# MINUTES OF THE QUARTERLY OPEN MEETING OF THE COLORADO MEDICAID DUR BOARD

University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences at the Anschutz Medical Campus, 12850 E. Montview Boulevard, Aurora
Feburary 11, 2020 5:00 PM to 9:00 PM

## 1. Call to Order

The meeting was officially called to order at 5:00 PM by S.Botts

## 2. Roll Call

All present board members, HCPF staff, and CO-DUR team introduced themselves. There were sufficient members for a quorum with six voting members participating. Quorum is five members.

a. **Members Present:**, Michael Noonan, MD; Liza Wilson Claus, PharmD; Alison Shmerling, MD; Scott VanEyk, MD; Allison Blackmer, PharmD; Sheila Botts, PharmD, Gosia Thomas, PharmD, Britt Boehner (Industry Representative)
b. **Members Absent:** Mary Wilkerson, MD
c. **Medicaid Pharmacy Staff:** Jeffrey Taylor, PharmD. DeAnn Roecker, PharmD
d. **CO-DUR Team**: Brandon Utter, PharmD. Robert Page, PharmD

## 3. Final Approval of Minutes from 11/12/19

S. Botts asked if there were any changes with the minutes from the November 2019 DUR Board meeting. With no discussion, a motion to approve the minutes was made by L. Claus, seconded by M. Noonan. None opposed. Motion passed.

## 4. Department Updates

J. Taylor read the following rules for Board and speakers:

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting. Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must disclose all relationships to pharmaceutical manufacturers.
DUR Board Conflicts of Interest: DUR Board Members must disclose any conflicts of interestthatwouldmakeitdifficulttofulfillDURBoarddutiesinanobjectivemanner. If a conflict of interest exists, members must recuse themselves from the applicable vote or discuss with the board during the meeting whether the situation rises to the level of an actual conflict. If a board member recuses themselves, they should not participate in the discussion of the agenda item or any vote regarding it.

B. Utter announced that the DUR Board Member training packet is being updated and feedback should be provided directly to him.

B. Utter announced board member term expirations (M. Wilkerson, S. VanEyk, L. Claus, S. Botts) and the current vice chair would be the next chair, effective 5/2020.

G. Thomas self-nominated for role of vice chair, seconded by M. Noonan, all board in favor. G. Thomas will be Vice Chair effective 4/1/2020.

J. Taylor reviewed prior authorization criteria implementations that differed from DUR Board recommendations from the November DUR Board Meeting.

B. Utter and R. Page proceeded to new business criteria proposals

Yellow highlights are add/change proposals
AND
Red highlights are removal proposals

***Proposed Criteria***

1. **Antimigraine Agents –Calcitonin Gene-Related Peptide (CGRP) Inhibitors**

   Preferred: Emgality 120mg (galcanezumab)
   Aimovig (erenumab)

Prior Authorization Criteria:

**Emgality 120mg** (galcanezumab) OR Aimovig (erenumab) may be approved for members meeting **Migraine Prevention** CGRP inhibitor prior authorization approval criteria below.

**Emgality 100mg** (galcanezumab) may be approved for members meeting **Episodic Cluster Headache** prior authorization approval criteria below.

Non-preferred migraine prevention medications may be approved if the member meets the CGRP inhibitor Migraine Prevention prior authorization approval criteria below AND the member has history of adequate trial and failure of Emgality 120mg AND Aimovig therapy (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Non-preferred CGRP inhibitors prescribed for migraine treatment may be approved if the member meets migraine treatment prior authorization approval criteria below.

CGRP Inhibitor Migraine Prevention Prior Authorization Approval Criteria (must meet all of the following):

- Member is 18 years of age or older AND
- Member is in need of prevention of episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura AND
- Member has tried and failed 2 oral preventative pharmacological agents listed as Level A per American Headache Society/American Academy of Neurology (i.e. divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND

- Headache count: If prescribed for episodic migraine member has history of 4-14 migraine days per month OR if prescribed for chronic migraine member has history of 15 or more headache days per month where 8 or more were migraine days for three or more months AND
- Member is not prescribed this medication for medication overuse headache AND
- Member does not have history of MI, stroke, TIA, unstable angina, coronary artery bypass surgery, or other revascularization procedures within previous 12 months AND
- Aimovig may be approved for members with chronic migraine diagnosis and medication overuse if they have not been using migraine prevention agent for 2 months prior to Aimovig prescription and they meet 1 of the bullets below defining medication overuse:
    - Monthly use of ≥ 15 days of analgesics per month(non-narcotic analgesics, such as acetaminophen or nonsteroidal anti-inflammatory drugs) OR
    - ≥ 10 days with triptans per month OR
    - ≥ 10 days of combination therapy per month (any combination of triptans, ergot derivatives, analgesics or simple analgesics with opiates or butalbital)
- Initial authorization will be limited to the following:
    - For episodic migraine: Initial authorization will be for 6 months. Continuation (12 month authorization) will require documentation of clinically significant improvement after 4 months use (and documentation of number of migraine days per month)
    - For chronic migraine: Initial authorization will be for 4 months. Continuation (12 month authorization) will require documentation of clinically significant improvement after 3 months use (and documentation of number of migraine days per month)

Migraine treatment Prior Authorization Approval Criteria (must meet all of the following):

- Member is 18 years of age or older AND
- Member is using Oral CGRP inhibitor is being prescribed to treat migraine headache with moderate to severe pain AND
- Member is not receiving injectable form of CGRP medication for any indication AND
- Member must have trial and failure of the following agents:
    - Member has trial and failure of three triptans, with 2 or more formulations AND
    - Member has trial and failure of two preferred NSAIDs AND
    - Member has trial of dihydroergotamine vial or ergotamine combination product

  (failure is defined as lack of efficacy with 4 week trial, contraindication to, allergy, intolerable side effects, or significant drug-drug interaction

Episodic Cluster Headache Prior Authorization Approval Criteria (must meet all of the following):

- Member is at least 19 years of age and no more than 65 years of age AND
- Member meets the following diagnostic criteria for episodic cluster headache:
    - Member has had no more than 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the week prior to Emgality being prescribed

  AND
- Member must not be receiving other treatment intended to reduce the frequency of cluster headache attacks (prevention agents) AND
- Member must have the following trial and failure without Emgality 100mg therapy first:
    - Member has tried and/or failed monotherapy treatment with sumatriptan subcutaneous/intranasal AND zolmitriptan intranasal. Failure is defined as lack of efficacy with 4 week trial, contraindication to, allergy, intolerable side effects, or significant drug-drug interaction AND

- Member has tried and/or failed oxygen therapy. Failure is defined as lack of efficacy with 4 week trial, intolerable side effects, or unfavorable logistical considerations

AND

- Member is not prescribed this medication for medication overuse headache AND
- Member does not have ECG abnormalities compatible with acute cardiovascular event or conduction delay AND
- Within the past 6 months, member does not have a history of myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism AND
- Member does not have a history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, or vasospastic angina, clinical evidence of peripheral vascular disease, or diagnosis of Raynaud's AND
- Initial authorization will be limited to 8 weeks, subsequent authorization may be approved if member with provider attestation and documentation showing clinically relevant improvement with no less than 30% reduction in headache frequency in a 4 week period.

