Michigan Pharmacy and Therapeutics Committee
Tuesday, March 7, 2023
Minutes - Final

Committee Members Present: Andrew Adair (Oakland County), Katie Axford (Kent County), Safwan Badr (Oakland County), Melanie Manary (Emmet County), Nora Orow (Macomb County), Patricia Railling (Kalamazoo County), Eric Roath (Ingham County), Ijeoma Opara (Wayne County), Prakash Sanghvi (Oakland County), Brad Uren (Livingston County)

Committee Members Absent: Mehvish Khan

MDHHS/Magellan Present: Trish Bouck (MDHHS), Jed Miller (MDHHS), Mike Melvin (MDHHS), Linda VanCamp (MDHHS), Grace Gere (MDHHS), Donna Johnson (Magellan Medicaid Administration), Hannah Silaphath (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 6:02 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 6, 2022 meeting were reviewed and approved.

Committee Business

The conflict of interest (COI) statement was reviewed. No conflicts were reported. All conflict of interest forms have been completed.

Dr. Manary asked for a pharmacist to self-nominate for the Vice-chairperson position to have balance across the Committee leadership. Dr. Axford offered to serve. Dr. Manary nominated Dr. Axford. Dr. Badr seconded the nomination. Dr. Axford was elected Vice-chairperson by acclimation.

MDHHS Updates

Ms. Bouck announced that the Governor's budget for Fiscal Year 2024 was released on February 8, 2023. Medicaid highlights of the budget include establishing a Michigan-based insulin manufacturing facility to lower insulin costs; additional Medicaid health access and equity; support to local health departments to provide essential services and a new Medicaid Plan First! Program to expand access to family planning services and cancer screening.

Ms. Bouck shared CMS announced that the Public Health Emergency (PHE) is terminating on May 11, 2023. MDHHS Department policies are being updated in accordance with the CMS approved Disaster Relief SPA and federal Guidance. MDHHS is likely to extend pharmacy flexibilities through September 30, 2023. Coverage of COVID-19 related FDA approved diagnostic tests, vaccines and treatments will be extended through at least September 30, 2024. Ms. Bouck also stated that during the PHE, Medicaid eligibility redeterminations were paused in March 2020 in compliance with Federal law. However, the Consolidate Appropriations Act of 2023 ended the continuous Medicaid coverage provisions. Therefore, in June 2023, Medicaid beneficiaries will begin having their eligibility reviewed and reassessed for the first time since the beginning of the PHE and the first round of individuals on the 12-month phased redetermination cycle who no longer meet eligibility requirements based on information provided may lose coverage beginning July 2023.

Additionally, Ms. Bouck announced the policy (MMP 22-42) has been finalized. This policy will allow for coverage of routine patient costs for items and services associated with participation in a qualifying clinical trial. This policy resulted from the Consolidated Appropriations Act of 2021. It provides a pathway to coverage of items and services that would otherwise be non-covered. MDHHS created an attestation form BPHASA-2210 to be submitted with the related prior authorization requests for coverage.

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 stated that a quarterly Summary of PDL changes update is available following the P&T Committee meetings at Recent Changes - MI Single Preferred Drug List (Single PDL). The next quarterly update will list the changes effective 5/1/2023. She also reminded everyone of the Brand Preferred Products (Brand over Generic) List that is posted on the website.

MDHHS received CMS approval in October 2018 to pursue Outcomes/Value-Based Purchasing 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 recently executed a third agreement with Janssen for their long-acting injectable antipsychotics (LAIs) Invega Sustenna, Invega Trinza and Invega Hafyera. MDHHS continues to review potential agreements with a couple drug manufacturers nearing finalization. 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.

Additionally, Ms. Bouck provided the website links to additional resources such as MDHHS policy bulletins, web announcements, DUR Board and P&T Committee.

Public Comments:

1. **Rick Szymialis**- Director, Health Economic Outcomes Research, on behalf of Bristol-Myers Squibb Company, on Sotyktu.
2. **Arlene Mejia, MD, MPH**, Medical Advisor, Medical Affairs Department, on behalf of Pierre Fabre Pharmaceuticals, on Beta-blockers – HEMANGEOL.
3. **Kimberly Simpson, Pharm. D.**, Senior HEOR Liaison, on behalf of United Therapeutics Corporation, on Tyvaso DPI (dry powder inhaled).
4. **Rosemarie Walch, DO**, Memorial Healthcare Institute for Neuroscience, on behalf of TG Therapeutics, on Briumvi.
5. **Sunny Hirpara, Pharm. D**., Clinical Account Director, on behalf of AstraZeneca, on Brilinta.
6. **Lauren D. Oshman, M.D., M.P.H., FAAFP**, Associate Professor, UofM, Program Director, MI Collaborative for Type 2 Diabetes on Saxenda™, Qsymia and Wegovy ™.
7. **Jeff Martin, Pharm.D. MPA**, Sr. HOPE Specialist- Medical Affairs, on behalf of Amgen, on Repatha (evolocumab).
8. **Harland Holman, MD**, Associate Chair Academic Affairs, Senior Academic Advisor, Primary Health, **Frank Mueller, MD PhD**, Adjunct Professor, Clinician Researcher, and **Michael J Bouthillier, PharmD**, Adjunct Associate Professor, Faculty, Associate Professor on Providing Non-Hydrocarbon-Based Metered Dose Inhalers as Preferred Agents.

