OHIO DEPARTMENT OF MEDICAID
Pharmacy & Therapeutics Committee
GoToMeeting
https://attendee.gotowebinar.com/register/7123053448818754319
September 30, 2020
9:00 AM
MEETING MINUTES

Committee Members Present:
Susan Baker, APN
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
Sean Eckard, PharmD

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

Also present were approximately 137 observers, most representing pharmaceutical manufacturers.

I. Call to Order
Dr. Jacobs called the meeting to order at 9:11 A.M.

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

III. Administrative Matters
S. Baran reviewed the procedure for the meeting. Conflict of Interest statement was reviewed.
IV. Department of Medicaid Update

S. Baran presented the Medicaid Health Plan Policy update. COVID-19 continues to be a focus for the Ohio Department of Medicaid (ODM). In ongoing reaction to this declared state of emergency, ODM has been working on implementing COVID-19 Point of Care testing strategies in pharmacies. Current discussions involve preferred testing modalities and reimbursement. The goal is for these claims to be submitted similar to existing vaccine logic by using a pharmacy (NCPDP) claim. The ‘professional service code’ (PT code) will be used to indicate that the pharmacy collected the specimen and performed an analysis on-site. Finalized details of this effort will be available soon.

Another project ODM is working on is Pharmacists to enroll as Providers. ODM is currently engaging stakeholders and working on rule language. ODM Pharmacy is collaborating with the ODM Managed Care Policy team to communicate efforts and expectations with the Managed Care Organizations (MCOs). ODM is also developing educational programs for prospective providers on topics including enrollment, Medicaid rules, and claims submission.

The Centers for Medicare and Medicaid Services (CMS) has issued the Federal Fiscal Year (FFY) 2019 Annual DUR Report to the states. Like last year’s survey, it includes information on both FFS and MCO DUR programs. ODM will communicate once the final report is posted to the Medicaid.gov website, which they anticipate will be later this year.

In other DUR related matters, last month ODM issued a fax-blast notice to Medicaid enrolled pharmacy providers asking them to remind their Medicaid members about the importance of getting an annual flu vaccine. Two other interventions that are underway include focusing on members taking an opioid along with a stimulant medication, as well as an intervention focusing on members who are taking multiple antipsychotic medications.

The 2020 Cost of Dispensing Survey has been administered to ODM-enrolled pharmacies and a final report with the findings will be generated and posted on the Medicaid Pharmacy website. Survey responses are due by October 1st.

Next, ODM is planning to update the format of the Unified Preferred Drug List (UPDL). The new appearance is intended to be a simpler design that will be more user friendly for providers and members to navigate.

Lastly, ODM has posted two pharmacologist positions. Further details about these postings can be found on the careers.ohio.gov jobs portal website.

V. Approval of the July 8th, 2020 Meeting Minutes

The minutes from the prior P&T meeting were reviewed and approved by the committee.

VI. Presentations by Drug Manufacturers

- a. Zeposia - Bristol-Myers Squibb Co.
- b. Kynmobi - Sunovion
- c. Ajovy - Teva
- d. Oriaahnn - Abbvie
- e. Eucrisa - Pfizer
- f. Dupixent - Sanofi Genzyme
- g. Fasenra - AstraZeneca
- h. Cosentyx, Xiidra - Novartis
- i. Aimovig - Amgen
- j. Symtuza - Janssen Scientific Affairs, LLC
- k. Epidiolex - Greenwich Biosciences
I. Jornay PM - Ironshore Pharmaceuticals and Development, Inc
m. Trulicity - Lilly USA, LLC
n. Ozempic - Novo Nordisk

VII. Interested Party Presentations
   b. Faizan Hafeez, MD, representing Wyandot Memorial Hospital. Aimovig
   c. Deborah Reed, MD, representing University Hospitals Neurological Institute. Aimovig
   d. Brian J. Beesley, DO, AAHIVS representing The Ohio State University College of Medicine, Ohio University Heritage College of Osteopathic Medicine, and Mount Carmel Medical Group, Victorian Village. HIV Treatment and Open Access to Medications
   e. Siu Fung Chan, MD, representing the Department of Pain Medicine and Anesthesiology at the University of Cincinnati. Aimovig

VIII. UPDL Drug Class Extractions
Following the completion of presentations from drug manufacturers and interested parties, the P&T Committee members deliberated on the classes for extraction. The following drug categories were extracted for discussion and review. The remainder of the categories were approved as recommended in the draft PDL document.

