Committee Members Present:
Scott Baran, RPh
Mary Ann Dzurec, PharmD
Suzanne Eastman, RPh, MS Vice Chair
Jennifer Gwilym, DO
Stephen Hersey, MD
Karen Jacobs, DO Chair
Melissa Jefferis, MD
Nathan Samsa, DO, PharmD

Ohio Medicaid Staff Present:
Tracey Archibald, PharmD
Michelle Barger, PharmD
Yana Doughty, PharmD
Sean Eckard, PharmD
Brian Gallow, PharmD

Contract Staff/Change Healthcare Staff Present:
Jeffrey Barkin, MD
Jill RK Griffith, BS, PharmD
Steve Liles, PharmD
Gail Master, RPh
Philip Verret, PharmD

Also present were approximately 60 observers, most representing pharmaceutical manufacturers.
I. Call to Order
Dr. Jacobs called the meeting to order at 10:02 A.M.

II. Introductions
Scott Baran welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. The committee members, ODM, and Change Healthcare each introduced themselves.

III. Approval of the January 13, 2021 Meeting Minutes
The minutes from the prior P&T meeting were reviewed and approved by the Committee.

IV. Administrative Matters
The conflict of interest statement was reviewed.

V. Department of Medicaid Update
S. Baran reported that Ohio Department of Medicaid (ODM) Director Maureen Corcoran has announced the selection of six health care organizations to lead the department’s evolution of managed care services for its more than 3 million members and thousands of medical providers. Ohio Medicaid’s next generation managed care selection, contingent upon the signing of contracts, will begin covering members in early 2022. Members will continue to receive services with their current plans through the transition period and will have the opportunity to select a new plan through an open enrollment period beginning in late summer.
Next, S. Baran stated that ODM is now accepting electronic NCPDP claims for COVID-19 vaccine administration. ODM, Change Healthcare, and the managed care plans have been proactive in ensuring access to COVID-19 vaccines during the public health emergency.
In related news, the Centers for Medicare and Medicaid Services recently announced an increased Medicare payment for COVID-19 vaccine administration. Beginning with dates of service on March 15, 2021, ODM will reimburse $37.98 for each dose of vaccine administered. ODM continues to enroll pharmacists into the Medicaid program as full providers. Currently, around 500 pharmacists have enrolled. These enrolled pharmacists represent a diverse range of practice settings, including independent practitioners, retail/community pharmacy, hospital and health system pharmacy, and clinics. ODM will continue to collect extensive data from this new program that will allow them to analyze utilization trends, health outcomes, and fiscal
metrics. ODM believes that pharmacists are an important provider type to secure optimal health outcomes for members in a fiscally responsible manner.

Next, S. Baran informed the committee that ODM is currently working on two new DUR interventions. The first intervention involves reaching out to prescribers who have issued an opioid prescription that is greater than 80 morphine equivalent doses. In accordance with the State Medical Board of Ohio rules, the goal is to remind prescribers to complete a pain treatment agreement with their patient, look for signs of opioid misuse, consult with a specialist, and offer a naloxone prescription. The second intervention is aimed at triple antithrombotic therapy (treatment with aspirin, a P2Y₁₂ inhibitor, and an oral anticoagulant) which carries an elevated bleeding risk that increases upon continued use. The goal of this intervention is to encourage use for the shortest possible length of time.

VI. Presentations by Drug Manufacturers
There were no Drug Manufacturer presentations.

VII. Presentations by Interested Parties
There were no Interested Party presentations.

VIII. Unified Preferred Drug List (PDL) Proposals

Nyvepria (pegfilgrastim-apgf), Pfizer, Inc.
S. Baran announced that Nyvepria is a biosimilar to Neulasta and therefore there is no clinical presentation. ODM recommended Nyvepria as “Non-Preferred, PA required”. The committee voted and recommended the proposed category as shown below:
Preferred Drug List (PDL) Proposals – Nyvepria

Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

<table>
<thead>
<tr>
<th>PREFERRED</th>
<th>NON-PREFERRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granix PA</td>
<td>Fulphila</td>
</tr>
<tr>
<td>Udenyca PA</td>
<td>Leukine</td>
</tr>
<tr>
<td>Zomextro PA</td>
<td>Neulasta</td>
</tr>
<tr>
<td></td>
<td>Neupogen</td>
</tr>
<tr>
<td></td>
<td>Nivestym</td>
</tr>
<tr>
<td></td>
<td><strong>Nyvepria</strong></td>
</tr>
<tr>
<td></td>
<td>Zanio</td>
</tr>
</tbody>
</table>

Link to Criteria: Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
BPG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Approval Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Myeloid Leukemia (AML)</td>
<td>14 days or duration of chemotherapy regimen</td>
</tr>
<tr>
<td>Malignancy at risk for febrile neutropenia or undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation</td>
<td>14 days or duration of chemotherapy regimen</td>
</tr>
<tr>
<td>Myeloid Engraftment for bone marrow transplant (BMT)</td>
<td>30 days</td>
</tr>
<tr>
<td>Severe, chronic neutropenia with absolute neutrophil count (ANC) of less than 500/mms and have symptoms associated with neutropenia (e.g. fever, infections, oropharyngeal ulcers)</td>
<td>30 days</td>
</tr>
<tr>
<td>Hematopoietic radiation injury syndrome</td>
<td>30 days</td>
</tr>
</tbody>
</table>

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Requested medication must be used for an approved FDA indication and duration

CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed a therapeutic trial of **14 days** with one preferred medication?
b. Ophthalmic Agents: Dry Eye Treatments. Eysuvis (loteprednol etabonate), Kala Pharmaceuticals, Inc

Dr. Barkin provided a clinical overview of Eysuvis. ODM recommended Eysuvis as “Non-Preferred, PA required”. The committee voted and recommended the proposed category as shown below:

Preferred Drug List (PDL) Proposals-Eysuvis

<table>
<thead>
<tr>
<th>Ophthalmic Agents: Dry Eye Treatments</th>
<th>Preferred</th>
<th>Non-Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restasis Trays ST</td>
<td>Cequa</td>
<td>Eysuvis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restasis Multi-Dose</td>
</tr>
</tbody>
</table>

Link to Criteria: Ophthalmic Agents: Dry Eye Treatments

LENGTH OF AUTHORIZATIONS:
- 365 Days for Cequa, Restasis Trays, Restasis Multi-Dose and Xiidra
- 14 Days for Eysuvis

All drugs in this class require step therapy: Patient must have a claim for an artificial tear or OTC dry eye drop in the previous 120 days.

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?
   Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindications to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval

2. Patient must have a therapeutic failure to at least 30 days of one of the preferred agents.
c. **Topical Agents: Corticosteroids. Impeklo (Clobetasol), Mylan Specialty L.P.**

Dr. Barkin provided a clinical overview of Impeklo. ODM recommended Impeklo as “Non-Preferred, PA required”. The committee voted and recommended the proposed category as shown below:

**Preferred Drug List (PDL) Proposals – Impeklo**

<table>
<thead>
<tr>
<th>Topical Agents: Corticosteroids</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PREFERRED</strong></td>
</tr>
<tr>
<td>Acridermide</td>
</tr>
<tr>
<td>Betamethasone Dipropionate/Calcipotriene Oint</td>
</tr>
<tr>
<td>Betamethasone Valerate</td>
</tr>
<tr>
<td>Clobetasol Precioate</td>
</tr>
<tr>
<td>Desonide</td>
</tr>
<tr>
<td>Diflurazone Diclopate</td>
</tr>
<tr>
<td>Flucinolone Acetonide 0.01%</td>
</tr>
<tr>
<td>Flucinolone</td>
</tr>
<tr>
<td>Flucinolone Pocipionate</td>
</tr>
<tr>
<td>Hydrocortisone</td>
</tr>
<tr>
<td>Mometasone Furoate</td>
</tr>
<tr>
<td>Prednicarbon</td>
</tr>
<tr>
<td>Triamcinolone</td>
</tr>
</tbody>
</table>