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New Drugs for Review

1. **Entadfi (finasteride/tadalafil) capsules** – added to the PDL class: BPH Agents – 5-Alpha Reductase (5AR) Inhibitors as non-preferred with the additional medication-specific criteria:
   - Prescriber attests that Entadfi is not being used for erectile dysfunction (ED)
   - Length of approval: 26 weeks

2. **Fylnetra (pegfilgrastim-pbbk) syringe** – added to the PDL class: Colony Stimulating factors as non-preferred with the additional medication-specific quantity limit:
   - Quantity Limit: 0.6 mL per 14 days

3. **Relyvrio (sodium phenylbutyrate and taurursodiol) packets for oral suspension** - Not a PDL class. Added to the Michigan Pharmaceutical Product List (MPPL) with the PA criteria listed below:
   - Patient ≥18 years of age; **AND**
   - Diagnosis of amyotrophic lateral sclerosis (ALS); **AND**
   - Prescribed by or in consultation with a neurologist
   - Length of approval: 1 year

4. **Ryaltris (olopatadine/mometasone) nasal spray** – added to the PDL Classes: Nasal Antihistamines and Nasal Corticosteroids as non-preferred.

5. **Sotyktu (deucravacitinib) tablets** - added to the PDL class: Biologics: Agents to Treat Plaque Psoriasis as non-preferred with the following medication-specific criteria:
   - 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

6. **Tadliq (tadalafil) oral suspension** – added to the PDL class: Pulmonary Arterial Hypertension (PAH) Agents as non-preferred with the additional medication-specific criteria:
   - Patient is ≥18 years of age

7. **Tascenso (fingolimod) orally disintegrating tablets** - added to the PDL class: Multiple Sclerosis Agents as non-preferred with the additional medication-specific criteria:
   - 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 <18 years; **AND**
   - Patient body weight ≤40 kg; **AND**
   - Prescribed by or in consultation with a neurologist; **AND**
   - Patient is unable to use brand Gilenya capsules due to swallowing difficulties.

8. **Tlando (testosterone undecanoate) capsules** - Not a PDL class. Added to the Michigan Pharmaceutical Product List (MPPL) with the PA criteria listed below:
   - 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**
   - Length of approval: 1 year

9. **Xaciato (clindamycin) vaginal gel** – added to the PDL class: Vaginal Antibiotics as non-preferred with the additional medication-specific criteria:
   - Patient age is 12 years or older
   - Length of approval: 6 months

10. **Xelstrym (dextroamphetamine) patch** – added to the PDL class: Drugs for ADHD – Amphetamines as non-preferred.

11. **Zoryve (roflumilast) cream** – Not a PDL class. Added to the Michigan Pharmaceutical Product List (MPPL) with the PA criteria listed below:
   - Patient is ≥ 12 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.
   - Length of approval: 1 year

12. **Rolvedon (eflapegrastim-xnst) syringe** – 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.

13. **Spevigo (spesolimab-sbzo) 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.

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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 members were recognized - Uren, Adair, Axford, Railling)

1. **ACE Inhibitors**
   a. **Move ramipril (generic for Altace) to preferred**
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. **Move Coreg CR (carvedilol ER) to preferred. It will be preferred over the generic.**
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. No change to the current classification of drug products
17. **Anticoagulants**
    a. No change to the current classification of drug products
    b. **Savaysa (edoxaban) medication-specific criteria removed.**
18. Platelet Aggregation Inhibitors
    a. No change to the current classification of drug products
19. **Pulmonary Arterial Hypertension (PAH) Agents**
    a. **Move sildenafil suspension (generic for Revatio) to preferred.**
    b. **Move Revatio suspension (sildenafil) to non-preferred**
    c. **Move Adempas (riociguat) to preferred**
    d. **Move Tyvaso DPI (Treprostinil) to non-preferred. Allow a 6-month grandfather period.**
    e. **Add Tadliq (tadalafil) suspension as non-preferred**

f. **PDL class criteria revised to add "or in consultation with" to the prescriber specialties of cardiologist or pulmonologist.**

Ophthalmic Classes

(The following workgroup members 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 Anti-Inflammatory/Immunomodulator
   a. No change to the current classification of drug products.
9. Ophthalmic Mast Cell Stabilizers
   a. No change to the current classification of drug products
10. Ophthalmic NSAIDs
    a. No change to the current classification of drug products.

Next Meeting

Tuesday, June 6, 2023 at 6:00 PM. The meetings will continue to be held virtually.

Adjourn

Meeting adjourned at 7:53 PM