   Endocrine Agents: Diabetes-Non-Insulin
   Immunomodulators Agents for Systemic Inflammatory Disease
   Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis
   Central Nervous System (CNS) Agents: Anticonvulsants
   Respiratory Agents: Inhaled Agents
   Infectious Disease Agents: Antivirals-HIV

IX. New Therapeutic Categories
   a. Central Nervous System (CNS) Agents: Movement Disorders
Change Healthcare provided a clinical overview of the category. Votes were taken, and the committee approved the category as shown below:

<table>
<thead>
<tr>
<th>Central Nervous System (CNS) Agents: Movement Disorders</th>
</tr>
</thead>
</table>

**LENGTH OF AUTHORIZATIONS:** 365 Days

**ADDITIONAL CRITERIA FOR THE TREATMENT OF TARDIVE DYSKINESIA:**
Prescribed by a Neurologist or Psychiatrist
Ingrezza is ONLY indicated for the treatment of Tardive Dyskinesia

**ADDITIONAL CRITERIA FOR AUSTEDO FOR THE TREATMENT OF HUNTINGTON’S DISEASE:**
The member must have a failure to respond to maximally tolerated dose of tetrabenazine
## Movement Disorders

<table>
<thead>
<tr>
<th>Clinical PA Required “Preferred”</th>
<th>PA Required “Non-Preferred”</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUSTEDO® (deutetrabenazine)†</td>
<td></td>
</tr>
<tr>
<td>INGREZZA® (valbenazine)</td>
<td></td>
</tr>
<tr>
<td>TETRABENAZINE (generic of Xenazine”)</td>
<td></td>
</tr>
</tbody>
</table>

† Quantity limit of 4 tablets per day

### b. Endocrine Agents: Diabetes – Hypoglycemia Treatments

Change Healthcare provided a clinical overview of the category. A discussion ensued around the route of administration of these products. Votes were taken, and the committee approved the category as shown below:

### Endocrine Agents: Diabetes – Hypoglycemia Treatments

**Length of Authorizations:** 365 Days

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

**Step Therapy:**

A drug requiring step therapy will be approved when a member and/or caregiver is unable to reconstitute and administer a preferred glucagon product in a timely fashion.

**PA Required Non-Preferred:**

A non-preferred medication will be approved after a trial with a step therapy preferred medication and/or the inability of the member and/or caregiver to reconstitute and administer a preferred glucagon product in a timely fashion.

**Quantity Limits:**

All agents are subject to a quantity limit of 2 per month

### Endocrine Agents: Diabetes – Hypoglycemia Treatments

<table>
<thead>
<tr>
<th>No PA Required “Preferred”</th>
<th>PA Required “Non-Preferred”</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAQSIMI nasal spray (glucagon)</td>
<td>GVOKE HYPOPEN 1-PACK (glucagon)</td>
</tr>
<tr>
<td>GLUCAGEN vial (glucagon, human recombinant)</td>
<td>GVOKE PFS (glucagon)</td>
</tr>
<tr>
<td>GLUCAGON EMERGENCY KIT (glucagon, human recombinant)</td>
<td></td>
</tr>
</tbody>
</table>
c. Endocrine Agents: Endometriosis

Change Healthcare provided a clinical overview of the category. Votes were taken, and the committee approved the category as shown below:

