitagliptin; **AND**
- Patient ≥ 18 years of age; **OR**
- Patient age ≥12 years (Wegovy, Xenical, Saxenda, phentermine/topiramate); **OR**
- Patient age ≥17 years (phentermine); **AND**
- Patient age ≥12 years to <18 years must have an initial BMI per CDC growth charts at the 95$^{th}$ percentile or greater for age and sex (obesity)**; OR**
- Patient age ≥12 years to <18 years with BMI in the 85$^{th}$ – 94$^{th}$ percentile (overweight) per CDC growth charts and has at least one of the following weight-related coexisting conditions:
  - diabetes, sleep apnea, hypertension, or dyslipidemia**; OR**
- Patient age ≥18 years (benzphetamine, diethylpropion, phendimetrazine, Zepbound®); **AND**
- Patient age ≥18 years must have an initial body mass index [BMI] ≥ than 30 kg/m$^2$; **OR**
- Patient age ≥18 years must have an initial body mass index [BMI] ≥ than 27 kg/m$^2$ but <30 kg/m$^2$ and at least one of the following risk factors:
  - hypertension, coronary artery disease, diabetes, dyslipidemia, or sleep apnea; **OR**
  - This medication is being prescribed for cardiovascular risk reduction in patients with prior myocardial infarction, prior stroke or peripheral arterial disease (Wegovy);
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this anti-obesity treatments**; AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.)**; AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability**; AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

#### RENEWAL REQUEST

- For patients age ≥12 years to <18 years, prescriber provides clinical documentation showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy.
- For patients age ≥18 years, prescriber provides clinical documentation showing that the patient has maintained a weight loss of ≥ 5% from baseline weight at initiation of therapy.

## QUANTITY LIMITS

| | |
|---|---|
| Saxenda (liraglutide) 18 mg/3 mL pens | 15 mL (5 pens) per 30 days |
| Wegovy (semaglutide) 0.25 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 0.50 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 1 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 1.7 mg/0.75 mL pens | 3 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 2.4 mg/0.75 mL pens | 3 mL (4 pens) per 28 days |
| Xenical (orlistat) 120 mg capsules | 90 caps per 30 days |
| Zepbound (tirzepatide) 2.5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 7.5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 10 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 12.5 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Zepbound (tirzepatide) 15 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |

# MISCELLANEOUS: IMMUNOMODULATORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

## DRUG CLASSES

- Agents to Treat Asthma
- Agents to Treat Atopic Dermatitis
- Agents to Treat Chronic Idiopathic Urticaria
- Agents to Treat Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
- Agents to Treat Eosinophilic Esophagitis (EoE)
- Agents to Treat Eosinophilic Granulomatosis with Polyangiitis (EGPA)
- Agents to Treat Hypereosinophilic Syndrome (HES)
- Agents to Treats Nonsegmental Vitiligo
- Agents to Treat Prurigo Nodularis (PN)
- Agents to Treat Ankylosing Spondylitis
- Agents to Treat Hidradenitis Suppurativa
- Agents to Treat Juvenile Idiopathic Arthritis
- Agents to Treat Non-radiographic Axial Spondyloarthritis
- Agents to Treat Plaque Psoriasis
- Agents to Treat Psoriatic Arthritis
- Agents to Treat Rheumatoid Arthritis
- Agents to Treat Uveitis
- Agents to Treat Crohn's Disease
- Agents to Treat Ulcerative Colitis

## AGENTS TO TREAT ASTHMA

| | |
|---|---|
| **Length of Authorization:** | 1 year |

## CRITERIA TO APPROVE

### CLINICAL PA CRITERIA FOR ASTHMA INDICATIONS FOR EACH AGENT

- Patient's asthma symptoms have not been adequately controlled by at least three months of an asthma treatment regimen that must include an inhaled corticosteroid; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

### NON-PREFERRED AGENT PA CRITERIA

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication

## MEDICATION-SPECIFIC PA CRITERIA

### DUPIXENT® *(DUPILUMAB)*

- Note:
  - A 56-day supply will be allowed for patients requiring dosing once every 28 days (every 4 weeks)
  - The pre-filled PEN is for use in adult and pediatric patients aged 2 years and older.
  - The pre-filled SYRINGE is for use in adult and pediatric patients aged 6 months and older.
- **Patient must have moderate to severe asthma diagnosed as ONE of the following types**:

- Asthma with eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL; **OR**
- Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months; **AND**
- Patient must be 6 years of age or older

### XOLAIR® *(OMALIZUMAB)*

- **Moderate to severe persistent asthma; AND**
  - Patient is 6 years of age or older; **AND**
  - Patient has a positive skin test or in vitro testing (RAST, etc.) for allergen specific IgE antibodies for one or more seasonal aeroallergens; **AND**
  - Baseline IgE level is ≥ 30 IU/ml

### FASENRA® *(BENRALIZUMAB)*

- **Patient must have severe asthma; AND**
  - Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months; **AND**
  - Patient must be 6 years of age or older

### NUCALA® *(MEPOLIZUMAB)*

- **Patient must have severe asthma; AND**
  - Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months; **AND**
  - Patient must be 6 years of age or older; **AND**
  - For Nucala 40mg/0.4 mL, patient age must be ≤ 11 years of age.

### TEZSPIRE® *(TEZEPELUMAB-EKKO)*

- **Patient must have severe asthma; AND**
  - Patient is 12 years of age or older; **AND**
  - Patient has been trained to self-administer this product; **AND**
  - Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Tezspire
  - Bypass PDL criteria if patient does not meet medication specific criteria for Preferred agents (e.g. eosinophil blood count and/or IgE blood level requirements)

## AGENTS TO TREAT ATOPIC DERMATITIS

| **Length of Authorization:** | 6 months for **FDA approved diagnosis** noted below |
|---|---|

## CRITERIA TO APPROVE

### CLINICAL PA CRITERIA FOR ATOPIC DERMATITIS INDICATIONS FOR EACH AGENT

Diagnosis of atopic dermatitis

- **Adbry® (tralokinumab-ldrm)**: moderate to severe for ages ≥ 12 years
- **Cibinqo® (abrocitinib)**: moderate to severe for ages ≥ 12 years
- **Dupixent® (dupilumab)**: moderate to severe for ages ≥ 6 months
- **Ebglyss® (lebrikizumab-lbkz):** moderate to severe for ages ≥12 years
- **Elidel® (pimecrolimus)**: mild to moderate for ages ≥ 2 years
- **Eucrisa® (crisaborole):** mild to moderate for ages ≥ 3 months
- **Nemluvio (nemolizumab-ilto):** moderate to severe for ages ≥12 years
- **Opzelura® (ruxolitinib):** mild to moderate for ages ≥12 years
- **Rinvoq® (upadacitinib):** moderate to severe for ages ≥ 12 years
- **tacrolimus 0.03%**: moderate to severe for ages ≥ 2 years
- **tacrolimus 0.1%:** moderate to severe for ages ≥ 16 years

### NON-PREFERRED AGENT PA CRITERIA

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with one preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication

## MEDICATION-SPECIFIC PA CRITERIA

### DUPIXENT® *(DUPILUMAB)*

Note:

- A 56-day supply will be allowed for patients requiring dosing once every 28 days (every 4 weeks)
- The pre-filled PEN is for use in adult and pediatric patients aged 2 years and older.
- The pre-filled SYRINGE is for use in adult and pediatric patients aged 6 months and older.

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient ≥ 6 months old

### EBGLYSS® *(LEBRIKIZUMAB-LBKZ)*

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient is 12 years of age or older; **AND**
- Patient weighs at least 40 kg (88 lbs)

### NEMLUVIO® *(NEMOLIZUMAB-ILTO)*

**Initial Request**

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient has atopic dermatitis estimated to affect ≤ 20% of the body surface area; **AND**
- Patient age ≥ 12 years old

**Renewal Request**

- Documentation submitted demonstrating a positive response to therapy.
    - Prescriber attests the patient has achieved clear or almost clear skin, and in accordance with the product label, the patient will be transitioned to a dosage of 1 pen (30 mg) every 8 weeks. *NOTE: renewal PA will limit dosage accordingly*; OR
    - Prescriber attests the patient has not achieved clear or almost clear skin yet but has had a positive response to therapy. Prescriber is requesting continuation of dosage of 1 pen (30 mg) every 4 weeks.

### OPZELURA® *(RUXOLITINIB)*

- Diagnosis of mild to moderate atopic dermatitis; **AND**
- Patient has atopic dermatitis estimated to affect ≤ 20% of the body surface area; **AND**
- Patient age ≥ 12 years old

## QUANTITY LIMITS

| | |
|---|---|
| Adbry® (tralokinumab-ldrm) 150 mg/mL syringes | 4 syringes (4 mL) per 28 days (special allowance for initial dose) |
| Adbry® (tralokinumab-ldrm) 300 mg/2 mL autoinjectors | 2 syringes (4 mL) per 28 days (special allowance for initial dose) |
| Ebglyss® (lebrikizumab-lbkz) 250mg/2 mL prefilled pens | 1 pen (2 mL) per 28 days (special allowance for initial and induction doses) |
| Elidel® (pimecrolimus) | 30 gm per 30 days |
| Eucrisa® (crisaborole) | 100 gm per 30 days |
| Nemluvio® (nemolizumab-ilto) 30 mg/0.49 mL prefilled pens | 1 pen (30 mg) per 28 days (special allowance of 2 pens for loading dose) |
| Opzelura (ruxolitinib) | 240 gm (4 x 60 gm) per 30 days |
| tacrolimus (generic for Protopic®) | 30gm per 30 days |

## AGENTS TO TREAT CHRONIC IDIOPATHIC URTICARIA/CHRONIC SPONTANEOUS URTICARIA

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

DUPIXENT® *(DUPILUMAB)*

- Diagnosis of Chronic Spontaneous Urticaria (CSU)/Chronic Idiopathic Urticaria; **AND**
- Patient is 12 years of age or older; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
- Patient has had urticaria for at least 6 weeks with symptoms present despite an adherent trial of at least 2 weeks duration of an H1-antihistamine.

XOLAIR® *(OMALIZUMAB)*

- Diagnosis of Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CSU); **AND**
- Patient is 12 years of age or older; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
- Patient has had urticaria for at least 6 weeks with symptoms present despite an adherent trial of at least 2 weeks duration of an H1-antihistamine.

## AGENTS TO TREAT CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

DUPIXENT® *(DUPILUMAB)*

- Diagnosis of inadequately controlled chronic obstructive pulmonary disease (COPD); **AND**
- Patient has an eosinophilic count ≥300 cells/mcL; **AND**
- Patient ≥ 18 years old; **AND**
- Patient is concurrently treated with triple therapy with inhaled corticosteroid [ICS], long-acting beta-2 agonist [LABA], and long-acting muscarinic antagonist [LAMA]; **OR**
- Patient is concurrently treated with a LABA and LAMA if ICS therapy is contraindicated.

NUCALA® *(MEPOLIZUMAB)*

- Diagnosis of inadequately controlled chronic obstructive pulmonary disease (COPD); **AND**
- Patient has had an eosinophilic count ≥300 cells/mcL; **AND**
- Patient ≥ 18 years old; **AND**
- Patient is concurrently treated with triple therapy with inhaled corticosteroid [ICS], long-acting beta-2 agonist [LABA], and long-acting muscarinic antagonist [LAMA]; **OR**
- Patient is concurrently treated with a LABA and LAMA if ICS therapy is contraindicated.

## AGENTS TO TREAT CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSOSIS (CRSwNP)

**Length of Authorization:** 1 year

### NON-PREFERRED AGENT PA CRITERIA

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication

### MEDICATION-SPECIFIC PA CRITERIA

#### DUPIXENT® *(DUPILUMAB)*

- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND**
- Patient ≥ 12 years old; **AND**
- Patient has inadequate response after 3 consistent months use of intranasal steroids or oral corticosteroids; **AND**
- Patient is concurrently treated with intranasal corticosteroids

#### XOLAIR® *(OMALIZUMAB)*

- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND**
- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with an allergist, immunologist or otolaryngologist; **AND**
- Patient has not been adequately controlled by at least three months of treatment with an intranasal steroids or oral corticosteroids; **AND**
- Baseline IgE level is ≥ 30 IU/mL**; AND**
- Patient is concurrently treated with intranasal corticosteroids

#### NUCALA® *(MEPOLIZUMAB)*

- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND**
- Patient is 18 years of age or older; **AND**
- Patient has inadequate response after 3 consistent months use of intranasal steroids or oral corticosteroids; **AND**
- Patient is concurrently treated with intranasal corticosteroids

## AGENTS TO TREAT EOSINOPHILIC ESOPHAGITIS (EoE)

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

#### DUPIXENT® *(DUPILUMAB)*

- Diagnosis of eosinophilic esophagitis (EoE); **AND**
- Patient ≥1 years old; **AND**
- Patient weighs ≥ 15 kg; **AND**
- Prescribed by or consultation with an allergist or gastroenterologist; **AND**
- Patient did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor

## AGENTS TO TREAT EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)

**Length of Authorization:** 1 year

### NON-PREFERRED AGENT PA CRITERIA

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication

### MEDICATION-SPECIFIC PA CRITERIA

FASENRA® *(BENRALIZUMAB)*

- Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA); **AND**
- Patient is 18 years of age or older

NUCALA® *(MEPOLIZUMAB)*

- Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA); **AND**
- Patient is 18 years of age or older

## AGENTS TO TREAT HYPEREOSINOPHILIC SYNDROME (HES)

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

NUCALA® *(MEPOLIZUMAB)*

- Diagnosis of hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause; **AND**
- Patient is 12 years of age or older

## AGENTS TO TREAT IgE-MEDIATED FOOD ALLERGY

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

XOLAIR® *(OMALIZUMAB)*

- Diagnosis of IgE-mediated food allergy; **AND**
- Patient is 1 year of age or older; **AND**
- Prescribed by or in consultation with an allergist or immunologist; **AND**
- Patient will follow food allergen avoidance in conjunction with Xolair; AND
- Baseline IgE level is ≥ 30 IU/mL

## AGENTS TO TREAT NONSEGMENTAL VITILIGO

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

OPZELURA® *(RUXOLITINIB)*

- Diagnosis of nonsegmental vitiligo; **AND**
- Patient has vitiligo involvement estimated to affect ≤ 10% of the body surface area; **AND**
- Patient is ≥12 years old; **AND**
- Prescribed by or in consultation with a dermatologist

## AGENTS TO TREAT PRURIGO NODULARIS (PN)

**Length of Authorization:** 1 year

### MEDICATION-SPECIFIC PA CRITERIA

DUPIXENT® *(DUPILUMAB)*

- Diagnosis of prurigo nodularis (PN); **AND**
- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with a dermatologist, allergist, or immunologist

NEMLUVIO® *(NEMOLIZUMAB-ILTO)*

- Diagnosis of prurigo nodularis (PN); **AND**
- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with a dermatologist, allergist, or immunologist
- Quantity Limit: 1 pen (30mg) per 28 days (special allowance of 2 pens for loading dose and patients weighing ≥90 kg)

## BIOLOGIC IMMUNOMODULATORS

**Length of Authorization:** 1 year, unless otherwise noted in Medication-Specific Information

- Agents to Treat Ankylosing Spondylitis
- Agents to Treat Hidradenitis Suppurativa
- Agents to Treat Juvenile Idiopathic Arthritis
- Agents to Treat Non-radiographic Axial Spondyloarthritis
- Agents to Treat Plaque Psoriasis
- Agents to Treat Psoriatic Arthritis
- Agents to Treat Rheumatoid Arthritis
- Agents to Treat Uveitis
- Agents to Treat Crohn's Disease
- Agents to Treat Ulcerative Colitis

## CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable at this time, so that switching medications would cause deterioration in their condition; **OR**
- Therapeutic failure with one preferred medication in the same subclass
- Bypass PDL criteria of a failure with a preferred agent when the non-preferred product has a unique FDA approved indication.

## MEDICATION-SPECIFIC PA CRITERIA

### ABRILADA® *(ADALIMUMAB-AFZB)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## ACTEMRA® *(TOCILIZUMAB)* SC

- Patient is 2 years of age or older; **AND**
  - Diagnosis of active polyarticular juvenile idiopathic arthritis; **OR**
  - Diagnosis of active systemic juvenile idiopathic arthritis; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of giant cell arteritis; **OR**
  - Diagnosis systemic sclerosis-associated interstitial lung disease

## AMJEVITA® *(ADALIMUMAB-ATTO)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## BIMZELX® *(BIMEKIZUMAB-BKZX)*

- Diagnosis of moderate to severe plaque psoriasis (PsO); **OR**
- Diagnosis of active psoriatic arthritis (PsA)**; OR**
- Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; **OR**
- Diagnosis of active ankylosing spondylitis (AS)**; OR**
- Diagnosis of moderate to severe hidradenitis suppurativa (HS); **AND**
- Patient must be 18 years or older

## CYLTEZO® AND UNBRANDED *(ADALIMUMAB-ADBM)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## ENTYVIO® *(VEDOLIZUMAB)*

- Diagnosis of Crohn's disease; **OR**
- Diagnosis of ulcerative colitis; **AND**
- Patient must be 18 years or older; **AND**
- Trial and failure on one medication from **each** of the following classes:
  - Aminosalicylate [i.e., mesalamine (Asacol®HD, Pentasa®, Lialda®, Apriso®, Delzicol®), olsalazine (Dipentum®), balsalazide (Colazal®, sulfasalazine (Azulfidine®)]
  - Oral steroid
  - Thiopurine [i.e., azathioprine (Imuran®), mercaptopurine (Purinethol®)]
  - TNF (tumor necrosis factor) blocker [i.e., infliximab (Remicade®), adalimumab (Humira®)]
  - Length of authorization: Initial approval = 14 weeks; renewal = 1 year

## HADLIMA® *(ADALIMUMAB-BWWD)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## HULIO® AND UNBRANDED *(ADALIMUMAB-FKJP)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## HYRIMOZ® AND UNBRANDED *(ADALIMUMAB-ADAZ)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**

- Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## IDACIO® *(ADALIMUMAB-AACF)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## ILUMYA® *(TILDRAKIZUMAB)*

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Patient must be 18 years or older

## KEVZARA® *(SARILUMAB) - PDL CRITERIA DO NOT APPLY FOR POLYMYALGIA RHEUMATICA (PMR)*

- Diagnosis of polymyalgia rheumatica (PMR); **OR**
- Diagnosis of moderately to severely active rheumatoid arthritis (RA); **OR**
- Diagnosis of polyarticular juvenile idiopathic arthritis; **AND**
- Patient must be 18 years or older

## OLUMIANT® *(BARICITINIB) – PDL CRITERIA DO NOT APPLY FOR ALOPECIA AREATA*

- Diagnosis of moderate to severe rheumatoid arthritis; **OR**
- Diagnosis of severe alopecia areata; **AND**
- Patient must be 18 years or older

## OMVOH® *(MIRIKIZUMAB-MRKZ)*

- Diagnosis of moderately to severely active ulcerative colitis (UC); **OR**
- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Patient must be 18 years or older; **AND**
- Prescribed by or in consultation with a gastroenterologist

## OTEZLA® *(APREMILAST)*

- Patient must be 6 years or older; **AND**
  - Diagnosis of plaque psoriasis; **OR**
- Patient must be 18 years or older; **AND**
  - Diagnosis of psoriatic arthritis with 3 or more swollen and tender joints; **OR**
  - Diagnosis of oral ulcers associated with Behçet's Disease; **AND**
- Must be prescribed by or in consultation with a rheumatologist or dermatologist.

## RINVOQ® / RINVOQ LQ® *(UPADACITINIB)*

- Patient must be 2 years or older; **AND**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of polyarticular juvenile idiopathic arthritis; **OR**
- Patient must be 18 years or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of giant cell arteritis; **OR**
  - Diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA); **OR**
  - Diagnosis of moderate to severely active Crohn's disease; **OR**
  - Diagnosis of moderate to severely active ulcerative colitis

## SILIQ® *(BRODALUMAB)*

- Diagnosis of plaque psoriasis; **AND**
- Patient must be 18 years or older

## SIMLANDI® AND UNBRANDED *(ADALIMUMAB-RYVK)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## SKYRIZI® *(RISANKIZUMAB)*

- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with a dermatologist or rheumatologist: **OR**
- Diagnosis of Crohn's disease; **OR**
- Diagnosis of ulcerative colitis; **AND**
- Prescribed by or in consultation with a gastroenterologist or rheumatologist

## SOTYKTU® *(DEUCRAVACITINIB)*

- Patient ≥18 years of age: **AND**
- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Must be prescribed by or in consultation with a dermatologist; **AND**
- Quantity Limit: 1 per day

## STELARA® *(USTEKINUMAB)*

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks

## TALTZ® *(IXEKIZUMAB)*

- Patient must be 6 years of age or older with a diagnosis of moderate to severe plaque psoriasis; **OR**
- Patient must be 18 years or older; **AND**
- Diagnosis of psoriatic arthritis; **OR**
- Diagnosis of active ankylosing spondylitis; **OR**
- Diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA); **AND**
- Must be prescribed by a rheumatologist or dermatologist or asthma/allergy specialist

## TREMFYA® *(GUSELKUMAB)*

- Diagnosis of moderate to severe plaque psoriasis (PSO); **OR**
- Diagnosis of psoriatic arthritis (PsA); **OR**
- Diagnosis of moderately to severely active ulcerative colitis (UC); **OR**
- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Patient must be 18 years or older

## TYENNE® *(TOCILIZUMAB-AAZG)* AUTOINJECTOR/SYRINGE

- Patient is 2 years of age or older; **AND**
  - Diagnosis of active polyarticular juvenile idiopathic arthritis; **OR**
  - Diagnosis of active systemic juvenile idiopathic arthritis; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of giant cell arteritis

## VELSIPITY® *(ESTASIMOD)*

- Diagnosis of moderately to severely active ulcerative colitis (UC); **AND**
- Patient must be 18 years or older; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**

- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes ONLY: A baseline ophthalmic evaluation of the fundus, including the macula, has been performed before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months.