Grandfathering: Members taking a non-preferred agent meeting who have shown clinically significant improvement for 4 months with diagnosis of episodic migraine or 3 months with diagnosis of chronic migraine will be allowed to continue the non-preferred agent.

Members taking a non-preferred agent who have not shown clinically significant improvement for 4 months with diagnosis of episodic migraine or 3 months with diagnosis of chronic migraine will be allowed to transition to a preferred CGRP agent without meeting the "headache count" criteria listed above.

Maximum Dosing:
**Aimovig® (erenumab):** 140mg monthly
**Ajovy® (fremanezumab):** 225mg monthly or 675mg every three months
**Emgality® (galcanezumab):** 240mg once as first loading dose then 120mg monthly for migraine prevention, 300mg monthly for episodic cluster headache
**Ubrelvy® (ubrogepant):** 16 tablets in 30-day period

Discussion: Board members made no disclosures. Dr. Michael Faith provided testimony on behalf of Camden Medical Affairs. Motion was made to accept the above highlighted changes with Emgality by indications dosing clarification and medication overuse headache literature review by G. Thomas, seconded by S. Botts, motion passed.

2. **Diabetes Management –Insulins**

Preferred:

**Rapid Acting**
Novolog
Humalog

**Short Acting**
Humulin R U-100 vial
Humulin R U-500 vial/pen

**Intermediate Acting**

Humulin N vial/pen

**Long Acting**

Levemir (insulin detemir)
Lantus (glargine)

**Mixtures**

Humulin 70/30 vial/pen
Humalog mix 50/50 vial
Humalog mix 75/25 vial
Humalog mix pen
Novolog mix 70/30 vial/pen

Prior Authorization Criteria:

**Rapid Acting:**

Non-preferred products will be approved if the member has failed treatment with two preferred products one of the preferred products (Failure is defined as: allergy hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects)

AFREZZA (human insulin) will be approved for members with the following criteria:

- Member is 18 years or older AND
- Member has tried and failed treatment with two preferred products AND intolerable side effects or severe allergic reactions to Novolog AND Humalog AND
- Member must not have chronic lung disease such as asthma and COPD AND
- If member is a type 1 diabetic, must use in conjunction with long-acting insulin AND
- Member must not be a smoker
  (Failure is defined as: allergy hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects)

**Short Acting**

Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects)

**Intermediate Acting**

Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects)

**Long Acting**

Non-preferred products will be approved if the member has failed treatment with Levemir and Lantus (Failure is defined as: allergy or intolerable side effects (or pediatric members with documented injection site reactions or at high risk for hypoglycemic reactions))

**Mixtures**

Non-preferred products will be approved if the member has failed treatment with two one of the preferred products in the last month (Failure is defined as: allergy or intolerable side effects)

Discussion: B. Boehner (industry representative) acknowledged a conflict of interest and Ryan Flugge, PharmD from Novo-Nordisk provided testimony on behalf of Novo Nordisk. No other Board members made disclosures. Motion was made to accept highlighted changes and consider expanding access to Tresiba for children by A. Blackmer, seconded by G. Thomas, motion passed.

**3. Glucagon, Self-Administered** (New Class)

Preferred: GlucaGen Hypokit
Glucagon Emergency Kit
Gvoke (glucagon) 2nd line

Prior Authorization Criteria:
Gvoke may be approved with trial and failure of GlucaGen Hypokit OR Glucagon Emergency Kit. (Failure is defined as allergy to ingredients in product, intolerable side effects, or inability to administer dosage form)

Non-preferred products will be approved if the member has failed treatment with Gvoke and one other preferred product. Failure is defined as allergy to ingredients in product, intolerable side effects, or contraindication to dosing form.

Quantity limit: 2 doses per year unless used / damaged / lost

Discussion: B. Boehner (industry representative) acknowledged a conflict of interest and William Lai, PharmD (Xeris) and Anthony Wheeler, PhD (Lilly) provided testimony. Motion was made to accept criteria with no changes by G. Thomas, seconded by S. VanEyk, motion passed.

**4. Multiple Sclerosis Agents**

Preferred: Avonex (interferon beta 1a)
Betaseron (interferon beta 1b)
Copaxone 20 mg injection (glatirmer) *BNR
2nd line Gilenya (fingolimod) *BNR
2nd line Tecfidera (dimethyl fumerate)
2nd line Aubagio (teriflunomide)

Prior Authorization Criteria:

Non-preferred **Interferon and oral products** may be approved if the member has tried and failed treatment with three preferred products for relapsing forms of multiple sclerosis (MS) in the last 12 months, unless otherwise noted. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

**Copaxone 40mg and glatiramer 40mg** may be approved for members who have severe intolerable injection site reactions (e.g, pain requiring local anesthetic, oozing, lipoatrophy, swelling, or ulceration) to Copaxone 20mg.

Approval Criteria for 2nd Line Preferred Agents:

*Gilenya, *Tecfidera, and*Aubagio may be approved for members that meet the following criteria:

- Documented diagnosis of multiple sclerosis made by neurologist in the last 3 years OR member has history of diagnosis made by a neurologist > 3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of MS
  AND
- Documentation provided by prescribing neurologist, or is prescribed in conjunction with a neurologist, for marked functional decline as demonstrated by two of the following: MRI, EDSS scale OR medical chart notes that specify increased burden of disease AND
- Provider attests to shared decision making with respect to risks versus benefits of medical treatment AND
- Safety criteria for prescribed agent are met (Table 1)
- Appropriate safety criteria are met below:

| Table 1: Safety Criteria for Select Agents Aubagio, Gilenya, and Tecfidera | |
|---|---|
| **Tecfidera (dimethyl fumerate)** | • Has no active infections AND<br>• Had a complete blood count with differential within the six months prior to initiating therapy |
| **Aubagio (teriflunomide)** | • Has no active infections AND<br>• If a female patient of child bearing age, has a negative pregnancy test at baseline and is using a form of highly effective contraceptive(e.g. long acting reversible contraception) AND<br>• Had transaminase and bilirubin levels with ALT < 2 times the upper limit of normal within the 6 months prior to initiating therapy AND<br>• Had a complete blood count with differential within the six months prior to initiating therapy AND<br>• Has a documented baseline blood pressure AND<br>• Has been evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative test) or blood test. |
| **Gilenya (fingolimod)** | • Has no active infections AND<br>• Does not have a recent history of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, OR New York Heart Association Class III-IV heart failure within six months of initiating therapy AND<br>• Does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker AND<br>• Has a baseline QTc interval < 500 ms prior to starting therapy AND<br>• Is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication AND<br>• Had an ophthalmologic evaluation (ocular coherence test) prior to starting therapy and within 3-4 months follow-up after starting therapy AND<br>• Had baseline complete blood count with differential and liver function tests |
| **Mayzent (simponimod)** | • Member does not have one of the following contraindications:<br>○ a CYP2C9*3/*3 genotype |