### Endocrine Agents: Endometriosis

<table>
<thead>
<tr>
<th>LENGTH OF AUTHORIZATIONS:</th>
<th>365 DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?</td>
<td></td>
</tr>
<tr>
<td>Acceptable reasons include:</td>
<td></td>
</tr>
<tr>
<td>□ Allergy to medications not requiring prior approval</td>
<td></td>
</tr>
<tr>
<td>□ Contraindication to or drug interaction with medications not requiring prior approval</td>
<td></td>
</tr>
<tr>
<td>□ History of unacceptable/toxic side effects to medications not requiring prior approval</td>
<td></td>
</tr>
</tbody>
</table>

**STEP THERAPY:**

For a drug requiring step therapy, there must have been a therapeutic failure of at least a 30-day trial with both a NSAID and an oral contraceptive.

**NON-PREFERRED:**

There must have been a therapeutic failure of at least a 30-day trial with both a NSAID and an oral contraceptive and a trial and a therapeutic failure of no less than 3 months on at least one step therapy required “preferred” medication.

### Endometriosis Treatments

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>STEP THERAPY REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>DANAZOL</td>
<td></td>
<td>SYNAREL® (nafarelin acetate)</td>
</tr>
<tr>
<td>DEPO-SUBQ PROVERA® 104</td>
<td>(medroxyprogesterone acetate)</td>
<td></td>
</tr>
<tr>
<td>LUPANETA PACK®</td>
<td>(leuprolide acetate and norethindrone acetate)</td>
<td></td>
</tr>
<tr>
<td>LUPRON DEPOT® 3.75 MG, 11.25 MG</td>
<td>(leuprolide acetate)</td>
<td></td>
</tr>
<tr>
<td>ORILISSA® (elagolix)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZOLADEX® (goserelin acetate)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Endocrine Agents: Uterine Fibroids

Change Healthcare provided a clinical overview of the category. Votes were taken, and the committee approved the category as shown below:

**LENGTH OF AUTHORIZATIONS:** 180 DAYS

Members who have been treated with Oriahnn® for 24 months or more are not eligible for additional authorizations.

Members who have been treated with Lupron Depot for 6 months or more are not eligible for additional authorizations.

The requested medication may be approved if the member has a diagnosis of uterine leiomyomas (fibroids) and has failed a 90 day or more trial with an oral contraceptive.

<table>
<thead>
<tr>
<th>CLINICAL PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPRON DEPOT® 3.75 MG, 11.25 MG (leuprolide acetate)</td>
<td></td>
</tr>
<tr>
<td>ORIAHNN® (elagolix and estradiol and norethindrone)</td>
<td></td>
</tr>
</tbody>
</table>
e. **Ophthalmic Agents: Ophthalmic Steroids**

Change Healthcare provided a clinical overview of the category. Votes were taken, and the committee approved the category as shown below:

**Ophthalmic Agents: Ophthalmic Steroids**

**LENGTH OF AUTHORIZATIONS**: 30 DAYS

For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than **14 days each** of at least **two** preferred products.

**OTHER APPROVAL 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 or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval

**OPHTHALMIC AGENTS: OPHTHALMIC STEROIDS**

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXAMETHASONE SODIUM PHOSPHATE</td>
<td>ALREX® (loteprednol etabonate)</td>
</tr>
<tr>
<td>DUREZOL® (difluprednate)</td>
<td>FLAREX® (fluorometholone acetate)</td>
</tr>
<tr>
<td>FLUOROMETHOLONE</td>
<td>INVELYS® (loteprednol etabonate)</td>
</tr>
<tr>
<td>FML FORTE® (fluorometholone)</td>
<td>LOTEMAX® (loteprednol etabonate)</td>
</tr>
<tr>
<td>FML S.O.P.®, (fluorometholone)</td>
<td>LOTEMAX® SM (loteprednol etabonate)</td>
</tr>
<tr>
<td>PRED MILD® (prednisolone acetate)</td>
<td>LOTEPRNOL</td>
</tr>
<tr>
<td>PREDNISOLONE ACETATE</td>
<td>MAXIDEX® (dexamethasone sodium phosphate)</td>
</tr>
<tr>
<td>PREDNISOLONE SODIUM PHOSPHATE</td>
<td></td>
</tr>
</tbody>
</table>

**f. Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE (Self-Administered)**

Change Healthcare provided a clinical overview of the category. A recommendation was made to amend the Clinical Criteria for Asthma section to say ‘in consultation with’ and thus be consistent with the Additional Criteria for Dupilumab (Dupixent) verbiage.

