Michigan Pharmacy and Therapeutics Committee
Tuesday, December 7, 2021
Minutes - Final

Committee Members Present: Brad Uren (Livingston County), Katie Axford (Kent County), Barika Butler-Quarles (Wayne County), Andrew Adair (Oakland County), Jayne Courts (Kent County), Rony Foumia (Oakland County), Melanie Manary (Emmet County), Nora Orow (Macomb County)

Committee Members Absent: Eric Roath

MDHHS/Magellan Present: Trish Bouck (MDHHS - Eaton County), Matt Giering (MDHHS – Ingram County), Donna Johnson (Magellan Medicaid Administration - Hanover County, VA)

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 6:01pm 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 September 7, 2021 meeting were reviewed and approved.

Committee Business

The conflict of interest (COI) statement was reviewed. Rony Foumia noted a potential conflict and abstained from voting on the antimigraine agent recommendations.

Public Comments:

1. Vijay M. Patel, PharmD., MBA, Regional Population Health, Medical Science Liaison, on behalf of Novartis Pharmaceuticals Corporation, on Kesimpta (ofatumumab).
2. Ryan C. Norman, PharmD/MBA, Field Value Evidence & Outcomes, U.S. Medial Affairs, on behalf of Teva Pharmaceuticals, on Ajovy.
3. Jamie Tobitt, PharmD, Medical Value Liaison, on behalf of Apellis Pharmaceuticals, on Empaveli
4. Bill Gittinger, Director, Government Accounts, on behalf of Mitsubishi Tanabe Pharma America, on Exservan. Mr. Gittinger requested that the Committee consider revising the proposed Exservan prior authorization criteria to “diagnosed with dysphagia” instead of “difficulty swallowing”.
5. G. Robert DeYoung, PharmD, FCCP, BCPS, Director, Women’s Health and Metabolism Team, Medical Affairs, on behalf of Pfizer, on Myfembree (relugolix, estradiol, norethindrone acetate).
6. Jared Pomeroy MD MPH FAHS, Medical Director, Headache Clinic, on behalf of Spectrum Health Medical Group, on CGRP mAbs and gepants for treatment of migraine.
7. Jeff Martin, Pharm.D., MPA, Sr. HOPE Specialist – Medical Affairs, on behalf of Amgen, on erenumab (Aimovig).
8. Kenneth DiGioia, Senior Director, Medical Affairs, on behalf of Albireo Pharma, Inc., on Bylvay (odevixibat).
9. Stacey Repotski, Pharm. D., Medical Managed Care Director, on behalf of Sanofi Genzyme, on Dupixent.
10. ~~George M. Dillon, M.D., Vascular Neurologist, on behalf of Michigan Neurology Associates, P.C., on Emgality.~~
11. Chelsea Leroue, Director, Field Medical Accounts, on behalf of Biohaven Pharmaceuticals, on Nurtec ODT.
12. Amit Masih, MD, Director of Headache and Facial Pain, on behalf of Memorial Neuroscience Institute, on rescue medications for migraine patients. Dr. Masih requested that the Committee consider adding a long-acting triptan such as frovatriptan or eletriptan to the PDL as preferred.

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MDHHS Updates

Ms. Bouck presented an update on the single Medicaid Preferred Drug List which was effective October 1, 2020. The Medicaid Health Plans began following the Single PDL. Implementation went smoothly. FY21 boilerplate reports captured the first two quarters of savings data. The FY22 Section 1879 report due June 2022 will provide additional monitoring data. 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. Ms. Bouck announced the new quarterly web posting "Summary of PDL Changes" effective 11/2021 is available as a reference. Ms. Bouck also reminded everyone of the Brand Preferred Products (Brand over Generic) List that is posted on the website.

Ms. Bouck announced that a new policy, MSA 21-49, will provide pharmacy coverage of anti-obesity drug products. Currently, the Medicaid State Plan excludes coverage for agents when used for anorexia, weight loss or weight gain. However, there has been an increasing number of non-formulary prior authorization requests for anti-obesity drugs that have been approved for medical necessity. Coverage of these products aligns with current standards of practice and supports recognized treatments of comorbid conditions, such as diabetes. MSA 21-49 will be effective February 1, 2022. The P&T Committee reviewed the specific covered drug products for the new Anti-Obesity PDL drug class.