| | |
|---|---|
| | ○ In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III or IV heart failure<br>○ Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker<br>AND<br>• Has a baseline QTc interval < 500 ms prior to starting therapy AND<br>• Has no active infections AND<br>• Member has not had hypersensitivity reaction to Gilenya (fingolimod) AND<br>• Had baseline complete blood count with differential and liver function tests |
| **Mavenclad (cladribine)** | • Member has negative pregnancy test within 30 days of request for Mavenclad AND<br>• Men and women of childbearing potential must have plan to use effective contraception during and 6-months after course of therapy AND<br>• Member does not have current evidence of malignancy AND<br>• Member has CBC with differential drawn prior to, during, and after treatments with Mavenclad due to risk of lymphopenia and hematologic toxicity AND<br>○ Lymphocytes must be:<br>▪ within normal limits before initiating the first treatment course<br>▪ at least 800 cells per microliter before initiating the second treatment course<br>• Member is not currently taking immunosuppressive or myelosuppressive therapy AND<br>• Member has no active infections AND<br>• Member has liver function tests drawn prior to first and second treatment course due to potential for liver injury |
| **Vumerity (dioroxemel fumerate)** | • Member has not had hypersensitivity reaction or angioedema as a result of Tecfidera (dimethyl fumerate) therapy AND<br>• Has no active infections AND<br>• Had a complete blood count with differential within the six months prior to initiating therapy AND<br>• Member has liver function tests drawn prior to treatment course due to potential for liver injury |

For members meeting NOT meeting criteria above, **Gilenya, Tecfidera, or Aubagio** may be approved for members that meet the following criteria:

- Member has failed COPAXONE or a preferred interferon product. [Failure will be defined as intolerable side effects drug-drug interaction, or lack of efficacy]
- One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy
- On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer AND
- Has a diagnosis of a relapsing form of MS AND
- Is being prescribed by a neurologist or is prescribed in conjunction with a neurologist AND
- Safety criteria for prescribed agent are met (Table 1)

Mayzent (simponimod) may be approved if member meets all of the following criteria:

- Medication is being prescribed by a neurologist AND
- Member is diagnosed with relapsing form of MS AND
- Member does not have diagnosis of macular degeneration AND

- Member meets the safety criteria listed in Table 1 above AND
- Member has baseline Expanded Disability Status Scale (EDSS) score of 3.0-6.5 AND
- Member has no evidence of relapse in the 3 months preceding request for Mayzent AND
- Member has had trial and failure of Gilenya (fingolimod) (Failure is defined as: lack of efficacy with 3 month trial, allergy, intolerable side effects or significant drug-drug interactions)
- Initial authorization will be for 3 months, for continued authorization member must have reduction of 1.0 point on the EDSS from baseline or if baseline EDSS 5.5-6.5, a reduction of 0.5 points

  Maximum dose: Mayzent 2mg daily

Mavenclad (cladribine) may be approved if member meets all of the following criteria:

- Medication is being prescribed by a neurologist AND
- Member is diagnosed with relapsing form of MS AND
- Member meets the safety criteria listed in Table 1 above AND
- Member has had one or more relapses in the 12 months preceding request for Mavenclad AND
- Member has had trial and failure of 3 other therapies for relapsing forms of multiple sclerosis (Failure is defined as: lack of efficacy with 3 month trial, allergy, intolerable side effects or significant drug-drug interactions)

  Maximum dose: Mavenclad 3.5mg/kg total dose every 4 years/year (given as 2 courses of 1.75mg/kg with 23-27 days gap in between courses)

Vumerity (dioroxemel fumerate) may be approved if member meets all of the following criteria:

- Medication is being prescribed by a neurologist AND
- Member is diagnosed with relapsing form of MS AND
- Member meets the safety criteria listed in Table 1 above AND
- Member has had trial and failure of Tecfidera (Failure is defined as: lack of efficacy with 3 month trial, allergy, intolerable side effects or significant drug-drug interactions)
- If member is being prescribed Vumerity due to gastrointestinal adverse effects with Tecfidera, the member must meet the following criteria:
  - Temporary dose reduction of Tecfidera (maintenance dose to be resumed within 4 weeks) AND
  - Trial of taking Tecfidera with food AND
  - Maximization of gastrointestinal symptomatic therapies including, but not limited to:
    - Antacids (calcium carbonate)
    - Bismuth subsalicylate
    - Acid secretion blocker (PPI, H2RA)
    - Anti-bloating/anti-constipation agent
    - Anti-diarrheals
    - Centrally acting anti-emetics
  - Initial authorization will be for 6 weeks, subsequent authorization will require clinically significant reduction in GI adverse events

  Maximum dose: Vumerity 462mg BID

Grandfathering: Members currently stabilized a non-preferred product in this class will receive approval to continue that product. on GILENYA, TECFIDERA, AUBAGIO, or a non-preferred interferon therapy may receive approval to continue on that agent.

**Symptom Management Therapies**

Ampyra (dalfampridine) prior authorization for a 3-month supply may be approved if all of the following criteria are met:

- Member has a diagnosis of MS;
- Member is ambulatory and has established a baseline which is defined as ambulating between 8-45 seconds Timed 25-foot Walk (T25FW) assessment OR has established a baseline activities of daily living (ADL);
- Member has no history of seizure disorder;
- Member has no history of moderate to severe renal dysfunction (CrCl > 50 ml/min);
- Prescriber is a neurologist or is prescribed in conjunction with a neurologist;
- The prescribed dose does not exceed 10 mg twice daily.

Extended coverage of Ampyra (dalfampridine) for up to one year may be approved if documentation shows improvement in ambulation (measured by T25FW assessment) or improvement in ADLs after three months of therapy.

Discussion: Board members made no disclosures and Chad Duncan (EMD Serono) gave testimony. Motion was made to accept criteria proposals with added language to protect patients of childbearing age/teratogenesis, and some other verbiage clarification by A. Shmerling, seconded by M. Noonan, motion passed.

**5. Immune Globulins (New Class)**

Preferred: Gammaplex
Privigen
Gammagard liquid
Gammaked
Gamunex-C
Hizentra
Cuvitru

Prior Authorization Criteria:

If immune globulin is being administered in a long-term care facility or in a member's home by a home healthcare provider, it should be billed as a pharmacy claim. All other claims must be submitted through the medical benefit.