## XELJANZ® / XELJANZ XR®/ XELJANZ® SOLUTION *(TOFACITINIB)*

**Xeljanz tablets and Xeljanz solution:**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (Note: Xeljanz Solution is only approved for pJIA.); **OR**

**Xeljanz and Xeljanz XR tablets:**

- Patient is 18 years of age or older; **AND**
  - Diagnosis of rheumatoid arthritis (RA) or
  - Diagnosis of psoriatic arthritis (PsA); **OR**
  - Diagnosis of ankylosing spondylitis (AS); **AND**
  - Must be prescribed by or in consultation with a rheumatologist or dermatologist; **OR**
  - Diagnosis of ulcerative colitis; **AND**
  - Prescribed by or in consultation with a gastroenterologist
- Xeljanz Solution is only approved for Polyarticular Juvenile Idiopathic Arthritis (pJIA)

## YUFLYMA® AND UNBRANDED *(ADALIMUMAB-AATY)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

## YUSIMRY® *(ADALIMUMAB-AQVH)*

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**

- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
- Diagnosis of non-infectious intermediate, posterior, or panuveitis

### ZEPOSIA® *(OZANIMOD)*

- Patient is 18 years of age or older; **AND**
- Diagnosis of moderately to severely active ulcerative colitis (UC); **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, has been performed before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months

### ZYMFENTRA® *(INFLIXIMAB-DYYB)*

- Patient is 18 years of age or older; **AND**
- Diagnosis is moderate to severe Crohn's disease; **OR**
- Diagnosis of moderate to severe ulcerative colitis; **AND**
- Prescriber attests that the patient has completed an intravenous induction regimen with an infliximab product; **AND**
- Prescribed by or in consultation with a gastroenterologist

## MISCELLANEOUS: BPH AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

## MISCELLANEOUS: COLONY STIMULATING FACTORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication
- See additional medication-specific criteria below:

### QUANTITY LIMITS

| | |
|---|---|
| Fulphila® (pegfilgrastim-jmdb) | 0.6 mL per 14 days |
| Fylnetra® (pegfilgrastim-pbbk) | 0.6 mL per 14 days |
| Neulasta® (pegfilgrastim) | 0.6 mL per 14 days |
| Neulasta Onpro® (pegfilgrastim) | 0.6 mL per 14 days |
| Nyvepria® (pegfilgrastim-abgf) | 0.6 mL per 14 days |
| Stimufend® (pegfilgrastim-fpgk) | 0.6 mL per 14 days |
| Udenyca® (pegfilgrastim-cbqv) | 0.6 mL per 14 days |
| Zarxio® (filgrastim-sndz) | 45 mL per 30 days |
| Ziextenzo® (pegfilgrastim-bmez) | 0.6 mL per 14 days |

## MISCELLANEOUS: EPINEPHRINE INJECTABLE

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

- Therapeutic failure or contraindication to use of a preferred medication
- See additional medication-specific criteria below:

### NEFFY® *(EPINEPHRINE) NASAL SPRAY*

- Patient weighs at least 30 kg

### QUANTITY LIMITS

| | |
|---|---|
| Adrenaclick® (epinephrine) | 4 per fill |
| Auvi-Q® (epinephrine) | 4 per fill |
| epinephrine | 4 per fill |
| Epipen® (epinephrine) | 4 per fill |
| Epipen Jr® (epinephrine) | 4 per fill |
| Neffy (epinephrine) nasal spray | 4 sprays (2 pkgs) per fill |

## MISCELLANEOUS: GROWTH HORMONES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

**Clinical Class PA Criteria**

- Requests must be submitted by an endocrinologist or nephrologist.
- Panhypopituitarism – Cachexia, pituitary; Necrosis of pituitary (postpartum); Pituitary insufficiency NOS; Sheehan's syndrome; Simmond's disease.
- Pituitary dwarfism – Isolated deficiency of (human) growth hormone [HGH]; Lorain-Levi dwarfism).
- Endocrine disorders – Other specified endocrine disorders: Pineal gland dysfunction; Progeria; Werner's syndrome.
- Indeterminate sex and pseudohermaphroditism – Gynandrism; Hermaphroditism; Ovotestis; Pseudohermaphroditism (male, female); Pure gonadal dysgenesis
- Gonadal dysgenesis – Turner's Syndrome (female only); XO syndrome; Ovarian dysgenesis
- Noonan Syndrome – Norditropin® is the only medication with this indication.
- Prader-Willi Syndrome - **Genotropin®**, **Norditropin FlexPro®** and **Omnitrope®** are the only medications with this indication
- **CKD – stage 1, 2 or 3** (CRI): **Nutropin®** is the only medication with this indication
- **CKD – stage 4 or 5** (CRF or ESRD)
- **SHOX: Humatrope®** is the only medication with this indication

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition

### REQUIRED TESTING INFORMATION

- **Growth hormone stimulation testing:**
  - Pituitary dwarfism: the patient must have failed ***two*** kinds of growth hormone stimulation tests for the diagnosis. Testing is required for pediatric, adolescent, and adult patients. For adolescent patients whose epiphyseal growth plates are closed and for adult patients, testing must be done after growth hormone therapy has been suspended for at least 3 months.
  - Requester should document the kinds of stimulation tests performed, the result (lab value), reference range and date.
- **Bone age x-rays (required regardless of diagnosis; x-ray does not have to be performed within a specific time frame):**
  - Pediatric patients - bone x-ray report is required ***unless*** the prescriber is a (pediatric) endocrinologist
  - Adolescent patients (13 to 19 years of age)– bone x-ray report is required UNLESS the prescriber is a (pediatric) endocrinologist; the requester must also note whether or not the epiphyseal growth plates have closed.
  - Adult patients – bone x-ray report is **NOT** required.

- **Papilledema:**
    - Provider is aware of the risk of intracranial hypertension and the role of fundoscopic examination to assess and monitor for papilledema.
- For Idiopathic Short Stature, individual medical record and necessity review will be required.
- Requests that do not meet clinical criteria will require MDHHS review and must include the patient's diagnosis including ICD-10, if available. Growth charts should be provided, if available, at time of review (ensure that the correct chart is being submitted based on the patient's age – i.e., 0–3 vs 2–20) in addition to documentation of small for gestational age at birth, if appropriate.

### NGENLA® (*SOMATROGON-GHLA)*

- Maximum patient age = 16 years

### SEROSTIM® (*SOMATROPIN)*

- MDHHS physician review required for all requests regardless of diagnosis.

### SKYTROFA® (*LONAPEGSOMATROPIN-TCGD)*

- Maximum patient age = 16 years

## MISCELLANEOUS: HEMATOPOIETIC AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** For the duration of the prescription up to 6 months; 6 months for #2 below

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial with one preferred medication
- See additional medication-specific criteria below:

CHRONIC KIDNEY DISEASE STAGE 3, STAGE 4 [CRF - CHRONIC RENAL FAILURE] AND STAGE 5 [ESRD END STAGE RENAL DISEASE] (EPOGEN®, PROCRIT®, RETACRIT® AND ARANESP®):

- Hemoglobin level < 10 g/dL before treatment with **Epogen®, Procrit®, Retacrit®, Aranesp®** or transfusions
- **RENEWAL:** CURRENT hemoglobin level < 12 g/dL

KIDNEY TRANSPLANT PATIENTS - TRANSPLANTED KIDNEY IS NOTED AS NOT YET FUNCTIONING TO ANTICIPATED POTENTIAL (EPOGEN®, PROCRIT®, RETACRIT® AND ARANESP®):

- < 1-year post transplant
- CURRENT hemoglobin level < 12 g/dL

CHEMOTHERAPY OR RADIATION THERAPY CONFIRMED AS CURRENT (EPOGEN®, PROCRIT®, RETACRIT® AND ARANESP® ONLY):

- Hemoglobin level < 10 g/dL before beginning treatment with **Epogen®, Procrit®, Retacrit®, Aranesp®** or transfusions
- **RENEWAL:** CURRENT hemoglobin level < 12 g/dL

ANEMIA IN AIDS PATIENTS: (EPOGEN®, PROCRIT®, RETACRIT® ONLY)

- Hemoglobin level < 10 g/dL

ANEMIC PATIENTS SCHEDULED TO UNDERGO NON-CARDIAC, NON-VASCULAR SURGERY TO DECREASE NEED FOR TRANSFUSIONS: (EPOGEN®, PROCRIT®, RETACRIT® ONLY).

- Clinical rationale why alternative approaches such as donating own blood prior or transfusion is not an option.
- CURRENT hemoglobin level < 10 g/dL

MYELODYSPLASIA AND MYELODYSPLASTIC SYNDROME (EPOGEN®, PROCRIT, RETACRIT® ONLY):

- CURRENT hemoglobin level < 10 g/dL

HEPATITIS C WITH CURRENT INTERFERON TREATMENT (EPOGEN®, PROCRIT, RETACRIT® ONLY):

- Beginning hemoglobin level < 10 g/dL
- **RENEWAL:** CURRENT hemoglobin level < 12 g/dL

## JESDUVROQ (DAPRODUSTAT)

**INITIAL REQUESTS**

- Patient is ≥18 years of age; **AND**
- Diagnosis of anemia due to chronic kidney disease (CKD); **AND**
- Patient has been receiving dialysis for ≥4 months; **AND**
- Prescribed by or in consultation with a nephrologist or hematologist; **AND**
- Recent documentation (within 30 days of request) of ALL the following:
    - Patient is currently receiving an erythropoiesis-stimulating agent AND transitioning to Jesduvroq; **AND**
    - Patient has a hemoglobin level ≤ 12.0 g/dL; **OR**
    - Patient is NOT currently receiving an erythropoiesis-stimulating agent; **AND**
    - Patient has a baseline (prior to initiation of Jesduvroq) hemoglobin level < 11 g/dL; **AND**
    - Serum ferritin > 100 ng/mL (mcg/L); **AND**
    - Transferrin saturation (TSAT) >20%
- Length of approval: 6 months

**RENEWAL REQUESTS**

- Patient must continue to meet the above criteria; **AND**
    - Patient has experienced an increase in Hb from baseline; **AND**
    - Hemoglobin is < 12 g/dL
- Length of approval: 1 year

## VAFSEO (VADADUSTAT)

**INITIAL REQUESTS**

- Patient is 18 years of age or older; **AND**
- Diagnosis of anemia due to chronic kidney disease (CKD); **AND**
- Patient has been receiving dialysis for ≥3 months; **AND**
- Prescribed by or in consultation with a nephrologist or hematologist; **AND**
- Recent documentation (within 30 days of request) of ALL the following:
    - Patient is currently receiving an erythropoiesis-stimulating agent AND transitioning to Vafseo; **AND**
    - Patient has a hemoglobin level ≤ 12.0 g/dL; **OR**
    - Patient is NOT currently receiving an erythropoiesis-stimulating agent; **AND**
    - Patient has a baseline (prior to initiation of Vafseo) hemoglobin level < 11 g/dL; **AND**
    - Serum ferritin > 100 ng/mL (mcg/L); **AND**
    - Transferrin saturation (TSAT) >20%
- Length of approval: 6 months

**RENEWAL REQUESTS**

- Patient must continue to meet the above criteria; **AND**
    - Patient has experienced an increase in Hb from baseline; **AND**
    - Hemoglobin is < 12 g/dL
- Length of approval: 1 year

## MISCELLANEOUS: OSTEOPOROSIS AGENTS - BISPHOSPHONATES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications
- See additional medication-specific criteria below:

### QUANTITY LIMITS

| | |
|---|---|
| Atelvia® (risedronate) – brand & generic | 4 per 30 days |
| Actonel® (risedronate) | 35mg - 4 per 28 days |

## MISCELLANEOUS: OSTEOPOROSIS AGENTS - OTHER

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year (Forteo and Tymlos – maximum 2 years per lifetime)

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications
- See additional medication-specific criteria below:

### FORTEO® *(TERIPARATIDE) - PDL CRITERIA DO NOT APPLY*

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures
- Increase of bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- Length of authorization: maximum cumulative duration of 2 years per lifetime, unless clinical documentation is provided showing patient remains at or has returned to having a high risk for fracture

### TYMLOS® *(ABALOPARATIDE) - PDL CRITERIA DO NOT APPLY*

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures; **OR**
- Treatment of osteoporosis in men who are at high risk for fractures
- Length of authorization: maximum cumulative duration of 2 years per lifetime (includes any prior use of Forteo)

## MISCELLANEOUS: OSTEOPOROSIS AGENTS - SERMs

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications

## MISCELLANEOUS: PHOSPHATE DEPLETERS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of chronic kidney disease; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one month with one preferred medication
- See additional medication-specific criteria below:

#### VELPHORO® (*SUCROFERRIC OXYHYDROXIDE*)

- Trial on **two** preferred medications.

#### XPHOZAH® (*TENAPANOR*)

- Trial on **two** preferred medications; **AND**
- Patient is currently receiving dialysis

## MISCELLANEOUS: POTASSIUM BINDERS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial of a preferred medication for the indication

## MISCELLANEOUS: PROGESTATIONAL AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial of a preferred medication for the indication
- See additional medication-specific criteria below:

#### CRINONE® *(PROGESTERONE)* VAGINAL

- Excluded for diagnosis of fertility
- This physician-administered drug can only be covered under the pharmacy benefit when billed and administered by Home Infusion agency or LTC.

## MISCELLANEOUS: UREA CYCLE DISORDER AGENTS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial of one preferred medication; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition

## MISCELLANEOUS: URINARY TRACT ANTISPASMODICS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial of one preferred medication

## MISCELLANEOUS: UTERINE DISORDER TREATMENT

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** Orilissa 200mg = 6 months (maximum total duration of 6 months);
Oriahnn, Orilissa 150mg and Myfembree = 1 year (maximum total duration of 24 months)

### CRITERIA TO APPROVE

#### ORILISSA (*ELAGOLIX*) 150 MG

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of endometriosis with dyspareunia; **AND**
- Failure on an adequate trial of the following therapies:
    - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
    - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss
- Quantity Limit: 28 tablets per 28 days

#### ORILISSA (*ELAGOLIX*) 200 MG

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of endometriosis with dyspareunia; **AND**
- Failure on an adequate trial of the following therapies:
    - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
    - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**

- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss; **AND**
- Treatment duration of Orilissa 200mg twice daily has not exceeded a total of 6 months.
- Quantity Limit: 56 tablets per 28 days

ORIAHNN (*ELAGOLIX/ESTRADIOL/NORETHINDRONE)*)

- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **AND**
- Confirmed diagnosis of uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
- Failure on an adequate trial of hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); AND
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss.
- Quantity Limit: 56 tablets per 28 days

MYFEMBREE (*RELUGOLIX/ESTRADIOL/NORETHINDRONE)*)

- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **AND**
- Confirmed diagnosis of:
  - Uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
  - Failure on an adequate trial of hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **OR**
  - Moderate to severe pain associated with endometriosis; **AND**
- Failure on an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss.
- Quantity Limit: 28 tablets per 28 days

## MULPLETA® (LUSUTROMBOPAG)

**Length of Authorization:** One-time approval

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Diagnosis of chronic liver disease; **AND**
- Platelet count < 50 x $10^9$/L (document date of lab and level); **AND**
- Patient has a procedure scheduled (document date of procedure).

## MULTI-INGREDIENT COMPOUNDS

### GUIDANCE FOR PRIOR AUTHORIZATION AND REIMBURSEMENT

- The list of active pharmaceutical ingredients (APIs) and excipients allow for reimbursement of selected ingredients when submitted in a multi- ingredient compound. Refer to the list located at API & Excipient Coverage List.
- A prior authorization fax form was created for multi-ingredient compound (MIC) claims to facilitate the prior authorization process. This form is available at https://mi.primetherapeutics.com/provider/forms
- Please ensure that the pharmacy has submitted the compound claim. If the claim reimburses appropriately and none of the ingredients require a prior authorization, then submission of a PA form is not needed.
- If a prior authorization is needed for any of the ingredients or if the claim did not reimburse for a particular ingredient(s), please submit the multi-ingredient compound PA fax form. For reimbursement consideration of all ingredients, the pharmacy **MUST NOT** submit the claim with Submission Clarification Code (SCC) = 8. Submission of SCC = 8 will allow a claim to continue processing if at least one ingredient is covered with reimbursement for the covered product(s) only. Use of this provider level override prevents the call center from being able to accurately process the PA request.
- The NDC, name, dosage form, strength, and quantity of each ingredient used in the compound MUST be listed on the fax form for reimbursement consideration.

## MYALEPT® (*METRELEPTIN*)

**Length of Authorization:** One-time approval

### DIAGNOSIS TO APPROVE

- Congenital or acquired lipodystrophy (not due to HIV-related lipodystrophy), **OR**
- Partial lipodystrophy, **OR**
- Metabolic disease without concurrent evidence of generalized lipodystrophy

## MYCAPSSA® (OCTREOTIDE ACETATE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient must be ≥18 years of age; **AND**
- Patient has confirmed diagnosis of acromegaly; **AND**
- Attestation of a documented response and tolerability to a somatostatin analogue (e.g., octreotide or lanreotide) injection prior to use

## NASCOBAL® (CYANOCOBALAMIN, INTRANASAL [B12])

**Length of Authorization:** Up to a year

### CRITERIA TO APPROVE

- Documented B-12 deficiency with anemia (Hg less than 10 g/dL); **AND**
- Rationale why the injectable is inappropriate

## NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)

**Length of Authorization:** 1 year

- Requests for clinical prior authorization should be referred to the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.
- Requests submitted for home administration will require MDHHS review and must specifically indicate that the medication will be home infused (versus being infused in an office/clinic/infusion center setting).

## NITROMIST® (*NITROGLYCERIN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Clinical rationale why covered nitroglycerin products that do not require PA are inappropriate.

## NITYR® (NITISINONE)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Genetic tyrosinemia Type-1 (hereditary tyrosinemia Type-1)

## NOCDURNA® SUBLINGUAL TABLETS *(DESMOPRESSIN ACETATE)*

**Length of Authorization:** Initial = 6 months; Renewal = 12 months

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient ≥ 18 years old; **AND**
- Diagnosis of nocturnal polyuria (void ≥ 2 times per night); **AND**
- Patient does not have a disease state that increases risk for hyponatremia or worsened with fluid retention (uncontrolled hypertension, heart failure, syndrome of inappropriate antidiuretic hormone secretion (SIADH)); **AND**
- Patient is not currently taking loop diuretics or systemic or inhaled glucocorticoids; **AND**
- Estimated glomerular filtration rate (eGFR) ≥ 50 mL/min/1.73 $m^2$.

#### RENEWAL REQUESTS

- Patient shows a decrease in nocturnal voiding; **AND**
- Patient is not experiencing any toxicity such as hyponatremia, fluid retention or electrolyte imbalances.

## NOCTIVA® NASAL SPRAY (*DESMOPRESSIN ACETATE*)

**Length of Authorization:** Initial = 6 months; Renewal = 12 months

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient ≥ 50 years old; **AND**
- Diagnosis of nocturnal polyuria (void ≥ 2 times per night); **AND**
- Patient does not have a disease state that increases risk for hyponatremia or worsened with fluid retention (uncontrolled hypertension, heart failure, syndrome of inappropriate antidiuretic hormone secretion (SIADH)); **AND**
- Patient is not currently taking loop diuretics or systemic or inhaled glucocorticoids; **AND**
- Estimated glomerular filtration rate (eGFR) ≥ 50 mL/min/1.73 $m^2$.

#### INITIAL REQUESTS

- Patient shows a decrease in nocturnal voiding; **AND**
- Patient is not experiencing any toxicity such as hyponatremia, fluid retention or electrolyte imbalances

## NON-FORMULARY PRIOR AUTHORIZATION REQUESTS

**Length of Authorization:** Up to 1 year

### CRITERIA TO APPROVE

- Requests for non-formulary medications (i.e., medications excluded from coverage) must include clinical rationale for why the product is more appropriate for the patient than a similar formulary product.
- Non-formulary requests may be reviewed by MDHHS physicians for medical necessity and appropriateness.

## NORTHERA® (*DROXIDOPA*)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Neurogenic orthostatic hypotension

## NUZYRA® (OMADACYCLINE)

**Length of Authorization:** 14 days total duration

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Diagnosis of acute bacterial skin and skin structure infection (ABSSSI) or community acquired bacterial pneumonia (CABP) caused by susceptible pathogens; **AND**
- Patient is continuing treatment from an acute care admission, **OR**
- Patient is initiating therapy and has failed treatment with at least two antibiotics from two different classes approved for the infection (i.e., macrolides, quinolones, beta lactams such as cephalosporins or penicillins)

## OCALIVA® (OBETICHOLIC ACID)

**Length of Authorization:** Initial = 6 months; renewal = 1 year

### CRITERIA TO APPROVE

- Diagnosis of primary biliary cholangitis (PBC); **AND**
- Must be prescribed by a hepatologist or gastroenterologist; **AND**
- Patient meets the following:
  - Failure to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (i.e. ursodiol); **AND**
  - Medication will be used in combination with ursodeoxycholic acid; **OR**
  - History or intolerance to ursodeoxycholic acid **AND** failure to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit.
- For renewal requests, documentation of reduction in ALP level from pre-treatment baseline while on medication must be submitted (copy of lab report required).

## OFEV® (NINTEDANIB)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Idiopathic pulmonary fibrosis; **OR**
- Chronic interstitial lung disease (ILD); **OR**
- Systemic sclerosis-associated interstitial lung disease

## OHTUVAYRE® (*ENSIFENTRINE*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 18 years of age or older; **AND**
- Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD) confirmed by the following:
  - Spirometry demonstrating $FEV_1/FVC$ ration <0.7; **AND**
  - Post-bronchodilator $FEV_1$ ≥30% and ≤ 80% of predicted normal; **AND**
  - Modified Medical Research Council (mMRC) dyspnea score of ≥ 2 **OR** COPD Assessment Test (CAT) score of ≥ 10; **AND**
- Prescribed by or in consultation with a pulmonologist; **AND**
- Patient had inadequate response after a 3-month trial of either a LAMA/LABA dual-maintenance therapy or LAMA/LABA/ICS triple-maintenance therapy; **AND**
- Patient will continue LAMA/LABA dual therapy or LAMA/LABA/ICS triple therapy in combination with Ohtuvayre unless not tolerated or contraindicated; **AND**
- Member does not have a diagnosis of asthma; **AND**
- Prescriber attests Ohtuvayre will not be used in combination with roflumilast.

#### RENEWAL REQUESTS

- Documentation must demonstrate a decrease in symptoms and/or COPD exacerbations vs baseline; **AND**
- Continue use of dual or triple therapy that includes (LABA/LAMA) in conjunction with Ohtuvayre; **AND**
- Prescriber attests Ohtuvayre will not be used in combination with roflumilast.

## OPFOLDA® (*MIGLUSTAT*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient will take Opfolda one hour before infusion of Pombiliti

## OPHTHALMICS: GLAUCOMA

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication within the same subclass

## OPHTHALMIC ANTIBIOTICS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication

## OPHTHALMICS: ANTIHISTAMINES

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

## OPHTHALMICS: ANTI-INFLAMMATORY/IMMUNOMODULATORS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year (except Eysuvis – 2 weeks)

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a six-week trial with one preferred medication
- See additional medication-specific criteria below:

#### EYSUVIS® *(LOTEPREDNOL)*

- For Renewal: Patient has had an examination under magnification (e.g., slit lamp) and evaluation of the intraocular pressure (IOP)
- Renewal length of approval: 2 weeks

#### MIEBO® *(PERFLUOROHEXYLOCTANE/PF)*

- Patient is ≥18 years of age

#### VERKAZIA® (*CYCLOSPORINE*) – ***PDL CRITERIA DO NOT APPLY***

- Patient is ≥4 years of age; **AND**
- Diagnosis of moderate to severe vernal keratoconjunctivitis; **AND**
- Trial and failure, contraindication, or intolerance to one of the following:
  - Topical ophthalmic "dual-action" mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine); **OR**
  - Topical ophthalmic mast cell stabilizers (e.g., cromolyn); **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist

#### VEVYE® *(CYCLOSPORINE)*

- Patient is ≥18 years of age

### QUANTITY LIMITS

| | |
|---|---|
| Cequa (cyclosporine) 0.09% ophthalmic solution single-use containers | 60 per 30 days |
| Eysuvis (loteprednol) 0.25% eye drops | 8.3 ml (1 bottle) per 14 days |
| Miebo (perfluorohexyloctane/PF) eye drops | 3.0 ml per 30 days |
| Restasis (cyclosporine) 0.05% eye emulsion multi-dose vials | 5.5 ml (1 vial) per 30 days |
| Restasis (cyclosporine) 0.05% eye emulsion single-use containers | 60 per 30 days |
| Tyrvaya (varenicline) nasal spray | 8.4 ml (2 bottles) per 30 days |
| Verkazia (cyclosporine) ophthalmic emulsion | 120 single-dose vials per 30 days |
| Vevye (cyclosporine) ophthalmic drops | 2.0 mL per 30 days |
| Xiidra (lifitegrast) 5% eye drops single-use containers | 60 per 30 days |

## OPHTHALMICS: MAST CELL STABILIZERS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

## OPHTHALMICS: NSAIDS

**(PDL Class – see MICHIGAN PREFERRED DRUG LIST)**

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Medical necessity of lower strength dosages for post-operative pain relief; **OR**
- Therapeutic failure with a one-week trial with one preferred medication

## ORACEA® (DOXYCYCLINE IMMEDIATE / EXTENDED-RELEASE COMBINATION)

**Length of Authorization:** Date of service

### CRITERIA TO APPROVE

- Treatment of *only* inflammatory lesions (papules and pustules) of rosacea; **AND**
- Therapeutic failure on generic doxycycline.

