COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING OF THE COLORADO MEDICAID DUR BOARD MEETING
Health First Colorado, Colorado Medicaid, Drug Utilization Review Board
Department of Health Care Policy and Financing

February 9, 2021
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:03 pm by Board Chair M Noonan.

2. Roll Call / Introductions

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

a. **Members Present:** Michael Noonan, DO (Chair); Allison Blackmer, PharmD; Liza Claus, PharmD; Alison Shmerling, MD, MPH; Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; W Lai, PharmD, MBA (Industry Representative); Scott VanEyk, MD (joined at approximately 4:00 pm)
b. **Members Absent:** Miroslav Anguelov, PharmD
c. **Medicaid Pharmacy Staff:** Jeffrey Taylor, PharmD; Rachel Crane, PharmD, Jim Leonard, PharmD
d. **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

Today's meeting is being recorded. Board members are encouraged to keep video turned on for all or most of the meeting time. Speakers providing testimony who have signed up in advance will be unmuted by the meeting hosts at the appropriate times during review of the proposed criteria.

Board members are reminded to delete the meeting binder for today after the meeting has adjourned. Shaded lines on market share tables indicate the current preferred products on the preferred drug list (PDL). Red highlighting indicates proposed deletions and yellow highlighting indicates proposed additions.

J Rasmussen and N Tieu, DUR interns, will be managing many of the technical aspects of today's meeting.

Drug subclass 4.c in today's proposed criteria should be listed under Anti-Parkinson's Agents – Dopamine Agonists, not under Multiple Sclerosis agents.

4. Department Updates

J Taylor provided several updates from the Department:

The Department recently welcomed Dr. Peter Walsh as the new Chief Medical Officer (CMO) at HCPF.

DUR Board terms for Drs. Noonan, Blackmer, Shmerling and Lai are expiring on March 31, 2021. Thank you to these four Board members for their service! Those who wish to continue service with the Department may provide notification and an updated CV to Drs. Taylor and Rawlings. The industry representative serves a 1-year term, so this is Dr. Lai's last DUR meeting.

The Department will be undertaking a review and update of the DUR Board policies and procedures and training packet by March 31. Information about any changes made to those documents will be reviewed at the May Board meeting.

The next Board meeting is scheduled for Tuesday, May 11, 2021, from 1:00 pm to 5:00 pm, held virtually on Zoom.

J Taylor announced that some therapeutic classes may be moved in (or out) of Mass Review during today's meeting. Glucagon products will be pulled out of Mass Review and undergo a full review. The following classes will be added to today's Mass Review:

- Leukotriene Modifiers
- Anti-Parkinson's Agents (all except the Dopamine Agonist subclass)
- Multiple Sclerosis (MAO-B Inhibitor subclass)
- Sedative-Hypnotics
- Hemorrhoidal Agents
- Ophthalmics, Anti-inflammatory and Glaucoma subclasses

The Department will also be rolling out a new prior authorization process for physician administered drugs under the medical benefit. The pharmacist who manages this benefit for the Department is Dr. Rachele Crane. The drugs to be reviewed under this benefit are listed in the agenda, this section will be moved to the end of day's meeting.

The Board will be electing a new Chair and Vice Chair today. Board members may nominate themselves or other Board members for these officer positions.

5. Election of Board Chair and Vice Chair

For this particular officer election, the Chair will be a pharmacist and the Vice Chair will be a physician.

M Noonan nominated A Shmerling as Vice Chair. A Shmerling nominated A Blackmer as Chair. Dr. Noonan offered to continue to serve as Chair for today's meeting since it is held virtually and he already has the materials available for facilitating the meeting. The Board agreed to this arrangement with no objections.

M Noonan asked for a show of hands vote to elect A Blackmer as the new Board Chair. Her election to this officer position was approved unanimously. None opposed.

M Noonan asked for a show of hands vote to elect A Shmerling as the new Board Vice-Chair. Her election to this officer position was approved unanimously. None opposed.

6. Final Approval of Minutes from November 10, 2020 Meeting

M. Noonan asked if there were any changes to propose for minutes from the November 2020 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by T Brubaker, seconded by P Lanius. None opposed. Motion passed unanimously.

6. Reading of Rules for Public Testimony and Disclosure of Conflicts of Interest

J Taylor announced that thirty speakers registered in advance to provide testimony during today's meeting. He thanked the registered speakers for their involvement and participation in this public process. Due to the larger number of speakers Dr. Taylor mentioned that if there is an opportunity to abbreviate speaking time or give time back to the Board, it will be appreciated.

J Taylor read the following rules for Board members 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 verbally disclose all relationships to pharmaceutical manufacturers at the time they are speaking.

DUR Board Conflicts of Interest: DUR Board Members must verbally disclose any conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner. 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, he or she should not participate in the discussion of the agenda item or any vote regarding it.

7. Updates on Business from Last Meeting:

J Taylor announced that, in light of the number of registered speakers and the time constraints for today's meeting, this agenda item will be deferred.

9. New Business

R Page and J Rawlings proceeded to New Business and presenting criteria proposals

Proposed Criteria

1. Diabetes Management Classes, Insulins

1.a Rapid-Acting Insulins

Preferred Agents:

No PA Required

NOVOLOG (insulin aspart) cartridge, vial, FlexTouch
HUMALOG (insulin lispro) cartridge, vial, KwikPen, pen
HUMALOG JUNIOR (insulin lispro) KwikPen

Non-preferred products may be approved following trial and failure of treatment with two 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) may be approved if meeting the following criteria:
- Member is 18 years or older **AND**
- Member has trialed and failed treatment with two preferred products. (Failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects) **AND**
- Member must not have chronic lung disease such as COPD or asthma **AND**
- If member is a type 1 diabetic, must use in conjunction with long-acting insulin **AND**
- Member must not be a smoker

Scheduled testimony presentations:
- B Bentz, Eli Lilly, Lyumjev
- S Bhavsar, MannKind, Afrezza

Discussion

- W Lai reported a conflict of interest for this therapeutic class.
- A Shmerling asked about how to approach the management of new dosing forms when members are potentially unable to use the preferred route of administration, such as lacking the manual dexterity to inject insulin. L Claus shared that Afrezza is delivered via an inhaler and dexterity issues may also be associated with use of that drug delivery system, so it may not offer a significant advantage in that regard.
- A Shmerling asked about potential use of inhaled insulin for homeless members who may not have access to a refrigerator. L Claus added that insulin vials may also be stored outside of refrigeration for up to 28 days after they are first punctured. Freezing outdoor temperatures may be problematic, however.
- Motion made by A Shmerling to accept criteria for this class as written. Seconded by P Lanius. Motion passed unanimously.

1.b Short-Acting Insulins

Preferred Agents:

No PA Required

HUMULIN R (regular insulin) vial (OTC)
HUMULIN R concentrated (regular insulin) U-500 Kwikpen
HUMULIN R concentrated (regular insulin) U-500 vial
NOVOLIN R (regular insulin) vial (OTC)
NOVOLIN R (regular insulin) KwikPen (OTC)

Non-preferred products may be approved following trial and failure of treatment with one preferred product. (Failure is defined as allergy or intolerable side effects).

Discussion

- No Board members reported a conflict of interest for this therapeutic subclass.
- Motion made by L Claus to accept criteria for this class as written. Seconded by A Shmerling. Motion passed unanimously.

1.c Intermediate-Acting Insulins

Preferred Agents:

No PA Required

HUMULIN N (insulin NPH) vial (OTC)
HUMULIN N (insulin NPH) KwikPen(OTC)
NOVOLIN N (insulin NPH) vial (OTC)
NOVOLIN N (insulin NPH) KwikPen (OTC)

Non-preferred products may be approved following trial and failure of treatment with one preferred product. (Failure is defined as allergy or intolerable side effects).

Discussion

- No Board members reported a conflict of interest for this therapeutic subclass.
- Motion made by P Lanius to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

1.d Long-Acting Insulins

Preferred Agents:

No PA Required

LEVEMIR (insulin detemir) vial, FlexTouch
LANTUS (insulin glargine) vial, SoloStar

Non-preferred products may be approved if the member has failed treatment with LEVEMIR **AND** LANTUS (Failure is defined as allergy or intolerable side effects).

Scheduled testimony presentation:

- J Chardoulias, NovoNordisk, Tresiba

Discussion

- No Board members reported a conflict of interest for this therapeutic subclass.
- Motion made by T Brubaker to accept criteria for this class as written. Seconded by P Lanius. Motion passed unanimously.

1.e Insulin Mixtures

Preferred Agents:

No PA Required
HUMULIN MIX 70/30 vial, KwikPen (OTC)
HUMALOG MIX 50/50 vial, KwikPen
HUMALOG MIX 75/25 vial, KwikPen
NOVOLOG MIX 70/30 vial, FlexPen

Non-preferred products may be approved if the member has failed treatment with two of the preferred products. (Failure is defined as allergy or intolerable side effects).

Discussion

- No Board members reported a conflict of interest for this therapeutic subclass.
- Motion made by A Blackmer to accept criteria for this class as written. Seconded by T Brubaker. Motion passed unanimously.

2. Lipotropics

2.a Bile Acid Sequestrants

Preferred Agents:

No PA Required
Colesevelam tablet
Colestipol tablet
Cholestyramine/sucrose packet
Cholestyramine/aspartame (light) packet

Non-preferred bile acid sequestrates sequestrants may 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).

2.b Other Lipotropics

Preferred Agents:

No PA Required (*Must meet eligibility criteria)
Ezetimibe tablet
Fenofibrate capsule, tablet (generic LOFIBRA/TRICOR)
Gemfibrozil tablet
Niacin ER tablet

*****Omega-3 ethyl esters capsule (generic LOVAZA)

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

Non-preferred fibrates may 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).