Preferred agents may be approved for members with an approved condition (below) at a prescribed dose not exceeding the maximum doses listed in "Table 1: FDA-approved Maximum Immune Globulin Dosing"

Non-preferred agents may be approved for members meeting the approved conditions below with trial and/or failure of two preferred agents.
(Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions)

Approved Conditions for Immune Globulin Use: Members must have one of the following conditions:

- Primary Humoral Immunodeficiency disorders:
    - Common Variable Immunodeficiency (CVID)
    - Severe Combined Immunodeficiency (SCID)

    - X-Linked Agammaglobulinemia
    - X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
    - Wiskott-Aldrich Syndrome
    - Pediatric Human Immunodeficiency Virus (HIV):
        - Members are less than 13 years of age and CD-4 Count is > 200/mm3
- Neurological disorders:
    - Guillain-Barre' Syndrome
    - Relapsing-Remitting Multiple Sclerosis
    - Chronic Inflammatory Demyelinating Polyneuropathy
    - Myasthenia Gravis
    - Polymyositis and Dermatomyositis
    - Multifocal Motor Neuropathy
- Chronic Lymphocytic Leukemia (CLL)
- Autoimmune Neutropenia (AN):
    - Absolute neutrophil count is less than 800 mm AND
    - Has recurrent bacterial infections
- Autoimmune Hemolytic Anemia (AHA)
- Liver or Intestinal Transplant
- Idiopathic Thrombocytopenic Purpura
- Immune Thrombocytopenia Purpura (ITP):
    - Preoperatively for members undergoing elective splenectomy with platelet count < 20,000
    - Members with active bleeding & platelet count <30,000.
    - Pregnant women with platelet counts <10,000 in the third trimester.
    - Pregnant women with platelet count 10,000 to 30,000 who are bleeding

Members currently receiving a preferred or non-preferred immunoglobulin product will receive approval to continue to receive that product.

| Table 1: FDA-approved Maximum Immune Globulin Dosing | |
|---|---|
| Gammaplex 5% - IV Infusion | 800mg/kg every 3 weeks |
| Privigen IV Infusion | 800mg/kg every 3 weeks |
| Gammagard liquid SQ or IV admin | 2.4 grams/kg/month |
| Gammaked SQ or IV admin | 600 mg/kg every 3 weeks |
| Gamunex-C SQ or IV admin | 600 mg/kg every 3 weeks |
| Hizentra SQ admin | 12 grams every 2 weeks |
| Cuvitru SQ admin | 12.6 grams every 2 weeks |

Discussion: Board members made no disclosures and there were no speakers for this class. Motion was made to accept criteria with addition of above "LTC or homehealth clause" by G. Thomas, seconded by A. Blackmer, motion passed.

**6. Anti-Parkinson's Agents**

Preferred: **Dopa Decarboxylase inhibitors and combinations**
Carbidopa/levodopa IR and ER

**MAO-B Inhibitors**
Selegiline cap/tab

**Dopamine Agonists**
Pramipexole IR
Ropinirole IR

**Other Parkinson's Agents**
Amantadine syrup and cap
Benztropine
Trihexyphenidyl tab and elixir

Prior Authorization Criteria:

**Dopa Decarboxylase inhibitors and combinations**
Non-preferred dopa-decarboxylase inhibitors and combinations will be approved with adequate trial and/or failure of carbidopa-levodopa IR and ER formulations. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Carbidopa or Levodopa single agent products will be approved for members with diagnosis of Parkinson's disease as add-on therapy to carbidopa-levodopa.

Non-preferred medications that are not prescribed for Parkinson's Disease or an indication related to Parkinson's Disease may receive approval without meeting trial and failure step criteria outlined in this section.

Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred.

Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

**MAO-B Inhibitors**
Non-preferred MAO-B inhibitors will be approved with adequate trial and/or failure of selegiline capsule or tablet. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred medications that are not prescribed for Parkinson's Disease or an indication related to Parkinson's Disease may receive approval without meeting trial and failure step criteria outlined in this section.

Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred.

Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

**Dopamine Agonists**
Non-preferred dopamine agonists will be approved with adequate trial and/or failure of ropinirole IR and pramipexole IR. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred medications that are not prescribed for Parkinson's Disease or an indication related to Parkinson's Disease may receive approval without meeting trial and failure step criteria outlined in this section.

Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred.

Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

**Other Parkinson's Agents**
Other non-preferred agents that are prescribed for Parkinson's Disease will be approved with adequate trial and/or failure of 2 preferred agents. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred medications that are not prescribed for Parkinson's Disease or an indication related to Parkinson's Disease may receive approval without meeting trial and failure step criteria outlined in this section.

Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred.

Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

Discussion: Board members made no disclosures and there were no speakers for this class. Motion was made to accept criteria with no changes by L. Claus, seconded by S. VanEyk, motion passed.

7. **Atypical Antipsychotics**

Preferred: Aripiprazole tablet, ODT, and oral solution
Clozapine tablets and ODT
**Latuda (lurasidone) *2nd Line*
Olanzapine tablet and ODT
***Quetiapine IR tablet and ER tablet
Risperidone tablet, oral solution, and ODT
Ziprasidone capsule

Prior Authorization Criteria:
Non-preferred products will only may be approved for members meeting all of the following criteria:

- Medication being prescribed for an FDA-approved indications (Table 1) AND age limits (Table 3) AND
- Member has adequate trial and/or failed on three preferred products. in the last 5 years. AND

- If non-preferred atypical antipsychotic agents has a preferred product with same strength, dosage form, and active ingredient; that preferred agent requires adequate trial and/or failure of the preferred product (such as preferred risperidone and Risperdal clozapine ODT and Fazaclo) and 2 other preferred products
- For aripiprazole use in pediatric patients (<18 years of age): if desired aripiprazole dose may not be achieved with preferred formulations and quantity limit of one tablet per day, aripiprazole quantity limit of two tabs per day may be approved (For example: Desired dose = aripiprazole 4mg per day, member may be approved for two-2mg tablets per day). Aripiprazole solution may be approved for pediatric members who have special dosing requirements that cannot be fulfilled by increasing aripiprazole tablet quantity
  (Failure defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing)

Non-preferred atypical antipsychotic agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product (such as preferred risperidone and Risperdal clozapine ODT and Fazaclo) and 2 other preferred products. (failure defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, significant drug-drug interactions or known interacting genetic polymorphism that prevents safe preferred product dosing).

*Age Limits: All products including preferred products will require a PA for members younger than the FDA approved age for the agent (Table 3). Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for grandfathering. **New Atypical Antipsychotic prescriptions for members under 5 years of age may require a provider-provider telephone consult with a child and adolescent psychiatrist (provided at no cost to provider or member).**

****Latuda** will be approved for the treatment of schizophrenia or bipolar depression if the member has tried and failed treatment with one preferred product (qualifying diagnosis verified by AutoPA).

*****Quetiapine IR** when given at sub therapeutic doses may be restricted for therapy. Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day except for utilization (when appropriate) in members 65 years or older. PA will be approved for members 10-17 years of age with approved diagnosis (Table 3) stabilized on <150mg quetiapine IR per day.

**Nuplazid** will be approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis and tried and failed either quetiapine OR clozapine (Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy).

**Abilify MyCite** tabs may be approved if member all of the following criteria:
- Adequate trial and/or failure of 5 preferred oral agents, one trial must include aripiprazole tablet AND
- Adequate trial and/or failure of 3 long-acting injectable formulations of atypical antipsychotics within the past 2 years, one of which must contain aripiprazole. AND
- Documentation of adherence measures recommended by provider and being followed by member (such as medication organizer or digital medication reminders) AND
- Abilify MyCite is being used with a MyCite patch and member is using a compatible mobile application. AND

- Medication adherence information is being shared with their provider via a web portal or dashboard

(Failure defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, significant drug-drug interactions)

Quantity Limits: Quantity limits will be applied to all products (Table 2). In order to receive approval for off-label dosing, the member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen.

