Michigan Pharmacy and Therapeutics Committee
Tuesday, March 8, 2022
Minutes – Final

Committee Members Present: Brad Uren (Livingston County), Katie Axford (Rockford, Kent County), Barika Butler (Wayne County), Andrew Adair (Oakland County), Jayne Courts (Kent County), Rony Foumia (Commerce Twp, Oakland County), Melanie Manary (Emmet County), Nora Orow (Macomb County), Eric Roath (Ingram County)

MDHHS/Magellan Present: Trish Bouck (MDHHS), Jed Miller (MDHHS), Donna Johnson (Magellan Medicaid Administration)

The MDHHS Pharmacy and Therapeutics (P&T) Committee was held via Microsoft Teams web conference with teleconference only option of participation also.

The meeting was called to order at 6:01 pm by Brad Uren (chair) with roll call of the members present. The members provided the location from which they were attending. Dr. Uren explained that pursuant to the Michigan Open Meetings Act, as amended, this will be a virtual meeting to mitigate the spread of COVID-19 and protect the health of the public and members of the Board. Committee quorum was established.

The agenda was reviewed and approved. The minutes of the December 7, 2021 meeting were reviewed and approved.

Committee Business

The conflict of interest (COI) statement was reviewed. No conflicts were reported. Dr. Uren reminded the members to submit their COI forms for 2022.

MDHHS Updates

Ms. Bouck announced that the Governor's FY23 Executive Budget Recommendation was posted on February 9, 2022. These recommendations will be considered by the Legislature. The primary focus is on numerous investments due to the current economy and COVID-19 additional funding. A summary of the recommendations summarized in a press release can be found at http://www.michigan.gov/budget.

Ms. Bouck also announced that MDHHS is undergoing an organizational restructuring. In January, the Health and Aging Services Administration (HASA) was created under Executive Order 2021-14 combining Aging and Adult Services and the former administration, Medical Services (MSA). Last week, it was announced that HASA will become Behavioral and Physical Health and Aging Services (BPHAS).

Dr. Jed Miller joined the Health and Aging Services Administration (HASA) as the Chief Medical Consultant in the Office of Medical Affairs on February 7, 2021. He is Board Certified in General Pediatrics and received a master's degree in Public Health from Johns Hopkins University. Dr. Miller also has a background in environmental health and with children with special health care needs.

Ms. Bouck presented summaries on a number of published L-Letters. L 22-05 provides clarification of Michigan Automated Prescription System (MAPS) record retention requirements. L 22-04 provides additional guidance and clarification for the coverage of COVID-19 prevention, treatment and support services. Ms. Bouck further announced several proposed policies. 2202-Pharmacy and HASA 22-02 would allow coverage of U.S. FDA EUA COVID-19 Monoclonal Antibody Injections by Pharmacy Providers. 2156-Pharmacy reaffirms that the signature log and proof of delivery requirements waived on March 26, 2020 remain waived due to the ongoing Public Health Emergency (PHE). Once the PHE waiver is terminated, the

enhanced new proof of delivery requirements will go into effect. 2155-Pharmacy proposes allowing up to 12-months supply per fill for contraceptives effective May 1, 2022.

Ms. Bouck announced that COVID-19 At-Home Tests are covered as a pharmacy benefit per MSA 21-50. A listing of the NDCs covered by Medicaid can be found at www.michigan.magellanrx.com> Providers> Documents> COVID-19 Test Products Covered NDC List. Dr. Uren asked if a prescription is needed for at-home COVID-19 tests. Ms. Bouck explained that policy requires a prescription for all covered pharmacy services however the pharmacists are authorized prescribers and can identify their own NPI as the prescriber on these claims.

CMS notified States that they are planning FFY2021 survey templates (FFS and MCO) to be finalized by 4/1/2022 and target due date of 6/30/2022. National summary and individual state reports for both FFS and MCOs from past years can be found at Medicaid.gov

Quarterly, the MCO Common Formulary workgroup provides input and recommendations on Single PDL coverage for P&T Workgroup consideration before each full P&T Committee meeting. The P&T Committee makes clinical recommendations for both the Michigan Pharmaceutical Product List (MPPL) and the subset of drugs on the Single PDL. A quarterly 'Summary of PDL changes' is available to better inform prescribers/pharmacies following P&T Committee: https://michigan.magellanrx.com> "Recent Changes –MI Single Preferred Drug List (Single PDL)". Ms. Bouck announced the new quarterly update after the March 8th P&T will be posted with a May 1, 2022 effective date. Ms. Bouck also reminded everyone of the Brand Preferred Products (Brand over Generic) List that is posted on the website.