**Legend**

- **AR** (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
- **BoG** (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
- **PA** (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
- **QL** (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
- **ST** (Step Therapy) - Medications require a trial with one or more preferred products before approval

**LENGTH OF AUTHORIZATIONS:**

- 365 days for low and medium potency
- 90 days for high and very high potency

1. **Is there any reason the patient cannot be changed to a medication not requiring prior approval?**
   Acceptable reasons include:
   - Allergy to at least **two** medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to at least **two** medications not requiring prior approval

2. **Has the patient failed therapeutic trials of 14 days with two medications not requiring prior approval in the same category?**
IX. **Drug Class Announcements**  
   a. **Central Nervous System (CNS) Agents: Narcolepsy**

Dr. Barkin provided a clinical review of this new class. Discussion ensued around the criteria. Votes were taken, and the committee recommended a 30-day trial of the preferred medications, a consult or referral to a specialist would not be part of the criteria, and adding the preferred amphetamine and methylphenidate medications to the preferred side of the UPDL. The committee voted and recommended the proposed category as shown below:

**Drug Class Announcement-CNS Agents: Narcolepsy**

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-PREFERRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine/Dextroamphetamine</td>
<td>Sunosi</td>
</tr>
<tr>
<td>Armodafinil</td>
<td>Wakix</td>
</tr>
<tr>
<td>Dextroamphetamine ER</td>
<td>Xyrem</td>
</tr>
<tr>
<td>Methylphenidate ER</td>
<td>Xywav</td>
</tr>
<tr>
<td>Methylphenidate Tab</td>
<td></td>
</tr>
<tr>
<td>Modafinil</td>
<td></td>
</tr>
</tbody>
</table>

**Link to Criteria:** [Central Nervous System (CNS) Agents: Narcolepsy](#)

**Legend**

- **AR** (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
- **BP** (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
- **PA** (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
- **QL** (Quantity Limit) - A limit on the quantity that can be covered within a given time frame
- **ST** (Step Therapy) - Medications require a trial with one or more preferred products before approval

**LENGTH OF AUTHORIZATIONS:** 365 Days

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindications to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
NON-PREFERRED MEDICATION:

☐ For non-preferred drugs without medication specific criteria, there must have been an inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred products

PRIOR AUTHORIZATION CRITERIA:

☐ Sunosi (soriamfetol)
  • Diagnosis of narcolepsy with excessive daytime sleepiness or obstructive sleep apnea with excessive daytime sleepiness AND
  • An inadequate response to or inability to tolerate a 30-day course of treatment with modafinil or armodafinil AND
  • An inadequate response to or inability to tolerate a 30-day course of treatment with a preferred methylphenidate or amphetamine product

☐ Wakix (pitolisant), Xyrem (sodium oxybate)
  • Diagnosis of narcolepsy with excessive daytime sleepiness AND
  • An inadequate response to or inability to tolerate a 30-day course of treatment with modafinil or armodafinil AND
  • An inadequate response to or inability to tolerate a 30-day course of treatment with a preferred methylphenidate or amphetamine product OR
  • Diagnosis of narcolepsy with cataplexy

☐ Xywav (calcium, magnesium, potassium & sodium oxybates)
  • Diagnosis of narcolepsy with excessive daytime sleepiness AND
  • An inadequate response to or inability to tolerate a 30-day course of treatment with modafinil or armodafinil AND
  • An inadequate response to or inability to tolerate a 30-day course of treatment with a preferred methylphenidate or amphetamine product AND
  • Sodium restriction with documented adherence to sodium restricted diet OR
  • Diagnosis of narcolepsy with cataplexy AND
  • Sodium restriction with documented adherence to sodium restricted diet
REAUTHORIZATION CRITERIA:

☐ Attestation that the patient’s condition has improved while taking the requested medication

X. Other Business

Next Meeting Dates
S. Baran announced the next meeting dates.
Wednesday, July 14th, 2021
Wednesday, October 6th, 2021

XI. Adjournment
Dr. Jacobs adjourned the meeting at 11:01 am EST.