Discussion ensued about the clinical effectiveness of Dupixent over Fasenra and Nucala. Xolair does not appear on the UPDL as it is administered in the prescriber’s office and billed as medical. Dr. Liles mentioned that Novartis has submitted an NDA for Xolair for home use to the FDA. It was suggested that if Xolair is added to the UPDL, then either the category name will need amended or a new category should be added. Votes were taken, and the committee approved the category as shown below:
Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE
(Self-Administered)

LENGTH OF AUTHORIZATIONS: 365 DAYS

Clinical Criteria for Asthma

- Indicated for moderate to severe asthma if:
  - Prescribed by or in consultation with an allergist/immunologist or pulmonologist
  - Preferred medications will be approved for patients with uncontrolled eosinophilic asthma symptoms and/or exacerbations despite at least one-month adherence to therapy with:
    - Medium dose preferred ICS/LABA inhaler (members 6-11 years old) – Nucala only
    - Medium dose preferred ICS/LABA inhaler with tiotropium or high dose preferred ICS/LABA inhaler (members 12 years and older) – Nucala or Fasenra
  - Non-preferred medications will be approved for patients with uncontrolled eosinophilic asthma symptoms and/or exacerbations despite at least three months adherence to therapy with a preferred agent
    - Patient has had asthma-related emergency treatments within the last 180 days

ADDITIONAL CRITERIA FOR DUPILUMAB (DUPIXENT®)

- Indicated for moderate to severe atopic dermatitis if:
  - Patient has minimum body surface area (BSA) involvement of at least 10%
  - Prescribed by or in consultation with a dermatologist or allergist/immunologist
  - Patient is 6 years of age or older
  - Patient has had inadequate response or contraindication to two of the following: topical corticosteroids, topical calcineurin inhibitors [e.g. Elidel®], or topical PDE-4 inhibitors [e.g. Eucrisa™] unless atopic dermatitis is severe and involves greater than 25% of BSA.
  - Initial authorization is limited to 112 days with re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).

- Indicated for chronic rhinosinusitis with nasal polyposis if:
  - Patient is 18 years of age or older
  - Patient had an inadequate response, intolerance or contraindication to one oral corticosteroid
  - Patient had a 30-day trial and experienced an inadequate response, intolerance or contraindication to one nasal corticosteroid spray

Monoclonal Antibodies-Anti-IL/Anti-IgE (Self-Administered)

<table>
<thead>
<tr>
<th>CLINICAL PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>FASENRA® (benralizumab)</td>
<td>DUPIXENT® (dupilumab)</td>
</tr>
<tr>
<td>NUCALA® (mepolizumab)</td>
<td></td>
</tr>
</tbody>
</table>
X. Other Business; Endocrine: Diabetes Cardiovascular Disease Update
Dr. Liles provided a clinical overview of the 2020 changes in standards of care for diabetes. He updated the committee with the recommendations of prescribing SGLT2 and GLP1 for patients with cardiovascular, renal and chronic kidney disease independent of A1C, after treatment with metformin. These classes of drugs are also indicated for patients who have cardiovascular risk factors. He noted that Farxiga has received the indication to reduce the risk of cardiovascular death and hospitalization for heart failure for non-diabetic patients and to consider adding Farxiga to the heart failure class in future UPDL design.