Ms. Bouck provided information on the Centers for Disease Control (CDC) and the State of Michigan website resources for the Coronavirus pandemic. All communications materials on the COVID-19 vaccine for providers to share with the public are available at www.Michigan.gov/covidvaccine. The CDC's information on local vaccine sites can be found at www.vaccinefinder.org. Additional coverage updates will be communicated via web announcements posted at https://michigan.magellanrx.com/provider/ and at www.Michigan.gov/MCOPharmacy. A listing of the currently approved and EUA-authorized tests is available on the FDA website at https://www.fda.gov/medicaldevices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd. A monoclonal antibody locator is available at www.michigan.gov/coronavirus > Resources > COVID-19 Therapeutics Information Page > Find An Antibody Treatment Site. Ms. Bouck noted that sotrovimab is currently available.

Ms. Bouck performed a walkthrough of the P&T Committee webpage to demonstrate how to locate the available information. She also showed how to locate the Public Comment information that provides instructions on how to submit requests to speak at the P&T meetings. She stressed the importance of submitting requests ahead of the deadline. All requests must be received at least 6 business days before the meeting date. This deadline ensures the Committee meeting materials, including agenda with list of public commenters can be finalized and distributed to the Committee members for review in advance of the meeting.

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Public Comments

1. Kimberly Hollar, Senior Medical Science Liaison, on behalf of Mirum Pharmaceuticals, on Livmarli.
2. Preety Gadhoke, PhD, MPH, Regional Medical Outcomes & Science Liaison, Michigan, on behalf of AbbVie, on Qulipta (atogepant) for migraine prevention.
3. Rick Szymialis, Director, Health Economic Outcomes Research, on behalf of Bristol-Myers Squibb Company, on Eliquis. Mr. Szymialis gave back his time to the Committee because Eliquis was proposed to remain PDL preferred.
4. Sharon Cahoon-Metzger, Ph.D., National Director, Field HEOR, on behalf of Ascendis Pharma, on Skytrofa.
5. Darcy Trimpe, Ph.D., Medical Science Liaison, on behalf of ChemoCentryx, on Tavneos® (avacopan).
6. Sunny Hirpara, PharmD, Regional Clinical Account Director – Great Lakes, on behalf of AstraZeneca, on Saphnelo.
7. Amy Kimber, MSN, NP, ANP-BC, Medical Science Liaison, on behalf of United Therapeutics Corporation, on Tyvaso (inhaled treprostinil).
8. Jeff Martin, Pharm.D. MPA, Amgen Sr. HOPE Specialist-Medical Affairs, on behalf of Amgen, on Tezspire (tezepelumab-ekko), and Repatha (evolucumab).

New Drugs for Review

The following new drugs and recommendations were reviewed by the Committee and approved:

1. **Livmarli (maralixibat chloride) oral solution** - Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) with the following PA criteria:

   Initial
   - Patient is ≥ 1 year 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)
   - Length of approval: 6 months

   Renewal
   - Patient has experienced a reduction in serum bile acid concentration; AND
   - Patient has experience improvement in pruritis
   - Length of approval: 1 year

2. **Opzelura (ruxolitinib phosphate) cream** - added to the PDL class: Immunomodulators – Atopic Dermatitis as non-preferred with the following 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 criteria:**
     - Diagnosis of mild to moderate atopic dermatitis

- Patient age ≥12 years old
- Quantity limit: 240 gm (4 x 60gm) per 30 days

3. **Qulipta (atogepant) tablets** – added to the PDL class: Antimigraine Agents, Preventive Treatment as non-preferred with the following criteria:

Initial

- 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
- For initial requests:
  - Patient has a diagnosis of migraine with or without aura; **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
  - Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches
- Length of authorization: initial = 6 months; renewal = 12 months
- **Medication-specific criteria:**
  - Quantity Limit: 90 tablets per 90 days

4. **Skytrofa (lonapegsomatropin-tcgd) cartridge** – added to the PDL class: Growth Hormones as non-preferred with the following criteria:

- Allergy to inactive ingredients in the preferred medications
- 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
- **Required Testing Information:**
  - **Growth hormone stimulation testing:**

1. 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.
2. 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):**
  1. Pediatric patients - bone x-ray report is required ***unless*** the prescriber is a (pediatric) endocrinologist
  2. 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.
  3. Adult patients – bone x-ray report is **NOT** required.
- 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.

- **Length of Approval:** 1 year

5. **Tavneos (avacopan) capsules** - Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) with the following PA criteria:
   - 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).
   - Length of approval: 1 year

6. **Trudhesa (dihydroergotamine mesylate) nasal spray** - Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) without PA.