## ORALAIR® (MIXED GRASS POLLEN ALLERGEN EXTRACT)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Trial and failure on two of the following drug classes: antihistamines, nasal steroids, leukotriene modifiers; **AND**
- Confirmation of IgE skin testing; **AND**
- Written by an allergist, ENT physician or physician who routinely gives allergy shots

## ORFADIN® (*NITISINONE*)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Genetic tyrosinemia Type-1 (hereditary tyrosinemia Type-1)

## OSPHENA® (*OSPEMIFENE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of dyspareunia (painful intercourse) due to menopause; **AND**
- Trial of conservative measures

## ORLADEYO® (*BEROTRALSTAT*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age ≥ 12 years; **AND**
- Diagnosis of Hereditary Angioedema (HAE) type I or type II; **AND**
- Patient has a history of ONE of the following criteria for long-term hereditary angioedema (HAE) prophylaxis:
    - History of two or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes); **OR**
    - Patient is disabled more than five days per month by HAE; **OR**
    - History of recurrent laryngeal attacks caused by HAE; **AND**
- Prescribed by or in consultation with an allergist, hematologist, pulmonologist or immunologist; **AND**
- Patient is not using Orladeyo in combination with another FDA-approved product for long-term prophylaxis of HAE attacks (e.g., Cinryze®, Haegarda®, Takhzyro™)

## ORTIKOS ER® (*BUDESONIDE*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age ≥ 8 years or older; **AND**
- Patient has a diagnosis of mild to moderate active Crohn's Disease; **OR**
- Patient age ≥ 18 years or older; **AND**
- Treatment is for the maintenance of remission of mild to moderate Crohn's Disease

## OTREXUP® (METHOTREXATE)

**Length of Authorization:** Psoriasis = 6 months; rheumatoid arthritis = 6 months for initial request and one year for renewal

### CRITERIA TO APPROVE

- Diagnosis of severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (polyarticular juvenile rheumatoid arthritis) or psoriasis; **AND**
- Trial and failure on oral methotrexate; **OR**
- Allergy to the preservative in methotrexate injection

## OVACE PLUS® (SULFACETAMIDE SODIUM)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Clinical rationale why a covered alternative is inappropriate

## OXANDRIN® (*OXANDROLONE*)

**Length of Authorization:** As noted below per diagnosis

### CRITERIA TO APPROVE

- To promote weight gain after weight loss following extensive surgery, severe trauma – 3-month approval
- To relieve bone pain accompanying osteoporosis – 6-month approval
- HIV Wasting syndrome – 6-month approval

## OXERVATE® (CENEGERMIN-BKBJ)

**Length of Authorization:** 8 weeks

### CRITERIA TO APPROVE

- Patient must be 2 years of age or older; **AND**
- Patient has diagnosis of moderate to severe neurotrophic keratitis; **AND**
- Prescribed by or in consultation with an ophthalmologist

## PALFORZIA® (PEANUT ALLERGEN POWDER-DNFP)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Diagnosis of peanut allergy; **AND**
- Confirmation of positive skin test or peanut-specific serum IgE; **AND**
- Prescribed by an allergist or immunologist; **AND**
- Patient is 1 to 17 years of age; **OR**
- Patient is greater than 17 years of age and in maintenance phase of therapy; **AND**
- Prescribed concurrently with injectable epinephrine; **AND**
- Prescriber is certified/enrolled in the Palforzia REMS Program

#### RENEWAL REQUEST

- Patient continues to exhibit a positive clinical response to therapy
- Patient has not experienced any treatment-restricting adverse reactions

## PALYNZIQ® (PEGVALIASE-PQPZ)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of phenylketonuria; **AND**
- Uncontrolled blood phenylalanine concentrations > 600 micromol/L with current therapy (document date of lab and level); **AND**
- Adherence to dietary restriction of protein and phenylalanine; **AND**
- Patient is not concurrently receiving sapropterin (Kuvan) therapy or will taper and discontinue once therapeutic dose of Palynziq is achieved.

## PHYSICIAN-ADMINISTERED INJECTION REQUESTS

**Length of Authorization:** Up to 1 year

### CRITERIA TO APPROVE

- Approval as a pharmacy benefit of injectable medications typically administered by a healthcare professional may be granted if the medication is to be administered in the home or in an LTC setting
- Injectable Medications administered in an office or clinic setting cannot be approved as a pharmacy benefit unless specific criteria exists

## POKONZA® (POTASSIUM CHLORIDE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient has had a 7-day trial and failure of, or is not a candidate for, a generic potassium chloride product

## PRETOMANID® (*PRETOMANID*)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Diagnosis of pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); **AND**
- Patient is concomitantly taking bedaquiline (Sirturo) and linezolid (Zyvox) as part of the recommended dosing regimen and use of bedaquiline and linezolid are not contraindicated in patient; **AND**
- Prescribed by or in consultation with an infectious disease specialist or pulmonologist

## PROCYSBI® (*CYSTEAMINE*)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Cystinosis

## PROMACTA® (*ELTROMBOPAG*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient age is ≥1 year

## PROVIGIL® (*MODAFINIL*) AND NUVIGIL® (*ARMODAFINIL*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

**Refer to STIMULANTS FOR NON-ATTENTION DEFICIT DISORDERS CRITERIA**

## PYRUKYND® (*MITAPIVAT*)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Patient age ≥ 18 years; **AND**
- Patient must have a diagnosis of hemolytic anemia due to pyruvate kinase deficiency; **AND**
- Patient must have ≥ 2 variant alleles (at least 1 must be a missense variant) in the pyruvate kinase liver and red blood cell (PKLR) gene; **AND**
- Patient must have hemoglobin ≤ 10 g/dL or receives regular blood transfusions (at least 6 in the past year)Patient is an allogeneic hematopoietic stem cell transplant (HSCT) recipient.

## RADICAVA® (*EDARAVONE*) ORS SUSPENSION

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥18 years of age; **AND**
- Diagnosis of amyotrophic lateral sclerosis (ALS); **AND**
- Prescribed by or in consultation with a neurologist

## RASUVO® (METHOTREXATE)

**Length of Authorization:** Psoriasis = 6 months; rheumatoid arthritis = 6 months for initial request and one year for renewal

### CRITERIA TO APPROVE

- Diagnosis of severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (polyarticular juvenile rheumatoid arthritis) or psoriasis; **AND**
- Trial and failure on oral methotrexate; **OR**
- Allergy to the preservative in methotrexate injection

## RAYALDEE® (*CALCIFEDIOL*)

**Length of Authorization:** Initial = 3 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Diagnosis of secondary hyperparathyroidism in adult with stage 3 or 4 chronic kidney disease; **AND**
- Serum total 25-hydroxyvitamin D level less than 30 ng/mL (document level); **AND**
- Serum calcium level below 9.8 mg/dL (document level); **AND**
- Previous treatment, intolerance or contraindication to generic calcitriol and paricalcitol or doxercalciferol

#### RENEWAL REQUESTS

- Intact parathyroid hormone (PTH) is above treatment goal; **AND**
- Serum total 25-hydroxyvitamin D level less than 100 ng/mL (document level); **AND**
- Serum calcium level below 9.8 mg/dL (document level)

## RECORLEV® (LEVOKETOCONAZOLE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥18 years of age; **AND**
- Patient has a diagnosis of endogenous Cushing's syndrome; **AND**
- Patient is not a candidate for surgical treatment or surgery has not been curative; **AND**
- Prescribed by or in consultation with an endocrinologist

## REDITREX® (*METHOTREXATE/PF*) SYRINGE

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (polyarticular juvenile rheumatoid arthritis) or psoriasis **AND**
- Trial and failure on generic oral or injectable methotrexate

## REZDIFFRA® (*RESMETIROM*)

**Length of Authorization:** Initial = 1 year; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 18 years of age or older; **AND**
- Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH); **AND**
- Prescriber attests that the disease is fibrosis stage F2 or F3 as confirmed by one of the following:
  - Liver biopsy; **OR**
  - Noninvasive tests such as FibroScan or magnetic resonance elastography (MRE); **AND**
- Prescriber attests that the medication will be used in conjunction with diet and exercise; **AND**
- Prescriber attests that the patient does not have decompensated cirrhosis; **AND**
- Medication is prescribed by or in consultation with a hepatologist or gastroenterologist or endocrinologist

#### RENEWAL REQUESTS

- Prescriber attests that the patient is showing disease improvement as evidenced by NASH resolution or improvement in liver fibrosis.

## RHOFADE® (*OXYMETAZOLINE*)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Diagnosis of rosacea; **AND**
- Patient ≥ 18 years old; **AND**
- Inadequate treatment response, intolerance, or contraindication to first line treatment with oral antibiotic (tetracycline, minocycline, doxycycline, erythromycin, clindamycin) or topical antibiotic (azelaic acid [Finacea], brimonidine [Mirvaso], ivermectin [Soolantra] and metronidazole [MetroGel, MetroLotion, MetroCream])

## RHOGAM® (RHO[D] IMMUNE GLOBULIN)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Self-administered by a Rh-negative woman to prevent hemolytic disease to newborn; **OR**
- Self-administered for the prevention of Rh immunization in any Rh-negative person after incompatible transfusion of Rh-positive blood or blood products

## RIVFLOZA® (*NEDOSIRAN*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 2 years of age; **AND**
- Patient has a definitive diagnosis of primary hyperoxaluria type 1 (PH1) with confirmed AGXT mutation via genetic testing or liver enzyme analysis; **AND**
- Patient does not have renal impairment defined as an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 $m^2$; **AND**
- Patient has NOT had a liver transplant; **AND**
- Rivfloza will NOT be used in combination with Oxlumo (lumasiran); **AND**
- Prescribed by, or in consultation with a nephrologist or urologist.

#### RENEWAL REQUEST

- Patient is demonstrating a positive response to therapy as evidenced by reduced urinary or plasma oxalate levels.

## RUCONEST® (C1 ESTERASE INHIBITOR, RECOMBINANT)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 13 years of age or older; **AND**
- Diagnosis of hereditary angioedema

## RUZURGI® (AMIFAMPRIDINE)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS); **AND**
- Patient is between 6 years old and 17 years old; **AND**
- Patient does not have a history of seizures; **AND**
- Prescribed by a neurologist

## RYVENT® (CARBINOXAMINE)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Intolerance or treatment failure of one-month trial of at least two generic antihistamines, either first generation (i.e., carbinoxamine, chlorpheniramine, brompheniramine) or second generation (i.e., cetirizine, loratadine)

## SAMSCA® (*TOLVAPTAN*)

**Length of Authorization:** 30 days

### CRITERIA TO APPROVE

- Hypervolemic or euvolemic hyponatremia – serum sodium < 125mEq/L

## SIGNIFOR® / SIGNIFOR® LAR *(PASIREOTIDE)*

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Cushing's disease or Cushing's syndrome if the patient has failed or is not a candidate for (pituitary) surgery

## SIRTURO® (*BEDAQUILINE*)

**Length of Authorization:** 6 months

### DIAGNOSIS TO APPROVE

- Multi-drug resistant tuberculosis (MDR-TB); **AND**
- Patient must be under observed therapy

## SKYCLARYS® *(OMAVLOXOLONE)* CAPSULES

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 16 years of age; **AND**
- Patient has a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing of the FXN gene; **AND**
- Prescriber confirmed that B-Type Natriuretic Peptide (BNP) is ≤ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; **AND**
- Prescriber obtained baseline aminotransferases (ALT, AST), total bilirubin and lipid parameters prior to initiating therapy and will monitor periodically during therapy as recommended; **AND**
- Prescriber obtained a baseline assessment of symptoms, signs, and manifestations of Friedreich's ataxia; **AND**
- Prescribed by or in consultation with a neurologist, cardiologist, physiatrist (physical medical and rehabilitation), or endocrinologist.

#### RENEWAL REQUEST

- Submission of most recent clinical notes (within 6 months of request) that demonstrate a response to therapy and lab monitoring in accordance with the product label.

## SOFDRA® (*SOFPIRONIUM*)

**Length of Authorization:** Initial = 3 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is 9 years of age or older; AND
- Diagnosis of primary axillary hyperhidrosis; AND
- Symptoms of hyperhidrosis have persisted for at least 6 months
- Quantity Limit: 1 bottle (50 mL) per 30 days

#### RENEWAL REQUEST

- Prescriber attests that the patient demonstrates clinical benefit to therapy

## SOHONOS® (*PALOVAROTENE*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 8 years of age for females; **OR**
- Patient is ≥ 10 years of age for males; **AND**
- Patient has an established diagnosis of fibrodysplasia ossificans progressiva as confirmed by the following findings:
  - Clinical presentation and imaging findings consistent with fibrodysplasia ossificans progressiva; **AND**
  - Identification of a heterozygous pathogenic variant in the *ACVR1* gene by molecular genetic testing; **AND**
- Patient has had a baseline assessment of skeletal maturity via hand/wrist and knee x-rays, standard growth curves, and pubertal staging and will have continued monitoring throughout therapy until the patient reaches skeletal maturity or final adult height; **AND**
- Female patients of reproductive potential must have a negative pregnancy test within 1 week prior to initiating treatment and periodically during therapy

#### RENEWAL REQUEST

- Patient must continue to meet the above criteria; **AND**
- Absence of unacceptable toxicity from the drug; **AND**
- Patient continues to be assessed for skeletal maturity; **AND**
- Female patients continue to be monitored for negative pregnancy test; **AND**
- Patient has shown a beneficial response to treatment as evidenced by ANY of the following:
  - Reduction, stabilization, or slowing of the rate of annualized volume of new heterotopic ossification (HO)
  - Reduction or improvement in the signs and symptoms of, or number of flare-ups as compared to baseline.

## SOLARAZE® *(DICLOFENAC)* 3% GEL

**Length of Authorization:** For the duration of the prescription up to 1 year

### DIAGNOSIS TO APPROVE

- Actinic keratosis

## SOLOSEC® *(SECNIDAZOLE)* GRANULES

**Length of Authorization:** Date of service

### CRITERIA TO APPROVE

- Female patient age is 12 years of age or older; **AND**
- Diagnosis of bacterial vaginosis; **AND**
- Patient has experienced a treatment failure for a previous bacterial vaginosis infection with at least one of the following agents: oral or vaginal metronidazole, oral or vaginal clindamycin, or oral tinidazole
- Quantity limit = 1 packet per 7 days

## SOOLANTRA® (*IVERMECTIN*) CREAM

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is greater than 18 years of age; **AND**
- Diagnosis of rosacea; **AND**
- Therapeutic failure on all of the following: one oral antibiotic, one topical antibiotic, azelaic acid and one sulfur containing product

## SORIATANE® (*ACITRETIN*) / OXSORALEN-ULTRA® (*METHOXSALEN*)

**Length of Authorization:** For the duration of the prescription up to 6 months

### DIAGNOSIS TO APPROVE

#### SORIATANE® (ACITRETIN)

- Severe psoriasis, including erythroderma and pustular types; **OR**
- Darier's disease (verrucous papular growths that coalesce into plaques on the skin); **OR**
- Palmoplantar pustulosis; **OR**
- Children with lamellar, nonbullous and bullous ichthyosiform erythroderma; **OR**
- Sjogren-Larsson syndrome (keratoconjunctivitis sicca)

#### OXSORALEN-ULTRA® (METHOXSALEN 10MG SOFT GELATIN CAPSULES)

- Psoriasis

#### 8-MOP (METHOXSALEN 10MG CAPSULES)

- Cutaneous T-cell lymphoma (CTCL); **OR**
- Vitiligo

## SPEVIGO® (SPESOLIMAB-SBZO)

**Length of Authorization:** Initial = 1 year; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 12 years of age or older; **AND**
- Prescriber attests that the patient has a known history of generalized pustular psoriasis (GPP); **AND**
- Prescriber attests that the patient is **NOT** experiencing a GPP flare; **AND**
- Prescribed by or in consultation with a dermatologist
-

#### RENEWAL REQUESTS

- Prescriber attests that the patient achieved and maintained a positive response to therapy; **AND**
- Prescriber attests that the patient is **NOT** experiencing a GPP flare

## SPINRAZA® (*NUSINERSEN*)

**Length of Authorization:** 4 months

### CRITERIA TO APPROVE

- Requests for clinical prior authorization for outpatient hospital providers and Ambulatory Surgical Centers (ASC) should be referred to the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## SPRAVATO® *(ESKETAMINE)* NASAL SPRAY

| | |
|---|---|
| **Length of Authorization:** | 4 months (TRD); 4 weeks (acute suicidal ideation) |

### CRITERIA TO APPROVE

#### TREATMENT RESISTANT DEPRESSION (TRD)

- Patient has treatment-resistant depression after failure on two different classes of antidepressants; **AND**
- Prescribed by or in consultation with a psychiatrist; **AND**
- Prescriber (or treatment center) and patient are enrolled in the REMS program (attestation only); **AND**
- Pharmacy must ship the medication directly to the physician's office (cannot be dispensed to the patient)

#### MAJOR DEPRESSIVE DISORDER (MDD) WITH ACUTE SUICIDAL IDEATION OR BEHAVIOR

- Patient has acute suicidal ideation or behavior; **AND**
- Concurrent therapy with another antidepressant; **AND**
- Prescribed by or in consultation with a psychiatrist; **AND**
- Prescriber (or treatment center) and patient are enrolled in the REMS program (attestation only); **AND**
- Pharmacy must ship the medication directly to the physician's office (cannot be dispensed to the patient)

#### RENEWAL REQUESTS

- Attestation only of prescriber (or treatment center) and patient enrollment in the REMS program (no documentation required)
- Pharmacy must ship the medication directly to the physician's office (cannot be dispensed to the patient)

## STIMULANTS FOR NON-ATTENTION DEFICIT DISORDERS

**Length of Authorization:** 1 year (Shift Work Disorder = 6 months)

### TOXICOLOGY SCREENING REQUIREMENTS

- The Department strongly encourages urine toxicology screening when appropriate; **AND**
- Toxicology results (within 2 months of request) may be required to be submitted in certain cases based on Department review for medical necessity and safety (e.g., MDHHS MAPS review indicates multiple controlled substances and/or multiple providers); **AND**
- Submission of current toxicology screening results (within 2 months of request) will be required for initial and renewal requests for doses in excess of FDA approved dosages.

### SLEEP DISORDER DIAGNOSES

- Narcolepsy
- Obstructive Sleep Apnea (OSA)
- Excessive Daytime Sleepiness
- Idiopathic Hypersomnia
- Chronic Fatigue – not due to chronic disease

**All initial requests for the above select sleep disorder diagnoses or symptoms must address the following:**

- Prescriber must **attest** to the following:
  - Patient has experienced > 3 months' duration of symptoms resulting in cognitive, social, occupational, or other significant stress; **AND**
  - Other medical conditions (e.g., hypothyroidism) and behavioral health conditions (e.g., depression) with similar symptoms have been actively evaluated along with ongoing treatment optimization; **AND**
  - Medical record notes that sedating drugs, marijuana, alcohol or other substances of abuse have been ruled out as contributing to sleep disorder symptoms; **AND**
  - Vital signs have been assessed; **AND**
  - Standard criteria (i.e., DSM-5, ISCD-3) have been utilized to confirm the diagnosis; **AND**
  - Epworth scale (score >= 10); **AND**
  - Failure of improvement with a two-week trial of standard sleep hygiene recommendations; **AND**
  - Treatment plan includes no more than 2 medications for this diagnosis**; AND**
  - MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results; **AND**
- Prescriber must **submit** the following documentation:
  - Current clinical notes supporting responses to each of the above criteria and describing all diagnoses, all medications, patient symptoms and treatment plan; **AND**
  - A COPY of confirmatory SLEEP TEST results and interpretation MUST BE SUBMITTED (NOTE: dates of tests must be within last five years) including (see reference table below for confirmatory test examples):
    - BOTH a Polysomnogram (PSG) and Multiple Sleep Latency Testing (MSLT) results and interpretation; **OR**
    - If diagnosis of OSA confirmed by PSG then submit both PSG and, if available, any MSLT results and interpretation

| Sleep Test | Narcolepsy | Obstructive Sleep Apnea (OSA) |
|---|---|---|
| **MSLT** | Mean Sleep Latency ≤ 8 minutes and ≥ 2 Sleep Onset REM Periods | |
| **PSG** | REM Sleep Latency ≤ 15 minutes | Apnea-Hypopnea Index ≥ 5 or<br>Apnea-Hypopnea Index < 5 and Respiratory Disturbance Index ≥ 5 |

**For renewal requests or continuation of therapy**:

- Prescriber attests that the patient has benefited from treatment with no adverse effects and continued treatment is medically necessary (if the patient has experienced adverse effects, please submit clinical notes outlining adverse response); **AND**
- Submission of current toxicology screening results (within 2 months of request) will be required for renewal requests for doses in excess of FDA approved dosages.

## OTHER DIAGNOSES AND CRITERIA

**Renewal requests and continuation of therapy for the diagnoses below:**

- Prescriber attests that the patient has benefited from treatment with no adverse effects and continued treatment is medically necessary (if the patient has experienced adverse effects, please submit clinical notes outlining adverse response); **AND**
- Submission of current toxicology screening results (within 2 months of request) will be required for renewal requests for doses in excess of FDA approved dosages.

**Binge Eating Disorder**

- Comprehensive evaluation has been performed which confirms the diagnosis of moderate to severe binge-eating disorder, including DSM 5 criteria, physical exam, and any necessary labs; **AND**
- Patient has been counseled on the benefits of cognitive behavioral therapy (CBT) and referred if appropriate; **AND**
- Current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan have been submitted; **AND**
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results.

**Chemotherapy/Radiation Related Fatigue**

- Prescriber is an oncologist, hematologist, radiation specialist or palliative care specialist; **AND**
- Patient is undergoing active chemotherapy and/or radiation therapy; **AND**
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results: **AND**
- If criteria have not been met, current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan must be submitted.

**Traumatic Brain Injury (TBI)**

- Prescriber is a psychiatrist, neurologist, or a physical medicine and rehabilitation specialist; **AND**
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results; **AND**
- If criteria have not been met, current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan must be submitted.

**Shift Work Sleep Disorder (SWSD)**

- Patient is on night shift or rotating shifts; **AND**
- Patient cannot decrease the number of rotating or night shifts; **AND**
- Other medical conditions (e.g., hypothyroidism), sleep disorders (i.e., narcolepsy and obstructive sleep apnea), and behavioral health conditions (e.g., depression) with similar symptoms have been actively evaluated along with ongoing treatment optimization; **AND**
- Medical record notes that sedating drugs, cannabinoids, alcohol or other substances of abuse have been ruled out as contributing to sleep disorder symptoms; **AND**
- Vital signs have been assessed; **AND**
- Patient has any two of the following: insomnia, excessive daytime sleepiness, difficulty concentrating, non-refreshing sleep; **AND**
- Patient has a 14-day sleep diary documents loss of one to four hours of sleep; **AND**
- Failure of improvement with a two-week trial of standard sleep hygiene recommendations; **AND**
- Actigraphy testing (within 1 year) supports a diagnosis of shift work sleep disorder; AND
- Current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan have been submitted; **AND**
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results.