Grandfathering: Members currently stabilized on a non-preferred atypical antipsychotic or Latuda can receive approval to continue therapy with that agent for one year.

Table 1. Approved Indications

| Brand (generic) | Indication |
|---|---|
| Abilify® (aripiprazole) | • Schizophrenia<br>• Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder<br>• Adjunctive Treatment of Major Depressive Disorder<br>• Irritability Associated with Autistic Disorder<br>• Treatment of Tourette's Disorder |
| Caplyta® (lumateperone) | • Schizophrenia |
| Fanapt® (iloperidone) | • Acute treatment of schizophrenia in adults |
| Fazaclo®, Versacloz® (clozapine) | • Treatment-resistant schizophrenia<br>• Reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder |
| Geodon® (ziprasidone) | • Schizophrenia<br>• Bipolar I Disorder (Acute Mixed or Manic Episodes and Maintenance Treatment as an Adjunct to Lithium or Valproate)<br>• Acute Treatment of Agitation in Schizophrenia |
| Latuda® (lurasidone) | • Schizophrenia<br>• Bipolar 1 Disorder |
| Nuplazid® (pimavanserin) | • hallucinations and delusions associated with Parkinson's disease psychosis |
| Invega® (paliperidone) | • Schizophrenia<br>• Schizoaffective disorder |
| Risperdal® (risperidone) | • Schizophrenia<br>• Bipolar Mania<br>• Irritability Associated with Autistic Disorder |
| Rexulti® (brexpiprazole) | • Adjunctive therapy to antidepressants for the treatment of major depressive disorder<br>• Schizophrenia |
| Saphris® (asenapine) | • Acute and maintenance of schizophrenia<br>• Bipolar mania, monotherapy |

| | |
|---|---|
| | • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex |
| Seroquel XR® (quetiapine) AND Seroquel XR® (quetiapine) | • Treatment of schizophrenia<br>• Acute treatment of manic or mixed episodes associated with bipolar I disorder, as monotherapy or as an adjunct to lithium or divalproex<br>• Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex<br>• Adjunctive treatment of major depressive disorder (MDD) (Seroquel XR only) |
| Symbyax® (olanzapine /fluoxetine) | • Treatment resistant depression<br>• Bipolar 1 Disorder |
| Vraylar® (cariprazine) | • Schizophrenia<br>• Bipolar (acute treatment) |
| Zyprexa® (olanzapine) | • Schizophrenia<br>• Bipolar 1 Disorder |

Table 2. Quantity Limits

| Brand (generic) | Quantity Limits |
|---|---|
| Abilify® (aripiprazole) | Maximum of one tablet per day |
| Clozaril® (clozapine) | Maximum dosage of 900mg per day |
| Caplyta® (lumateperone) | Maximum dosage of 42mg per day |
| Fazaclo® (clozapine) | Maximum dosage of 900mg per day |
| Fanapt® (iloperidone) | Maximum of two tablets per day |
| Geodon® (ziprasidone) | Maximum two capsules per day |
| Invega® (paliperidone) | Maximum of one capsule per day |
| Latuda® (lurasidone) | Maximum of one tablet per day (If dosing 160mg for schizophrenia, then max of two tablets per day) |
| Nuplazid® (pimavanserin) | Maximum of 34mg daily |
| Risperdal® (risperidone) | Maximum dosage of 12mg per day |
| Rexulti® (brexpiprazole) | Maximum of 3mg/day for MDD adjunctive therapy, Maximum of 4mg/day for schizophrenia |
| Saphris® (asenapine) | Maximum of two tablets per day |
| Secuado® (asenapine patch) | Maximum 1 patch per day |
| Seroquel® (quetiapine) | Maximum of three tablets per day |
| Seroquel XR® (quetiapine XR) | Maximum one tablet per day (for 300mg & 400mg tablets, max 2 tablets per day) |
| Symbyax® (olanzapine/fluoxetine) | Maximum of 3 capsules or 18 mg of olanzapine and 75 mg of fluoxetine |
| Vraylar® (cariprazine) | Maximum dosage of 6mg/day |
| Zyprexa® (olanzapine) | Maximum one tablet per day |

Table 3. FDA Approved Dosing for Members Under 18 years of Age.

| Brand (generic) | FDA Approved Indication | FDA Approved Age | Maximal FDA Approved Dose |
|---|---|---|---|
| Seroquel XR® (quetiapine fumarate) | APPROVED FOR ADULTS ONLY | | |
| Geodon® (ziprasidone) | | | |
| Saphris® and Secuado® (asenapine) | | | |
| Rexulti® (brexpiprazole) | | | |
| Nuplazid® (pimavanserin) | | | |
| Caplyta® (lumateperone) | | | |
| Vraylar® (cariprazine) | | | |
| Fazaclo®, Clozaril® (clozapine) | | | |
| Fanapt® (iloperidone) | | | |
| Abilify® (aripiprazole) | Autism/Psychomotor Agitation<br>Bipolar Disorder/Mixed Mania<br>Schizophrenia<br>Gilles de la Tourette's syndrome | 6-17 years<br>10-17 years<br>13-17 years<br>6-17 years | 15mg/day<br>30mgday<br>30mg/day<br>20 mg/day |
| Latuda® (lurasidone) | Schizophrenia<br>Bipolar Depression | 13-17 years<br>10-17 years | 80 mg/day<br>80 mg/day |
| Zyprexa® (olanzapine) | Schizophrenia<br>Bipolar Disorder/Mixed Mania | 13-17 years<br>13-17 years | 10mg/day<br>10mg/day |
| Zyprexa Zydis® (olanzapine) | | | |
| Invega ER® (paliperidone) | Schizophrenia | 12-17 years | 12mg/day |
| Risperdal® (risperidone) | Autism/Psychomotor Agitation | 5-16 years<br>10-17 years<br>13-17 years | 3mg/day<br>6mg/day<br>6mg/day |

| | | | |
|---|---|---|---|
| | Bipolar Disorder/Mixed Mania<br>Schizophrenia | | |
| Seroquel® (quetiapine fumarate) | Schizophrenia<br>Bipolar Disorder/Mixed Mania | 13-17 years<br>10-17 years | 800 mg/day<br>600 mg/day |

Discussion: Board members made no disclosures. Rick Kegler, PharmD gave a testimony on Rexulti and Abilify on behalf of Otsuka. Motion was made to reevaluate criteria for Abilify MyCite by G. Thomas, seconded by S.Botts, motion passed. Motion was made to accept above highlighted changes and adjust aripiprazole quantity limits for pediatric patients if incremental dosing is not achievable by currently set limits by A. Blackmer, seconded by G. Thomas, motion approved.

8. **Lithium Agents (New Class)**

Preferred:
Lithium Carbonate
Lithium Carbonate ER

Prior Authorization Criteria:
Non-preferred lithium agents may be approved with trial and failure of one preferred agent. (Failure defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, significant drug-drug interactions, intolerance to dosage form).