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

LOVAZA (brand name) may be approved if meeting the following:

- 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 be approved if meeting the following:

- Member has a baseline triglyceride level > 500 mg/dL **AND**
- Member has failed an adequate trial of generic 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) **OR**
- VASCEPA (icosapent ethyl) is being prescribed to reduce CV risk for members on maximally tolerated statin therapy with triglyceride levels ≥ 150mg/dL and LDL-C levels between 41-100 mg/dL **AND** member meets one of the following:
    - Member is ≥ 45 years of age and has established atherosclerotic CV disease (such as coronary artery disease, cerebrovascular/carotid disease, peripheral arterial disease) **OR**
    - Member is ≥ 50 years of age with diabetes mellitus and has one or more of the following additional risk factors for CV disease:
        - Male ≥ 55 years of age, or female ≥ 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 (icosapent ethyl) 4g daily

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- T Brubaker commented that LOVAZA (omega-3 ethyl esters) is currently being recommended as part of some COVID-19 treatment protocols (inpatient and outpatient).
- Motion made by T Brubaker to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

3. Cardiovascular Agents

3.a Alpha Blockers

Preferred Agents:

No PA Required
Prazosin capsule

The non-preferred product may be approved if the member has trialed and failed the preferred product. (Failure is defined as lack of efficacy with 4 week trial, allergy or intolerable side effects).

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by L Claus to accept criteria for this class as written. Seconded by A Shmerling. Motion passed unanimously.

3.b Beta Blockers & Combinations

Preferred Agents:

No PA Required
Acebutolol capsule
Atenolol tablet
Atenolol-Chlorthalidone tablet
Betaxolol tablet
Bisoprolol tablet
Bisoprolol-HCTZ tablet
BYSTOLIC (nevibolol) tablet
Nadolol tablet
Carvedilol tablet
Carvedilol ER capsule
Labetalol tablet
Metoprolol succinate (ER) tablet
Metoprolol tartrate tablet
Metoprolol-HCTZ tablet
Nadolol tablet
Pindolol tablet
Propranolol tablet, oral solution
Propranolol ER capsule

3.c Beta Blockers, Antiarrhythmic

Preferred Agents:

No PA Required
Sotalol tablet
Sotalol AF tablet
SOTYLIZE (sotalol) solution

SOTYLIZE (sotalol) oral solution may be approved for members 3 days to < 5 years of age. For members ≥ 5 years of age, SOTYLIZE (sotalol) oral solution may be approved for members who cannot swallow a sotalol tablet. (Failure is defined as allergy or intolerable side effects.)

Maximum dose: 320 mg/day

Non-preferred beta blocker products may be approved if the member has failed treatment with two 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).

HEMANGEOL (propranolol) oral solution may be approved for members between 5 weeks and 1 year of age with proliferating infantile hemangioma requiring systemic therapy, after trial and failure of the preferred propranolol oral solution. (Failure is defined as allergy or intolerable side effects).

KAPSPARGO SPRINKLE (metoprolol succinate) extended-release capsule may be approved if member has difficulty swallowing or requires medication administration via a feeding tube.

Grandfathering: Members currently taking **timolol oral tablet** non-preferred products, may receive approval to continue on that product.

Table 1: Receptor Selectivity and Other Properties of Preferred Beta Blockers

	$ß_1$	$ß_2$	Alpha-1 receptor antagonist	Intrinsic sympathomimetic activity (ISA)
Acebutolol	X			X
Atenolol	X			
Betaxolol	X			
Bisoprolol	X			
Carvedilol	X	X	X	
Labetalol	X	X	X	
Metoprolol succinate	X			
Metoprolol tartrate	X			
Nadolol	X	X		
Nevibolol	X			
Pindolol	X	X		X
Propranolol	X	X		

Scheduled testimony presentation:

- D Bassett, Pierre Fabre, Hemangeol

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- T Brubaker mentioned that, in his past experience, pediatric patients had tolerated the adult oral solution formulation of propranolol well for dermatology indications.
- A Blacker stated that for the hemangioma indication in particular, Hemangeol, the alcohol-free propranolol oral solution designed for pediatric patients, is a safer and more appropriate product for use in children, especially the very young (< 2 years of age), T Brubaker concurred.
- Motion made by A Blackmer to strike "…after trial and failure of the preferred propranolol oral solution. (Failure is defined as allergy or intolerable side effects)" from the proposed criteria and retain "HEMANGEOL (propranolol**)** oral solution may be approved for members between 5 weeks and 1 year of age with proliferating infantile hemangioma requiring systemic therapy" and to accept criteria for this class with that change. Seconded by T Brubaker. Motion passed unanimously.

3.d Calcium Channel Blockers & Combinations

♦ Calcium Channel Blockers, Dihydropyridine (DHP)

Preferred Agents:

No PA Required
Amlodipine tablet
Felodipine ER tablet
Nifedipine IR capsule
Nifedipine ER tablet

All non-preferred dihydropyridine calcium channel blocker agents may be approved following trial and failure‡ of two preferred agents **AND** not exceeding the FDA-approved minimum age and maximum dose limits (Table 1). (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.)

NYMALIZE (nimodipine) oral syringe may be approved for adult members > 18 years of age with subarachnoid hemorrhage who also have a feeding tube or have difficulty swallowing solid dosage forms.

Maximum dose: 360 mg/day for 21 days (6 syringes/day or 126 syringes/21 days)

KATERZIA (amlodipine) suspension may be approved for members age ≥ 6 years of age who have a feeding tube or have difficulty swallowing solid oral dosage forms.

Maximum dose: 10 mg/day (adult), and 5 mg/day (pediatric)

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by P Lanius to accept criteria for this class as written. Seconded by A Shmerling. Motion passed unanimously.

♦ Calcium Channel Blockers, Non-Dihydropyridine (Non-DHP)

Preferred Agents:

No PA Required
Diltiazem tablet
Diltiazem ER capsule
Verapamil tablet
Verapamil ER tablet
Verapamil ER capsule

All non-preferred non-dihydropyridine calcium channel blockers may be approved following trial and failure of three preferred agents **AND** not exceeding the FDA-approved minimum age and maximum dose limits (Table 1). (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.)

Table 1: Cardiovascular Agents, Non-Solid Dosage Forms — Minimum Age and Maximum Dose				
Brand	**Generic**	**Dosage Form**	**Minimum Age**	**FDA Maximum Dose**
HEMANGEOL	Propranolol	Oral solution	—	1.7 mg/kg twice daily
KAPSPARGO SPRINKLE	Metoprolol succinate	Extended release sprinkle capsule	6 years	Adult: 200 mg daily Pediatric: 50 mg daily
KATERZIA	Amlodipine	Oral suspension	6 years	Adult: 10 mg daily Pediatric: 5 mg daily
—	Propranolol	Oral solution	—	320 mg daily
NYMALIZE	Nimodipine	Oral/enteral solution	> 18 years	360 mg daily for 21 days

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- J Taylor noted that Table 1 includes products from throughout the Cardiovascular agent class, so the Board may provide additional feedback specific to that table if needed. P Lanius noted that a minimum age was not included for Hemangeol in Table 1.
- Motion made by A Shmerling to accept criteria for this class as written. Seconded by T Brubaker. Motion passed unanimously.

4. Multiple Sclerosis Agents

4.a Multiple Sclerosis – Disease Modifying Therapies

Preferred agents

No PA Required (unless indicated*)
AVONEX (interferon beta 1a) injection
BETASERON (interferon beta 1b) injection
COPAXONE[BNR] (glatiramer) 20 mg injection
AUBAGIO (teriflunomide) tablet ****2nd Line*
GILENYA[BNR] (fingolimod) 0.5 mg tablet (30-ct bottle) ****2nd Line*
TECFIDERA[BNR] (dimethyl fumarate) tablet ****2nd Line*

*Second-line preferred agents (**GILENYA, TECFIDERA, AUBAGIO**) may be approved if meeting the following are met:

- Member has documented diagnosis of multiple sclerosis (MS) made by a neurologist within the last 3 years **OR** member has history of diagnosis made was diagnosed with MS by a neurologist >3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of multiple sclerosis **AND**
- Documentation is provided to support marked functional decline. This documentation must include either (1) a statement from the by prescribing neurologist, or (2) a statement from the prescriber that includes the or name of the neurologist consulted. may be indicated) supporting Documentation of marked functional decline as demonstrated by must include two of the following:
  - MRI evidence
  - Increase in EDSS scale score(s), or

    - mMedical chart record notes documentation of supporting increased disease burden of disease **AND**
- Prescriber attests to shared decision making with the member with respect to potential risks and versus benefits of taking GILENYA, TECFIDERA or AUBAGIO medical treatment **AND**
- Additional safety criteria for prescribed agent GILENYA, TECFIDERA or AUBAGIO are met (Table 1).

For members who do NOT meeting the above criteria above, second-line preferred agents (**GILENYA, TECFIDERA, AUBAGIO**) may be approved if meeting all of the following criteria are met:

- Member has a diagnosis of a relapsing form of multiple sclerosis confirmed on MRI by presence of new spinal lesions, cerebellar lesions, brain stem lesions, or change in brain atrophy **AND**
- Medication is being prescribed by a neurologist or in conjunction with consultation by with a neurologist **AND**
- Member has trialed and failed treatment with a preferred interferon product (AVONEX (interferon beta 1a) or BETASERON (interferon beta 1b) OR with COPAXONE (glatiramer). OR a preferred interferon product (Failure is defined as intolerable side effects, drug-drug interaction, or lack of efficacy)

AND

- Most recent MRI results showed the presence of new spinal lesions, cerebellar lesions, brain stem lesions, or change in brain atrophy **AND**
- On clinical exam, member has signs and symptoms consistent with functional limitations due to multiple sclerosis that have lasted lasting one month or longer **AND**
- Additional safety criteria for the prescribed agent are met (See Table 1).

Non-Preferred Products:

All other nNon-preferred products may be approved following trial and failure with three preferred products. **MAYZENT** (simponimod), **MAVENCLAD** (cladribine), and **VUMERITY** (dioroxemel fumarate) must also meet specific criteria listed for those agents below. All other non-preferred products may be approved following trial and failure with three preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions).

COPAXONE (glatiramer) **40mg** may be approved for members who have severe intolerable injection site reactions to brand COPAXONE 20mg (such as pain requiring local anesthetic, oozing, lipoatrophy, swelling, or ulceration).