**Long-COVID**

- Patient has clinical presentation consistent with long COVID; **AND**
- Patient has experienced > 3 months' duration of symptoms resulting in cognitive, social, occupational, or other significant stress; **AND**
- Other medical conditions (e.g., hypothyroidism) and behavioral health conditions (e.g., depression) with similar symptoms have been actively evaluated along with ongoing treatment optimization; **AND**
- Medical record notes that sedating drugs, cannabinoids, alcohol or other substances of abuse have been ruled out as contributing to sleep disorder symptoms; **AND**
- Vital signs have been assessed; **AND**
- Standard criteria (i.e., DSM-5, ISCD-3) have been utilized to confirm a sleep disorder diagnosis; **AND**
- Epworth scale (score >= 10); **AND**
- Failure of improvement with a two-week trial of standard sleep hygiene recommendations; **AND**
- Polysomnogram (PSG) and multiple sleep latency testing (MSLT) have been performed and results submitted; **AND**
- Current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan have been submitted; **AND**
- Any available toxicology results (within 2 months of request); **AND**
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results.

**Chronic Fatigue due to chronic disease (e.g. multiple sclerosis/cancer)**

- Prescribed by or in consultation with a specialist experienced in the treatment of the chronic disease or a palliative care specialist; **AND**
- Current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan have been submitted; **AND**
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results.

**Myotonic Dystrophy – [Provigil (modafinil) Only]**

- Prescribed by or in consultation with a specialist experienced in the treatment of myotonic dystrophy or a palliative care specialist; **AND**
- Current clinical notes describing all diagnoses, current medications, patient symptoms and treatment plan have been submitted; **AND**
  MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results

## MEDICATION-SPECIFIC CRITERIA

### DEXTROAMPHETAMINE, DEXTROAMPHETAMINE/AMPHETAMINE, METHYLPHENIDATE (IMMEDIATE-RELEASE AND EXTENDED-RELEASE FORMULATIONS)

- Diagnosis of narcolepsy; **AND**
- If female patient of childbearing age (10–50 years of age), patient is not pregnant; **OR**
- Patient is pregnant and has been counseled on risks and benefits of this drug
- Renewal requests: Submission of current toxicology screening results (within 2 months of request) will be required for doses that exceed FDA approved dosages and must confirm presence of the prescribed drug.

### PROVIGIL® *(MODAFINIL)* AND NUVIGIL® (*ARMODAFINIL*)

- Patient age ≥18 years old; **AND**
- Diagnosis of narcolepsy; **OR**
- Diagnosis of obstructive sleep apnea (OSA); **OR**
- Diagnosis of shift-work disorder; **AND**
- If female patient of childbearing age (10 to 50 years of age), patient is not pregnant; **OR**
- Patient is pregnant and has been counseled on risks and benefits of this drug.

## SUNOSI® *(SOLRIAMFETOL)*

- Patient age ≥18 years old; **AND**
- Diagnosis of narcolepsy or obstructive sleep apnea (OSA); **AND**
- Prescribed by, or in consultation with, a neurologist, pulmonologist or sleep specialist; **AND**
- Patient has tried and failed armodafinil or modafinil for a period of at least 30 days or has an contraindication to both agents; **AND**
- If patient has an underlying airway obstruction, confirmation of compliance with continuous positive airway pressure (CPAP) or similar device for a minimum of 90 days prior to starting Sunosi® and for the duration of treatment with Sunosi®; **AND**
- If female patient of childbearing age (10 to 50 years of age), patient is not pregnant; **OR**
- Patient is pregnant and has been counseled on risks and benefits of this drug.

## VYVANSE® *(LISDEXAMFETAMINE DIMESYLATE)*

- Patient age ≥18 years old; **AND**
- Diagnosis of moderate to severe binge-eating disorder in accordance with DSM 5 criteria, physical exam, and any necessary labs; **AND**
- Patient has been counseled on the benefits of cognitive behavioral therapy (CBT) and referred if appropriate; **AND**
- If female patient of childbearing age (10 to 50 years of age), patient is not pregnant; **OR**
- Patient is pregnant and has been counseled on risks and benefits of this drug.

## XYREM® (*SODIUM OXYBATE*) )

- Patient ≥ 7 years of age; **AND**
- Diagnosis of cataplexy associated with narcolepsy; **OR**
- Diagnosis of excessive daytime sleepiness associated with narcolepsy; **AND**
- Prescribed by or in consultation with a neurologist or pulmonologist or sleep specialist; **AND**
- The patient, prescriber and pharmacy must be enrolled in the Xyrem REMS program (must provide documentation of confirmed enrollment); **AND**
- Patient has a documented inadequate response, contraindication, or intolerance to monotherapy with a central nervous system stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate, etc.); **AND**
- Patient has a documented inadequate response, contraindication, or intolerance to monotherapy with a wakefulness promoting agent (e.g., modafinil, armodafinil, etc.); **AND**
- If female patient of childbearing age (10 to 50 years of age), patient is not pregnant; **OR**
- Patient is pregnant and has been counseled on risks and benefits of this drug; **AND**
- Quantity limit: 540 mL per 30 days

## XYWAV® (*SODIUM, CALCIUM, MAG, POTASSIUM OXYBATE*)

- Patient ≥ 7 years of age; **AND**
- Diagnosis of cataplexy associated with narcolepsy; **OR**
- Diagnosis of excessive daytime sleepiness associated with narcolepsy; **OR**
- Patient ≥ 18 years of age; **AND**
- Diagnosis of Idiopathic Hypersomnia (IH); **AND**
- Prescribed by or in consultation with a neurologist or pulmonologist or sleep specialist; **AND**
- Diagnosis must be confirmed by submission of supporting documentation of sleep studies; **AND**
- The patient, prescriber and pharmacy must be enrolled in the Xywav REMS program (must provide documentation of confirmed enrollment); **AND**
- Patient has a documented inadequate response, contraindication, or intolerance to monotherapy with a central nervous system stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate, etc.); **AND**

- Patient has a documented inadequate response, contraindication, or intolerance to monotherapy with a wakefulness promoting agent (e.g., modafinil, armodafinil, etc.); **AND**
- If female patient of childbearing age (10 to 50 years of age), patient is not pregnant; **OR**
- Patient is pregnant and has been counseled on risks and benefits of this drug; **AND**
- Quantity limit: 540 mL per 30 days

## SUFLAVE® (PEG 3350/SOD SULF,CHLR/POT/MAG) POWDER

**Length of Authorization:** 1 fill

### CRITERIA TO APPROVE

- Patient has trialed and failed, or is not a candidate for, a generic OTC colonoscopy preparation product

## SUNOSI® (SOLRIAMFETOL)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

**Refer to STIMULANTS FOR NON-ATTENTION DEFICIT DISORDERS CRITERIA**

## SYNDROS® *(DRONABINOL)* SOLUTION

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Diagnosis of anorexia due to AIDS or chemo-induced nausea and vomiting; **AND**
- Patient ≥ 18 years old; **AND**
- Patient is unable to take dronabinol capsules
- Quantity limit = 120 units per 30 days

## SYNAGIS® (*PALIVIZUMAB*)

| | |
|---|---|
| **Length of Authorization:** | Maximum of 5 doses or thru the end of RSV season, whichever comes first (RSV season: October 1 thru April 30) |

### CRITERIA TO APPROVE

- Children who have *not* had a dose of Beyfortus™ (nirsevimab) in the current RSV season; **AND**
- Mother did not receive vaccination against RSV in the 2nd or 3rd trimester; **AND**
- Children < 12 months of age on October 1st of the current year and born <29 weeks gestational age; **OR**
- Children < 12 months of age on October 1st of the current year, with chronic lung disease (CLD) of prematurity, defined as <32 weeks gestational age and requiring >21% oxygen for at least 28 days after birth; **OR**
- Children < 24 months of age on October 1st of the current year, with a history of CLD and who continued to receive medical treatment such as oxygen, chronic corticosteroids or diuretic medications during the previous 6 months; **OR**
- Children <12 months of age on October 1st of the current year, with hemodynamically significant cyanotic or acyanotic congenital heart disease; **OR**
- Children <12 months of age on October 1st of the current year, with pulmonary abnormalities or neuromuscular disease that affects the ability to clear secretions; **OR**
- Children <24 months of age on October 1st of the current year, who are severely immunocompromised (e.g., receiving chemotherapy) during RSV season

## TACLONEX® (CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE TOPICAL)

| | |
|---|---|
| **Length of Authorization:** | As determined per MDHHS review |

### CRITERIA TO APPROVE

- Approval requires clinical reason why covered topical steroids cannot be used**; AND**
- Patient must be 18 years old or above
- Daily quantity limit: 15 gm
- Maximum length of therapy edit: four weeks (28 days) per calendar year for ointment; eight weeks (56 days) per calendar year for scalp suspension

## TAKHZYRO® (LANADELUMAB-FLYO)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 12 years of age or older; **AND**
- Attestation that diagnosis was confirmed by a C4 level below the lower limit of normal as defined by laboratory test and any of the following:
- C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test; **OR**
- C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test; **OR**
- Presence of a known HAE-causing C1-INH mutation; **AND**
- Patient has a history of ONE of the following criteria for long-term hereditary angioedema (HAE) prophylaxis:
- History of two or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes); **OR**
- Patient is disabled more than five days per month by HAE; **OR**
- History of recurrent laryngeal attacks caused by HAE; **AND**
- Prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology or medical genetics; **AND**
- Attestation that the treatment with 'on demand' therapy (i.e., Kalbitor, Firazyr, Ruconest, Berinert) did not provide satisfactory control (i.e., treatment for acute attacks was unsuccessful); **AND**
- Therapeutic failure, intolerance or contraindication to attenuated (17 alpha-alkylated) androgens (i.e., danazol) for HAE prophylaxis

## TARPEYO® (*BUDESONIDE*)

**Length of Authorization:** 10 months

### CRITERIA TO APPROVE

- Patient is ≥18 years of age; **AND**
- Patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; **AND**
- Patient continues to have proteinuria ≥ 1 g/24 hour; **AND**
- Patient has an estimated glomerular filtration filter (eGFR) ≥ 35 mL/min/1.73 m2; **AND**
- Patient is on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), unless contraindicated, and has been for ≥ 3 months.

## TAVALISSE® (*FOSTAMATINIB*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Diagnosis of chronic immune thrombocytopenia (ITP); **AND**
- Failure on at least one other therapy for chronic ITP which did not achieve a platelet count ≥ 50 x $10^9$/L [i.e., corticosteroids, immunoglobulins, splenectomy or thrombopoietin receptor agonists (e.g., Promacta, Alvaiz, Nplate)]; **AND**
- Attestation that patient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) of less than 30 x $10^9$/L (document date of lab and level).

## TAVNEOS® (*AVACOPAN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 years old; **AND**
- Patient has severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; **AND**
- Avacopan (Tavneos) will be used as adjunctive therapy in combination with standard therapy (e.g., corticosteroids, cyclophosphamide, azathioprine, mycophenolate, rituximab).

## TAZORAC® (*TAZAROTENE*)

**Length of Authorization:** For the duration of the prescription up to 1 year

### CRITERIA TO APPROVE

- Acne unresponsive to a tretinoin product or clinical rationale why tretinoin product not appropriate; **OR**
- Plaque psoriasis as step therapy with history of a failure of at least a two-month trial on any high potency topical steroid.

## TEGSEDI® (*INOTERSEN*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Definitive diagnosis of hereditary ATTR (hATTR) amyloidosis/familial amyloid polyneuropathy (FAP) as documented by amyloid deposition on tissue biopsy and identification of a pathogenic transthyretin (TTR) variant using molecular genetic testing; **AND**
- Platelet count ≥ 100 x $10^9$/L (document date of lab and level); **AND**
- Patient is enrolled in the Tegsedi REMS program; **AND**
- Patient is receiving vitamin A supplementation at the recommended daily allowance (i.e., 400-900 retinol activity equivalents [RAE]); **AND**
- Med will not be used in combination with other transthyretin (TTR) reducing agents (i.e., patisiran).
- Quantity limit = 6 mL (4 syringes) per 28 days

## TESTOSTERONE / METHYLTESTOSTERONE REPLACEMENT THERAPY

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Serum testosterone < 300 ng/dL; **AND**
- Injectable products must be administered in home environment and justification why not given in office and billed via medical
- For requests submitted for gender dysphoria, please refer to the **Hormone Therapy for Gender Dysphoria criteria**
- Contraindications:
  - Severe renal or cardiac diseases
  - Benign prostatic hyperplasia with obstruction
  - Prostate cancer
  - Undiagnosed genital bleeding
  - Breast cancer
  - Pregnancy

## TIGLUTIK® *(RILUZOLE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Diagnosis of amyotrophic lateral sclerosis (ALS); **AND**
- Patient cannot swallow tablets; **AND**
- Prescribed by or in consultation with a neurologist

## TLANDO® (TESTOSTERONE UNDECANOATE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); **AND**
- Patient is 18 years of age or older; **AND**
- Serum testosterone < 300 ng/dL
- For requests submitted for gender dysphoria, please refer to the **Hormone Therapy for Gender Dysphoria** criteria

## TRETINOIN (TRANS-RETINOIC ACID; RETINOIC ACID; VITAMIN A ACID)

**Length of Authorization:** For the duration of the prescription up to 6 months

### DIAGNOSIS TO APPROVE

- Acne vulgaris; **OR**
- Cystic acne unresponsive to other treatments; **OR**
- Different forms of skin cancer; **OR**
- Lamellar ichthyosis; different forms of ichthyosis; **OR**
- Mollusca contagiosa; **OR**
- Verrucae plantaris; juvenilis; **OR**
- Bullous congenital ichthyosiform and pityriasis ruba pilaris

### ZIANA® / VELTIN® GEL

- Diagnosis of acne. Maximum approval 84 days (12 weeks).

## TRYVIO® *(APROCITENTAN)*

**Length of Authorization:** Initial = 1 year; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient 18 years of age or older; **AND**
- Diagnosis of resistant hypertension (RH) despite the concurrent use of 3 or more antihypertensive drug classes; **AND**
- Clinical documentation demonstrating failure to reach blood pressure goal despite concurrent use of 3 or more antihypertensive drug classes; **AND**
- Clinical documentation demonstrating failure to reach blood pressure goal despite addition of a mineralocorticoid receptor antagonist (i.e., spironolactone OR eplerenone) to the current 3 drug regimen; **OR**
- Contraindication (i.e. hyperkalemia, renal impairment, etc.) or drug to drug interaction (i.e. CYP3A4 Inhibitors, potassium-sparing diuretics, etc.) preventing the use of both spironolactone and eplerenone; **AND**
- For patients who can become pregnant, the prescriber attests:
    - patient is not pregnant or lactating
    - patient has been counseled on the risk of major birth defects AND to use acceptable methods of contraception before treatment with Tryvio, during treatment with Tryvio, and for one month after
    - treatment discontinuation; **AND**
- Prescriber is enrolled in Tryvio REMS program
- Prescribed by or in consultation with a specialist with experience in the treatment of RH such as a cardiologist, nephrologist or endocrinologist
- Quantity limit: 1 per day

#### RENEWAL REQUESTS

- For patients who can become pregnant, prescriber attests patient is not pregnant or lactating
- Clinical documentation demonstrates blood pressure improvement compared to baseline
- Prescriber attests that patient has not experienced unacceptable adverse effects from Tryvio therapy (i.e. hepatotoxicity, clinically significant anemia, clinically significant edema)

## TWYNEO® *(TRETINOIN/BENZOYL PEROXIDE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 9 years old; AND
- Patient has a diagnosis of moderate to severe acne vulgaris; AND
- Therapeutic failure of a two-month trial of benzoyl peroxide or tretinoin.

## UNDECATREX® (TESTOSTERONE UNDECANOATE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); **AND**
- Patient is 18 years of age or older; **AND**
- Serum testosterone < 300 ng/dL
- For requests submitted for gender dysphoria, please refer to the **Hormone Therapy for Gender Dysphoria** criteria

## UREA POWDER

**Length of Authorization:** 6 months

### DIAGNOSIS TO APPROVE

- Ichthyosis

## VEMLIDY® (TENOFOVIR ALAFENAMIDE)

**Length of Authorization:** 1 year

### DIAGNOSIS TO APPROVE

- Diagnosis of chronic hepatitis B virus (HBV); **AND**
- Compensated liver disease

## VEOZAH® (FEZOLINETANT)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient has a diagnosis of menopause with moderate to severe vasomotor symptoms; **AND**
- Patient does not have cirrhosis; **AND**
- Patient does not have severe renal impairment or end-stage renal disease; **AND**
- Patient will avoid concomitant therapy with CYP1A2 inhibitors (e.g., fluvoxamine, mexiletine, cimetidine); **AND**
- Prescriber attests that baseline liver function tests have been conducted and total bilirubin, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) levels are not elevated ≥ 2 times the upper limit of normal (ULN); **AND**
- Prescriber attests that liver function testing follow-up will be conducted as outlined in prescribing information; **AND**
- Patient has trialed and failed, or is not a candidate for, hormone therapy or an SSRI or SNRI.

#### RENEWAL REQUEST

- Patient must continue to meet the above criteria; AND
- Patient must have symptom improvement; AND
- Patient has not experienced any treatment-restricting adverse effects.

## VERQUVO® (*VERICIGUAT*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of heart failure; **AND**
- Patient's ejection fraction is < 45%; **AND**
- Patient meets ≥ 1 of the following criteria:
  - Patient has required the use of intravenous diuretics as an outpatient in the past 3 months; **OR**
  - Patient was recently hospitalized for heart failure (within the last 6 months); **AND**
- Patient is on guideline-directed therapy for heart failure, unless contraindicated (e.g., beta-blocker, angiotensin-converting enzyme [ACE] inhibitor or angiotensin II receptor blockers [ARB], or mineralocorticoid receptor antagonists/aldosterone antagonists); **AND**
- Patient is NOT taking another soluble guanylate cyclase (sGC) stimulator (e.g. riociguat (Adempas) or a phosphodiesterase-5 (PDE-5) inhibitor (e.g. sildenafil, tadalafil, vardenafil); **AND**
- If patient is of childbearing potential, patient is NOT pregnant AND is using contraception.

## VEREGEN® (SINECATECHINS)

**Length of Authorization:** 16 weeks

### CRITERIA TO APPROVE

- Patient is greater than 18 years of age; **AND**
- Topical treatment of external genital and perianal warts (Condyloma acuminatum) in immunocompetent patients; **AND**
- Trial/ failure or contraindication to non-prior authorized medications

## VIJOICE® (*ALPELISIB*)

**Length of Authorization:** Initial: 6 months; renewal: 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is at least 2 years of age; **AND**
- Patient has a diagnosis of PIK3CA-related overgrowth spectrum (PROS) (Examples include fibroadipose hyperplasia, CLOVES syndrome, megalencephaly-capillary malformation syndrome, hemihyperplasia-multiple lipomatosis syndrome, hemimegalencephaly, and facial infiltrating lipomatosis); **AND**
- Patient has the presence of a PIK3CA-mutation as detected by an FDA-approved or CLIA-compliant test; **AND**
- Prescribed by, or in consultation with, a physician that specializes in treatment of genetic disorders

#### RENEWAL REQUEST

- Patient has been established on Vijoice for at least 6 months; AND
- Patient has disease response as defined by stabilization or decrease in lesion volume(s) in the absence of new lesions

## VILTEPSO® (*VILTOLARSEN*)

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for home administration will require MDHHS review and must specifically indicate that the medication will be home infused (versus being infused in an office/clinic/infusion center setting).
- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## VOQUEZNA® (*VONOPRAZAN*)

**Length of Authorization:** Initial = 8 months; Renewal = 6 months

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥ 18 years of age; **AND**
- Diagnosis of erosive esophagitis; **OR**
- Diagnosis of non-erosive gastroesophageal reflux disease (GERD); **AND**
- Clinical documentation demonstrates patient had a therapeutic failure after one-month trial with one preferred proton pump inhibitor (PPI); **AND**
- Quantity limit: 1 tablet per day

#### RENEWAL REQUEST

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Provider attests significant improvement in signs and symptoms of erosive esophagitis; **AND**
  - Provider attests that continuation beyond the FDA-approved duration of therapy is medically necessary; **AND**
  - Provider attests risks vs. benefits of continuation have been weighed and discussed with the patient (i.e. Risks of C. difficile-associated infection, fractures, fundic gland polyps, hypomagnesemia, tubulointerstitial nephritis, vitamin B12 deficiency, etc.)

## VOWST® (FECAL MICROBIOTA SPORES. LIVE-BRPK)

**Length of Authorization:** 3 days

### CRITERIA TO APPROVE

- Patient ≥ 18 years of age; **AND**
- Patient has a confirmed diagnosis of recurrent Clostridioides difficile infection (CDI) with a total of ≥3 episodes of CDI within 12 months; **AND**
- Antibiotic treatment for recurrent CDI must be completed 2 to 4 days prior to initiation of Vowst therapy.
- Quantity Limit: 12 capsules

## VOXZOGO® (*VOSORITIDE*)

**Length of Authorization:** Initial: 6 months; Renewal: 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient has diagnosis of achondroplasia; **AND**
- Patient does not have closure of epiphyses; **AND**
- Patient body weight, growth, and physical development will be measured at baseline and monitored throughout therapy; **AND**
- Patient has an estimated glomerular filtration rate (eGFR) ≥ 60 mL/min/1.73 m2; **AND**
- Patient has not received limb-lengthening surgery within the previous 18 months

#### RENEWAL REQUEST

- Patient continues to meet above criteria; **AND**
- Patients does not have closure of epiphyses; **AND**
- Patient has shown improvement in height compared to pre-treatment baseline; **AND**
- Patient has shown Improvement in growth velocity compared to pre-treatment baseline.

## VOYDEYA® (*DANICOPAN*)

**Length of Authorization:** Initial: 6 months; Renewal: 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is 18 years of age or older; **AND**
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) with clinically significant hemolysis (EVH); **AND**
- Prescriber attests that Voydeya will be used concurrently with either ravulizumab-xwvz (Ultomiris) or eculizumab (Soliris); **AND**
- Prescriber by or in consultation with a hematologist

#### RENEWAL REQUEST

- Prescriber attests that the patient has demonstrated improvement or stabilization of PNH from baseline

## VTAMA® (*TAPINAROF*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient ≥18 years of age: **AND**
- Diagnosis of plaque psoriasis; **OR**
- Patient is ≥ 2 years of age; **AND**
- Diagnosis of atopic dermatitis; **AND**
- Must be prescribed by or in consultation with a dermatologist; **AND**
- Patient had an inadequate treatment response, intolerance, or contraindication to topical steroids.
- Quantity limit: 60 gm (1 tube)

## VUITY® (PILOCARPINE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient has diagnosis of presbyopia; **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
- Patient age between 40 and 55 years; **AND**
- Patient has contraindication and/or failure of corrective lenses to resolve presbyopia symptoms.