Grandfathering: Members currently stabilized on a non-preferred lithium product may receive approval to continue therapy with that agent for one year.

Discussion: Board members made no disclosures and there were no speakers for this class. Motion was made to accept criteria with no changes by A. Blackmer, seconded by L. Claus, motion passed.

9. **Ophthalmic Anti-Inflammatories (New Class)**

Preferred:
Acuvail
Bromfenac
Diclofenac
Ketorolac
Flurbiprofen
Lotemax drops/ointment
Pred Mild
FML Forte
Flarex
Prednisolone acetate

Prior Authorization Criteria:

Non-preferred ophthalmic anti-inflammatory agents may be approved with trial and failure of three preferred agents. Failure is defined as lack of efficacy with 2 week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction.

Lotemax SM® (loteprednol etoabonate) may be approved for members meeting the following criteria:

- Member is 18 years of age or older AND
- Lotemax SM (loteprednol etoabonate) is being used for the treatment of post-operative inflammation and pain following ocular surgery AND
- Member does not have any of the following conditions:
    - Viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella
    - Mycobacterial infection of the eye and fungal diseases of ocular structures
      AND
- Member has trialed and failed TWO preferred lotoprednol formulations. of the following: Lotemax (loteprednol) gel, Lotemax (loteprednol) suspension Lotemax (loteprednol) ointment (failure is defined as lack of efficacy with 2 week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction)
  AND
- Member has trialed and failed TWO other preferred ophthalmic anti-inflammatory agents a generic topical corticosteroid (such as dexamethasone ophthalmic, fluorometholone ophthalmic, prednisolone acetate ophthalmic). Failure is defined as lack of efficacy with 2 week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction.

Discussion: Board members made no disclosures and there were no speakers for this class. Motion was made to accept criteria with no changes by M. Noonan, seconded by G. Thomas, motion passed.

**10. Lipotropics (other)**

Preferred: Colestipol tab
Cholestyramine
Colesevelam tab
Ezetimibe
Fenofibrate tab/cap (generic Lofibra and generic Tricor)
Gemfibrozil
Niacin ER
Omega-3 (generic Lovaza)

Prior Authorization Criteria:

Non-preferred bile acid sequestrates will be approved if the member has failed treatment with 2 preferred products in the last 12 months. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred fibrates will be approved if the member has failed treatment with generic gemfibrozil or generic fenofibrate and niacin ER in the last 12 months. (Failure is defined as: lack of efficacy with 4 week trial of each drug, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

*Omega-3 ethyl esters (generic Lovaza) will be approved for members who have a baseline triglyceride level ≥ 500 mg/dL

*Vascepa (icosapent ethyl) OR Lovaza (omega-3 fatty acids) will be approved for members who meet the following criteria:

- Member has a baseline triglyceride level >500 mg/dl AND
- Member has failed an adequate trial of omega-3 Ethyl Esters and an adequate trial of gemfibrozil or fenofibrate (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

*Vascepa (icosapent ethyl) may also be approved for members meeting all of the following criteria:

- Vascepa is being prescribed to reduce CV risk for members on maximally tolerated statin therapy with triglyceride levels >/= 150mg/dL, LDL-C between 41-100 mg/dL AND
- Member is age 45 years or older and has established atherosclerotic CV disease (i.e., coronary artery disease, cerebrovascular/carotid disease, peripheral arterial disease) OR
- Member is age 50 years or older and has diabetes mellitus and one or more additional risk factors for CV disease listed below
    - Men ≥55 years of age and women ≥65 years of age
    - Cigarette smoker
    - Hypertension
    - HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
    - hsCRP >3.00 mg/L (0.3 mg/dL)
    - CrCl 30 to 59 mL/min
    - Retinopathy
    - Micro- or macroalbuminuria
    - ABI <0.9 without symptoms of intermittent claudication

  Maximum dose: Vascepa 4g daily (4 capsules daily)

Discussion: Board members made no disclosures and there were no speakers for this class. Motion was made to accept criteria with no changes by G. Thomas, seconded by L. Claus, motion passed.

**11. Sedative Hypnotics**

Preferred:

**Non-Benzodiazepine**
Zolpidem IR
Zolpidem ER
Zaleplon
Eszopiclone

**Benzodiazepine**
Temazepam 15mg/30mg
Triazolam

Prior Authorization Criteria:

**Non-Benzodiazepines**
Non-preferred non-benzodiazepine sedative hypnotics will be approved for members who have failed treatment with two preferred non-benzodiazepine agents in the last 12 months (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Children: Prior authorization will be required for all agents for children < 18 years of age

Duplications: Only one agent in the sedative hypnotic drug class will be approved at a time (e.g. concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved) All sedative hypnotics will require PA for member's ≥65 years of age exceeding 90 days of therapy.

**Belsomra** (suvorexant) or **Dayvigo** (lemborexant) may be approved for adult members that meet the following criteria:

- Members who have trial and/or failure of treatment with two preferred agents in the last 12 months. (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member is not receiving strong inhibitors (e.g, erythmromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (e.g, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 **AND**
- Member does not have a diagnosis of narcolepsy **AND**
- Dayvigo will only be approved for members who have had trial and/or failure with Belsomra (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interaction)

**Rozerem** (ramelteon) will be approved for adult members with a history/concern of substance abuse or for documented concern of diversion within the household without failed treatment on a preferred agent

Prior authorization will be required if member exceeds FDA recommended dose listed in the table below.

**Benzodiazepines**

Temazepam 7.5mg and 22.5 mg will be approved if the member have trial and/or failure of temazepam 15mg or 30mg AND one other preferred product (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Non-preferred benzodiazepine sedative hypnotics will be approved for members who have trial and/or failure with two preferred benzodiazepine agents in the last 12 months. (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Children: Prior authorization will be required for all sedative hypnotic agents when prescribed for children < 18 years of age

Duplications: Only one agent in the sedative hypnotic drug class will be approved at a time (e.g. concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved)

All sedative hypnotics will require PA for member's ≥65 years of age exceeding 90 days of therapy.

Grandfathering: Members currently stabilized on a non-preferred benzodiazepine medication will receive authorization to continue that medication.
Prior authorization will be required if member exceeds FDA recommended dose listed in the table below.

| Brand | Generic | FDA Maximum Dose |
|---|---|---|
| **Non-Benzodiazepine** | | |
| Ambien CR | Zolpidem CR | 12.5mg/day |
| Ambien IR | Zolpidem IR | 10mg/day |
| Belsomra | Suvorexant | 20mg/day |
| Dayvigo | Lemborexant | 10mg/day |
| Edluar | Zolpidem sublingual | Men: 10mg/day<br>Women: 5mg/day |
| Intermezzo | Zolpidem sublingual | Men: 3.5mg/day<br>Women: 1.75mg/day |
| Lunesta | Eszopiclone | 3mg/day |
| Sonata | Zaleplon | 20mg/day |
| Rozerem | Ramelteon | 8mg/day |
| Zolpimist | Zolpidem spray | Men: 10mg (2 sprays)/day<br>Women: 5mg (1 spray)/day |
| **Benzodiazepines** | | |
| Halcion | Triazolam | 0.5mg/day |
| Restoril | Temazepam | 30mg/day |
| - | Estazolam | 2mg/day |
| - | Flurazepam | 30mg/day |
| - | Quazepam | 15mg/day |

Discussion: Board members made no disclosures and there were no speakers for this class. Motion to accept proposed criteria with above highlighted changes made by G. Thomas, seconded by A. Blackmer, motion passed.