XI. Unified Preferred Drug List (Unified PDL) Annual Review
a. Endocrine Agents: Diabetes-Non-Insulin
Change Healthcare provided a clinical overview of the category. Discussion ensued regarding Rybelsus and whether it should be moved to preferred. S. Baran explained that Farxiga, Invokana and Invokamet have moved to Step Therapy Required “Preferred” where they were PA Required “Non-Preferred” previously. The committee voted and approved the criteria as shown below:

**Endocrine Agents: Diabetes – Non-Insulin**

<table>
<thead>
<tr>
<th>LENGTH OF AUTHORIZATIONS:</th>
<th>365 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STEP THERAPY:</strong></td>
<td></td>
</tr>
<tr>
<td>1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/ metformin or TZD/metformin combination), including a trial of no less than 9060 days of at least one preferred metformin product</td>
<td></td>
</tr>
<tr>
<td>2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than 9060 days of at least one preferred or step therapy product</td>
<td></td>
</tr>
<tr>
<td>Note: Inadequate clinical response is the inability to reach A1C goal after at least 9060 days of recommended therapeutic dose with documented adherence to the regimen.</td>
<td></td>
</tr>
</tbody>
</table>

**OTHER APPROVAL CRITERIA:**
Is there any reason the patient cannot be changed to a medication within the same class not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

**DIABETES – ORAL HYPOGLYCEMICs, SODIUM–GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR**

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>STEP THERAPY REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>FARXIGA® (dapagliflozin)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVOKANA® (canagliflozin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JARDIANCE® (emagliflozin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEGLATRO™ (ertugliflozin)</td>
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</table>

* Step Therapy Requirements are waived for members with a diagnosis of Heart Failure, Chronic Kidney Disease, Cardiovascular Disease or with multiple Cardiovascular Disease risk factors

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Columbus, Ohio 43215
Pharmacy.medicaid.ohio.gov
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**Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis**

Change Healthcare provided a clinical overview of the category. ODM announced that Aimovig and Ajovy are moved to “Step Therapy Required- Preferred”. Discussion ensued around Emgality remaining a PA required “Non-Preferred”. Votes were taken, and the committee approved the changes as shown below:

### Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis

**LENGTH OF AUTHORIZATIONS:**
- Initial Authorization 180 days
- Subsequent Authorizations 365 days

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

**GRANDFATHERING:**
- Patients who have a claim for a step therapy required “preferred” drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug previously, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**STEP THERAPY REQUIRED PREFERRED MEDICATION:**
- For a drug requiring step therapy, there must have been inadequate clinical response to a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).

**NON-PREFERRED MEDICATION:**
- For a non-preferred medication drug requiring step therapy, there must have been inadequate...
clinical response to a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin norepinephrine reuptake inhibitors) AND an inadequate clinical response to a trial of at least 30 days of one step therapy required preferred medication.

**ADDITIONAL CRITERIA FOR EPISODIC MIGRAINE PROPHYLAXIS:**

1. Patient must have a diagnosis of episodic migraine with the following frequencies of migraine:
   - 4-15 headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average.
2. Prior Authorization may be approved if the patient has failed a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).
3. Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control. Re-authorization requests may be managed in consultation with a specialist.

**ADDITIONAL INFORMATION**

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer’s package insert.

**CNS AGENTS: ANTI-MIGRAINE AGENTS – PROPHYLAXIS TREATMENT**

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED” (Trials of at least 3 controller medications)</th>
<th>STEP THERAPY REQUIRED “PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Agents: Beta-blockers</td>
<td>AIMOVIG™ (erenumab-aooe) †</td>
</tr>
<tr>
<td>CNS Agents: Anticonvulsants</td>
<td>AJOVY™ (fremanezumab-vfrm)*</td>
</tr>
<tr>
<td>CNS Agents: Serotonin-norepinephrine reuptake inhibitors</td>
<td>EMGALITY™ (galcanezumab)</td>
</tr>
<tr>
<td>CNS Agents: Tricyclic antidepressants</td>
<td></td>
</tr>
</tbody>
</table>