## VYNDAMAX® (TAFAMIDIS FREE ACID)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Patient has cardiomyopathy secondary to transthyretin-mediated amyloidosis (ATTR-CM) confirmed either histologically or by genetic testing (testing not required to be faxed); **AND**
- Prescribed by or in consultation with a cardiologist
- Quantity limit = 30 caps per 30 days

## VYNDAQEL® (TAFAMIDIS MEFLUMINE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is 18 years of age or older; **AND**
- Patient has cardiomyopathy secondary to transthyretin-mediated amyloidosis (ATTR-CM) confirmed either histologically or by genetic testing (testing not required to be faxed); **AND**
- Prescribed by or in consultation with a cardiologist
- Quantity limit = 120 caps per 30 days

## VYONDYS-53® *(GOLODIRSEN)*

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for home administration will require MDHHS review and must specifically indicate that the medication will be home infused (versus being infused in an office/clinic/infusion center setting).
- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## WAINUA® (EPLONTERSEN)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis with confirmed genetic mutation in *TTR* gene; **AND**
- The patient has clinical manifestations of polyneuropathy (e.g., neuropathic pain, altered sensation, numbness, tingling, impaired balance, motor disability); **AND**
- Wainua will not be used in combination with any other medication approved for the treatment of hereditary transthyretin-mediated amyloidosis [ e.g. inotersen (Tegsedi®), vutrisiran (Amvuttra®), patisiran (Onpattro®), tafamidis (Vyndamax®), tafamidis meglumine (Vyndaqel®)]; **AND**
- The patient has NOT received a liver transplant; **AND**
- Prescribed by or in consultation with a neurologist, cardiologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

## WINLEVI® (CLASCOTERONE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 12 years old; **AND**
- Patient has a diagnosis of acne vulgaris; **AND**
- Patient has had an inadequate response to a generic topical product (e.g. tretinoin, benzoyl peroxide, clindamycin/benzoyl peroxide)

## XDEMVY® (*LOTILANER*) EYE DROPS

**Length of Authorization:** 6 weeks

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Patient has a documented diagnosis of Demodex blepharitis (e.g., slit-lamp examination, light microscopy of epilated eyelashes); **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist

## XERMELO® (TELOTRISTAT ETHYL)

**Length of Authorization:** 6 months

### CRITERIA TO APPROVE

- Diagnosis of carcinoid syndrome diarrhea; **AND**
- Inadequate treatment response to at least a 3-month trial of somatostatin analog therapy (i.e., Sandostatin (octreotide), Signifor (pasireotide), Somatuline (lanreotide)); **AND**
- Must be used in combination with a somatostatin analog; **AND**
- Four or more bowel movements daily
- Quantity limit = 84 tablets per 28 days

## XIMINO® (MINOCYCLINE)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of acne vulgaris; **AND**
- Patient is 12 years of age or older; **AND**
- Clinical reason why (covered) generic minocycline cannot be used

## XOLREMDI® (*MAVORIXAFOR*)

**Length of Authorization:** Initial = 6 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 12 years of age or older; **AND**
- Diagnosis of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome confirmed by genotype variant of *CXCR4*; **AND**
- At baseline, patient had an absolute neutrophil count ≤ 500 cells/µL; **AND**
- Prescribed by or in consultation with an immunologist, hematologist, dermatologist, or infectious disease specialist.

#### RENEWAL REQUESTS

- Prescriber attests that the patient is continuing to derive benefit from therapy as determined by objective measurements such as improved absolute neutrophil count, absolute lymphocyte count, reduced frequency, duration, or severity of infections, less frequent treatment with antibiotics, or fewer warts.

## XYOSTED® AUTO INJECTOR *(TESTOSTERONE)*

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); **AND**
- Patient is 18 years of age or older; **AND**
- Serum testosterone < 300 ng/dL; **AND**
- Clinical reason why a preferred topical testosterone agent (i.e., AndroGel) cannot be used
- For requests submitted for gender dysphoria, please refer to the **Hormone Therapy for Gender Dysphoria criteria**

## XYREM® (SODIUM OXYBATE) / XYWAV® (SODIUM, CALCIUM, MAG, POTASSIUM OXYBATE)

**Length of Authorization:** 3 months

### CRITERIA TO APPROVE

**Refer to STIMULANTS FOR NON-ATTENTION DEFICIT DISORDERS CRITERIA**

## YORVIPATH® (PALOPEGTERIPARATIDE)

**Length of Authorization:** Initial = 1 year; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUESTS

- Patient is 18 years of age or older; **AND**
- Diagnosis of hypoparathyroidism; **AND**
- Patient is currently receiving conventional therapy with vitamin D (calcitriol) and elemental calcium; **AND**
- Prescribed by or in consultation with an endocrinologist
- Quantity Limit: 2 pens per 28 days

#### RENEWAL REQUESTS

- Prescriber attests that the patient is responding to therapy; **AND**
  - Patient no longer requires active vitamin D or therapeutic doses of calcium; **OR**
  - Patient has had a significant reduction in required dosages and is still actively titrating doses of Yorvipath.

## ZILXI® (*MINOCYCLINE*) FOAM

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient has a diagnosis of rosacea; **AND**
- Patient has a documented intolerance, contraindication, or treatment failure to one of the following:
  - metronidazole cream, metronidazole lotion, or metronidazole gel.

## ZILBRYSQ® (*ZILUCOPLAN*)

**Length of Authorization:** Initial = 3 months; Renewal = 1 year

### CRITERIA TO APPROVE

#### INITIAL REQUEST

- Patient is ≥18 years of age; **AND**
- Diagnosis of generalized myasthenia gravis (gMG) with a positive serological test for anti-AChR antibodies; **AND**
- Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV disease at the start of therapy; **AND**
- Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score ≥6; **AND**
- Prescribed by or in consultation with a neurologist

#### RENEWAL REQUEST

- Patient is demonstrating a positive response to therapy via stable MG-ADL score compared to baseline.

## ZOKINVY® (*LORNAFARNIB*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- Patient is ≥ 12 months of age; **AND**
- Patient has a body-surface area of ≥ 0.39 $m^2$; **AND**
- Must be prescribed by, or in consultation with, a specialist in genetics or metabolic disorders; **AND**
- Patient has a diagnosis of 1 of the following:
  - Hutchinson-Gilford progeria syndrome (HGPS); **OR**
  - Processing-deficient progeroid laminopathies; **AND**
- Patient does NOT have other non-laminopathy progeroid syndromes or processing-proficient progeroid laminopathies or laminopathies with no progeria features (mutation in the *LMNA* gene with no clinical characteristic features)

## ZORYVE® (*ROFLUMILAST*)

**Length of Authorization:** 1 year

### CRITERIA TO APPROVE

- **Zoryve Cream 0.15%**
  - Patient is ≥ 6 years old; **AND**
  - Patient has a diagnosis of mild to moderate atopic dermatitis; **AND**
  - Must be prescribed by or in consultation with a dermatologist; **AND**
  - Patient must have an adequate trial and failure, contraindication, or intolerance of ≥ 1 topical corticosteroid; **OR**
- **Zoryve Cream 0.3%**
  - Patient is ≥ 6 years old; **AND**
  - Patient has a diagnosis of mild to severe plaque psoriasis; **AND**
  - Must be prescribed by or in consultation with a dermatologist; **AND**
  - Patient must have an adequate trial and failure, contraindication, or intolerance of ≥ 1 topical corticosteroid; **OR**
- **Zoryve Foam 0.3%**
  - Patient is ≥ 9 years old; **AND**
  - Patient has a diagnosis of seborrheic dermatitis; **OR**
  - Patient is ≥ 12 years old; **AND**
  - Patient has a diagnosis of plaque psoriasis; **AND**
  - Must be prescribed by or in consultation with a dermatologist; **AND**
  - Patient must have an adequate trial and failure, contraindication, or intolerance of ≥ 1 topical corticosteroid

## ZURZUVAE® (ZURANOLONE)

**Length of Authorization:** One 14-day course of treatment per pregnancy

### CRITERIA TO APPROVE

- Patient is ≥ 18 years of age; **AND**
- Diagnosis of postpartum/peripartum depression (PPD) based on Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for a major depressive episode (DSM-5); **AND**
- Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery; **AND**
- Other medical conditions that may contribute to a depressive disorder, e.g., thyroid dysfunction, have been ruled out; **AND**
- Patient is ≤ 12 months postpartum; **AND**
- Patient is not currently pregnant; **AND**
- Prescriber attests to the patient having been informed that, whereas data on the concentration of this drug in breast milk is thought to be under a standard safety threshold, there are no data on the effects of zuranolone on breastfed infants; **AND**

- MAPS confirmed that no other Zurzuvae treatment has been given following this pregnancy

## ZYCLARA 3.75%®; ZYCLARA 2.5% CREAM PUMP® *(IMIQUIMOD)*

**Length of Authorization:** 3 months

### CRITERIA TO APPROVE

- Therapeutic failure on generic imiquimod 5%.

## ZYNTEGLO® (BETIBEGLOGENE AUTOTEMCEL)

**Length of Authorization:** Determined by MDHHS

### CRITERIA TO APPROVE

- Requests submitted for infusion center administration which the pharmacy will bill as a pharmacy benefit must first be approved by the Program Review Division (PRD) at MDHHS. Providers should fax requests to 517-335-0075.

## REVISION HISTORY

| Version | Date | Comments |
|---|---|---|
| 05012025v3 | 07012025 | • Nucala (mepolizumab) – criteria revised to add new diagnosis of COPD<br>• Rinvoq (upadacitinib) – criteria revised to add new diagnosis of giant cell arteritis<br>• Zoryve 0.3% Foam (roflumilast) – criteria revised to add new diagnosis of plaque psoriasis<br>• perampanel (generic for Fycompa) – added to PDL as preferred<br>• Bucapsol (buspirone) – added to PDL as preferred<br>• Sitagliptin/metformin XR (generic for Zituvimet XR) – added to PDL as non-preferred<br>• Avmapki/Fakzynja (avutometinib/defactinib) – added to the MPPL without PA<br>• Emrelis (telisotuzumab vedotin-tllv) - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Seglentis (tramadol/celecoxib) – removed from MPPL and PDL due to loss of Federal rebate. |
| 05012025v2 | 06012025 | • phentermine/topiramate – added to the PDL as preferred with PA<br>• Dupixent (dupilumab) – criteria revised to add new indication for CSU<br>• umeclidinium-vilanterol (generic for Anoro Ellipta) – added to the PDL as non-preferred.<br>• Dolobid 375 mg (diflunisal) – added to the PDL as non-preferred<br>• ticagrelor (generic for Brilinta) – added to the PDL as non-preferred<br>• Fabhalta (iptacopan) – criteria revised to add new indications for immunoglobulin A nephropathy (IgAN) and complement 3 glomerulopathy (C3G)<br>• Rivfloza (nedosiran) – criteria revised for new age indication<br>• Tavalisse (fostamatinib) – criteria revised to update other examples of ITP therapy.<br>• Anzemet (dolasetron) – removed from MPPL and PDL. Drug Obsolete.<br>• Taztia XT (diltiazem) – removed from MPPL and PDL. Drug Obsolete.<br>• Airduo Digihaler (fluticasone/salmeterol) – removed from MPPL and PDL. Drug Obsolete.<br>• Armonair Digihaler (fluticasone)– removed from MPPL and PDL. Drug Obsolete.<br>• ProAir Digihaler (albuterol) – removed from MPPL and PDL. Drug Obsolete.<br>• Osmolex ER (amantadine) – removed from MPPL and PDL due to loss of Federal rebate. |
| 05012025v1 | 05012025 | • Crexont (carbidopa/levodopa) – added to the PDL as non-preferred with clinical PA<br>• Ebglyss (lebrikizumab-lbkz) – added to the PDL as non-preferred with clinical PA and qty limits<br>• Lodoco (colchicine) – added to the MPPL with PA and qty limits<br>• Miplyffa (arimoclomol) – added to the MPPL with PA<br>• Neffy (epinephrine) – added to the PDL as non-preferred with clinical PA<br>• Nemluvio (nemolizumab-ilto) – added to the PDL as non-preferred with clinical PA and qty limits<br>• Sofdra (sofpironium) – added to the MPPL with PA<br>• Undecatrex (testosterone undecanoate) – added to the MPPL with PA<br>• Vyalev (foslevodopa/foscarbidopa) – added to the PDL as non-preferred with clinical PA<br>• Entresto (sacubitril/valsartan) Sprinkles – moved to PDL non-preferred with medication-specific criteria to allow PDL bypass if patient is unable to swallow tablets.<br>• bisoprolol tablets – moved to PDL preferred<br>• Bystolic (nebivolol) tablets – moved to PDL non-preferred<br>• carvedilol ER capsules – moved to PDL non-preferred with 90-day grandfather to allow for transition.<br>• nadolol tablets – moved to PDL preferred<br>• Hemangeol (propranolol) oral solution – moved to PDL preferred with max age edit of <1 year |

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| | | • Norliqva (amlodipine) oral solution – move to PDL preferred with existing clinical PA.<br>• ezetimibe/simvastatin (generic for Vytorin) – moved to PDL preferred<br>• Azopt (brinzolamide) – moved to PDL non-preferred<br>• brinzolamide (generic for Azopt) – moved to PDL preferred<br>• Restasis Multidose drops (cyclosporine) – moved to PDL preferred<br>• Furoscix (furosemide) – criteria revised to add new indication for CKD<br>• Tremfya (guselkumab) – criteria revised for new indication for CD.<br>• Promacta (eltrombopag) – criteria revised for age indication.<br>• Oxbryta (voxelotor) - removed from MPPL and PDL due to product withdrawn from market due to safety concerns.<br>• Anti-obesity Medications (Saxenda, Wegovy, Xenical, Zepbound) – quantity limits added.<br>• ferric citrate (generic for Auryxia) – added to the PDL as non-preferred<br>• adalimumab-adaz (generic for Hyrimoz) – added to the PDL as non-preferred with clinical PA.<br>• Westab One (cyanocobalamin/folic ac/vit b6) – added to the MPPL<br>• Liqrev (sildenafil) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Evekeo ODT (amphetamine) – removed from MPPL and PDL. Drug Obsolete.<br>• Glucagen Hypokit (glucagon) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Mentax (butenafine) – removed from MPPL and PDL. Drug Obsolete.<br>• Lonhala Magnair (glycopyrrolate) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Flovent Diskus (fluticasone) – removed from the MPPL and PDL. Drug Obsolete.<br>• Flovent HFA (fluticasone) – removed from MPPL and PDL. Drug Obsolete.<br>• Patanase (olopatadine) Nasal Spray – removed from MPPL and PDL. Drug Obsolete.<br>• Ciloxan (ciprofloxacin) ophthalmic drops – removed from MPPL and PDL. Drug Obsolete. |
| 02012025V3 | 04012025 | • Multi-Ingredient Compound – criteria added to facilitate prior authorization and reimbursement<br>• Bronchitol (mannitol) – criteria revised to clarify allowance for BTT.<br>• Azilect (rasagiline) – age criteria clarified<br>• Gelnique (oxybutynin) - removed from MPPL and PDL. Drug Obsolete.<br>• Aciphex (rabeprazole) - removed from MPPL and PDL. Drug Obsolete.<br>• Urso (ursodiol) – removed from MPPL and PDL. Drug Obsolete.<br>• Lovaza (omega-3 ethyl esters) - removed from MPPL and PDL due to loss of Federal rebate. |
| 02012025v2 | 03012025 | • Omvoh (mirikizumab-mrkz) – criteria revised to add new indication for Crohn's disease<br>• Spravato (esketamine) – criteria revised for expanded indication as monotherapy in TRD<br>• metroniadzole 125mg tablets – added to the PDL as non-preferred<br>• metformin 750mg tablets – added to the PDL as non-preferred<br>• Slo-Niacin 750mg (OTC) – moved to PDL preferred<br>• Furoscix (furosemide) – CHF criterion revised<br>• Kombiglyze XR (saxagliptin/metformin) - removed from MPPL and PDL. Drug Obsolete.<br>• Onglyza (saxagliptin) - removed from MPPL and PDL. Drug Obsolete.<br>• Stalevo (carbidopa/levodopa) - removed from MPPL and PDL. Drug Obsolete.<br>• Alocril (nedocromil) - removed from MPPL and PDL. Drug Obsolete. |
| 02012025v1 | 02012025 | • Duvyzat (givinostat) – added to the MPPL with PA<br>• Iqirvo (elafibranor) – added to the MPPL with PA<br>• Livdelzi (seladelpar) – added to the MPPL with PA<br>• Ohtuvayre (ensifentrine) – added to the MPPL with PA<br>• Vafseo (vadadustat) – added to the PDL as non-preferred with clinical PA<br>• Xolremdi (mavorixafor) – added to the MPPL with PA |

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| | | • Yorvipath (palopegteriparatide) – added to the MPPL with PA and quantity limit<br>• Zituvimet and Zituvimet XR (sitagliptin/metformin) – added to the PDL as non-preferred<br>• Focinvez (fosaprepitant) - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• PiaSky (crovalimab-akkz) - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Tofidence (tocilizumab-bavi) - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• OxyContin (oxycodone) – moved to PDL preferred<br>• Roxybond (oxycodone) – added medication-specific criteria to allow PDL bypass if an abuse deterrent needed.<br>• Kesimpta (ofatumumab) – moved to PDL preferred. Clinical criteria removed.<br>• Zeposia (ozanimod) – criteria revised to add patient age<br>• PDL Class Multiple Sclerosis Agents – non-preferred agent PA criteria revised to require trial/failure of two preferred agents.<br>• fluocinonide cream, gel, ointment and solution – moved to PDL preferred<br>• PDL Class Topical Steroids – Medium and High Potency – non-preferred agent PA criteria revised to allow after trial and failure of 14 days with one preferred agent.<br>• PDL Class Diabetes: Incretin Mimetics and Combinations – criteria revised to require discontinuation of concurrent use with DPP-4 inhibitors<br>• PDL Class Diabetes: Oral Hypoglycemics – DPP-4 Inhibitors – criteria revised to require discontinuation of concurrent use with GLP-1 agonists<br>• PDL Class Diabetes: Oral Hypoglycemics – Combinations – criteria revised for those products that contain a DPP-4 inhibitor to require discontinuation of concurrent use with a GLP-1 agonist<br>• PDL Class Anti-Obesity Agents – criteria revised for the anti-obesity GLP-1 agonists to require discontinuation of concurrent use with DPP-4 inhibitors<br>• Jesduvroq (daprodustat) - criteria revised to add prescriber specialty<br>• Nucynta/Nucynta ER (tapentadol) - removed from MPPL and PDL due to loss of Federal rebate.<br>• Xtampza® ER (oxycodone myristate capsule) - removed from MPPL and PDL due to loss of Federal rebate.<br>• morphine oral syringes – quantity limitation added<br>• prucalopride (generic for Motegrity) - added to the PDL as non-preferred<br>• Imitrex Nasal Spray (sumatriptan) - removed from MPPL and PDL. Drug Obsolete.<br>• Diastat/Diastat Accudial( diazepam) - removed from MPPL and PDL. Drug Obsolete.<br>• Temovate (clobetasol) ointment - removed from MPPL and PDL. Drug Obsolete.<br>• Symbyax (olanzapine/fluoxetine) - removed from MPPL and PDL due to loss of Federal rebate.<br>• Imcivree (setmelanotide) – criteria revised for expanded age indication<br>• Tekturna HCT (aliskiren/HCTZ) - removed from MPPL and PDL. Drug Obsolete.<br>• Crestor (rosuvastatin) – added back to the MPPL and PDL as non-preferred. Has Federal rebate.<br>• Spravato (esketamine) – criteria revised to allow attestation of prescriber (or treatment center) and patient enrollment in REMS |
| 11012024v3 | 01012025 | • Vtama (tapinarof) – criteria revised to add new indication for atopic dermatitis<br>• Casgevy (exagamglogene autotemcel) – added to the MPPL with prior authorization required via the Program Review Division (PRD) at MDHHS.<br>• Bimzelz (bimekizumab-bkzx) – criteria revised to add new indication for hidradenitis suppurativa<br>• Zurzuvae (zuranolone) – criteria revised to allow prescriber attestation that patient has been counselled on the risks of breastfeeding during treatment. |

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| 11012024v2 | 12012024 | • Livtencity (maribavir) – PA criteria removed<br>• Prevymis (letermovir) – PA criteria removed<br>• Coreg (carvedilol) - removed from MPPL and PDL. Drug Obsolete.<br>• Beconase AQ (beclomethasone) - removed from MPPL and PDL. Drug Obsolete.<br>• Opipza (aripiprazole) – added to the PDL as preferred<br>• sacubitril/valsartan (generic for Entresto) – added to the PDL as non-preferred<br>• timolol (generic for Betimol) – added to the PDL as non-preferred |
| 11012024v1 | 11012024 | • Mifeprex (mifepristone) – added to the MPPL with PA<br>• Alvaiz (eltrombopgag) – added to MPPL with PA<br>• Opsynvi (macitentan/tadalafil) – added to PDL as non-preferred with clinical PA<br>• Rezdiffra (resmetirom) – added to the MPPL with PA<br>• Simlandi (adalimumab-ryvk) and unbranded adalimumab-ryvk – added to PDL as non-preferred with clinical PA<br>• Spevigo (Spesolimab-sbzo) – added to MPPL with PA<br>• Tryvio (aprocitentan) – added to MPPL with PA<br>• Tyenne (tocilizumab-aazg) autoinjector/syringe – added to PDL as non-preferred with clinical PA<br>• Voydeya (danicopan) – added to MPPL with PA.<br>• Winrevair (sotatoercept-csrk) – added to PDL as non-preferred with clinical PA<br>• Zymfentra (infliximab-dyyb) – added to PDL as non-preferred with clinical PA<br>• Tyenne (tozilizumab-aazg) vials - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Ozempic (semaglutide) – moved to PDL preferred<br>• metformin 625mg tablets – moved to PDL non-preferred<br>• Synjardy XR (empagliflozin/metformin) – moved to PDL preferred<br>• Invokamet (canagliflozin/metformin) – moved to PDL non-preferred with 3-month grandfather for established patients.<br>• Invokana (canagliflozin) – moved to PDL non-preferred with 3-month grandfather for established patients.<br>• Glucagon Emergency Kit (Lilly) – moved to PDL non-preferred<br>• Protonix (pantoprazole) tablets – moved to PDL non-preferred<br>• Pentasa (mesalamine) – moved to PDL preferred<br>• Amitiza (lubiprostone) and generic – quantity limit and minimum age edits added<br>• Linzess (linaclotide) – quantity limit and minimum age edits added<br>• tacrolimus ointment – moved to PDL preferred<br>• PDL class Electrolyte Depleters renamed as Phosphate Depleters<br>• Potassium Binders – new PDL class added<br>  ○ Lokelma, sodium polystyrene sulfonate powder and suspension, SPS suspension – added as preferred<br>  ○ Veltassa – added as non-preferred<br>• PDL Class Anti-Obesity Agents – criteria revised to not allow more than one weight loss medication concurrently and to add new cardiovascular risk reduction indication for Wegovy and also revised patient age for phentermine.<br>• Xolair (omalizumab) – criteria revised to add baseline IgE levels and “persistent” to asthma diagnosis |