**12. Hemorrhoidal and Related Anorectal Agents (New Class)**

Preferred: hydrocortisone acetate 25mg sup
cortifoam aerosol
proctosol-HC 2.5% cream
hydrocortisone 2.5% cream
proctozone-HC 2.5% cream
procto-Pak 1% cream
procto-med HC 2.5% cream
hydrocortisone enema

proctofoam-HC 1%-1%
hydrocortisone-pramoxine 1%-1%/2.5%-1% cream
lidocaine-hydrocortisone 3-0.5% cream

Prior Authorization Criteria:

Non-preferred hemorrhoidal and related anorectal agents may be approved if the member has failed treatment with 3 preferred products. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Rectiv (nitroglycerin) 0.4% ointment may be approved for members with a diagnosis of anal fissure AND maximization of appropriate supportive therapies including sitz bath, fiber, topical analgesics (i.e. lidocaine), and stool softeners/laxative.

Discussion: Board members made no disclosures and there were no speakers for this class. Motion wasmade to accept criteria with no changes by A. Blackmer, seconded by G. Thomas, motion passed.

13. **Bile Salts**

Preferred: Ursodiol cap/tab

Prior Authorization Criteria:
Non-preferred bile salts agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ursodiol tabletandUrso tablet). (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

**Chenodal** (chenodiol) and **Actigall** (ursodiol) will be approved for members who meet the following criteria:

- Member >18 years of age AND
- Members has tried and failed a 12-month trial of ursodiol.

**Cholbam** (cholic acid) capsules may be approved for members who meet the following criteria:

- Bile acid synthesis disorders:
  - Member must be greater than 3 weeks old in age AND
  - Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz).
- Peroxisomal disorder including Zellweger spectrum disorders:
  - Member must be greater than 3 weeks old in age AND
  - Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND
  - Member has manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.

**Ocaliva** (obeticholic acid) and **Urso** (ursodiol)will be approved for members who meet the following criteria:

- Member is >18 years of age AND
- Ocaliva® or Urso® is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
- Member has the diagnosis of Primary Biliary Cholangitis as evidenced by two of the following at the time of diagnosis:
    - Evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal
    - Presence of anti-mitochondrial antibody: a titer of 1:40 or higher
    - Histologic evidence of non-suppurative destruction cholangitis and destruction of interlobular bile ducts AND
- Member has failed treatment with ursodiol for at least 1 year with an inadequate response OR
- Member has intolerable side effects, drug-drug interaction, or allergy to ursodiol.

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**14. Growth Hormones**

Preferred: Genotropoin
Norditropin

Prior Authorization Criteria:

All preferred products will be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND prescription does not exceed limitations for maximum dosing (Table 1) based on prescriber submission/verification of patient weight from most recent clinical documentation

Non-preferred Growth Hormones may be approved if the following criteria are met:

- Member failed treatment with one preferred growth hormone product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
- Member has one of the qualifying diagnoses listed below AND
- Prescription does not exceed limitations for maximum dosing (Table 1) based on prescriber submission/verification of patient weight from most recent clinical documentation

Growth Hormone Qualifying Diagnosis:

- Prader-Willi
- Chronic renal insufficiency/failure requiring transplantation (defined as Creatinine Clearance < 30mL/min)
- Turner's Syndrome
- Small for Gestational Age: and failure to manifest catch-up growth by 2 years of age
- Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma verified by one of the following:
    - Has failed at least one GH stimulation test (peak GH level < 10 ng/mL) OR
    - Has at least one documented low IGF-1 level (below normal range for patient's age –refer to range on submitted lab document) OR
    - Has deficiencies in ≥ 3 pituitary axes (i.e. TSH, LH, FSH, ACTH, ADH)

- Cachexia associated with AIDS
- Noonan Syndrome
- Short bowel syndrome

| Table 1: Growth Hormone Product Maximum Dosing* | | |
|---|---|---|
| Medication | Pediatric Max Dosing(age < 18 years) | Adult Max Dosing(age ≥ 18 years) |
| Genotropin | 0.33 mg/kg/week | 0.08 mg/kg/week |
| Humatrope | 0.375 mg/kg/week | 0.0875 mg/kg/week |
| Norditropin Flexpro | 0.47 mg/kg/week | 0.112 mg/kg/week |
| Nutropin AQ Nuspin | 0.375 mg/kg/week | 0.175 mg/kg/week for ≤36 years of age<br>0.0875 mg/kg/week for >35 years of age |
| Omnitrope | 0.33 mg/kg/week | 0.08 mg/kg/week |
| Saizen | 0.18 mg/kg/week | 0.07 mg/kg/week |
| Serostim | Not indicated | 42<br>mg/week for cachexia with HIV only, in combination with antiretroviral therapy |
| Zomacton | 0.375 mg/kg/week | 0.0875 mg/kg/week |
| Zorbtive | Not indicated | 8mg for 28 days for short bowel syndrome only |

Discussion: B. Boehner disclosed a conflict and there were no speakers for this class. Motion was made to add qualifying diagnoses: symptomatic neonatal growth hormone deficiency and small gestational age by A. Blackmer, seconded by M. Noonan, motion passed.

**15. Intranasal Rhinitis Agents**

Preferred: Fluticasone Propionate (generic Flonase)
Budesonide OTC
Azelastine
Ipratropium
Triamcinolone acetonide (generic Nasacort, OTC)

Prior Authorization Criteria:

Non-preferred intranasal rhinitis agents will be approved if the member has failed treatment with 3preferred products (Failure is defined as: lack of efficacy with a 2 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred combination agents will be approved if member has trial of each individual agent and 1 additional agent. (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred intranasal rhinitis agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product (and 2 additional agents. (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions)

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**16. Leukotriene Modifiers**

Preferred: Montelukast tab and chewable tab

Prior Authorization Criteria:

Non-preferred Leukotrienes will be approved if **both** of the following criteria are met:

- Member failed treatment with montelukast in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
- Member has a diagnosis of Asthma

**Montelukast granules** will be approved if a member has tried and failed montelukast chewable tablets AND has difficulty swallowing.

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**17. Neurocognitive Disorder Agents**

Preferred: *Donepezil 5mg/10mg tablet and ODT
*Rivastigmine cap/patch
*Memantine tablets

Prior Authorization Criteria:

*Eligibility criteria for Preferred Agents – All preferred products will be approved without PA if the member has a diagnosis of neurocognitive disorder which can be verified by SMART PA.

Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred neurocognitive disorder agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as memantine and Namenda). (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions.