MAYZENT (simponimod) may be approved if meeting all of the following:

- Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist **AND**
- Member has a diagnosis of a relapsing form of multiple sclerosis **AND**
- Member does not have diagnosis of macular degeneration **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 initiation of therapy **AND**
- Member has previous trial and failure of GILENYA (fingolimod) therapy. (Failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Additional safety criteria for prescribed agent are met (Table 1) **AND**
- Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of EDSS reduction of 1.0 point from baseline (or reduction of 0.5 points if baseline EDSS is 5.5-6.5).

MAVENCLAD (cladribine) may be approved if meeting all of the following:

- Medication is being prescribed by a neurologist or in conjunction with consultation by with a neurologist **AND**
- Member has a diagnosis of a relapsing form of multiple sclerosis **AND**
- Member has history of ≥ 1 relapse in the 12 months preceding initiation of therapy **AND**
- Member has previous trial and failure of three 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) **AND**
- Additional safety criteria for the prescribed agent are met (See Table 1).

VUMERITY (diroximel fumarate) may be approved if meeting all of the following:

- Medication is being prescribed by a neurologist or in conjunction with consultation with by a neurologist **AND**
- Member has a diagnosis of a relapsing form of multiple sclerosis **AND**
- Additional safety criteria for the prescribed agent are met (See Table 1) **AND**
- Member has previous trial and failure of TECFIDERA (dimethyl fumarate) therapy. (Failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects [if GI adverse events, must meet additional criteria below], or significant drug-drug interactions) **AND**
- If VUMERITY (diroximel fumarate) is being prescribed due to GI adverse events with TECFIDERA (dimethyl fumarate) therapy (and no other reason for failure of TECFIDERA is given), then the following additional criteria must be met:
    - Member has trialed a temporary dose reduction of TECFIDERA (with maintenance dose being resumed within 4 weeks) **AND**
    - Member has trialed taking TECFIDERA (dimethyl fumarate) with food **AND**
    - GI adverse events remain significant despite maximized use of gastrointestinal symptomatic therapies (such as calcium carbonate, bismuth subsalicylate, PPIs, H2 blockers, anti-bloating/anti-constipation agents, anti-diarrheal, and centrally acting anti-emetics) **AND**
    - Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of clinically significant reduction in GI adverse events with VUMERITY (diroximel fumarate) therapy.

BAFIERTAM (monomethyl fumarate DR) capsule may be approved if meeting all of the following:

- Medication is being prescribed by a neurologist or in consultation with a neurologist **AND**
- Member has a diagnosis of a relapsing form of multiple sclerosis **AND**
- Additional safety criteria for the prescribed agent are met (See Table 1) **AND**
- Member has previous trial and failure of TECFIDERA (dimethyl fumarate) therapy. (Failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects [if GI adverse events, must meet additional criteria below], or significant drug-drug interactions) **AND**
- If BAFIERTAM (monomethyl fumarate DR) is being prescribed due to GI adverse events with TECFIDERA (dimethyl fumarate) therapy (and no other reason for failure of TECFIDERA is given), then the following additional criteria must be met:
    - Member has trialed a temporary dose reduction of TECFIDERA (with maintenance dose being resumed within 4 weeks) **AND**
    - Member has trialed taking TECFIDERA (dimethyl fumarate) with food **AND**
    - GI adverse events remain significant despite maximized use of gastrointestinal symptomatic therapies (such as calcium carbonate, bismuth subsalicylate, PPIs, H2 blockers, anti-bloating/anti-constipation agents, anti-diarrheal, and centrally acting anti-emetics) **AND**

- Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of clinically significant reduction in GI adverse events with BAFIERTAM (monomethyl fumarate DR) therapy.

Table 1: Safety Criteria for Select Agents AUBAGIO, GILENYA, and TECFIDERA	
TECFIDERA (dimethyl fumarate)	• Member has no active infections **AND** • Member has had a CBC with differential drawn within the six months prior to initiating therapy **AND** • Member does not severe hepatic impairment and/or a serum alanine aminotransferase (ALT) greater than two times the upper limit of normal within the 6 months prior to initiating therapy • Member does not have a bilirubin level greater than 2 times the upper limits of normal within the 6 months prior to initiating therapy **AND** • Member has been counseled to withhold TECIFDERA (dimethyl fumarate) therapy at first sign or symptoms of anaphylaxis, angioedema, or progressive multifocal leukoencephalopathy (PML) Maximum dose: 240 mg twice a day (adults)
AUBAGIO (teriflunomide)	• Member has no active infections **AND** • For female mMembers is of childbearing age potential, have and has a negative pregnancy test at baseline **AND** is using a form of highly effective contraception (such as long-acting reversible contraception) **AND** • Member has transaminase and bilirubin levels with ALT < 2 times does not have severe hepatic impairment and/or a serum ALT, AST or bilirubin greater than two times the upper limit of normal within the 6 months prior to initiating therapy **AND** • Member has had a CBC with differential drawn within the six months prior to initiating therapy **AND** • Member has a documented baseline blood pressure **AND** • Member has been evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative test) or blood test. of a tuberculin skin test or blood test for *Mycobacterium tuberculosis* Maximum dose: 14 mg per day (adults)
GILENYA (fingolimod)	• Member has no active infections **AND** • Member does not have a 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** • Member 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** • Member has a baseline QTc interval < 500 ms prior to starting therapy **AND** • Member is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication **AND**

	• Member does not have severe hepatic impairment and/or a serum ALT, AST or bilirubin greater than two times the upper limit of normal within the 6 months prior to initiating therapy, and will have these labs drawn periodically throughout therapy until two months after discontinuation of GILENYA (fingolimod) **AND** • Member has an ophthalmologic evaluation (ocular coherence test) prior to starting therapy, and will have follow up within 3 to 4 months after therapy is initiated **AND** Maximum Dose: ≥ 10 years of age and > 40 kg body weight: 0.5 mg once daily ≥ 10 years of age and ≤ 40 kg body weight: 0.25 mg once daily
MAYZENT (simponimod)	• Member does not have one of the following contraindications: ○ CYP2C9*3/*3 genotype ○ In the last 6 months, has experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III or IV heart failure ○ Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker **AND** • Member has a baseline QTc interval < 500 ms prior to starting therapy **AND** • Member has no active infections **AND** • Member has not had a hypersensitivity reaction to GILENYA (fingolimod) **AND** • Member has had baseline complete blood count (CBC) with differential and liver function tests conducted prior to initiating therapy • Has had an ophthalmic evaluation that includes a macula exam • Member is of childbearing potential and has a negative pregnancy test at baseline **AND** is using highly effective contraceptive (such as long-acting reversible contraception) Maximum Dose: 60 mg per 30 days (adults)
MAVENCLAD (cladribine)	• Has no active infections **AND** • Does not have chronic infections (such as hepatitis, tuberculosis, HIV) • Does not have current evidence of malignancy **AND** • Has liver function tests drawn prior to first and second treatment course due to potential for liver injury • Member has CBC with differential drawn prior to, during at two and six months post-initiation, and periodically thereafter due to risk of lymphopenia and hematologic toxicity **AND** ○ Lymphocytes must be: ▪ within normal limits before initiating the first treatment course ▪ ≥ 800 cells per microliter before initiating the second treatment course • Member is not currently taking immunosuppressive or myelosuppressive therapy **AND**

	• If member is of childbearing potential, has a negative pregnancy test at baseline **AND** If female, has a negative pregnancy test within 30 days and is not breastfeeding **AND** • Men and women of childbearing potential must have plan to use effective contraception during MAVENCLAD therapy and 6- for at least six months after the last dose of MAVENCLAD therapy Maximum Dose: Not exceeding 3.5mg/kg during full treatment course
VUMERITY (dioroxemel fumarate)	• Member has not had hypersensitivity reaction or angioedema as a result of TECFIDERA (dimethyl fumarate) or diroximel fumarate, or BAFIERTAM (monomethyl fumarate DR) therapy or any excipients of VUMERITY **AND** • Member Is not currently on TECFIDERA (dimethyl fumarate) therapy **AND** • Member has no active herpes zoster or other serious infections **AND** • Member has had a complete blood count with differential within the six months prior to initiating therapy **AND** • Member has had a liver function test drawn prior to treatment course due to potential for liver injury Maximum dose: 924 mg per day
BAFIERTAM (monomethyl fumarate DR)	• Member has not had a hypersensitivity reaction or angioedema as a result of TECFIDERA (dimethyl fumarate) or VUMERITY (diroximel fumarate) or any excipients **AND** • Member is not currently taking TECFIDERA (dimethyl fumarate) or VUMERITY (diroximel fumarate) therapy **AND** • Member has no active herpes zoster or other serious infections **AND** • Member has had a complete blood count with differential within the six months prior to initiating therapy **AND** • If member is of childbearing potential, has a negative pregnancy test at baseline **AND** is using highly effective contraception (such as long-acting reversible contraception) • Prescriber confirms that member has had liver function tests conducted within the 6 months prior to initiating therapy AND bilirubin, ALT and AST are not greater than 2 times the upper limit of normal AND these lab tests will be drawn periodically throughout BAFIERTAM (monomethyl fumarate DR) therapy as clinically indicated

Grandfathering**:** Members currently stabilized on a preferred second-line product or a nonpreferred product may receive approval to continue therapy with that agent.

Scheduled testimony presentations:

- M Sommers, Novartis, Mayzent – speaker relinquished time
- M Sommers, Novartis, Kesimpta
- R Gross, Assistant Professor, CU Department of Neurology, Kesimpta
- G Okano, Bristol Myers Squibb, Zeposia
- C Hulstein, clinical pharmacist at UCHealth Neurology/Rocky Mountain Multiple Sclerosis Center
- Letter – J Bainbridge, CU Skaggs School of Pharmacy, Kesimpta

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling noted that the criteria for this class are rather complex and dense. Specifically removing information about indications for use, baseline assessments and monitoring parameters and trusting individual providers to manage those areas might be helpful.
- P Lanius contributed concerns that language regarding accurate diagnosis, neurologist involvement, safety criteria, and shared decision making with members needs to be preserved.
- A Blackmer and M Noonan asked if this MS therapeutic class could be added back to the May 2021 meeting agenda to allow more time for review and expert input. J Taylor acknowledge that this would be a novel situation; however, he will take that suggestion back to the Department for further discussion. J Leonard added that the proposed unique workflow is not currently an option. J Taylor assured the Board that these criteria will undergo additional stringent review internally, as well as with the HCPF Chief Medical Officer before they are finalized for posting on the PDL.