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

* 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days.
c. Central Nervous System (CNS) Agents: Anticonvulsants

Change Healthcare provided a clinical overview of the category. Discussion ensued regarding the new indication for Epidiolex: Tuberous Sclerosis Complex (TSC). The committee voted and approved the changes as shown below:

### Central Nervous System (CNS) Agents: Anticonvulsants

**ADDITIONAL CRITERIA FOR CANNABINOIDS**

**LENGTH OF AUTHORIZATIONS:**
- Initial Authorization 180 days
- Subsequent Authorizations 365 days.

- Patient has a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or **tuberous sclerosis complex**
- Patient has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for 30 days each (Note: not required to be met for a diagnosis of Dravet Syndrome)
- Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
- Maximum daily dose (QL) not to exceed 20 mg/kg/day (titration based on response/tolerability) for Lennox-Gastaut syndrome or Dravet syndrome and not to exceed 25 mg/kg/day (titration based on response/tolerability) for tuberous sclerosis complex

**ANTICONVULSANTS: CANNABINOIDS**

<table>
<thead>
<tr>
<th>CLINICAL PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “Non-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPIDIOLEX® (cannabidiol)†</td>
<td></td>
</tr>
</tbody>
</table>

† Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).
d. Immunomodulator Agents for Systemic Inflammatory Disease

Change Healthcare provided a clinical overview of the category. ODM announced that Cosentyx moved from Step Therapy Required “Preferred” to PA Required “Non-Preferred” and that Taltz has moved from PA Required “Non-Preferred” to Clinical PA Required “Preferred”. Xeljanz 5mg moved to Clinical PA Required “Preferred” but Xeljanz 10mg remains as PA Required “Non-Preferred”. Votes were taken, and the category was approved as shown below:

**Immunomodulator Agents for Systemic Inflammatory Disease**

**LENGTH OF AUTHORIZATIONS:** Dependent on diagnosis

**All products in this class require Clinical Prior Authorization:**
- No current infection; and
- Prior first-generation therapy appropriate for diagnosis; and
- Diagnosis of one of the following: 365 days approval
  - Rheumatoid Arthritis
  - Plaque Psoriasis
  - Psoriatic Arthritis
  - Polyarticular Juvenile Idiopathic Arthritis
  - Crohn’s Disease
  - Ankylosing Spondylitis
  - Psoriasis
  - Uveitis
  - Cryopyrin-Associated Periodic Syndrome
  - Giant Cell Arteritis
  - Hidradenitis Suppurativa

Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira, Simponi, and Xeljanz only): initial approval 56 days, reapprovals 365 days
Humira may be approved if there is an inadequate clinical response to at least 90 days of therapy with both 5-ASA and immuno-suppressants.
Initial approval for Humira will be for 56 days. If clinical response is not seen in 56 days, further therapy with TNF inhibitors will not be approved. If there is an initial clinical response to Humira after 56 days of therapy, but no improvement in the progression of ulcerative colitis symptoms after 180 days, Simponi or Xeljanz may be approved.
Quantity limits for UC diagnosis:
Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month
Xeljanz – 60 pills per month

**PDL CRITERIA:**
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 or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
ADDITIONAL INFORMATION
The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a 90-day trial of at least two preferred medications
- For patients with a diagnosis of moderate to severe plaque psoriasis receiving phototherapy, initial authorization for Humira® or Enbrel® will only be approved if there is inadequate clinical response to at least 90 days of phototherapy.

ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST

<table>
<thead>
<tr>
<th>CLINICAL PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>TALTZ™ (ixekizumab injection)</td>
<td>ACTEMRA® syringe (tocilizumab)</td>
</tr>
<tr>
<td></td>
<td>COSENTYX™ (secukinumab)</td>
</tr>
<tr>
<td></td>
<td>ILUMYA™ (tildarizumab-asrn)</td>
</tr>
<tr>
<td></td>
<td>KEVZARA® (sarilumab)</td>
</tr>
<tr>
<td></td>
<td>KINERET® syringe (anakinra)</td>
</tr>
<tr>
<td></td>
<td>SILIQ™ (brodalumab)</td>
</tr>
<tr>
<td></td>
<td>SKYRIZI™ (risankizumab-rrza)</td>
</tr>
<tr>
<td></td>
<td>TREMFYA™ (guselkumab)</td>
</tr>
</tbody>
</table>

JANUS KINASE INHIBITOR

<table>
<thead>
<tr>
<th>CLINICAL PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>XELJANZ® 5mg tablets (tofacitinib citrate)</td>
<td>OLMIANT® (baricitinib)</td>
</tr>
<tr>
<td></td>
<td>RINVOQ® (upadacitinib)</td>
</tr>
<tr>
<td></td>
<td>XELJANZ® 10mg tablets (tofacitinib citrate)</td>
</tr>
<tr>
<td></td>
<td>XELJANZ® XR (tofacitinib tablet, extended release)</td>
</tr>
</tbody>
</table>
e. **Infectious Disease Agents: Antivirals—HIV**

Discussion ensued around the clinical efficacy of Symtuza. Dr Liles stated that Symtuza is not recommended as first line therapy by NIH guidelines, and that there are preferred drugs that are recommended by NIH as initial treatment. Votes were taken, and the category was approved as shown below:

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**Infectious Disease Agents: Antivirals – HIV**

**LENGTH OF AUTHORIZATIONS:** 365 Days

**GRANDFATHERING:**

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**APPROVAL CRITERIA:**

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

1. Allergy to medications not requiring prior approval
2. Contraindication to recommended regimens not requiring prior approval
3. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient had a therapeutic trial of at least 30 days with at least one medication not requiring prior approval? If applicable, the request must address the inability to use the individual components.

**HIV NON-PEPTIDIC PROTEASE INHIBITORS AND COMBINATIONS**

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREZCOBIX® (darunavir/cobicistat)</td>
<td>APTIVUS® (tipranavir; tipranavir/vitamin E)</td>
</tr>
<tr>
<td>PREZISTA® (darunavir ethanolate)</td>
<td>SYMTUZA™ (darunavir, cobicistat, emtricitabine, tenofovir alafenamide) *</td>
</tr>
</tbody>
</table>

* Request must document clinical justification for patient inability to use the individual components (PREZCOBIX and DESCOVY)
\textbf{Respiratory Agents: Inhaled Agents}

Discussion ensued around the coverage of Striverdi Respimat and the ability of patients to breathe dry powder inhalers. Votes were taken, and the category was approved as shown below:

**Respiratory Agents: Inhaled Agents**

**LENGTH OF AUTHORIZATIONS:** 365 DAYS

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

2. The requested medication may be approved if there has been a therapeutic failure to no less than a 14-day trial of at least one medication not requiring prior approval within the same class and formulation (must try two medications if anticholinergic).

**RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING (LABA)**

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEREVENT DISKUS\textsuperscript{®} (salmeterol)\textsuperscript{†}</td>
<td>BROVANA\textsuperscript{™} (arformoterol)</td>
</tr>
<tr>
<td></td>
<td>PERFOROMIST\textsuperscript{®} (formoterol)</td>
</tr>
<tr>
<td></td>
<td>STRIVERDI RESPIMAT\textsuperscript{®} (olodaterol)</td>
</tr>
</tbody>
</table>

\textsuperscript{†}Denotes breath actuated inhaler

\textbf{XII. Next Meeting Dates}

The next meeting dates were set as follows:

\textbf{a.} Quarter 1-Wednesday January 13, 2021  
\textbf{b.} Quarter 2-Wednesday April 14, 2021  
\textbf{c.} Quarter 3-Wednesday July 14, 2021  
\textbf{d.} Quarter 4-Wednesday October 6, 2021

\textbf{XII. Adjournment}

Dr. Jacobs adjourned the meeting at 3:50 P.M.