7. **Tyrvaya (varenicline tartrate) nasal spray** – added to the *new* PDL Class – Ophthalmic Anti-Inflammatory/Immunomodulator as non-preferred with the following 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 a six-week trial with one preferred medication
   - Length of approval: 1 year
   - **Medication-specific criteria:**
     - Quantity limit: 8.4ml (2 bottles) every 30 days

8. **Winlevi (clascoterone) cream** - Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) with the following PA criteria:
   - 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)
   - Length of approval: 1 year

9. **Saphnelo (anifrolumab-fnia) vials** - Not a PDL class - Typically physician-administered therefore add to MPPL as a covered pharmacy benefit only when not administered in the physician office/clinic

Preferred Drug List (PDL) Classes

A review of the following Preferred Drug Classes was performed, and the following actions were taken.

Cardiovascular Classes

(The following workgroup member were recognized: Uren, Adair, Axford, Foumia)

1. ACE Inhibitors
   a. No change to the current classification of drug products.
2. Alpha Adrenergic Agents
   a. No change to the current classification of drug products
3. Antihypertensive Combinations: ACEI-CCB
   a. No change to the current classification of drug products
4. Antihypertensive Combinations: ARB-CCB
   a. No change to the current classification of drug products.
5. Angiotensin Receptor Antagonists (ARBs)
   a. No change to the current classification of drug products.
6. Angiotensin-II Receptor Neprilysin Inhibitors (ANRIs)
   a. No change to the current classification of drug products
7. Direct Renin Inhibitors
   a. No change to the current classification of drug products
8. Beta Blockers
   a. No change to the current classification of drug products
9. Calcium Channel Blockers-Dihydropyridine
   a. No change to the current classification of drug products
10. Calcium Channel Blockers-Non-Dihydropyridine
    a. No change to the current classification of drug products
11. Lipotropics: Fibric Acid Derivatives
    a. No change to the current classification of drug products.
12. Lipotropics: Bile Acid Sequestrants
    a. No change to the current classification of drug products
13. Lipotropics: Statins
    a. No change to the current classification of drug products
14. Lipotropics: Niacin Derivatives
    a. No change to the current classification of drug products
15. Lipotropics: Other
    a. No change to the current classification of drug products

16. Lipotropics: PCSK9 Inhibitors
    a. Move Praluent (evolocumab) to preferred
17. Anticoagulants
    a. No change to the current classification of drug products
18. Platelet Aggregation Inhibitors
    a. No change to the current classification of drug products
19. Pulmonary Arterial Hypertension (PAH) Agents
    a. No change to the current classification of drug products.

Ophthalmic Classes

(The following workgroup member were recognized: Uren, Manary, Orow)

1. Glaucoma: Alpha-2 Adrenergics
    a. No change to the current classification of drug products
2. Glaucoma: Beta Blockers
    a. No change to the current classification of drug products.
3. Glaucoma: Prostaglandin Analogues
    a. No change to the current classification of drug products.
4. Glaucoma: Carbonic Anhydrase Inhibitors
    a. No change to the current classification of drug products.
5. Glaucoma: Combination Alpha-2 Adrenergic/Beta Blocker
    a. No change to the current classification of drug products
6. Glaucoma: Rho Kinase Inhibitors
    a. No change to the current classification of drug products
7. Ophthalmic Antihistamines
    a. No change to the current classification of drug products.
8. Ophthalmic Mast Cell Stabilizers
    a. No change to the current classification of drug products
9. Ophthalmic NSAIDs
    a. No change to the current classification of drug products.
10. Ophthalmic Anti-Inflammatory/Immunomodulator – *new class*
    a. The following agents were added to the PDL as preferred:
        i. Restasis (cyclosporine) 0.05% eye emulsion (single-use)
        ii. Restasis (cyclosporine) Multidose 0.05%
        iii. Xiidra (lifitegrast) 5% eye drops
    b. The following agents were added to the PDL as non-preferred
        i. Cequa (cyclosporine) 0.09% ophthalmic solution
        ii. Cyclosporine 0.05% eye emulsion (generic for Restasis single-use containers)
        iii. Eysuvis (loteprednol) 0.25% eye drops
        iv. Tyrvaya (varenicline) nasal spray

    The following non-preferred PA criteria was added:
    - 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
    - Length of approval: 1 year (except Eysuvis – 2 weeks)
    - 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
- **Quantity Limits:**
    - Restasis: single-use containers: 60 per 30 days; multi-dose vial: 5.5ml (1 vial) per 30 days
    - Xiidra: 60 single-use containers per 30 days
    - Cequa: 60 single-use containers per 30 days
    - Eysuvis: 8.3ml (1 bottle) per 14 days
    - Tyrvaya: 8.4ml (2 bottles) per 30 days

The March P&T actions will be effective May 1, 2022.

The next P&T meeting will be held on Tuesday, June 7, 2022 at 6pm. Ms. Bouck confirmed that it will be held as a virtual meeting.

Adjourn

Meeting adjourned at 7:41 PM