- T Brubaker moved, and A Shmerling seconded, a motion with the following components:
  - The DUR Board strongly recommends opening up access so that all preferred MS agents may be used first line, while recognizing the importance of neurology consultation, appropriate diagnosis of multiple sclerosis, and following all relevant safety criteria.
  - The Board also recommends that these criteria be reviewed specifically as related to use of the EDSS Scale for patient assessments.
  - Motion passed unanimously. No objections.

- P Lanius moved to reduce the number of products trialed and failed before approval of a non-preferred product in this subclass be reduced three products to one product. Seconded by L Claus. Motion was passed unanimously by the five Board members present. T Brubaker was away from his computer at this time.

- Motion made by L Claus to remove the bullet under Mayzent criteria that states “Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of EDSS reduction of 1.0 point from baseline (or reduction of 0.5 points if baseline EDSS is 5.5-6.5).” Motion seconded by A Shmerling. Motion passed unanimously. No objections.

4.b Multiple Sclerosis – Symptom Management Therapies

Preferred agents

PA Required

NONE

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 (T25-FW) assessment **OR** has established a baseline activities of daily living (ADLs) **AND**
- Member has no history of seizure disorder **AND**
- Member has no history of moderate to severe renal dysfunction (CrCl > 50 mL/min) **AND**
- Prescriber is a neurologist or is prescribed in conjunction consultation with a neurologist **AND**
- The prescribed dose does not exceed 10 mg twice daily

Reauthorization of AMPYRA Extended coverage of AMPYRA (dalfampridine) for up to one year may be approved if documentation shows improvement in ambulation (measured by T25-FW assessment) or improvement in ADLs after three months of therapy.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by A Shmerling to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

4.c Dopamine Agonists

Preferred agents

No PA Required

Pramipexole IR tablet

Ropinirole IR tablet

Non-preferred agents may be approved with adequate trial and 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).

APOKYN (apomorphine injection cartridges) may be approved if meeting the following:

- APOKYN (apomorphine) is being used as an adjunct to other medications for acute, intermittent treatment of hypomobility, “off” episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson’s disease **AND**
- Due to the risk of profound hypotension and loss of consciousness, member is not concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron.

Maximum dose: 6mg (0.6mL) three times per day

KYNMOBI (apomorphine sublingual film) may be approved if meeting the following:

- KYNMOBI (apomorphine) is being used for the acute, intermittent treatment of “off” episodes in patients with Parkinson's Disease
- Due to the risk of profound hypotension and loss of consciousness, member must not be concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron.

Maximum dose: 30mg five times per day

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 therapy criteria.

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.

Scheduled testimony presentation:

- B O’Neill, Sunovion, Kynmobi

Discussion

- No Board members reported a conflict of interest for this therapeutic class.

- J Taylor clarified that Apokyn and Kynmobi (apomorphine products) have their own freestanding drug utilization criteria and do not fall under the more general criteria for non-preferred agents in this class.
- Motion made by P Lanius to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

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

Preferred agents

PA Required for all agents

*****AIMOVIG (erenumab) autoinjector

*****EMGALITY 120mg (galcanezumab) pen, syringe

*****EMGALITY 120mg (galcanezumab) or AIMOVIG (erenumab) may be approved for members meeting Migraine Prevention Prior Authorization Criteria below.

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

- Member is 18 years of age or older **AND**
- Member is in needs of preventive therapy of for episodic or chronic migraine **AND**
- Member has diagnosis of migraine with or without aura **AND**
- Member has tried and failed 2 oral preventative pharmacologic agents listed as Level A per American Headache Society/American Academy of Neurology (i.e. such as 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 does not have history of MI, stroke, TIA, unstable angina, coronary artery bypass surgery, or other revascularization procedures within previous 12 months **AND**
- Prescription meets one of the following:
  - Medication is not prescribed for chronic migraine with medication overuse headache **OR**
  - Member is prescribed AIMOVIG for chronic migraine with medication overuse headache resulting from using triptans ≥ 10 days/month, non-narcotic analgesics ≥ 15 days/month (such as acetaminophen, NSAID), or a combination of analgesics ≥ 10 days/month (including non-narcotic, ergot, opioid, butalbital) **AND** member has not been using a migraine prevention medication for 2months prior to AIMOVIG prescription **AND**
- 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)

Non-Preferred Medications for Migraine Prevention:

Non-preferred medications for migraine prevention may be approved if the member meets the Migraine Prevention Prior Authorization Criteria above **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).

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

Non-Preferred Medications for Acute Migraine Treatment or Cluster Headache Treatment:

Non-preferred medications for acute migraine treatment (UBRELVY) may be approved for members meeting all of the following:

- Member is 18 years of age or older **AND**
- Medication is being prescribed to treat migraine headache with moderate to severe pain **AND**
- Member is not receiving an injectable form of CGRP medication for any indication **AND**
- Member has history of trial and failure of all of the following. (Failure is defined as lack of efficacy with 4-week trial, contraindication, allergy, intolerable side effects, or significant drug-drug interaction):
    - Three triptans (including at least two different routes of administration)
      AND
    - Two NSAID agents **AND**
    - Dihydroergotamine vial or an ergotamine combination product

Non-preferred medications for treatment of cluster headache (EMGALITY 100mg) may be approved for members meeting all of the following:

- Member is 19-65 years of age **AND**
- Member meets diagnostic criteria for episodic cluster headache (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 this medication being prescribed) **AND**
- Member is not taking other preventative medications to reduce the frequency of cluster headache attacks **AND**
- Member has history of trial and failure of all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication, allergy, intolerable side effects, or significant drug-drug interaction):
    - Oxygen therapy **AND**
    - Sumatriptan subcutaneous or intranasal **AND**
    - Zolmitriptan intranasal **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**
    - Member does not have a history within the last 6 months 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. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4 week period.

Maximum Dosing:
AIMOVIG (erenumab): 140 mg per in 30 days
EMGALITY 120 mg (galcanezumab): 240 mg once as first loading dose, then 120 mg monthly
EMGALITY 100 mg (galcanezumab): 300 mg per every 30 days during cluster headache period
AJOVY (fremanezumab): 225 mg monthly or 675 mg every three months
UBRELVY 50 mg (ubrogepant): 16 tablets/30 days (800 mg per in 30 days)
UBRELVY 100 mg (ubrogepant): 16 tablets/30 days (1600 mg per in 30 days)

Scheduled testimony presentations:

- B Bentz, Eli Lilly, Emgality
- J Shear, Teva, Ajovy
- J Gianninoto, AbbVie, Ubrelvy
- Z Glasscock, DNP-BC, Pueblo,CO, Ubrelvy
- M Faithe, Amgen, Aimovig (relinquished his time)
- C Leroue, Biohaven, Nurtec
- Letter – C Kutz, PhD, PA-C, Colorado Springs (CGRPi class)
- Letter – A Ross, FNP, AQH, St. Mary's Neurology, Grand Junction, CO (Nurtec)
- Letter – Creekside Physical Medicine, Boulder, CO (Nurtec)
- Letter – A Komatineni, NorthStar Neurology, Colorado Springs, CO (Nurtec)
- Letter – H Bui, Lakewood Medical Center, Lakewood, CO (Nurtec)
- Letter – CSNA group, Colorado Springs, CO (Nurtec)
- Letter – R Barnhart, PharmD, BCPP, UCHealth Neurology Clinic (CGRPi class)

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- M Noonan noticed recommendations in stakeholder input to require trial and failure of two triptans prior to approval of a CGRP inhibitor, rather than trial and failure of three triptans. L Claus agrees with these recommendations, as they are more in line with American Headache Society guidance.
- M Noonan raised a question about the concomitant use of CGRP inhibitors (using an acute treatment CGRP inhibitor product while the member is also receiving a preventative CGRP inhibitor).
- A Shmerling asked whether the CO Medicaid benefit covers home oxygen for members with cluster headache, since that language is included in the current criteria. J Taylor confirmed that there are covered home oxygen options available under those circumstances.
- L Claus made a motion for the following changes, seconded by T Brubaker:
  - Under the non-preferred agents section, strike “UBRELVY” from the sentence “Non-preferred medications for acute migraine treatment (UBRELVY) may be approved for members meeting all of the following:”
  - Reduce triptan trial and failure from three triptans to two triptans
  - Remove the requirement for two or more different routes of administration
  - Remove the NSAID and dihydroergotamine/ergotamine trials required to receive approval for a CGRP inhibitor.
  - Motion passed unanimously.
- L Claus made a motion to delete this sentence from the criteria: ““AND member has not been using a migraine prevention medication for 2 months prior to AIMOVIG prescription.” Seconded by A Shmerling. Motion passed unanimously.
- L Claus made a motion to delete this line from the non-preferred CGRP inhibitor acute therapy section: “Member is not receiving an injectable form of CGRP medication for any indication **AND**…**”** Seconded by A Blackmer. Motion passed unanimously.

- A Shmerling moved to approve the criteria in this class as amended. Seconded by Brubaker. Motion passed unanimously. No objections.

6. Atypical Antipsychotics

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.

For injectable Atypical Antipsychotics please see Appendix P for criteria

Preferred agents

No PA Required*
Aripiprazole tablet
Clozapine tablet
LATUDA (lurasidone)** ****2nd line****
Olanzapine tablet, ODT
Quetiapine IR tablet***
Quetiapine ER tablet
Risperidone tablet, oral solution, ODT
Ziprasidone

Non-preferred products may be approved for members meeting all of the following:

- Medication is being prescribed for an FDA-Approved indication (Table 1) **AND**
- Prescription meets dose and age limitations (Table 13) **AND**
- Member has history of trial and failure of three 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 13). Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for grandfathering. **Atypical Antipsychotic prescriptions for members under 5 years of age may require a provider-provider telephone consultation with a child and adolescent psychiatrist (provided at no cost to provider or member).**

****LATUDA (lurasidone)** may 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 (<150 mg/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 may be approved for members 10-17 years of age with approved diagnosis (Table 13) stabilized on <150 mg quetiapine IR per day.