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| | | • Dupixent (dupilumab) – revised criteria for new age indication for CRSwNP and to add criteria for new COPD indication<br>• Fasenra (benralizumab) – criteria revised to add new indication for eosinophilic granulomatosis with polyangiitis (EPGA)<br>• Actemra SC (tocilizumab) – criteria added for all indications<br>• Bimzelx (bimekizumab-bkzx) – criteria revised to add new indications for PsA, nr-axSpA and AS<br>• Stelara (ustekinumab) – criteria revised to add medication-specific quantity limits for diagnoses<br>• Tremfya (guselkumab) – criteria revised to add new indication for ulcerative colitis<br>• Xeljanz (tofacitinib) – criteria revised to add covered diagnoses by age and to remove the failure/inadequate response to methotrexate.<br>• Forteo (teriparatide) – criteria revised to limit the length of approval to a cumulative duration of 2 years per lifetime.<br>• Tymlos (abaloparatide) - criteria revised to limit the length of approval to a cumulative duration of 2 years per lifetime including any prior use of Forteo.<br>• Tezspire (tezepelumab-ekko) – criteria revised to allow bypass of PDL criteria if the patient does not meet criteria for preferred agents (e.g. eosinophil count and/or IgE levels)<br>• Breo Ellipta (fluticasone/vilanterol) 50-25mg – maximum age edit added<br>• Dulera (mometasone/formoterol) 50 mcg/5mcg – maximum age edit added<br>• Arnuity Ellipta (fluticasone) 50 mcg – maximum age edit added<br>• Asmanex (mometasone) HFA 50 mcg and Twisthaler 110mcg – maximum age edit added<br>• Pulmicort (budesonide) respules – maximum age edit added<br>• Ngenla (somatrogon-ghla) – maximum age edit added<br>• Skytrofa (lonapegsomatropin-tcgd) – maximum age edit added<br>• Vusion (miconazole/zinc oxide/petrolatum) – maximum age edit added<br>• Dificid (fidaxomicin) 40 mg/ml oral suspension – maximum age edit added<br>• Noxafil (posaconazole) 300mg suspension – maximum age edit added<br>• Nucala (mepolizumab) 40mg/0.4mL – maximum age edit added<br>• Cuvposa (glycopyrrolate) oral solution – maximum age edit added<br>• Fensolvi (leuprolide) – maximum age edit added<br>• Malarone (atovaquone/proguanil) 62.5/25 mg ped tabs – maximum age edit added<br>• Increlex (mecasermin) 40 mg/4ml vials – maximum age edit added<br>• Cystic Fibrosis Agents – Kalydeco, Orkambi, Symdeko, Trikafta – maximum age edits added to select strengths<br>• Infuvite Pediatric vials – maximum age edit added<br>• V-GO – criteria removed. Coverage moved to DME unless COB 2 or 4.<br>• Comtan (entacapone) - removed from MPPL and PDL due to loss of Federal rebate.<br>• Corgard (nadolol) - removed from MPPL and PDL due to loss of Federal rebate.<br>• Phoslyra (calcium acetate) - removed from MPPL and PDL. Drug Obsolete. |
| 08012024v3 | 10012024 | • Stimulants for Non-ADHD Disorders – criteria revised<br>• Drugs for ADHD – criteria revised<br>• Ciclopirox shampoo – criteria added to allow a trial and failure of one preferred shampoo medication.<br>• Voquezna (vonoprazan) – criteria revised to add new indication for GERD<br>• Palforzia (peanut allergen powder-dnfp) – criteria revised for expanded age indication<br>• Licart (diclofenac epolamine) patch – removed from MPPL and PDL due to loss of Federal rebate. |

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| | | • Flector (diclofenac epolamine) patch and generic – removed from MPPL and PDL due to loss of Federal rebate.<br>• Vascepa (icosapent ethyl) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Lexette (halobetasol) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Ciprodex Otic (ciprofloxacin/dexamethasone) – removed from MPPL and PDL. Drug obsolete.<br>• Ziac (bisoprolol/HCTZ) – removed from MPPL and PDL. Drug Obsolete.<br>• Relyvrio (sodium phenylbutyrate/taurursodiol) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Androderm (testosterone) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Lindane Shampoo – removed from MPPL and PDL. Drug obsolete.<br>• Catapres TTS (clonidine) – removed from MPPL and PDL. Drug obsolete.<br>• Extavia (interferon beta-1b) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Glynase (glyburide, micronized) – removed from MPPL and PDL. Drug obsolete.<br>• Kerydin (tavaborole) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Parlodel (bromocriptine) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Proventil HFA (albuterol) – removed from MPPL and PDL. Drug obsolete.<br>• Zymaxid (gatifloxacin) – removed from MPPL and PDL due to loss of Federal rebate.<br>• V-Go (sub-Q insulin device) – criteria removed. Coverage moved to DME. |
| 08012024v2 | 09012024 | • Effective 8/23/2024 – Buprenorphine products for treatment of opioid use disorder – maximum accumulated daily dose increased to 32 mg/day.<br>• Livmarli (marilixibat) – revised criteria for expanded age indication for PFIC<br>• Kevzara (sarilumab) – criteria revised to add indication for polyarticular juvenile idiopathic arthritis<br>• Otezla (apremilast) – criteria revised to add indication for plaque psoriasis<br>• Skyrizi (Risankizumab) – criteria revised to add indication for ulcerative colitis<br>• Yuflyma (adalimumab-aaty) – criteria revised to add indication for non-infectious intermediate, posterior or panuveitis<br>• Zoryve (roflumilast) 0.15% cream – criteria added for this new strength indicated for mild to moderate atopic dermatitis<br>• sumatriptan nasal spray (generic for Imitrex) – moved to PDL preferred<br>• Adderall (amphetamine salts combo) immediate-release – moved to PDL preferred<br>• Tanlor (methocarbamol) – added to PDL as non-preferred<br>• lofexidine (generic for Lucemyra) – added to the PDL as preferred<br>• Cloderm (clocortolone) – removed from MPPL and PDL. Drug obsolete.<br>• Impeklo (clobetasol) – removed from MPPL and PDL. Drug obsolete.<br>• Sorine (sotalol) – removed from MPPL and PDL. Drug obsolete.<br>• Mirapex ER (pramipexole) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Aygestin (norethindrone) – removed from MPPL and PDL due to loss of Federal rebate.<br>• Amaryl (glimepiride) – removed from MPPPL and PDL. Drug obsolete. |
| 08012024v1 | 08012024 | • Agamree (vamorolone) – added to the MPPL without PA<br>• Cabtreo (adapalene/benzoyl/clindamycin) – add to the PDL as non-preferred<br>• Eohilia (budesonide) – added to the MPPL with PA and quantity limit<br>• Fabhalta (iptacopan) – added to the MPPL with PA<br>• Filsuvez (birch bark extract) – added to the MPPL with PA and quantity limit |

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| | | • Omvoh (mirikizumab-mrkz) pens – added to the PDL as non-preferred with clinical PA<br>• Omvoh (mirikizumab-mrkz) vials - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Rivfloza (nedosiran) – added to the MPPL with PA<br>• Vevye (cyclosporine) – added to the PDL as non-preferred with clinical PA and quantity limit<br>• Voquezna (vonoprazan) – added to the MPPL with PA and quantity limit<br>• Voquezna Dual Pak (vonoprazan/amoxicillin) – added to the PDL as non-preferred<br>• Voquezna Triple Pak (vonoprazan/amoxicillin/clarithromycin) – added to the PDL as non-preferred<br>• Wainua (eplontersen) – added to the MPPL with PA<br>• Xphozah (tenapanor) – added to the PDL as non-preferred with clinical PA<br>• Zilbrysq (zilucoplan) – added to the MPPL with PA<br>• Zituvio (sitagliptin) and generic – added to PDL as non-preferred<br>• Adzynma (adamts13, recombinant-krhn) - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Combogesiv IV (ibuprofen/acetaminophen) - added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• acyclovir cream (generic for Zovirax) – moved to PDL preferred<br>• Zovirax (acyclovir) cream – moved to PDL non-preferred<br>• PDL Class Otic Macrolides – change the name of the class to Otic Antibiotics<br>• neomycin/polymyxin/hydrocortisone otic suspension and solution – added to the PDL as preferred<br>• vancomycin solution (generic for Firvanq) – moved to PDL preferred<br>• Firvanq (vancomycin) solution – moved to PDL non-preferred<br>• fluticasone/salmeterol diskus (generic for Advair Diskus) (DPI) – moved to PDL non-preferred<br>• fluticasone/salmeterol HFA (generic for Advair HFA) (MDI) – moved to PDL non-preferred<br>• Pulmicort Flexhaler (budesonide) (DPI) – moved to PDL preferred<br>• Arnuity Ellipta (fluticasone) (DPI) – moved to PDL preferred<br>• Qvar Redihaler (beclomethasone) (MDI) – moved to PDL preferred<br>• PDL Class: Nasal Corticosteroids – Xhance (fluticasone) nasal spray – criteria revised to include the expanded indication for chronic rhinosinusitis without nasal polyps.<br>• Adderall XR (dextroamphetamine/amphetamine) – moved to the PDL non-preferred<br>• dextroamphetamine/amphetamine (generic for Adderall XR) – moved to the PDL preferred<br>• Vyvanse Chew Tablets (lisdexamfetamine) – moved to PDL non-preferred<br>• lisdexamfetamine chew tablets (generic for Vyvanse Chew Tabs) – moved to PDL preferred<br>• Concerta (methylphenidate) – moved to the PDL non-preferred<br>• methylphenidate (generic for Concerta) – moved to PDL preferred<br>• Lialda (mesalamine) – moved to the PDL non-preferred<br>• mesalamine (generic for Lialda) – moved to the PDL preferred<br>• Amitiza (lubiprostone) – moved to PDL non-preferred<br>• lubiprostone (generic for Amitiza) – moved to PDL preferred<br>• Emend capsules (aprepitant) – moved to PDL non-preferred<br>• aprepitant capsules (generic for Emend) – moved to PDL preferred<br>• Toviaz (fesoterodine) – moved to PDL non-preferred<br>• fesoterodine (generic for Toviaz) – moved to PDL preferred<br>• PDL Class Anti-Obesity Agents – clinical PA criteria to revise the age indication for phentermine. |

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| | | • liraglutide (generic for Victoza) – added to the PDL as non-preferred<br>• Micotrin AC (clotrimazole) – moved to PDL non-preferred<br>• methamphetamine – clinical PA criteria and quantity limit added<br>• ondansetron ODT 16mg – added as non-preferred with quantity limit<br>• BPCO (balsam-Peru-castor oil) – added to the MPPL without PA<br>• Asacol HD (mesalamine) - removed from PDL and MPPL. Drug obsolete.<br>• Crestor (rosuvastatin) – removed from PDL an MPPL due to loss of Federal rebate.<br>• Protopic (tacrolimus) 0.1% and 0.3% ointment - removed from PDL and MPPL. Drug obsolete.<br>• Entadfi (finasteride/tadalafil) - removed from PDL and MPPL. Drug obsolete.<br>• Sitavig (acyclovir) - removed from PDL and MPPL. Drug obsolete.<br>• Timoptic (timolol) eye drops – removed from PDL and MPPL. Drug obsolete.<br>• Timoptic XE (timolol) gel solution - removed from PDL and MPPL. Drug obsolete. |
| 05012024v5 | 07012024 | • Rinvoq (upadacitinib) – criteria revised to add new indication for polyarticular juvenile idiopathic artheritis and an expanded age indication for psoriatic arthritis in pts 2y and older.<br>• Alkindi (hydrocortisone) – clinical PA criteria removed.<br>• Rayos (prednisone) – clinical PA criteria removed.<br>• Prednisone ODT – clinical PA criteria removed.<br>• Ovide (malathion) – clinical PA criteria removed. Minimum age edit added.<br>• Sklice (ivermectin) – clinical PA criteria removed. Minimum age edit added.<br>• Natroba (Spinosad) – clinical PA criteria removed. Minimum age edit added.<br>• Lindane – clinical PA criteria revised to clarify trial and failure requirement.<br>• metronidazole (generic for Nuvessa) – added to the PDL as non-preferred. |
| 05012024v4 | 06012024 | • Gralise (gabapentin) – moved to PDL preferred. Quantity limit removed.<br>• Horizant (gabapentin enacarbil) – moved to PDL preferred. Quantity limit removed.<br>• Gabapentin (Neurontin, others) – cumulative daily dose edit removed.<br>• Savella (milnacipran) – quantity limit removed. |
| 05012024v3 | 06012024 | • Lyfgenia (lovotibeglogene autotemcel) – added to the MPPL with prior authorization required via the Program Review Division (PRD) at MDHHS.<br>• Zynteglo (betibeglogene autotemcel) - added to the MPPL with prior authorization required via the Program Review Division (PRD) at **MDHHS.** |
| 05012024v2 | 05152024 | • Arcalyst (rilonacept) – criteria revised to add indications for deficiency of IL-1 receptor antagonist and pericarditis.<br>• Daybue (trofinetide) – criteria revised to allow prescriber attestation of baseline assessments for initial requests.<br>• Joenja (leniolisib) – criteria revised to allow prescriber attestation of baseline assessments for initial requests.<br>• Skyclarys (omavloxolone) - criteria revised to allow prescriber attestation of baseline assessments for initial requests.<br>• Bylvay (odevixibat) – criteria revised to add indication of Alagille syndrome.<br>• Livmarli (maralixibat) – criteria revised for expanded age indication for Alagille syndrome and to add indication for progressive familial intrahepatice cholestasis (PFIC).<br>• Fasenra (benralizumab) – criteria revised for expanded age indication for asthma. |
| 05012024v1 | 05012024 | • Abrilada ((adalimumab-afzb) – added to the PDL as non-preferred with clinical PA<br>• Airsupra (albuterol/budesonide) – added to the PDL as non-preferred with quantity limit<br>• Bimzelx ((bimekizumab-bkzx) – added to the PDL as non-preferred with clinical PA |

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| | | • Breyna (budesonide/formoterol) – added to the PDL as non-preferred with quantity limit<br>• Iyuzeh (latanoprost/PF) – added to the PDL as non-preferred<br>• Jesduvroq (daprodustat) – added to the PDL as non-preferred with clinical PA<br>• Likmez (metronidazole) – added to the PDL as non-preferred with quantity limit<br>• Ngenla (somatrogon-ghla) – added to the PDL as non-preferred<br>• Pokonza (potassium chloride) – added to the MPPL with PA<br>• Velsipity (etrasimod arginine) – added to the PDL as non-preferred with PA<br>• Zepbound (tirzepatide) – added to the PDL as preferred with clinical PA<br>• Zurzuvae (zuranolone) – added to the MPPL with PA<br>• Opfolda (miglustat) - added to the MPPL with PA<br>• Pombiliti (cipaglucosidase alfa-atga) - not added to the MPPL. Clinical prior authorization required through the Department's Program Review Division.<br>• Veopoz (pozelimab-bbfg) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• nebivolol (generic for Bystolic) – moved to PDL preferred<br>• carvedilol ER (generic for Coreg CR) – moved to PDL preferred<br>• Coreg CR (cavedilol ER) – moved to PDL non-preferred<br>• PDL class Lipotropics: PCSK9 Inhibitors – criteria revised to change the target LDL-C levels per updated evidence-based literature.<br>• moxifloxacin (generic foe Vigamox) – move to PDL preferred<br>• Vigamox (moxifloxacin) – moved to PDL non-preferred<br>• Zaditor (ketotifen) – move to PDL non-preferred<br>• olopatadine Rx (generic for Pataday) – moved to PDL non-preferred<br>• PDL class Growth Hormone – criteria revised to modify the papilledema requirement and to revise the non-preferred agent PA criteria.<br>• Voxzogo (vosoritide) – criteria revised to remove age requirement.<br>• Xolair (omalizumab) – criteria added for new indication of IgE-mediated food allergy |
| 02012024v4 | 04012024 | • Pimecrolimus (generic for Elidel) – moved to PDL preferred.<br>• Jalyn (dustasteride/tamsulosin) – removed from PDL and MPPL due to loss of Federal rebate.<br>• Suprax (cefixime) caspules – removed from PDL and MPPL due to loss of Federal rebate.<br>• Viekira Pak (ombitasivr/paritaprevir/dasabuvir) – removed from PDL and MPPL. Drug obsolete. |
| 02012024v3 | 03042024 | • Benlysta (belimumab) – criteria revised for the expanded age indication |
| 02012024v2 | 03012024 | • Dupixent (dupilumab) – criteria revised for the expanded age and weight indication for eosinophilic esophagitis.<br>• Entyvio (vedolizumab) – criteria revised to clarify the TNF blocker requirement<br>• PDL classes – Insulins – criteria added to allow for continuation of therapy when switching would cause deterioration of clinical condition |
| 02012024v1 | 02012024 | • PDL class Incretin Mimetics – criteria was added to preferred agents to require diagnosis of DM2 and to require discontinuation of other GLP-1 agonists.<br>• Zoryve (roflumilast) – criteria was revised to add new indication for the foam formulation<br>• Adbry (tralokinumab-ldrm) – criteria revised to add new age indication<br>• Cyltezo (adalimumab-adbm) - added to the PDL as non-preferred<br>• Hadlima (adalimumab-bwwd) - added to the PDL as non-preferred<br>• Hulio and unbranded (adalimumab-fkjp) - added to the PDL as non-preferred<br>• Hyrimoz and unbranded (adalimumab-adaz) – added to the PDL as non-preferred |

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| | | • Idacio (adalimumab-aacf) – added to the PDL as non-preferred<br>• Yuflyma (adalimumab-aaty) – added to the PDL as non-preferred<br>• Yusimry (adalimumab-aqvh) – added to the PDL as non-preferred<br>• Inpefa (sotagliflozin) – added to the PDL as non-preferred<br>• Liqrev (sildenafil) - added to the PDL as non-preferred<br>• Litfulo (ritlecitinib) – added to the MPPL with PA and quantity limit<br>• Miebo (perfluorohexyloctane/PF) – added to the PDL as non-preferred with quantity limit<br>• Olpruva (sodium phenylbutyrate) - added to the PDL as non-preferred<br>• Sogroya (somapacitan-beco) – added to the PDL as non-preferred with clinical PA<br>• Growth Hormones - PDL class criteria revised to add papilledema<br>• Sohonos (palovarotene) – added to the MPPL with PA<br>• Suflave (PEG 3350/sod sulf,chlr/pot/mag) – added to the MPPL with PA<br>• Veozah (fezolinetant) – added to the MPPL with PA<br>• Xdemvy (lotilaner) – added to the MPPL with PA<br>• Zavzpret (zavegepant) – added to the PDL as non-preferred with quantity limit<br>• Elfabrio (pegunigalsidase alfa-iwxj) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Rezzayo (rezafungin) – added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Rystiggo (rozanolixizumab-noli) – added to the MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Analgesic PDL Classes – renamed the Narcotic PDL classes to replace “Narcotic” with “Opioids”<br>• teriflunomide (generic for Aubagio) – moved to PDL preferred<br>• fingolimod (generic for Gilenya) – moved to PDL preferred<br>• Gilenya (fingolimod) – moved to PDL non-preferred<br>• entacapone – move to PDL preferred<br>• Ajovy (fremanezumab-vfrm) – moved to PDL preferred with clinical PA<br>• Multiple Sclerosis Agents - refined the medication-specific criteria for the non-preferred agents that require a trial of two preferred medications to change therapeutic failure from "two preferred medications" to "one month trial of at least two preferred medications".<br>• Analgesics: Chronic Opioid Management with High MME – criteria revised to add new reference<br>• Evrysdi (risdiplam) – criteria revised to remove lab monitoring |
| 11012023v4 | 01012024 | • Wakix (pitolisant) – PA criteria removed<br>• Doxepin (generic for Silenor) – moved to PDL preferred<br>• Rozerem (ramelteon) – moved to PDL preferred<br>• Hetlioz (tasimelteon) and generic – moved to PDL preferred<br>• Kynmobi (apomorphine) - removed from PDL and MPPL due to loss of Federal rebate. |
| 11012023v3 | 12132023 | • Stimulants for Non-Attention Deficit Disorder Criteria revised to clarify that MAPS requirement does not apply to non-controlled medications. |
| 11012023v2 | 12012023 | • Daybue (trofinetide) – criteria revised to add physical medicine and rehab (PM&R) physicians<br>• Siklos (hydroxyurea) – prior authorization (PA) removed.<br>• Sickle Cell Agents – added to the maintenance medication list |
| 11012023v1 | 11012023 | • Amjevita (adalimumab-atto) – added to the PDL as non-preferred<br>• Atorvaliq (atorvastatin) – added to the PDL as non-preferred with quantity limit<br>• Cuvrior (trientine tetrahydrochloride) – add to the MPPL with PA<br>• Joenja (leniolisib) – added to the MPPL with PA |

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| | | • Konvomep (omeprazole/sodium bicarbonate) - added to the PDL as non-preferred<br>• Rezvoglar (insulin glargine-aglr) – added the PDL as non-preferred<br>• Skyclarys (omavloxolone) – added to the MPPL with PA<br>• Vowst (fecal microbiota spores, live-brpk) - added to the MPPL with PA<br>• Vyjuvek (beremagene geperpavec-svdt) gel – not added to the MPPL. Clinical prior authorization required through the Department's Program Review Division.<br>• Lamzede (velmanase alfa-tycv) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Tzield (teplizumab-mzwv) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Novolog pens and vials (insulin aspart) - moved to PDL non-preferred<br>• insulin aspart pens and vials (generic for Novolog) – moved to PDL preferred<br>• Novolog Mix pens (insulin aspart prot/insulin asp) – moved to PDL non-preferred<br>• insulin aspart prot/insulin asp pens (generic for Novolog Mix) – moved to PDL preferred<br>• Zegalogue (dasiglucagon) – moved to PDL preferred<br>• PDL class Incretin Mimetics – non-preferred PDL criteria revised to add discontinuation of other GLP-1 agonists. Quantity limits added.<br>• Ozempic (semaglutide) – medication-specific criteria removed.<br>• Movantik (naloxegol) – moved to PDL non-preferred. Allow a 90-day grandfather period.<br>• Fasenra (benralizumab) – moved to PDL preferred with clinical PA<br>• Adbry (tralokinumab-ldrm) – moved to PDL preferred with clinical PA<br>• Urea Cycle Disorder Agents – new PDL class added<br>  ○ Buphenyl powder and tablets, Carbaglu – added as PDL preferred<br>  ○ carglumic acid, Pheburane, Ravicti, sodium phenylbutyrate powder and tablets – added as PDL non-preferred<br>• Anti-Obesity Agents – criteria revised<br>• Uterine Disorder Treatment – criteria was revised and quantity limits added for each agent<br>• PDL class Immunomodulators – Agents to Treat Asthma – moved to the Miscellaneous Category with the Biologic Immunomodulators<br>• PDL class Immunomodulators – Agents to Treat Atopic Dermatitis – moved to the Miscellaneous Category with the Biologic Immunomodulators<br>• Daybue (trofinetide) – criteria revised<br>• Combination Nasal Sprays – new PDL class added<br>  ○ azelastine/fluticasone, Dymista and Ryaltris added as non-preferred<br>• Zoryve (roflumilast) – criteria revised for new age indication for ages 6 years and older<br>• Sivextro (tedizolid) – added back to the PDL and MPPL due to reinstatement of Federal rebate |
| 08012023v4 | 10012023 | • Prevymis (letermovir) – length of authorization for HSCT extended to 200 days per FDA approved changes.<br>• Contrave (naltrexone/bupropion) – removed from PDL and MPPL due to loss of Federal rebate.<br>• Onzetra Xsail (sumatriptan) – removed from PDL and MPPL due to loss of Federal rebate.<br>• Silenor (doxepin) – removed from PDL and MPPL due to loss of Federal rebate.<br>• Sivextro (tedizolid) – removed from PDL and MPPL due to loss of Federal rebate.<br>• Treximet (sumatriptan/naproxen) – removed from PDL and MPPL due to loss of Federal rebate<br>• Xenleta (lefamulin) – removed from MPPL due to loss of Federal rebate. |
| 08012023v3 | 09052023 | • Adderall and Adderall XR (amphetamine salts combo) – quantity limits added |