Ms. Bouck provided updates on the COVID-19 vaccine policies. Effective August 12, 2021, MDHHS began covering an additional/booster dose. MDHHS will reimburse a $37.85 incentive fee regardless of first, second, single dose, or additional dose. Effective June 8, 2021, COVID-19 vaccine administration is covered for Medicaid recipients in their place of residence/home. An additional $33.24 will be reimbursed for administration in the home (i.e., Place of Service = 12). There is no co-pay required for COVID-19 vaccines. COVID-19 vaccines are covered for Emergency Services Only (ESO) when claim is submitted with Level of Service = 3 in accordance with provisions in MSA 20-40. MSA 21-50 provides coverage of COVID-19 testing. Effective for dates of service on or after August 30, 2021, both full at-home tests or samples taken at home then mailed to a lab for results will be covered. Copays are excluded for both Medicaid FFS and Health Plans. Authorized prescribers include pharmacists. Pharmacy-specific billing instructions and a list of covered FDA-approved COVID-19 tests are available at www.michigan.magellanrx.com/. The Centers for Disease Control (CDC) and the State of Michigan website resources for the Coronavirus pandemic (i.e. COVID-19) were provided. For FAQs, a data dashboard, and communications materials on the COVID-19 vaccine for providers to share with the public at www.Michigan.gov/covidvaccine. Additional coverage updates will be communicated via web announcements posted at https://michigan.magellanrx.com/provider/ and at www.Michigan.gov/MCOPharmacy.

CMS notified States on December 3, 2021 that the FFY2020 Drug Utilization Review (DUR) Reports are complete. National summary and individual State reports for both FFS and MCOs are posted at Medicaid.gov.

MDHHS reported on the "We Treat Hep C" initiative. MDHHS Public Health Administration has begun implementing the statewide elimination plan and development of provider training and consultation resources. This includes MDHHS partnering with Medicaid Health Plans to increase Hepatitis C virus (HCV) screening/testing rates in accordance with new CDC guidelines. Effective April 1, 2021, MDHHS contracted with AbbVie and removed all prior authorization and list their pangenotypic Hep C direct-acting antiviral (DAA), Mavyret as the sole preferred product for the Medicaid program. All other Hep C DAA non-preferred products can still be approved when medically necessary via prior authorization. Pharmacies are encouraged to have an adequate supply of MAVYRET in stock, including ability to fill the entire prescription days supply of an 8-week regimen when prescribed as single fill. Ms. Bouck presented slides of the State's "We Treat Hep C" website. The program's success depends on getting more providers to treat HCV.

MDHHS received CMS approval in October 2018 to pursue Outcomes-Based Contracts/Value-Based Agreements with drug manufacturers to address high-cost drugs. In August 2020, MDHHS executed its first outcomes-based contract with Novartis Gene Therapies for the gene therapy drug Zolgensma. The April 2021 contract with Abbvie for the drug Mavyret was the second agreement. MDHHS continues to review potential agreements with several drug manufacturers. Agreements that allow MDHHS staff to track outcomes instead of by a third-party data aggregator are preferred. MDHHS also prefers contracts where the outcomes can be easily tracked using claims data.

New Drugs for Review:

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

1. **Aemcolo (rifamycin) tablets** – added to the PDL class: Gastrointestinal Antibiotics as non- preferred with the following prior authorization (PA) criteria:
    - Travelers' diarrhea caused by noninvasive strains of *E. coli* and age ≥ 18 years of age (PDL criteria do not apply); **AND**
    - The patient has had an inadequate response, intolerance or contraindication to azithromycin or a fluroquinolone.
    - Quantity Limit: 12 tablets
    - Length of approval: 3 days

2. **Brexafemme (ibrexafungerp) tablets** – added to the PDL class: Antifungals – Oral 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**
    - Trial and failure with one month with one preferred medication; **OR**
    - Serious illness resulting immunocompromised status.
    - **Medication-specific criteria:**
        - Diagnosis of vulvovaginal candidiasis
        - Patient is a post-menarchal female
        - Quantity Limit: 4 tablets
        - Length of approval: one time

3. **Bylvay (odevixibat) capsules and pellets** – Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) with the following PA criteria:
    Initial
    - 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)
    - 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

4. **Empaveli (pegcetacoplan) vials** – Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) with the following PA criteria:

Initial

- 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.
- Length of approval: 1 year

Renewal

- 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
- Length of approval: 1 year

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

6. **Kerendia (finerenone) tablets** - Not a PDL class - added to the Michigan Pharmaceutical Product List (MPPL) with the following PA criteria:
   - 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 m^2; **AND**
   - Serum potassium is ≤ 5 mEq/L.
   - Length of approval: 1 year

7. **Myfembree (relugolix/estradiol/norethindrone) tablets** – added to the PDL class: Uterine Disorder Treatments as non-preferred with following 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 one-month trial with the preferred medication, Oriahnn
    - See additional medication-specific criteria below:
        - 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)
        - Length of approval: 1 year (maximum total duration of 24 months)

8. **Kimyrsa (oritavancin) vials** - is a lipoglycopeptide antibacterial drug indicated for the treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganism. **[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.