******Aripiprazole solution**: Aripiprazole tablet quantity limit is 2 tablets/day for pediatric members to allow for incremental dose titration and use of the preferred tablet formulation should be considered for dose titrations when possible and clinically appropriate. If incremental dose cannot be achieved with titration of the aripiprazole tablet for members < 18 years of age **OR** for members unable to swallow solid tablet dosage form, aripiprazole solution may be approved. For all other cases, aripiprazole solution is subject to meeting non-preferred product approval criteria listed above.

NUPLAZID (pimavanserin tartrate) may be approved for the treatment of hallucinations and delusions associated with Parkinson's Disease psychosis **AND** following trial and failure of therapy with quetiapine or clozapine. (Failure is defined as intolerable side effects, drug-drug interaction, or lack of efficacy).

ABILIFY MyCite may be approved if meeting all of the following:

- Member has history of adequate trial and failure of 5 preferred agents (one trial must include aripiprazole tablet). Failure is defined as lack of efficacy with 6-week trial on maximally tolerated dose, allergy, intolerable side effects, significant drug-drug interactions **AND**
- Information is provided regarding adherence measures being recommended by provider and followed by member (such as medication organizer or digital medication reminders) **AND**
- Member has history of adequate trial and failure of 3 long-acting injectable formulations of atypical antipsychotics, one of which must contain aripiprazole. (Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, significant drug-drug interactions) **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.

Quantity Limits: Quantity limits Maximum dose limitations will may be applied to all products (Table 12). 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 may receive approval to continue therapy with that agent for one year.

[Three clinical tables were combined into one]

Brand (generic)	FDA-Approved Indication(s)
ABILIFY (aripiprazole)	• Schizophrenia • Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder • Adjunctive Treatment of Major Depressive Disorder • Irritability Associated with Autistic Disorder • Treatment of Tourette's Disorder
CAPLYTA (lumateperone)	• Schizophrenia
FANAPT (iloperidone)	• Acute treatment of Schizophrenia in adults
FAZACLO, VERSACLOZ (clozapine)	• Treatment-resistant schizophrenia • Reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder
GEODON (ziprasidone)	• Schizophrenia • Bipolar I Disorder (Acute Mixed or Manic Episodes and Maintenance Treatment as an Adjunct to Lithium or Valproate) • Acute treatment of agitation in schizophrenia
LATUDA (lurasidone)	• Schizophrenia • Bipolar 1 Disorder
NUPLAZID (pimavanserin)	• Hallucinations and delusions associated with Parkinson's disease psychosis
INVEGA	• Schizophrenia

(paliperidone)	• Schizoaffective disorder
RISPERDAL (risperidone)	• Schizophrenia • Bipolar Mania • Irritability associated with autistic disorder
REXULTI (brexpiprazole)	• Adjunctive therapy to antidepressants for the treatment of major depressive disorder • Schizophrenia
SAPHRIS (asenapine)	• Acute and maintenance of Schizophrenia • Bipolar 1 disorder • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex
SEROQUEL (quetiapine) AND SEROQUEL XR (quetiapine ER)	• Treatment of schizophrenia • Acute treatment of manic or mixed episodes associated with bipolar I disorder, as monotherapy or as an adjunct to lithium or divalproex • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex • Adjunctive treatment of major depressive disorder (MDD) (Seroquel XR only)
SYMBYAX (olanzapine /fluoxetine)	• Treatment resistant depression • Bipolar 1 disorder
VRAYLAR (cariprazine)	• Schizophrenia • Bipolar 1 disorder acute treatment • Bipolar disorder depressive episodes
ZYPREXA (olanzapine)	• Schizophrenia • Bipolar 1 disorder

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

Brand (generic)	FDA Approved Indications	FDA Approved Age	Maximal FDA Approved Dose
GEODON (ziprasidone)	APPROVED FOR ADULTS ONLY		
SAPHRIS and (asenapine)			
VRAYLAR (cariprazine)			
FAZACLO, CLOZARIL (clozapine)			
FANAPT (iloperidone)			
LATUDA (lurasidone)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia Gilles de la Tourette's syndrome	6-17 years 10-17 years 13-17 years 6-17 years	15mg/day 30mgday 30mg/day 20 mg/day
ABILIFY (aripiprazole)	Schizophrenia Bipolar mania Irritability associated with autistic disorder Tourette's disorder	13-17 years 10-17 years 6-17 years 6-17 years	30mg/day 30mg/day 15mg/day 20mg/day
ZYPREXA, (olanzapine)	Schizophrenia Bipolar 1 disorder	13-17 years 13-17 years	20 mg/day 20 mg/day
ZYPREXA ZYDIS (olanzapine)	Schizophrenia Bipolar Disorder/Mania	13-17 years 13-17 years	10mg/day 10mg/day
INVEGA ER (paliperidone)	Schizophrenia	12-17 years	12mg/day
RISPERDAL (risperidone)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia	5-16 years 10-17 years 13-17 years	3mg/day 6mg/day 6mg/day
SEROQUEL (quetiapine fumarate)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years 10-17 years	800 mg/day 600 mg/day

Table 1 Atypical Antipsychotics – FDA Approved Age Range and Maximum Dose				
Brand	**Generic**	**Approved Indications**	**Age Range**	**Maximum Daily Dose**
ABILIFY	aripiprazole	Schizophrenia Bipolar I Disorder (adult) Bipolar I Disorder (peds) Irritability w/autistic disorder Tourette's disorder	≥ 13 years ≥ 18 years 10-17 years 6-17 years 6-18 years	30 mg 30 mg 15 mg 15 mg 20 mg
CLOZARIL	clozapine	Treatment-resistant schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg
CAPLYTA	lumateperone	Schizophrenia	≥ 18 years	42 mg
FAZACLO	clozapine	Treatment-resistant Schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg
FANAPT	iloperidone	Schizophrenia	≥ 18 years	24 mg
GEODON	ziprasidone	Schizophrenia Bipolar I Disorder	≥ 18 years ≥ 18 years	200 mg 160 mg
INVEGA	paliperidone	Schizophrenia & schizoaffective disorder	≥ 12 years and weight ≥ 51 kg ≥ 12 years and weight < 51 kg	12 mg 6 mg
LATUDA	lurasidone	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar I disorder (adult) Bipolar I disorder (peds)	≥ 18 years 13-17 years ≥ 18 years 10–17 years	160 mg 80 mg 120 mg 80 mg
NUPLAZID	pimavanserin	Parkinson's disease psychosis	≥ 18 years	34 mg
RISPERDAL	risperidone	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar mania (adult & peds) Irritability w/autistic disorder	≥ 18 years 13-17 years ≥ 10 years 5–17 years	1600mg 6 mg 6 mg 3 mg
REXULTI	brexpiprazole	Schizophrenia (adult) Adjunctive treatment of MDD	≥ 18 years	4 mg 3 mg
SAPHRIS	asenapine	Schizophrenia (adult) Bipolar mania or mixed episodes	≥ 10 years ≥ 10 years	20 mg 20 mg
SECUADO	asenapine patch	Schizophrenia (adult)	≥ 18 years	7.6 mg/ 24 hours
SEROQUEL	quetiapine	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar I mania or mixed (adult) Bipolar I mania or mixed (peds) Bipolar I depression (adults) Bipolar I Disorder Maintenance	≥ 18 years 13-17 years ≥ 18 years 10-17 years ≥ 18 years ≥ 18 years	750 mg 800 mg 800 mg 600 mg 300 mg 800 mg
SEROQUEL XR	quetiapine ER	Schizophrenia (adult/adolescent) Bipolar I mania (adult) Bipolar I mania (peds) Bipolar I depression (adults)	≥ 13 years ≥ 18 years 10-17 years ≥ 18 years	800 mg 800 mg 600 mg 300 mg

		Adjunctive treatment of MDD	≥ 18 years	300 mg
SYMBYAX	olanzapine/ fluoxetine	Acute depression in Bipolar I Disorder Treatment resistant depression (MDD)	≥ 10 years	12 mg olanzapine/ 50 mg fluoxetine
VRAYLAR	cariprazine	Schizophrenia Acute manic or mixed episodes with Bipolar I Disorder Depressive episodes with Bipolar I disorder	≥ 18 years ≥ 18 years ≥ 18 years	6 mg 6 mg 3 mg
ZYPREXA ZYPREXA ZYDIS	olanzapine	Schizophrenia Acute manic or mixed episodes with Bipolar I Disorder	≥ 13 years	20 mg

Scheduled testimony presentations:

- T McKinley, Otsuka, Rexulti
- D Smith, Psychiatric Nurse Practitioner, Pueblo, CO, Vraylar
- J Gianninioto, AbbVie, Vraylar
- T Skinner, Psychiatric Nurse Practioner,
- L Sanders, MD, Psychiatrist, Denver, CO, Vraylar
- Letter – John Hardy, MD, Psychiatrist, Rexulti

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- P Lanius asked about the requirement to trial/failure three preferred agents for approval of a non-preferred agent; however, for some indications are FDA approved for only two preferred drug products within this class (such as the adjunctive treatment of major depressive disorder).
- Motion made by P Lanius to change this phrase under non-preferred product criteria to say, “Member has history of trial and failure of two preferred products” to reduce the number of trials/failures of preferred products from three to two. Seconded by A Blackmer. Motion passed unanimously.

7. Anxiolytics

7.a Anxiolytics, Benzodiazepine

Preferred agents

Alprazolam IR tablet
Alprazolam ER tablet
Chlordiazepoxide capsule
Clorazepate tablet
Diazepam tablet, oral solution
Lorazepam tablet, oral concentrated solution
Oxazepam capsule

All non-preferred oral agents may be approved following trial and failure of three preferred agents. (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.)