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| | | • zolpidem products – quantity limits added |
| 08012023v2 | 09012023 | • Ingrezza (valbenazine) – criteria revised to add new indication for chorea associated with Huntington's disease<br>• tiotropium (generic for Spiriva Handihaler) – quantity limit added |
| 08012023v1 | 08012023 | • Daybue (trofinetide) – added to the MPPL with PA<br>• Ermeza (levothyroxine) – added to the MPPL without PA<br>• Filspari (sparsentan) – added to the MPPL with PA<br>• Pheburane (sodium phenylbutyrate) – added to the MPPL with PA<br>• Stimufend (pegfilgrastim-fpgk) – added to the PDL as non-preferred<br>• Briumvi (ublituximab-xiiy) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• tobramycin solution for inhalation (generic for TOBI) – moved to PDL preferred<br>• Dificid (fidaxomicin) – moved to PDL preferred. Clinical PA removed.<br>• Clindesse (clindamycin) – moved to PDL preferred<br>• Xopenex HFA (levalbuterol) – moved to PDL preferred<br>• Roflumilast (generic for Daliresp) – moved to preferred with clinical PA<br>• Alvesco (ciclesonide) – moved to PDL preferred. Clinical PA removed.<br>• Inhaled Glucocorticoids PDL class – non-preferred PDL criteria revised to require a 2-week trial of one preferred medication<br>• Arnuity Ellipta (fluticasone) – remove trial of all preferred agents to align with the non-preferred PDL criteria for the inhaled glucocorticoids class.<br>• Anticholinergic Agents – Long Acting – quantity limit added to Incruse Ellipta (umeclidinium)<br>• Beta Adrenergic/Anticholinergic Combinations – quantity limited added to Anoro Ellipta (umeclidinium/vilanterol), Bevespi (glycopyrrolate/formoterol), Combivent Respimat (ipratropium/albuterol) and Stiolto Respimat (tiotropium/olodaterol)<br>• Beta Adrenergic/Anticholinergic/Corticosteroid Combinations – quantity limit added to Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), Breztri Aerosphere (budesonide/glycopyrrolate/formoterol)<br>• Inhaled Glucocorticoids – quantity limit added to Pulmicort (budesonide) Respules<br>• Proton Pump Inhibitors – quantity limit added to Nexium (esomeprazole), omeprazole (Rx), Protonix (pantoprazole)<br>• Anticoagulants – quantity limit added to Eliquis (apixaban), Pradaxa (dabigatran), Xarelto (rivaroxaban)<br>• Platelet Aggregation Inhibitors – quantity limit added to Plavix (clopidogrel) 75mg<br>• Miacalcin (calcitonin) nasal spray – criteria for the brand nasal spray removed. No longer on the market.<br>• Prevymis (letermovir) – criteria revised to add new indication for kidney transplant recipients. |
| 05012023v4 | 07012023 | • Rinvoq ER (upadacitinib)– criteria revised to add new indication of Crohn's disease<br>• Tascenso (fingolimod) – criteria revised to add new age indication and remove weight requirement |
| 05012023v3 | 06132023 | • Stimulants for Non-Attention Deficit Disorder Criteria added. |

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| 05012023v2 | 06012023 | • Thyquidity (levothyroxine) – PA criteria removed<br>• Tirosint (levothyroxine) – PA criteria removed<br>• Kalydeco (ivacaftor) – criteria revised to add new age indication<br>• Furoscix (furosemide) – added to the MPPL with PA and quantity limit |
| 05012023v1 | 05012023 | • Entadfi (finasteride/tadalafil) – added to the PDL as non-preferred with the additional medication-specific criteria<br>• Fylnetra (pegfilgrastim-pbbk) – added to the PDL as non-preferred<br>• Relyvrio (sodium phenylbutyrate and taurursodiol) – added to the MPPL with PA<br>• Ryaltris (olopatadine/mometasone) – added to the PDL as non-preferred<br>• Sotyktu (deucravacitinib) – added to the PDL as non-preferred<br>• Tadliq (tadalafil) – added to the PDL as non-preferred with medication-specific PA criteria<br>• Tascenso (fingolimod) – added to the PDL as non-preferred with medication-specific PA criteria<br>• Tlando (testosterone undecanoate) – added to the MPPL with PA<br>• Xaciato (clindamycin) - added to the PDL as non-preferred with medication-specific PA criteria<br>• Xelstrym (dextroamphetamine) – added to the PDL as non-preferred<br>• Zoryve (roflumilast) – added to the MPPL with PA<br>• Rolvedon (eflapegrastim-xnst) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Spevigo (spesolimab-sbzo) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Ramipril (generic for Altace) - moved to PDL preferred<br>• Coreg CR (carvedilol ER) – moved to PDL preferred<br>• Savaysa (edoxaban) – medication-specific criteria removed<br>• Sildenafil suspension (generic for Revatio) – moved to PDL preferred.<br>• Revatio suspension (sildenafil) – moved to PDL non-preferred<br>• Adempas (riociguat) – moved to PDL preferred<br>• Tyvaso DPI (Treprostinil) – moved to PDL non-preferred<br>• Pulmonary Arterial Hypertension (PAH) Agents – PDL class criteria revised to add “or in consultation with” to the prescriber specialties of cardiologist or pulmonologist<br>• Tezspire (tezepelumab-ekko) pre-filled pens – added to the PDL as non-preferred with medication-specific PA criteria<br>• Kevzara (sarilumab) – criteria revised to add new indication for polymyalgia rheumatica.<br>• Sporanox (itraconazole) 100 mg capsules – quantity limit changed to 100 caps per 30 days.<br>• Jublia ((efinaconazole) – criteria revised to add new age indication<br>• Kerydin (tavaborole) – criteria revised to add new age indication |
| 02012023v3 | 04012023 | • Pradaxa Oral Pellets (dabigatran) – added to the PDL as non-preferred with medication-specific criteria |
| 02012023v2 | 03012023 | • Cibinqo (abrocitinib) – criteria revised for new age indication<br>• Tymlos (abaloparatide) – criteria revised for new indication for men |
| 02012023v1 | 02012023 | • Qsymia (phentermine-topiramate) – removed from PDL and MPPL due loss of Federal rebate.<br>• Adlarity (donepezil) – added to the PDL as non-preferred<br>• Aspruzyo (ranolazine) – added to the MPPL with PA<br>• Camzyos (mavacamten) - added to the MPPL with PA<br>• Epsolay (benzoyl peroxide) – reviewed by P&T but the mfr no longer participates in the Medicaid Drug Rebate Program. Therefore, it will not be added to the MPPL. |

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| | | • Hyftor (sirolimus) - added to the MPPL with PA<br>• Lyvispah (baclofen) – added to the PDL as non-preferred with medication-specific criteria to allow if patient had trial/failure with baclofen oral solution.<br>• Mounjaro (tirzepatide) – added to the PDL as non-preferred<br>• Radicava (edaravone) – added to the MPPL with PA<br>• Verkazia (cyclosporine) – added to the PDL as non-preferred with medication-specific PA criteria<br>• Vivjoa (oteseconazole) – added to the PDL as non-preferred<br>• Vtama (tapinarof) – added to the MPPL with PA<br>• Amvuttra (vutrisiran) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Xenpozyme (olipudase alfa-rpcp) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Seglentis (celecoxib/tramadol) – criteria revised to add age edit for post-operative management of pain in tonsillectomy and/or adenoidectomy<br>• Ketoprofen immediate-release capsules – moved to PDL non-preferred<br>• Quillichew ER (methylphenidate ER) – moved to PDL non-preferred<br>• Quillivant XR (methylphenidate XR) – moved to PDL non-preferred<br>• Drugs for ADHD PDL Class – criteria revised to allow PDL non-preferred liquid formulations to be approved if patient has swallowing difficulties.<br>• Rasagiline (generic for Azilect) – moved to PDL preferred<br>• Elyxyb (celecoxib) – added quantity limit of 14 doses per 30 days<br>• Nurtec ODT (rimegepant) – quantity limit revised to 54 tablets per 90 days<br>• Antimigraine Agents, Preventive Treatment – class criteria revised to add minimum age of 18 years<br>• Baclofen oral solution – moved to PDL preferred with PA for swallowing difficulties.<br>• Chlorzoxazone (generic for Lorzone) – move to PDL non-preferred. Allow a 90-day grandfather period.<br>• Fleqsuvy (baclofen) – medication-specific criteria revised to allow if patient had trial/failure with baclofen oral solution.<br>• Hydrocortisone/aloe cream – moved to PDL preferred<br>• Clobetasol gel – moved to PDL non-preferred<br>• Moxifloxacin – medication-specific criteria added to bypass PDL criteria and quantity limit when used for the treatment of active drug-susceptible pulmonary tuberculosis for patients ≥12 years of age. Length of approval = 17 weeks for this diagnosis.<br>• Vascepa (icosapent ethyl) - criteria revised for clarity.<br>• Rinvoq ER (upadacitinib) – atopic dermatitis criteria revised to remove the word “refractory”<br>• Brexafemme (ibrexafungerp) – criteria revised to add diagnosis of recurrent vulvovaginal candidiasis and maintenance quantity.<br>• Wegovy (semaglutide) – criteria revised with new age indication |
| 11012022v3 | 01012023 | • Lyumjev (insulin lispro-aabc) – criteria revised to remove age edit.<br>• Opzelura (ruxolitinib) – criteria added for new indication for vitiligo.<br>• Dupixent (dupilumab) – age criteria revised for PENS and SYRINGES |
| 11012022v2 | 12012022 | • Qsymia (phentermine/topiramate) – new age indication added to criteria.<br>• Clopidogrel 300mg – added quantity limit of 2 tablets per 30 days; removed from maintenance therapy list.<br>• Spravato (esketamine) – criteria revised to only require an attestation of REMS enrollment for PA renewal requests.<br>• CNS Drugs: Sedative Hypnotics – revised criteria for allow requests for ramelteon (Rozerem) and doxepin (Silenor) to bypass PDL criteria for patients with history of substance use disorder. |

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| 11012022v1 | 11012022 | • Dupixent (dupilumab) – criteria revised to allow 56-day supply for every 4 weeks dosing and age edit added to pre-filled PENS and new indication for prurigo nodularis (PN).<br>• Codeine-containing and tramadol-containing medications – minimum age 12 years added<br>• Cibinqo (abrocitinib) – added to the PDL as non-preferred<br>• Dartisla ODT (glycopyrrolate) -added to the MPPL with PA<br>• Fleqsuvy (baclofen) – added to the PDL as non-preferred<br>• Ibsrela (tenapanor) – added to the PDL as non-preferred<br>• Levamlodipine – added to the PDL as non-preferred<br>• Norliqva (amlodipine) – added to the PDL as non-preferred<br>• Pyrukynd (mitapivat) – added to the MPPL with PA and to the MCO carveout<br>• Quviviq (daridorexant) – added to the PDL as non-preferred<br>• Releuko (filgrastim-ayow) – added to the PDL as non-preferred<br>• Seglentis (celecoxib/tramadol) – added to the PDL as non-preferred<br>• Twyneo (tretinoin/benzoyl peroxide) – added to the MPPL with PA<br>• Vijoice (alpelisib) - added to the MPPL with PA and to the MCO carveout.<br>• Enjaymo (sutimlimab-jome) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Glyxambi (empagliflozin/linagliptin) - moved to PDL non-preferred<br>• Gvoke Hypopen (glucagon) – moved to PDL preferred<br>• Insulin Suppressants – new PDL class<br>  ○ Proglycem (diazoxide) – added as PDL preferred<br>  ○ Diazoxide (generic for Proglycem) – added as PDL non-preferred **(glucagon) pen to**<br>• Protonix (pantoprazole) tablets and suspension – moved to PDL preferred<br>• Udenyca (pegfilgrastim-cbqv) – moved to PDL non-preferred<br>• EpiPen and EpiPen Jr (epinephrine) – moved to PDL preferred<br>• Epinephrine (generic for EpiPen/EpiPen Jr) – moved to PDL non-preferred<br>• Myfembree (relugolix/estradiol/norethindrone) – moved to PDL preferred with PA. PA criteria revised to include the new indication for endometriosis.<br>• Rinvoq ER (upadacitinib) – criteria revised for new indication for non-radiographic axial spondyloarthritis (nr-axSpA)<br>• Taltz (ixekizumab) – criteria revised to add indication for non-radiographic axial spondyloarthritis (nr-axSpA) |
| 08012022v4 | 10012022 | • Emflaza (deflazacort) - criteria removed<br>• Orkambi (lumacaftor/ivacaftor) - new age indication added to criteria |
| 08012022v3 | 09012022 | • Doptelet (avatrombopag) – criteria revised to align with indications<br>• Immunomodulators: Asthma – criteria revised for indications other than asthma. |
| 08012022v2 | 08152022 | • Dupixent (dupilumab) – criteria revised for new indication for eosinophilic esophagitis<br>• Skyrizi (risankizumab-rzaa) – criteria revised for new indication for Crohn's disease<br>• Hydroxyprogesterone caproate (generic for Makena) – clinical prior authorization criteria added<br>• Olumiant (baricitinib) – criteria added for new indication for alopecia areata |
| 08012022v1 | 08012022 | • Adbry (tralokinumab-ldrm) – added to the PDL as non-preferred<br>• Elyxyb (celecoxib) – add to the PDL as non-preferred |

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| | | • Imcivree (setmelanotide) – criteria revised for new indication<br>• Livtencity (maribavir) – added to the MPPL with PA<br>• Recorlev (levoketoconazole) – added to the MPPL with PA<br>• Tarpeyo (budesonide) – added to the MPPL with PA<br>• Voxzogo (vosoritide) – added to the MPPL with PA<br>• Vuity (pilocarpine) – added to the MPPL with PA<br>• Leqvio (inclisiran) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Tezspire (tezepelumab-ekko) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Vyvgart (efgartigimod alfa-fcab) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Tamiflu (oseltamivir) – moved to PDL non-preferred<br>• Vigamox (moxifloxacin) – moved to PDL preferred<br>• Moxifloxacin (generic for Vigamox) – move to PDL non-preferred<br>• Proventil HFA (albuterol) – moved to PDL preferred<br>• Fexofenadine – moved to PDL preferred<br>• Immunomodulators – Asthma – new PDL class created<br>  ○ Xolair (omalizumab) syringes; Dupixent (dupilumab) – added as preferred<br>  ○ Nucala (mepolizumab) auto-injector, syringe; Fasenra (benralizumab) pen – added as non-preferred<br>• Niacin OTC products – moved to PDL preferred<br>• Varubi (rolapitant) – criteria removed. Medication discontinued. |
| 05012022v4 | 07012022 | • Hydroxyprogesterone caproate – clinical prior authorization criteria removed<br>• Evrysdi (risdiplam) – criteria revised for new indication for patients less than 2 months of age. |
| 05012022v3 | 06082022 | • Lucemyra (lofexidine) – moved to PDL preferred. Clinical prior authorization and quantity limits removed. |
| 05012022v2 | 06012022 | • Wakix (pitolisant) – criteria revised to allow sleep specialist<br>• Rinvoq ER (upadacitinib)– criteria revised to add new indication of ankylosing spondylitis<br>• Solesec (secnidazole) – criteria revised for new age indication<br>• Intron A (interferon alfa-2B, recomb.) – criteria removed. Discontinued. |
| 05012022v1 | 05012022 | • Livmarli (maralixibat) – added to the MPPL with PA<br>• Opzelura (ruxolitinib) – add to the PDL as non-preferred<br>• Qulipta (atogepant) – added to the PDL as non-preferred<br>• Skytrofa (lonapegsomatropin-tcgd) – added to the PDL as non-preferred<br>• Tavneos (avacopan) – added to the MPPL with PA<br>• Trudhesa (dihydroergotamine mesylate) – added to the MPPL without PA<br>• Winlevi (clascoterone) – added to the MPPL with PA<br>• Saphnelo (anifrolumab-fnia) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Praluent (evolocumab) – moved to PDL preferred with PA<br>• Ophthalmic Anti-Inflammatory/Immunomodulator – new PDL class created.<br>  ○ Restasis (cyclosporine), Xiidra (lifitegrast) – added as preferred |

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| | | ○ Cequa (cyclosporine), cyclosporine (generic for Restasis single-use), Eysuvis (loteprednol), Tyrvaya (varenicline) – added as non-preferred<br>• Nurtec ODT (rimegepant) – quantity limit increased to 48 tabs per 96 days<br>• Imcivree (setmelanotide) – added to the MPPL with PA<br>• Intensol (alprazolam, diazepam, lorazepam) criteria added to allow for swallowing difficulties<br>• Baclofen oral solution added to PDL as non-preferred with allowance for swallowing difficulties<br>• Zelnorm (tegaserod) – criteria removed. Discontinued. |
| 02012022v1 | 02152022 | • Rinvoq ER (upadacitinib) – criteria revisions:<br>○ Biologic Immunomodulator criteria revised to add new indication for psoriatic arthritis<br>○ Added to PDL class Immunomodulators: Atopic Dermatitis as non-preferred for new indication for atopic dermatitis.<br>• Skyrizi (risankizumab) – criteria revised to add new indication for active psoriatic arthritis<br>• Palynziq (pegvaliase-pqpz) – criteria revised to allow taper of sapropterin (Kuvan) therapy<br>• Hetlioz (tasimelteon) – criteria revised to add the diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients ages 16 years and older.<br>• Bevyxxa (betrixaban) – criteria removed. Discontinued by manufacturer. |
| 02012022v1 | 02012022 | • Aemcolo (rifamycin) – added to the PDL as non-preferred with additional clinical criteria<br>• Brexafemme (ibrexafungerp) – added to the PDL as non-preferred with additional clinical criteria<br>• Bylvay (odevixibat) – added to the MPPL with PA<br>• Empaveli (pegcetacoplan) – added to the MPPL with PA<br>• Exservan (riluzole) – added to the MPPL with PA<br>• Kerendia (finerenone) – added to the MPPL with PA<br>• Myfembree (relugolix/estradiol/norethindrone) – added to the PDL as non-preferred with additional clinical criteria.<br>Kimyrsa (oritavancin) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Anti-Parkinson's Agents-Other: Gocovri (amantadine extended-release) – criteria updated with new indication for adjunctive treatment for patients experiencing "off" episodes while on levodopa/carbidopa.<br>• Immunomodulators- Atopic Dermatitis: Dupixent (dupilumab) moved to preferred with clinical PA<br>• Anti-Obesity Agents – new PDL class added. All agents added as preferred with additional clinical PA.<br>○ Orlistat (Xenical), liraglutide (Saxenda), semaglutide (Wegovy), phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), benzphetamine (only available as generic), diethylpropion (only available as generic), phentermine (generic, Adipex-P, Lomaira), phendimetrazine (only available as generic)<br>• Lipid Lowering Agents-Other: Vascepa (icosapent ethyl) – criteria revised.<br>• Synagis (palivizumab) – criteria clarified to identify the start of the current RSV season. |
| 11012021v5 | 01192022 | • Hetlioz (tasimelteon) – criteria correction. Removal of total blindness. Operational call center criteria was updated on March 26, 2020 but the revision was inadvertently not made to the public criteria document at that time. |
| 11012021v4 | 01012022 | • Xeljanz/ Xeljanz XR (tofacitinib) – criteria revised to add new indication for ankylosing spondylitis (AS)<br>• Oxbryta (voxelotor) – expanded age indication added to criteria |
| 11012021v3 | 12202021 | • Belsomra (suvorexant) – criteria revised to require a trial of one preferred medication in line with |

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| | | the standard PDL non-preferred criteria for the sedative hypnotics. |
| 11012021v2 | 12072021 | • Spravato (esketamine) – criteria revised to allow prescriber consultation with a psychiatrist<br>• Hydroxyprogesterone caproate – criteria revised. |
| 11012021v1 | 11012021 | • Makena (hydroxyprogesterone caproate) – revised criteria. PDL criteria do not apply.<br>• Dupixent (dupilumab) – age indication for asthma revised (previously 12 yrs old; now 6 yrs old).<br>• Bronchitol (mannitol) – added to MPPL with PA<br>• Gemtesa (vibegron) – added to PDL as non-preferred<br>• Ponvory (ponesimod) – added to PDL as non-preferred with additional clinical criteria<br>• Qdolo (tramadol) – added to PDL as non-preferred with age and quantity limit<br>• Reltone (ursodiol) – added to PDL as non-preferred<br>• Zegalogue (dasiglucagon) – added to PDL as non-preferred<br>• Evkeeza (evinacumab-dgnb) – added to MPPL as a physician-administered injectable for home infusion or LTC administration<br>• Nulibry (fosdenopterin) – added to MPPL as a physician-administered injectable for home infusion or LTC administration.<br>• Synjardy (empagliflozin/metformin) – moved to PDL preferred<br>• Diabetes: Glucagon Agents – new PDL class created<br>  • Baqsimi (glucagon), Glucagen Hypokit (glucagon), Glucagon Emergency Kit (Lilly), Proglycem (diazoxide) – added as preferred<br>  • Diazoxide (gen for Proglycem), Glucagon Emergency Kit (Fresenius), Gvoke (glucagon), Zegalogue (dasiglucagon) – added as non-preferred<br>• Gastrointestinal: Chronic GI Motility – Lotronex (alosetron) criteria revised to require that patient is female<br>• Pantoprazole suspension (generic for Protonix) – moved to PDL non-preferred<br>• Colchicine tablets (generic for Colcrys) – moved to PDL preferred<br>• Mitigare capsules (colchicine) – moved to PDL non-preferred<br>• Fulphila (pegfilgrastim-jmdb) – moved to PDL non-preferred<br>• Miscellaneous: Urinary Tract Antispasmodics – criteria revised to change to a trial of one preferred medication<br>• Nexviazyme (avalglucosidase alfa-ngpt) – added to MPPL with PA<br>• Analgesics: Opioid Use Disorder Treatments – added maximum daily dosage of 24mg/day across all oral buprenorphine products and strengths<br>• Nurtec ODT (rimegepant) – quantity limit changed to 16 tabs per 32 days |
| 08012021v6 | 10042021 | • Dojolvi (triheptanoin) – added to MPPL with PA |
| 08012021v5 | 09212021 | • Synagis (palivizumab) – criteria clarified to identify the start of the current RSV season. |
| 08012021V4 | 09152021 | • Suboxone 4mg/1mg films (buprenorphine/naloxone) – quantity limit increased to 3 films per day<br>• Ivermectin (Stromectol) 3mg tablets – quantity limitation added of 10 tabs per 30 days |
| 08012021V3 | 09082021 | • Xolair (omalizumab) – criteria added |
| 08012021V2 | 08102021 | • Synagis (palivizumab) – criteria revised to allow 5 doses every 365 days.<br>• Nucala (mepolizumab) – criteria revised to add new indication for chronic rhinosinusitis with nasal polyposis (CRSwNP)<br>• Amondys-45 (casimersen) – criteria added<br>• Viltepso (viltolarsen) – criteria added |
| 08012021V1 | 08012021 | • Eysuvis (loteprednol) – added to MPPL with PA<br>• Gimoti (metoclopramide) – added to MPPL with PA<br>• Impeklo (clobetasol) – added to PDL as non-preferred |