Members currently stabilized on a non-preferred product can receive approval to continue on that agent for one year if medically necessary and if there is a diagnosis of neurocognitive disorder.

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**18. Ophthalmic Allergy Agents**

Preferred:
Alrex (loteprednol)
Cromolyn
Ketotifen
Olopatadine 0.1% (generic Patanol)
Pazeo (olopatadine 0.7%)
Lastacaft (alcaftadine)

Prior Authorization Criteria:
Non-preferred Ophthalmic Allergy medications will be approved if the member has failed treatment with two preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

Non-preferred ophthalmic allergy agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product (such as preferred olopatadine 0.1% and non-preferred Patanol) and 1 additional agent. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**19. Ophthalmic Glaucoma Agents**

Preferred:
Alphagan P
Azopt
Brimonidine
Combigan
Dorzolamide
Dorzolamide/Timolol
Dorzolamide/Timolol PF
Latanoprost
Levobunolol
Lumigan
Timolol
Travatan Z

Prior Authorization Criteria:
Non-preferred agents will be approved with adequate trial and/or failure of 3 preferred products. One trial must be a preferred product with the same mechanism of action (for example prostaglandin analogues, Alpha2-adrenergic agonists, beta-blocking agents, carbonic anhydrase inhibitors, etc) as the non-preferred product being requested. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred combination products may be approved following adequate trial and/or failure of a preferred combination product AND an adequate trial of individual products in combination product being requested (if available) to establish tolerance. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred ophthalmic glaucoma agents with a preferred product with the same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product (such as preferred timolol and Timoptic) and 2 additional agents. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

Preservative free products may be approved with provider documentation of adverse effect to preservative-containing product.

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**20. Statins & Statin Combinations**

Preferred:
Atorvastatin
Lovastatin
Rosuvastatin
Pravastatin
Simvastatin

Prior Authorization Criteria:

Non-preferred Statin/Statin combinations will be approved if the member has failed treatment with two preferred products in the last 24 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

Children: Altoprev, Advicor, Livalo, and Vytorin will not be approved for members < 18 years of age. Caduet, fluvastatin and lovastatin will not be approved for clients < 10 years of age.

*Simvastatin 80mg dose products will only be covered for members who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in members who have not met cholesterol goals on simvastatin at doses up to 40mg per day. Please refer to the FDA communication titled, “FDA Drug Safety Communication: New restrictions, contraindications and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury” for updated guidance on contraindications, dose limits and relative LDL lowering doses of alternatives.

**Statin Combinations:**

Non-preferred Statin/Statin combinations will be approved if the member has failed treatment with two preferred products in the last 24 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**21. Topical Steroids**

Preferred:

**Low Potency:**
Fluocinolone acetonide cream
Hydrocortisone cream/oint/supp/lotion
Derma-Smoothe oil
Desonide cream/oint

**Medium Potency:**
Fluticasone cream/oint
Mometasone cream/oint/solution
Betamethasone Dipropionate lotion
Betamethasone Valerate oint
Triamcinolone cream/oint/lotion

**High Potency:**
Betamethasone Dipropionate/Propylene Glycol cream
Fluocinonide gel/solution
Triamcinolone cream/oint
Fluocinonide oint

**Very High Potency:**
Clobetasol Propionate cream/gel/oint/solution
Betamethasone Dipropionate/Propylene Glycol oint

Prior Authorization Criteria:

**Low Potency**

Non-preferred Low Potency topical corticosteroids will require adequate trial of 2 preferred agents of the same potency. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions)

**Medium Potency**

Non-preferred Medium Potency topical corticosteroids will require adequate trial of 2 preferred agents of the same potency. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

**High Potency**

Non-preferred High Potency topical corticosteroids will require adequate trial of 2 preferred agents of the same potency. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

*All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a moderate or low potency topical steroid after this time has elapsed.

**Very High Potency**
Non-preferred Very High Potency topical corticosteroids will require adequate trial and/or failure of clobetasol propionate in the same formulation as the non-preferred product being requested if possible. If formulation of non-preferred product is not available in preferred clobetasol propionate, then trial of any preferred clobetasol propionate is required. (Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions).

*All Very High Potency topical corticosteroids will require prior authorization beyond 2 weeks of therapy. If clobetasol propionate shampoo is being used to treat plaque psoriasis, then prior authorization will be required beyond 4 weeks of therapy. The provider will be encouraged to transition to a moderate or low potency topical steroid after this time has elapsed.

Discussion: Board members made no disclosures and there were no speakers for this class. This class was mass-reviewed. Motion was made to accept criteria with no changes by L. Claus, seconded by A. Blackmer, motion passed.

**Proposed ProDUR and Prior Authorization Criteria for Other Selected Products:**

22. **Trikafta (elexacaftor, tezacaftor, and ivacaftor)**

**Trikafta** may be approved if member meets all of the following criteria:

- Member is 12 years of age or older AND
- Member has at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CTFR*) gene
    - If member has one F508del mutation at the CTFR gene, the second allele must have a mutation that results in no CTFR protein OR a CTFR protein that is not responsive to ivacaftor and tezacaftor/ivacaftor

  AND
- Member continues to receive standard of care CF therapies (e.g., bronchodilators, inhaled antibiotics, dornase alfa, and hypertonic saline) AND
- Member does not have a history of colonization with organisms associated with a more rapid decline in pulmonary status including, but not limited to, *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus* AND
- Member must have liver function tests checked within 3 months without abnormal results (ALT, AST, ALP, or GGT ≥3 × ULN, or total bilirubin ≥2 × ULN) AND
- Baseline Forced Expiratory Volume (ppFEV$_1$) must be collected

Maximum dose: Trikafta 84 tablets per 28 days

Discussion: Kyle Tollefson, PhD provided testimony on behalf of Vertex. Edith Zemanick, MD provided testimony from Children's Hospital Colorado. Board members made no disclosures. Motion was made to accept criteria with above highlighted changes by S. VanEyk, seconded by A. Blackmer, motion passed.

**23. Exondys 51 (eteplirsen injection) AND Vyondys 53 (golodirsen)**

Vyondys 53 (golodirsen) OR Exondys 51 (etepliresen) will be approved if member meets all of the following criteria:

- Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
- Member must be at least six years of age for Vyondys or four years of age for Exondys AND
- Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND
- Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 53 skipping for Vyondys or to exon 51 skipping for Exondys AND
- Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. pediatric neurologist, cardiologist or pulmonary specialist) AND
- The patient must be on corticosteroids at baseline or has a contraindication to corticosteroids AND
- If the patient is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, patient must have a Brooke Upper Extremity Function Scale of five or less documented and OR a Forced Vital Capacity of 30% or more.

Maximum dose: Exondys 51 and Vyondys 53, 30mg/kg per week

Discussion: Leslie Zanetti , PharmD provided testimony on behalf of Sarepta. Anne Stratton, MD and Matthew Wicklund, MD provided testimony from the University of Colorado. Board members made no disclosures. Motion was made to accept criteria with above highlighted changes by A. Blackmer, seconded by M. Noonan, motion passed.