Children: Prior authorization will be required for all anxiolytic agents when prescribed for children <18 years of age and may be approved with prescriber verification of necessity of use for member age.

All benzodiazepine anxiolytics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy.

Grandfathering: Members <65 years of age who are currently stabilized on a non-preferred benzodiazepine medication may receive authorization to continue that medication.

Prior authorization will be required for prescribed doses that exceed the maximum (Table 1).

Table 1 Benzodiazepine Anxiolytics Maximum Doses

Product	Maximum Daily Dose	Maximum Monthly Dose
Alprazolam tablet Alprazolam ER tablet Alprazolam ODT XANAX (alprazolam) tablet XANAX XR (alprazolam ER) tablet Alprazolam Intensol oral concentrate 1 mg/mL	Adults ≥ 18 years: 10 mg/day	Total of 300 mg from all dosage forms per 30 days
Clorazepate tablet TRANXENE (clorazepate) T-Tab	>12 years: 90 mg/day Children 9-12 years: up to 60 mg/day	Total of 2,700 mg (adults) and 1,800 mg (children) from all tablet strengths per 30 days
Chlordiazepoxide capsule	Adults ≥ 18 years: 300 mg/day Children 6-12 years: up to 40 mg/day (pre-operative apprehension and anxiety)	Total of 3,000 mg (adults) and 120 mg (children, pre-op therapy) from all tablet strengths per 30 days
Diazepam Intensol oral concentrate 5 mg/mL Diazepam solution Diazepam tablet	Adults ≥ 18 years: 40 mg/day Children 6 months to 18 years: up to 10 mg/day	Total of 1200 mg (adults) and 300 mg (pediatrics) from all dosage forms per 30 days
ATIVAN (lorazepam) Intensol concentrate 2 mg/mL ATIVAN (lorazepam) tablet Lorazepam oral concentrate Lorazepam tablet	Adults ≥ 18 years: 10 mg/day	Total of 300 mg (adults) from all dosage forms per 30 days
Oxazepam capsule	Adults ≥ 18 years: 120 mg/day (alcohol-related indications) Children 6-12 years: maximum dose not established	Total of 300 mg (adults) from all dosage forms per 30 days

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Blackmer had concerns that since diazepam is used for muscle spasm, spasticity, dystonia and/or seizure control in pediatric patients, often those who have cerebral palsy or traumatic brain injury, which are FDA approved uses, requiring a prior authorization for diazepam for all members < 18 years of age would potentially create access issues (delayed access) in this subset of members receiving the care that they need. An additional consideration is that diazepam is not a drug that should be stopped abruptly. J Taylor offered that the Department could consider creating auto-PAs for specific ICD-10 codes in order to grandfather pediatric members already stable on a benzodiazepine for one of the indications above.
- A Blackmer also raised a concern about the 10mg/day maximum dose for diazepam. This dose limit will be quickly exceed by adolescent members, particularly those using diazepam to manage severe spasticity, since usual dosing would be in the range of 10 mg three to four times per day.
- Motion was made by A Blackmer for members (pediatric and adult) using diazepam for muscle spasm associated with spasticity, spasticity, dystonia and/or seizures, no prior authorization will be required and the dose limits to not apply. Seconded by S VanEyk. Motion passed unanimously.

- Motion was made by L Claus, seconded by P Lanius to accept criteria as amended. Motion passed unanimously.

7.b. Anxiolytics, Non-Benzodiazepine

Preferred agents

NO PA REQUIRED

Buspirone tablet

Non-preferred oral agents may be approved following trial and failure of buspirone. (Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.)

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by L Claus to accept criteria for this class as written. Seconded by P Lanius. Motion passed unanimously.

8. Ophthalmics, Anti-Inflammatory

8.a NSAIDs

Preferred Agents

No PA Required

ACUVAIL (ketorolac)

Bromfenac 0.09%

Diclofenac 0.1%

Flurbiprofen 0.03%

ILEVRO (nepafenac) 0.3%

Ketorolac 0.5%

Ketorolac LS 0.4%

8.b Corticosteroids

Preferred Agents

No PA Required

FLAREX (fluorometholone) 0.1% drops

Fluorometholone 0.1% drops

FML FORTE (fluorometholone) 0.25% drops

LOTEMAX^{BNR} (loteprednol) 0.5% drops, 0.5% ointment

MAXIDEX (dexamethasone) 0.1% drops

PRED MILD (prednisolone) 0.12% drops

Prednisolone acetate 1% drops (generic PRED FORTE 1%)

Non-preferred products 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).

DUREZOL (difluprednate) may be approved if meeting the following criteria:

- Member has a diagnosis of severe intermediate uveitis, severe panuveitis, or severe uveitis with the complication of uveitic macular edema **AND** has trialed and failed at least a 2 week trial of prednisolone acetate 1%. (Failure is defined as lack of efficacy with 2 week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction)
  OR
- Members with a diagnosis other than those listed above require 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 etabonate) may be approved if meeting all of the following:

- Member is ≥18 years of age **AND**
- LOTEMAX SM (loteprednol etabonate) is being used for the treatment of postoperative inflammation and pain following ocular surgery **AND**
- Member has trialed and failed therapy with two preferred loteprednol formulations. (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 therapy with two preferred agents that do not contain loteprednol. (Failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) **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 **OR**
  - Mycobacterial infection of the eye and fungal diseases of ocular structures

Discussion

- No Board members reported a conflict of interest for these two therapeutic subclasses.
- Motion made by T Brubaker to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

9.e Glucagon, Self-administered *(pulled from Mass Review for a full review)*

Preferred agents

No PA Required (*Must meet eligibility criteria)

GLUCAGEN HYPOKIT (glucagon)
Glucagon Emergency Kit
* GVOKE (glucagon) HypoPen/syringe

***GVOKE (glucagon)** may be approved following trial and failure of GLUCAGEN (glucagon) 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 may be approved if the member has failed treatment with GVOKE (glucagon) 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

Scheduled testimony presentations:

- B Owen, PTCB Pharmacy Technician, Barbara Davis Center
- B Bentz, Eli Lilly, Baqsimi

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- Motion made by A Blackmer to increase the quantity limit to 4 doses per year unless used/damaged/lost. Seconded by T Brubaker. Motion passed unanimously.
- Motion made by A Blackmer to recommend that Baqsimi (glucacon nasal spray) may be approved for members ≥ 4 years of age if it is specifically requested by scholastic, camp, or organized group activities. Seconded by T Brubaker. Motion passed unanimously. None opposed.
- Motion made by P Lanius to approve this class as amended. Seconded by S VanEyk. Motion passed unanimously.

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9. Mass review drug classes*

**Proposed criteria for drug classes designated for mass review will not be read aloud at the time of DUR Board review, as there are no proposed changes to criteria currently implemented for these designated classes. The DUR Board may determine if designated mass review drug classes will undergo full review based on board vote.*

9.a Statins & Statin Combinations

- **Preferred agents -Statins**

  No PA Required
  Atorvastatin tablet
  Lovastatin tablet
  Pravastatin tablet
  Rosuvastatin tablet
  Simvastatin tablet

Non-preferred statins may be approved following trial and failure of treatment with two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Age Limitations:

ALTOPREV will not be approved for members < 18 years of age
Fluvastatin and lovastatin will not be approved for members < 10 years of age
LIVALO will not be approved for members < 6 8 years of age

- **Preferred agents - Statin Combinations**

  NONE

Non-preferred Statin combinations may be approved following trial and failure of treatment with two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Children Age Limitations:
VYTORIN and generic ezetimibe/simvastatin will not be approved for members < 18 years of age
CADUET and generic amlodipine/atorvastatin will not be approved for members < 10 years of age

9.b Lithium Agents

Preferred agents
No PA Required
Lithium carbonate capsule
Lithium carbonate tablet
Lithium carbonate ER tablet

Non-preferred products may be approved with trial and failure of one preferred agent. (Failure is 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 product may receive approval to continue therapy with that product.

9.c Neurocognitive Disorder Agents

Preferred agents
***Must meet eligibility criteria**
*Donepezil 5mg,10mg tablet
*Donepezil ODT
*Memantine tablets
*Rivastigmine capsule, patch

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

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

9.d Topical Steroids

- **Low Potency**

Preferred agents
No PA Required
Hydrocortisone (Rx) cream, ointment, lotion
DERMA-SMOOTHE/FS [BNR] (fluocinolone acetonide) oil
Desonide 0.05% cream, ointment
Fluocinolone acetonide 0.01% cream

Non-preferred Low Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Low Potency class. (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

- **Medium Potency**

  Preferred agents

  No PA Required

  Betamethasone dipropionate 0.05% lotion
  Betamethasone valerate 0.1% ointment
  Fluocinolone acetonide 0.025% cream
  Fluticasone propionate 0.05% cream, 0.05% ointment
  Mometasone furoate 0.1% cream, 0.1% ointment, 0.1% solution
  Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion

Non-preferred Medium Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Medium Potency class. (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

- **High Potency**

  Preferred agents

  No PA Required (unless exceeds recommended duration of therapy*)

  * Betamethasone dipropionate/propylene glycol (augmented) 0.05% cream
  * Fluocinonide 0.05% gel, 0.05% solution, 0.05% ointment
  * Triamcinolone acetonide 0.5% cream, 0.5% ointment

Non-preferred High Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the High Potency class. (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 Medium or Low Potency topical steroid after this time has elapsed.

- **Very High Potency**

  Preferred agents

  No PA Required (unless exceeds recommended duration of therapy*)

  * Betamethasone dipropionate/propylene glycol (augmented) 0.05% ointment
  * Clobetasol 0.05% cream, 0.05% gel, 0.05% ointment, 0.05% solution
  Fluocinonide 0.1% cream

Non-preferred Very High Potency topical corticosteroids may be approved following adequate trial and failure of clobetasol propionate in the same formulation as the product being requested (if the formulation of the requested non-preferred product is not available in preferred clobetasol product options, then trial and failure of any preferred clobetasol product formulation will be 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 Medium or Low potency topical steroid after this time has elapsed.