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| | | • Lupkynis (voclosporin) - added to MPPL with PA<br>• Minolira (minocycline) – added to MPPL with PA<br>• Nyvepria (pegfilgrastim-apgf) - added to PDL as preferred with quantity limit<br>• Colony Stimulating Factors – Fulphila (pegfilgrastim-jmdb), Neulasta (pegfilgrastim), Neulasta Onpro (pegfilgrastim), Udenyca (pegfilgrastim-abgf), Ziextenzo (pegfilgrastim-bmez) – added quantity limit<br>• Orladeyo (berotralstat) – added to MPPL with PA<br>• Reditrex (methotrexate/pf) – added to MPPL with PA<br>• Verquvo (vericiguat) – added to MPPL with PA<br>• Zokinvy (lornafarnib) – added to MPPL with PA<br>• Olinvyk (oliceridine) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Oxlumo (lumasiran) - added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Ketoconazole tablets – moved to PDL preferred<br>• Nystatin tablets – moved to PDL preferred<br>• Ciclopirox 0.77% cream (generic for Loprox and Ciclodan) – moved to PDL preferred<br>• Ciclopirox 8% solution (generic for Ciclodan) – moved to PDL preferred<br>• Ciclopirox suspension (generic for Loprox) – moved to PDL non-preferred<br>• Zovirax ointment (acyclovir) – moved to PDL preferred<br>• Cefixime suspension (generic for Suprax) – moved to PDL non-preferred<br>• E.E.S. 200mg/5mL suspension (erythromycin) – moved to PDL non-preferred<br>• Zithromax suspension (azithromycin) – age edit removed<br>• Ciprofloxacin suspension (generic for Cipro) – moved to PDL preferred<br>• Cipro suspension (ciprofloxacin) – moved to PDL non-preferred<br>• Moxifloxacin eye drops (generic for Vigamox) – moved to PDL preferred<br>• Vigamox eye drops (moxifloxacin) – moved to PDL non-preferred<br>• Neomycin tablets – moved to PDL preferred and clinical criteria removed<br>• Tinidazole tablets – moved to PDL preferred<br>• Clindamycin 2% cream (generic for Cleocin) – moved to PDL preferred<br>• Metronidazole 0.75% gel (generic for Metro-gel and Vandazole) – moved to PDL preferred<br>• Clindesse 2% cream (clindamycin) – moved to PDL non-preferred<br>• Vandazole 0.75% gel (metronidazole) – moved to PDL non-preferred<br>• Spiriva Respimat (tiotropium) – moved to PDL preferred<br>• Incruse Ellipta (umeclidinium) – moved to PDL preferred<br>• Anticholinergic Agents–Long Acting – revised PDL criteria to require a 2-week trial of preferred agent<br>• Anoro Ellipta (umeclidinium/vilanterol) – moved to PDL preferred<br>• Beta Adrenergic/Anticholinergic/Corticosteroid Inhaler Combinations – new PDL class created for triple combination products with Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) added as preferred and Breztri Aerosphere (budesonide/glycopyrrolate/formoterol) added as non-preferred<br>• Ventolin HFA (albuterol) – moved to PDL preferred<br>• Proventil HFA (albuterol) – moved to PDL non-preferred and grandfather for 90 days (8/1/21-10/31/21).<br>• Symbicort (budesonide/formoterol) – quantity limit changed to 2 per 30 days<br>• Asmanex HFA (mometasone) – quantity limit added of 1 inhaler per 30 days<br>• Pulmicort Flexhaler (budesonide) – quantity limit added (180 mcg – 2 per 30 days; 90mcg – 1 per 30 days)<br>• Inhaled Glucocorticoids - revised PDL criteria to require a 2-week trial of preferred agent<br>• Nurtec ODT (rimegepant) – added to Antimigraine Agents, Preventive Treatment as preferred with current preventive treatment clinical criteria.<br>• Zeposia (ozanimod) – clinical criteria added for new indication of ulcerative colitis.<br>• Anti-anxiety Agents – General – removed hydroxyzine HCl and hydroxyzine pamoate (Vistaril)<br>• Cystic Fibrosis Agents (Kalydeco, Orkambi, Symdeko, Trikafta) – renewal criteria revised |

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| 07012021 | 07122021 | • Evrysdi (risdiplam) – criteria revised<br>• Chronic opioid management criteria revised |
| 07012021 | 07012021 | • Chronic opioid management criteria revised<br>• Opioid (long-acting and short-acting) quantity limit changes<br>• Austedo (deutetrabenazine) – criteria revised<br>• Ingrezza (valbenazine) – criteria revised<br>• Trikafta (elexacaftor/tezacaftor/ivacaftor) – expanded age indication added |
| 06012021 | 06012021 | • Oxbryta (voxelotor) – criteria revised to extend initial length of approval and renewal criteria<br>• Emgality (galcanezumab-gnlm) – criteria revised to accommodate loading doses. |
| 05012021 | 05012021 | • Alkindi (hydrocortisone) – added to MPPL with PA<br>• Bafiertam (monomethyl fumarate) – added to PDL as non-preferred with additional clinical criteria<br>• Breztri Aerosphere (budesonide/glycopyrrolate/formoterol) – added to PDL as non-preferred<br>• Enspryng (satralizumab-mwge) – added to MPPL with PA<br>• Kesimpta (ofatumumab) – added to PDL as non-preferred with additional clinical criteria<br>• Lampit (nifurtimox) – added to MPPL with PA<br>• Mycapssa (octreotide) – added to MPPL with PA<br>• Ongentys (opicapone) – added to PDL as non-preferred with additional clinical criteria<br>• Semglee (insulin glargine) – added to PDL as non-preferred<br>• Xywav (sodium, calcium, magnesium, potassium oxybate) – added to MPPL with PA<br>• Xyrem (sodium oxybate) – added the same PA criteria as Xywav<br>• Enalapril HCT (generic for Vaseretic) – moved to PDL preferred<br>• Amlodipine/olmesartan (generic for Azor) – moved to PDL preferred<br>• Olmesartan and olmesartan HCT (generic for Benicar/Benicar HCT) – moved to PDL preferred<br>• Fenofibrate capsules (generic for Lofibra) – moved to PDL preferred<br>• Lipotropics: PCSK9 Inhibitors – combined class criteria for both Repatha and Praluent.<br>• Repatha 420 mg/3.5 mL Pushtronex – changed quantity limit to 7.0 mL per 28 days<br>• Ambrisentan (generic for Letairis) – moved to PDL preferred<br>• Letairis (ambrisentan) – moved to PDL non-preferred<br>• Timolol (generic for Timoptic Occudose) – move to PDL non-preferred<br>• Travatan Z (travoprost)- move to PDL non-preferred<br>• Dorzolamide/timolol PF (generic for Cosopt PF) – move to PDL non-preferred<br>• Azelastine (generic for Optivar) – move to PDL preferred<br>• Ophthalmic Antihistamines – revised PDL criteria to require only a trial of one preferred agent<br>• Acular (ketorolac tromethamine) – moved to PDL non-preferred<br>• Ketorolac LS (generic for Acular LS) – moved to PDL non-preferred<br>• Ophthalmic NSAIDs – criteria revised to add a bullet to the standard PDL criteria to allow lower strength doses such as Acular LS and ketorolac LS when for medical necessity of lower strength dosages for post-operative pain relief<br>• Antimigraine Agents, Preventive Treatments – add to maintenance medication list<br>• Nitazoxanide (generic for Alinia) – criteria added. PDL criteria does not apply.<br>• Oxbryta (voxelotor) – criteria revised to remove Patient had at least one vaso-occlusive crisis in the past 12 months<br>• Asmanex Twisthaler 110 mcg (mometasone) – added age and QL criteria<br>• Analgesics: Narcotics – Long-Acting – removed Arymo ER criteria. No longer on market.<br>• Proton Pump Inhibitors – revised PDL criteria to require a trial of one preferred medication<br>• Growth Hormones – added criteria for idiopathic short stature diagnosis.<br>• Ubrelvy – criteria revised to bypass PDL criteria when twice daily dosing required.<br>• Qelbree – added to PDL Class - Drugs for ADHD – Non-Stimulants as preferred<br>• Pregabalin ER – added to PDL Class- Neuropathic Pain as preferred<br>• Trulicity (dulaglutide) – moved to PDL preferred<br>• Acthar HP (corticotropin) - removed clinical PA criteria |
| 04012021 | 04012021 | • Hepatitis C: Direct Acting Antivirals – removed clinical PA criteria. Revised PDL non-preferred criteria. Moved sofosbuvir/velpatasvir (generic for Epclusa), Vosevi and Zepatier to PDL non-preferred |

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| | | • Provigil (modafinil) and Nuvigil (armodafinil) – criteria added for Hypersomnolence/EDS and Shift Work Sleep Disorder<br>• Lidotral 3.88% (lidocaine) – criteria added |
| 02012021 | 02012021 | • Bynfezia (octreotide) - added to MPPL with PA<br>• Dayvigo (lemborexant) – added to PDL as non-preferred<br>• Evrysdi (risdiplam) – added to MPPL with PA<br>• Fensolvi (leuprolide acetate) – added to MPPL with PA<br>• Kynmobi (apomorphine) – added to PDL as non-preferred<br>• Licart (diclofenac epolamine) – added to PDL as non-preferred<br>• Lyumjev (insulin lispro-aabc) – added to PDL as non-preferred<br>• Nexlizet (bempedoic acid/ezetimibe) – added to PDL as non-preferred<br>• Oriahnn (elagolix/estradiol/norethindrone) – added to PDL as preferred with clinical PA<br>• Ortikos ER (budesonide) – added to MPPL with PA<br>• Xepi (ozenoxacin) – added to PDL as non-preferred<br>• Zeposia (ozanimod) – added to PDL as non-preferred with additional clinical criteria<br>• Zilxi (minocycline) – added to MPPL with PA<br>• Tramadol ER (generic for Ultram ER) – moved to PDL preferred<br>• Tramadol/acetaminophen (generic for Ultracet) – moved to PDL preferred<br>• Butrans (buprenorphine) – moved to PDL preferred<br>• Celebrex (celecoxib) – quantity limits changed to 2 per day<br>• Opioid Withdrawal Symptom Management – created new PDL class<br>  ○ Clonidine, guanfacine and guanfacine ER – added as preferred<br>  ○ Catapres (clonidine) – added as non-preferred<br>  ○ Lucemyra (lofexidine) – added as non-preferred with additional clinical criteria<br>• Concerta (methylphenidate ER- OROS) – moved to PDL preferred<br>• Methylphenidate CD (generic for Metadate CD)- moved to PDL non-preferred<br>• Aptensio XR (methylphenidate ER) – moved to PDL non-preferred<br>• Gralise (gabapentin) 300mg - quantity limit changed to 3 tabs per day<br>• Horizant (gabapentin enacarbil) 300mg - quantity limit changed to 2 tabs per day<br>• Savella (milnacipran) all strengths – added quantity limit of 60 tabs per 30 days<br>• Anti-Parkinson's Agents, Dopamine Agonists – class criteria revised to allow bromocriptine (Parlodel) for indications other than Parkinson's.<br>• Rebif and Rebif Rebidose (interferon beta-1A/albumin) – moved to PDL non-preferred<br>• Neupro (rotigotine) all strengths - added quantity limit of 30 patches per 30 days<br>• Carbidopa/levodopa ER - moved to PDL preferred<br>• Relpax (eletriptan) - moved to PDL non-preferred<br>• Zomig nasal spray (zolmitriptan) – moved to PDL non-preferred<br>• Imitrex nasal spray (sumatriptan) - moved to PDL preferred<br>• Maxalt/Maxalt MLT (rizatriptan) – changed quantity limit to 18 tabs per fill<br>• Nurtec ODT (rimegepant) – changed quantity limit to 16 tabs per 34 days<br>• Clindamycin/benzoyl peroxide (generic for Acanya) – moved to PDL preferred<br>• Acne Agents - Combination Benzoyl Peroxide/Clindamycin – removed class criteria requirement of a trial of OTC benzoyl peroxide<br>• Eucrisa (crisaborole) – moved to PDL preferred with PA<br>• Dupixent (dupilumab) – atopic dermatitis criteria revised to change from a trial of "calcineurin inhibitor (i.e Elidel)" to "one preferred medication"<br>• Dupixent (dupilumab) – additional criteria added for diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)<br>• Betamethasone dipropionate cream, lotion, and ointment - moved to PDL preferred<br>• Uterine Treatment Disorder – created new PDL class<br>  ○ Orilissa (elagolix) – added as preferred with PA<br>  ○ Oriahnn (elagolix/estradiol/norethindrone) – added as preferred with PA<br>• Emend (fosaprepitant) 40mg (only) - moved to PDL non-preferred<br>• Catapres TTS (clonidine) – moved to PDL preferred<br>• Catapress TTS (clonidine) – removed age edit for patients over 65 years<br>• Zithromax 250mg (azithromycin) – removed quantity limit of 6 tab per fill |

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| | | • Nexium (esomeprazole) brand suspension packets – moved to PDL preferred<br>• Thyquidity (levothyroxine) oral solution – added to MPPL with PA<br>• Benlysta (belimumab) – new indication for lupus nephritis added to criteria<br>• Cystic Fibrosis Agents – Kalydeco, Symdeco, Trikafta – expanded indications added to criteria<br>• Macrolides: move erythromycin ethylsuccinate 200mg suspension (generic for E.E.S) to PDL preferred due to a drug shortage of the brand. |
| 01012021 | 01012021 | • Oral Hypoglycemics: SGLT2 Inhibitors – removed criteria for preferred agents to require trial of metformin or metformin-containing medication<br><br>• Quantity Limits revised for the following inhalers:<br>o Albuterol HFA 90mcg (Proair HFA, Proventil HFA, and Ventolin HFA) – 2 inhalers per 30 days<br>o Atrovent HFA 17 mcg – 2 inhalers per 30 days<br>o Flovent HFA 44 mcg – 1 inhaler per 30 days<br>o Flovent HFA 110 mcg – 1 inhaler per 30 days<br>o Flovent HFA 220 mcg – 2 inhalers per 30 days<br>o Serevent Diskus 50 mcg – 1 inhaler per 30 days<br>o Spiriva Handihaler 18 mcg: kit size variations - 1 per 30 days; 1 per 90 days; 1 per 5 days<br>o Spiriva Respimat 1.25mcg and 2.5mcg – 1 per 30 days<br>o Xopenex HFA 45mcg – 2 inhalers per 30 days<br><br>• Gastrointestinal: Proton Pump Inhibitors – non-preferred criteria revised to add patient is unable to swallow a tablet or capsule **AND** therapeutic failure after one-month trial with preferred omeprazole(rx); **OR** Patient weighs less than 10kg |
| 12152020 | 12152020 | • Aimovig (erenumab-aooe) – moved to PDL preferred<br>• Methocarbamol (generic for Robaxin) – moved to PDL preferred<br>• Campral (acamprosate) – prior authorization removed<br>• ADHD medication criteria revised for patients 18 yrs and older<br>• Vyvanse – criteria for binge-eating disorder revised<br>• Neomycin – added diagnosis of preoperative bowel preparation for patients undergoing colorectal surgery<br>• Celebrex (celecoxib) – revised criteria to include requirement of trial of a preferred agent as well as 2 NSAIDs<br>• Growth Hormones – revised criteria to clarify that diagnoses not listed will require MDHHS review |
| 11012020 | 11012020 | • Arazlo® – added to MPPL with PA<br>• Isturisa® – added to MPPL with PA<br>• Nexletol – added to PDL as non-preferred<br>• Nurtec ODT® – added to PDL as preferred with clinical PA<br>• Palforzia® – added to MPPL with PA<br>• Reyvow®– added to PDL as non-preferred<br>• Talicia® – added to PDL as non-preferred<br>• Trijardy XR® – added to PDL as non-preferred<br>• Vyepti® – added to MPPL as a physician-administered injectable for home infusion or LTC admin.<br>• Zerviate® – added to PDL as non-preferred<br>• Humulin® 70/30 KwikPens – moved to PDL preferred<br>• Novolin® 70/30 Pens – moved to PDL non-preferred<br>• Metformin solution (generic for Riomet®) – moved to PDL non-preferred<br>• Ursodiol capsules – moved to PDL preferred<br>• Androgel® gel packets and pump – moved to PDL non-preferred<br>• Testosterone (generic for Androgel®) pump – moved to PDL preferred |

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| | | • Sevelamer HCL tablets (generic for Renagel®) - moved to PDL non-preferred<br>• Sevelamer carbonate powder packs (generic for Renvela® powder – moved to PDL non-preferred<br>• Nutropin AQ® – moved to PDL non-preferred<br>• Procrit® – moved to PDL non-preferred<br>• Epogen® – moved to PDL preferred<br>• Vesicare® – moved to PDL non-preferred<br>• Solifenacin (generic for Vesicare®) – moved to PDL preferred<br>• Tremfya® - new indication for psoriatic arthritis added to criteria<br>• Xeljanz® - new indication for polyarticular juvenile idiopathic arthritis added to criteria<br>• Nucala® - new indication for hypereosinophilic syndrome (HES) and eosinophilic granulomatosis with polyangiitis (EGPA) added to criteria<br>• Haegarda®– expanded age indication<br>• Kalydeco® - expanded age indication<br>• Emflaza® - initial length of approval changed to 6 months<br>• Montelukast granules – criteria clarified |
| 10012020 | 10102020 | • Ozempic® and Trulicity® – criteria revised to allow continuation of care due to CV risk reduction benefits and once weekly dosing.<br>• Gastrointestinal: Chronic GI Motility – clinical PA removed from preferred medications<br>• Motegrity® (prucalopride) – removed pregnancy contraindication and female indication from criteria<br>• Gastrointestinal: Antiemetics – PDL criteria clarified.<br>• Makena® – criteria applies to both preferred generic and non-preferred brand<br>• Biologic Immunomodulators – PDL criteria may be bypassed when non-preferred agent has a unique FDA approved indication.<br>• Lamisil (terbinafine) tablets – quantity limit clarified.<br>• Actonel 75mg (risedronate) – quantity limit removed. Strength obsolete.<br>• Didronel (etidronate) – removed. Drug obsolete.<br>• Forteo – clinical criteria clarified. PDL criteria do not apply.<br>• Tymlos – clinical criteria clarified. PDL criteria do not apply. |
| 07142020 | 09032020 | • Spravato® - criteria added for acute suicidal ideation<br>• Vyondys-53® - criteria added<br>• Analgesics: Narcotics – created separate criteria for the transdermal agents<br>• Hormone Therapy for Gender Dysphoria criteria added<br>• Testosterone agents – decreased serum testosterone levels revised to <300 ng/dL<br>• Immunomodulators: Atopic Dermatitis - non-preferred PDL criteria clarified<br>• Brovana® and Perforomist® nebulizer solutions - criteria revised for patients that cannot use a DPI<br>• Long-Acting Narcotics – criteria revised to require trial of one preferred medication<br>• Lovaza® and Vascepa® – clinical criteria clarified. PDL criteria do not apply.<br>• Celebrex® (celecoxib) step therapy added to criteria<br>• Epaned® – criteria clarified |
| 07142020 | 07162020 | • Xifaxan® – added diagnosis of IBS-D to criteria |
| 07142020 | 07142020 | • Amzeeq® – added to MPPL with PA<br>• Gloperba® – added to PDL as non-preferred |

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| | | • Jatenzo® – added to MPPL with PA<br>• Pretomanid® – added to MPPL with PA<br>• Ubrelvy® – added to PDL as non-preferred with quantity limit<br>• Vumerity® – added to PDL as non-preferred<br>• Ziextenzo® – added to PDL as non-preferred<br>• Nystatin/triamcinolone cream and ointment – moved to PDL preferred<br>• Suprax® capsules and chew tabs – moved to PDL non-preferred<br>• Epclusa® – moved to PDL non-preferred<br>• sofosbuvir/velpatasvir (generic for Epclusa®) – move to PDL preferred<br>• linezolid (generic for Zyvox®**) –** moved to PDL non-preferred<br>• Cipro® suspension – moved to PDL preferred<br>• Moxeza® – moved to PDL non-preferred<br>• erythromycin ophthalmic ointment – add to PDL as preferred<br>• Azasite – moved to PDL non-preferred<br>• ofloxacin otic drops – moved to PDL preferred<br>• Firvanq® **-** moved to PDL preferred<br>• Vaginal Antibiotics – new class added to PDL:<br>  ○ Cleocin® Ovules, Clindesse®, Vandazole®, Nuvessa® – added to PDL as preferred<br>  ○ Cleocin® cream, clindamycin (generic for Cleocin®) cream, metronidazole (generic for Metro-Gel®, Vandazole®), Metro-Gel® – added to PDL as non-preferred<br>• Advair Diskus® – moved to PDL preferred<br>• fluticasone/salmeterol inhaler (generic for Advair Diskus) – moved to PDL non-preferred<br>• Wixela® (generic for Advair Diskus) – moved to PDL non-preferred<br>• cetirizine 5mg/5ml solution (cups) – moved to PDL non-preferred<br>• Penlac® (ciclopirox) 8% solution removed – obsolete<br>• Antibiotics/Anti-infectives: Antivirals – Influenza – criteria changed to 5-day trial of non-preferred medications<br>• Antibiotics/Anti-infectives: Quinolones – clarified length of authorization as date of service<br>• Gralise® – revised dosage limit as 1800 mg/day<br>• Horizant® - revised dosage limit as 1200 mg/day and added diagnosis of postherpetic neuralgia<br>• Eucrisa® – age indication revised (previously ages ≥2 years; now ≥3 months)<br>• Oral Hypoglycemics: SGLT2 Inhibitors – clarified criteria (preferred agents require trial of metformin or metformin-containing medication)<br>• Doptelet® – added indication of chronic immune thrombocytopenia<br>• Cimzia® – removed criteria to allow the PDL criteria to be bypassed for diagnosis of non-radiographic axial spondyloarthritis because the preferred product, Cosentyx now has this indication.<br>• Flomax (tamsulosin) – removed gender criteria<br>• Velphoro® – removed age criteria<br>• Retacrit® – added to the indications for Epogen and Procrit<br>• Testosterone/Methyltestosterone Replacement therapy – gender criteria removed<br>• Xyosted® (testosterone) – gender criteria removed<br>• Jalyn® (dutasteride/tamsulosin) – gender criteria removed<br>• Immunoglobulin Gamma – added indication of chronic inflammatory demyelinating polyneuropathy (CIDP) |

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| | | • Oral Hypoglycemics – Dopamine Receptor Agonists – removed from PDL. Moved Cycloset to drug-specific criteria.<br>• Non-formulary PA request criteria added<br>• Physician-administered injection request criteria added |
| 06102020 | 6/10/2020 | • Aranesp® - Clinical criteria for revised (indicated for chemo/radiation).<br>• Corlanor® - Age indication revised (previously 18 years old; now 6 months old)<br>• Dupixent® - Age indication for atopic dermatitis revised (previously 12 yrs old; now 6 yrs old).<br>• Ofev® - New indications added (chronic interstitial lung disease (ILD) and systemic sclerosis-associated interstitial lung disease)<br>• Otezla® - Medication-specific criteria revised (Behçet's disease added).<br>• Praluent® - Medication-specific criteria revised. ("Patient has not had a documented trial and failure, contraindication to or hypersensitivity to an alternative PCSK9 inhibitor" removed)<br>• Repatha® - Medication-specific criteria revised. ("Maximally tolerated statin will continue to be used; AND Patient has not had a documented trial and failure, contraindication to or hypersensitivity to an alternative PCSK9 inhibitor" removed) |