Analgesics

(The following analgesics workgroup members were recognized: Uren, Butler, Axford, Foumia)

1. Narcotics, Long acting
    a. No change to the current classification of drug products
2. Narcotics, Short and intermediate acting
    a. No change to the current classification of drug products
3. Narcotics, Transdermal
    a. No change to the current classification of drug products
4. NSAIDs
    a. No change to the current classification of drug products
5. NSAIDs – COX-II Inhibitors
    a. No change to the current classification of drug products
6. Opioid Use Disorder Treatments
    a. No change to the current classification of drug products
7. Opioid Withdrawal Symptom Management
    a. No change to the current classification of drug products

Central Nervous System (CNS) Drugs

(The following CNS workgroup members were recognized: Uren, Butler, Orow)

1. Alzheimer's Agents
    a. No change to the current classification of drug products
2. Anti-anxiety Agents
    a. No change to the current classification of drug products
3. Drugs for ADHD – Amphetamines
    a. No change to the current classification of drug products
4. Drugs for ADHD – Pseudoamphetamines
    a. No change to the current classification of drug products
5. Drugs for ADHD - Non-stimulants
    a. No change to the current classification of drug products
6. Neuropathic Pain
    a. No change to the current classification of drug products
7. Multiple Sclerosis Agents
    a. No change to the current classification of drug products
8. Anti-Parkinson's Agents - Dopamine Agonists
    a. No change to the current classification of drug products
9. Anti-Parkinson's Agents – Other
    a. No change to the current classification of drug products
    b. Criteria update: Gocovri (amantadine extended-release)- add new indication for adjunctive treatment to levodopa/carbidopa in patients with Parkinson's Disease experiencing "off" episodes
10. Sedative Hypnotics - Non-barbiturates
    a. No change to the current classification of drug products
11. Antimigraine Agents, Acute Treatment – Triptans
    a. No change to the current classification of drug products
12. Antimigraine Agents, Acute Treatment – Other
    b. No change to the current classification of drug products
13. Antimigraine Agents, Preventive Treatment
    c. No change to the current classification of drug products
14. Skeletal Muscle Relaxants
    d. No change to the current classification of drug products

Dermatological Agents

(The following dermatological workgroup members were recognized: Uren, Courts, Roath)

1. Acne Agents - Combination Benzoyl Peroxide/Clindamycin
    a. No change to the current classification of drug products
2. Immunomodulators - Atopic Dermatitis
    a. Move Dupixent (dupilumab) to preferred with prior authorization for diagnosis of moderate to severe atopic dermatitis in patients ages ≥6 years.
3. Topical Steroids - Low Potency
    a. No change to the current classification of drug products
4. Topical Steroids - Medium Potency
    a. No change to the current classification of drug products
5. Topical Steroids - High Potency
    a. No change to the current classification of drug products

6. Topical Steroids - Very High Potency
    a. No change to the current classification of drug products

Anti-Obesity Agents – *new PDL class*

(The following analgesics workgroup members were recognized: Uren, Butler, Roath)

1. The following agents were added to the PDL as preferred
    - **Pancreatic Lipase Inhibitors:**
        - orlistat (*Xenical*)
    - **GLP-1 Agonists:**
        - liraglutide (*Saxenda)*
        - semaglutide (*Wegovy*)
    - **Combination Products:**
        - phentermine/topiramate (*Qsymia*); C-IV
        - bupropion/naltrexone (*Contrave*)
    - **Noradrenergic Sympathomimetic Agents:**
        - benzphetamine (only available as generic); C-III
        - diethylpropion (only available as generic); C-IV
        - phentermine (*Adipex-P, Lomaira*); C-IV
        - phendimetrazine (only available as generic); C-III
2. The following clinical prior authorization (PA) criteria was added:

    Initial

    - Patient must have a body mass index [BMI] ≥ than 30 kg/m^2; **OR**
    - Patient must have a 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; **AND**
    - Patient age ≥12 years (Xenical, Saxenda); **OR**
    - Patient age ≥18 years (Wegovy, Qsymia, Contrave, benzphetamine, diethylpropion, phentermine, phendimetrazine); **AND**
    - Prescriber attests to patient's absence of any contraindications to use requested product; **AND**
    - Prescriber attests that the patient is not pregnant or lactating; **AND**
    - Prescriber attests that at least one previously documented weight reduction attempt in the past year; **AND**
    - Prescriber attests medication therapy is part of a total treatment plan including a calorie and fat restricted diet and exercise regimen.

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

    Renewal

    - Prescriber attests that patient has achieved a weight loss of ≥ 5% of weight at time of last prior authorization.

    Length of approval for both initial and renewal: 6 months

2022 Meeting Dates

Proposed Dates

- March 8, 2022 (2nd Tuesday)
- June 7, 2022 (1st Tuesday)
- September 6, 2022 (1st Tuesday immediately following Labor Day holiday)
- December 6, 2022 (1st Tuesday)

Adjourn

Meeting adjourned at 8:06 PM