9.e Glucagon, Self-administered

(pulled from Mass Review for a full review—see above)

9.f Growth Hormone

Preferred agents

No PA Required (if diagnosis and dose met)
GENOTROPIN
NORDITROPIN

All preferred products may be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND if prescription does not exceed limitations for maximum dosing (Table 1).

Non-preferred Growth Hormone products 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 a qualifying diagnosis:
  - Prader-Willi Syndrome (PWS)
  - Chronic renal insufficiency/failure requiring transplantation (defined as creatinine clearance < 30mL/min)
  - Turner's Syndrome
  - 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)
    - Has at least one documented low IGF-1 level (below normal range for patient's age – refer to range on submitted lab document)
    - Has deficiencies in ≥ 3 pituitary axes (such as TSH, LH, FSH, ACTH, ADH)
    - Cachexia associated with AIDS
    - Noonan Syndrome
    - Short bowel syndrome
    - Neonatal symptomatic growth hormone deficiency (limited to 3 month PA approval)

- Prescription does not exceed limitations for FDA labeled maximum dosing (Table 1) for prescribed indication based on prescriber submission/verification of patient weight from most recent clinical documentation.

Table 1: Growth Hormone Product Maximum Dosing*

Medication	**Pediatric Maximum Dosing** (age < 18 years)	**Adult Maximum Dosing** (age ≥ 18 years)
GENOTROPIN	0.33 mg 0.48 mg/kg/week	0.08 mg/kg/week
HUMATROPE	0.375 0.47 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 0.7 mg/kg/week	0.175 mg/kg/week for ≤36 years of age 0.0875 mg/kg/week for >35 years of age
OMNITROPE	0.33 0.47 mg/kg/week	0.08 mg/kg/week
SAIZEN	0.18 mg/kg/week	0.07 mg/kg/week
SEROSTIM	Not indicated	42 mg/week for cachexia with HIV only, in combination with antiretroviral therapy
ZOMACTON	0.375 0.47 mg/kg/week	0.0875 mg/kg/week
ZORBTIVE	Not indicated	8mg per day for 28 days for short bowel syndrome only
* Based on FDA labeled indications and dosing		

9.g Bile Salts

Preferred agents
No PA Required
Ursodiol capsule
Ursodiol tablet

CHENODAL (chenodiol) and **ACTIGALL** (ursodiol) may be approved for members who meet the following criteria:

- Member is >18 years of age **AND**
- Member has tried and failed therapy with a 12-month trial of a preferred ursodiol agent. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

CHOLBAM (cholic acid) may be approved for members who meet the following criteria:

- Bile acid synthesis disorders:
  - Member must be greater than 3 weeks old in of 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 of 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), **URSO** (ursodiol), and **URSO FORTE** (ursodiol) may be approved for members meeting the following criteria:

- Member is > 18 years of age **AND**
- Medication 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 antimitochondrial antibody: with a titer of 1:40 or higher
  - Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts
    AND
  - Member has failed treatment with a preferred ursodiol product for at least 1 year with an inadequate response **OR**
  - Member has intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations.

9.h Immune Globulins

Preferred agents
PA Required for all agents in this class*
CUVITRU 20% SQ liquid
GAMMAGARD 10% IV/SQ liquid
GAMMAKED 10% IV/SQ liquid
GAMMAPLEX 5%, 10% IV liquid
GAMUNEX-C 10% IV/SQ liquid
HIZENTRA 20% SQ liquid
PRIVIGEN 10% IV liquid

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 meeting at least one of the approved conditions listed below for prescribed doses not exceeding maximum (Table 1).

Non-preferred agents may be approved for members meeting the following:
- Member meets at least one of the approved conditions listed below AND
- Member has history of trial and 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) AND
- Prescribed dose does not exceed listed maximum (Table 1)

Approved Conditions for Immune Globulin Use:
- Primary Humoral Immunodeficiency disorders including:
  - Common Variable Immunodeficiency (CVID)
  - Severe Combined Immunodeficiency (SCID)
  - X-Linked Agammaglobulinemia
  - X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
  - Wiskott-Aldrich Syndrome
  - Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm^3
- Neurological disorders including:
  - Guillain-Barré Syndrome
  - Relapsing-Remitting Multiple Sclerosis
  - Chronic Inflammatory Demyelinating Polyneuropathy
  - Myasthenia Gravis
  - Polymyositis and Dermatomyositis
  - Multifocal Motor Neuropathy
- Chronic Lymphocytic Leukemia (CLL)
- Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections
- Autoimmune Hemolytic Anemia (AHA)
- Liver or Intestinal Transplant
- Immune Thrombocytopenia Purpura (ITP) including:
  - Requiring preoperative therapy for undergoing elective splenectomy with platelet count < 20,000
  - Members with active bleeding & platelet count <30,000
  - Pregnant members with platelet counts <10,000 in the third trimester
  - Pregnant members with platelet count 10,000 to 30,000 who are bleeding

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 IV administration	2.4 g/kg/month
GAMMAKED Subcutaneous or IV administration	600 mg/kg every 3 weeks
Gamunex-C Subcutaneous or IV administration	600 mg/kg every 3 weeks
Hizentra Subcutaneous administration	0.4 g/kg per week
Cuvitru Subcutaneous administration	12.6 grams every 2 weeks

Grandfathering: Members currently receiving a preferred or non-preferred immunoglobulin product may receive approval to continue therapy with that product at prescribed doses not exceeding maximum (Table 1).

9.i Intranasal Rhinitis Agents

Preferred agents

No PA Required
Azelastine 0.1%,137 mcg/spray
Azelastine 0.15%, 205.5 mcg/spray
Budesonide 32 mcg (OTC)
Fluticasone 50 mcg (Rx) (generic FLONASE)
Ipratropium
Triamcinolone acetonide (OTC) (generic NASACORT)

Non-preferred products may be approved following trial and failure of treatment with three preferred 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 may be approved following trial of individual products with same active ingredients AND trial and failure of one additional preferred agent. (Failure is defined as lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions).

9.j Ophthalmic Agents, Allergy

Preferred agents

No PA Required
ALREX (loteprednol) 2%
Cromolyn 4%
Ketotifen (generic ZADITOR) 0.025% (OTC)
LASTACAFT (alcaftadine) 0.25%
Olopatadine (Rx) 0.1%, 0.2%
PAZEO (Rx) (olopatadine) 0.7%

9.k Leukotriene Modifiers

Preferred agents

No PA Required

Montelukast tablet, chewable tablet

Non-preferred products may be approved if meeting the following criteria:

1. Member has trialed and failed treatment with one preferred product. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) **AND**
2. Member has a diagnosis of asthma.

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

Non-preferred products may be approved following trial and failure of therapy with two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

9.l Anti-Parkinson's Agents, Dopa Decarboxylase Inhibitors & Combinations

Preferred agents

No PA Required

Carbidopa/Levodopa IR, ER tablet

Carbidopa/levodopa/entacapone tablet

Non-preferred agents may be approved with adequate trial and failure of carbidopa-levodopa IR and ER formulations. (Failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Carbidopa or levodopa single agent products may 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 therapy criteria.

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.

9.m Multiple Sclerosis, MAO-B Inhibitors

Preferred agents

No PA Required

Selegiline capsule

Selegiline tablet

Non-preferred agents may be approved with adequate trial and failure of selegiline capsule or tablet. (Failure is defined as lack of efficacy with a 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 therapy criteria.

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.

9.n Sedative Hypnotics, Non-Benzodiazepines

Preferred agents

No PA Required* (unless age, dose, or duplication criteria apply)
Eszopiclone tablet
Zaleplon capsule
Zolpidem IR tablet
Zolpidem ER tablet

Non-preferred non-benzodiazepine sedative hypnotics may be approved for members who have failed treatment with two preferred non-benzodiazepine agents. (Failure is defined as lack of efficacy with a 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. (Concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved).

All sedative hypnotics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy.

BELSOMRA (suvorexant) may be approved for adult members that meet the following:

- Member has trialed and failed therapy with two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Member is not receiving strong inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (such as 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

DAYVIGO (lemborexant) may be approved for adult member that meet the following:

- Member has trialed and failed therapy with two preferred agents **AND** BELSOMRA (surovexant). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**

- Member is not receiving strong inhibitors of CYP3A4 (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers of CYP3A4 (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) **AND**
- Member does not have a diagnosis of narcolepsy

ROZEREM (ramelteon) may 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 for prescribed doses exceeding maximum (Table 1).

9.o Sedative Hypnotics, Benzodiazepines

Preferred agents

No PA Required* (unless age, dose, or duplication criteria apply)
Temazepam 15mg, 30mg capsule
Triazolam tablet

Non-preferred benzodiazepine sedative hypnotics may be approved for members who have trialed and failed therapy with two preferred benzodiazepine agents. (Failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction).

Temazepam 7.5mg and **22.5 mg** may be approved if the member has trialed and failed temazepam 15mg or 30mg **AND** one other preferred product. (Failure is defined as lack of efficacy with a 2 week trail, 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 (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved).

All sedative hypnotics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy.

Grandfathering: Members currently stabilized on a non-preferred benzodiazepine medication may receive authorization to continue that medication.

Prior authorization will be required for prescribed doses exceeding maximum (Table 1).

Table 1: Sedative Hypnotic Maximum Dosing		
Brand	**Generic**	**FDA Maximum Dose**
Non-Benzodiazepine		
AMBIEN CR	zolpidem CR	12.5 mg/day
AMBIEN IR	zolpidem IR	10 mg/day
BELSOMRA	suvorexant	20 mg/day
DAYVIGO	lemborexant	10 mg/day
EDLUAR	zolpidem sublingual	Men: 10 mg/day Women: 5mg/day
INTERMEZZO	zolpidem sublingual	Men: 3.5 mg/day Women: 1.75 mg/day
LUNESTA	eszopiclone	3 mg/day
SONATA	zaleplon	20 mg/day
ROZEREM	ramelteon	8 mg/day
ZOLPIMIST	zolpidem spray	Men: 10 mg (2 sprays)/day Women: 5mg (1 spray)/day
Benzodiazepine		
HALCION	triazolam	0.5 mg/day
RESTORIL	temazepam	30 mg/day
—	estazolam	2 mg/day
—	flurazepam	30 mg/day
—	quazepam	15 mg/day

9.p Hemorrhoidal and Related Anorectal Agents

Preferred agent

No PA Required

Anusol-HC (hydrocortisone) 2.5% cream
CORTIFOAM (hydrocortisone) 10% aerosol
Hydrocortisone enema
Hydrocortisone 1% (Rx) cream/kit
Hydrocortisone 2.5% cream/kit with applicator
Hydrocortisone-Pramoxine 1%-1% cream
Lidocaine 5% ointment
Lidocaine-Hydrocortisone 3%-0.5% cream
Lidocaine-prilocaine 2.5%-2.5% cream
PROCTOFOAM (hydrocortisone-pramoxine) 1%-1% foam
PROCTO-MED HC (hydrocortisone) 2.5% cream
PROCTO-PAK (hydrocortisone) 1% cream
PROCTOSOL-HC 2.5% (hydrocortisone) cream
PROCTOZONE-HC 2.5% (hydrocortisone) cream

Non-preferred products may be approved following trial and failure of therapy 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) ointment may be approved if meeting the following:

- Member has a diagnosis of anal fissure **AND**

• Prescriber attests that member has trialed and maximized use of appropriate supportive therapies including sitz bath, fiber, topical analgesics (such as lidocaine), and stool softeners/laxatives.

9.q Ophthalmics, Glaucoma Agents

♦ **Beta Blockers**

Preferred Agents

No PA Required
Levobunolol
Timolol (generic TIMOPTIC)

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha$_2$-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). 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 trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the 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.

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

♦ **Carbonic Anhydrase Inhibitors**

Preferred Agents

No PA Required
AZOPT^{BNR} (brinzolamide) 1% drops
Dorzolamide 2% drops

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha$_2$-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). 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 trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the 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.

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

♦ **Prostaglandin Analogue**

Preferred Agents

No PA Required
Latanoprost

LUMIGAN[BNR] (bimatoprost)
TRAVATAN Z[BNR] (travoprost)

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha$_2$-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). 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 trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the 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.

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

- **Alpha-2 adrenergic agonists**

Preferred Agents

No PA Required
ALPHAGAN P 0.1% (brimonidine)
ALPHAGAN P [BNR] 0.15% (brimonidine)
Brimonidine 0.2%

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha$_2$-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). 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 trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the 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.

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

- **Other ophthalmic, glaucoma and combinations**

Preferred Agents

No PA Required
COMBIGAN (brimonidine/timolol)
Dorzolamide/Timolol
Dorzolamide/Timolol PF

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha2-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). 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 trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the 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.

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

Discussion

- No Board members reported a conflict of interest for the Mass Review drug classes.
- Motion made by S VanEyk to accept criteria for the Mass Review class as written. Seconded by L Claus. Motion passed unanimously.

Proposed ProDUR and Prior Authorization Criteria for Other Selected Products

10. LAMPIT (nifurtimox) oral tablets

LAMPIT (nifurtimox) may be approved for members when the following criteria are met:

1. Member's age falls between term newborn and < 18 years of age **AND**
2. Member weight is provided and is at least 2.5 kg (5.5 pounds) **AND**
3. Member has a diagnosis, confirmed by blood smear and documented, of Chagas disease (American Trypanosomiasis) caused by *Trypanosoma cruzi* **AND**
4. Pediatric member, 2 to 12 years of age, has failed treatment with benznidazole. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.
5. LAMPIT is prescribed by or in conjunction with an infectious disease specialist, cardiologist or gastroenterologist **AND**
6. Female members of childbearing potential having a documented negative pregnancy test within 2 weeks of initiating LAMPIT therapy **AND**
7. Member has been counseled and made a commitment to not consume alcohol during treatment with LAMPIT **AND**
8. Member meets recommended daily dosing:

Dosage of LAMPIT (nifurtimox) in Pediatric Patients	
Body weight group	Total daily dose
40 kg or greater	8 to 10 mg/kg
Less than 40 kg	10 to 20 mg/kg

Maximum daily dose: 300mg three times a day (900mg/day) for 60 days

11. BYNFEZIA Pen (octreotide acetate injection)

BYNFEZIA (octreotide acetate) may be approved when the following criteria are met:

1. Member is an adult (≥ 18 years of age) with a confirmed diagnosis of acromegaly OR severe diarrhea and flushing episodes associated with metastatic carcinoid tumors OR vasoactive intestinal peptide tumors (VIPomas) **AND**
2. BYNFEZIA is prescribed by, or in consultation with, an endocrinologist or oncologist
3. For acromegaly, member has trialed and failed bromocriptine mesylate at maximally tolerated doses. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
4. For acromegaly, member cannot be treated with surgical resection or pituitary irradiation **AND**
5. Member has trialed and failed octreotide acetate injection solution (vial). Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.
6. Provider confirms that member has had a baseline thyroid function test drawn prior to the initiation of BYNFEZIA and plans to monitor periodically during treatment

Maximum dose in acromegaly: 1500 mcg/day (however, doses greater than 300 mcg/day seldom result in additional benefit)

Maximum dose for carcinoid tumors: 750 mcg/day

Maximum dose for VIPomas: 750 mcg/day (however, doses above 450 mcg/day are usually not required)

12. XYWAV (calcium, magnesium, potassium, sodium oxybates) oral solution

XYWAV (calcium, magnesium, potassium, sodium oxybates) oral solution may be approved when the following criteria are met:

1. Member is ≥ 7 years of age **AND**
2. Member has a diagnosis of excessive daytime sleepiness with narcolepsy (confirmed by one of the following):
   - Hypocretin deficiency **OR**
   - Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency less than or equal to 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency less than or equal to 8 minutes and two or more sleep-onset REM periods

     AND
   - Baseline excessive daytime sleepiness is measured using the Epworth Sleepiness Scale or cataplexy episode count **AND**
   - Member has adequately trialed and/or failed therapy with 3 stimulants for narcolepsy (examples include methylphenidate and amphetamine salts). Failure is defined as: lack of efficacy with 2 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions **AND**
   - Member must not have recent (within 1 year) history of substance abuse **AND**
   - Member is not taking opioids, benzodiazepines, sedative hypnotics (such as zolpidem, zaleplon, eszopiclone, chloral hydrate, etc.) or consuming alcohol concomitantly with XYWAV

     AND
   - Prescriber is enrolled in XYWAV REMS program **AND**

- If member is an adult (≥ 18 years of age), they have had an adequate trial and/or failure of therapy with 3 sedative hypnotic medications (examples include zolpidem and eszopiclone). Failure is defined as: lack of efficacy with 2 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions.

Initial and Continuation Prior Authorization Approval:

Initial prior authorization approval will be for 30 days. For continuation approval for one year, the following information must be provided:

• Verification of Epworth Sleepiness Scale score reduction on follow-up

OR

• Verification of cataplexy episode count reduction on follow-up

Maximum dose: 9 grams per night

Scheduled testimony presentation:

- D Profant, Jazz Pharmaceuticals, Xywav

13. JYNARQUE (tolvaptan) tablets

JYNARQUE (tolvaptan) may be approved for members when the following criteria are met:

1. Member is an adult (≥ 18 years of age) and has been diagnosed with slow kidney function decline and at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD) **AND**
2. Medication is being prescribed by a nephrologist **AND**
3. Member does not have a history or sign/symptoms of significant liver impairment or injury. (Uncomplicated polycystic liver disease is not a contraindication for JYNARQUE therapy) **AND**
4. Member is not taking a strong Cytochrome 3A inhibitor (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan, delavirdine and milk thistle) **AND**
5. Member is not taking a OATP1B1/B3 or OAT3 substrate (such as a statin, bosentan, glyburide, nateglinide, repaglinide, methotrexate or furosemide) **AND**
6. Member is not taking a BCRP substrate such as rosuvastatin, prazosin, pantoprazole, teriflunomide or chlorothiazide) **AND**
7. Member is not using desmopressin (dDAVP) **AND**
8. If member is taking a moderate Cytochrome 3A inhibitor (such as erythromycin, fluconazole or verapamil) JYNARQUE (tolvaptan) will be prescribed at a reduced dose **AND**
9. Member has normal blood sodium concentrations, is able to sense or respond to thirst, and has a normal blood volume **AND**
10. Member does not have urinary outflow obstruction or anuria

Maximum dose: 120mg per day

Scheduled testimony presentation:

- C Pinto, Otsuka, Jynarque

Discussion

- No Board members reported a conflict of interest for the ProDUR products reviewed today: LAMPIT, BENFEZIA, XYWAV and JYNARQUE.
- Motion made by L Claus to accept criteria for LAMPIT, BENFEZIA, XYWAV and JYNARQUE as written. Seconded by P Lanius. Motion passed unanimously.
- Three medications included in the ProDUR/Other Selected Products section—UPLINZA (inebilizumab), VILTEPSO (viltolarsen), and HEMADY (dexamethasone)—were not reviewed during this meeting due to time limitations and will be rescheduled for a later meeting.

14. Proposed Prior Authorization Criteria for Medical Benefit Physician Administered Drug Products

The planned review of criteria for physician administered drugs (PAD) was deferred to a future date due to time limitations.

15. Unfinished Business and General Orders

- Retrospective DUR Updates
- Quarterly Module Summary
- Quarterly Drug Utilization Reports
- RDUR Provider Letters

The unfinished business and general orders section of today's agenda was deferred due to time limitations.

16. Adjournment

Board Chair M Noonan reminded attendees that the next DUR Board meeting is scheduled for Tuesday, May 11, starting at 1:00 pm. Dr. Noonan also reminded Board members to delete all meeting binder materials from their computers.

Motion to adjourn made by S VanEyk to adjourn the meeting. Seconded by L Claus. Motion passed unanimously.

The meeting was adjourned at 6:06 pm.