COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING
Health First Colorado, Colorado's Medicaid Program
Drug Utilization Review Board
Department of Health Care Policy and Financing

February 8, 2022
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 1:01 pm by L Claus, Board Chair.

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 eight voting members participating. Quorum is five members.

a. **Members Present:** Liza Claus, PharmD (Chair); Allison Shmerling, MD, MPH (Vice Chair); Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; L Laird, PharmD (Industry Representative); Scott VanEyk, MD; Miroslav Anguelov, PharmD; Brian Jackson, MD, MA; Shilpa Klocke, PharmD
b. **Members Absent:** None
c. **Medicaid Pharmacy Staff:** Jim Leonard, PharmD; Jeffrey Taylor, PharmD
d. **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department
- We ask that speakers and other attendees who are not on the Board or facilitating the meeting to remain off-video with microphones muted.
- Ryan Tran and Juliana Gassmann, University of Colorado DUR pharmacy interns, will be managing the technical aspects of today's Zoom meeting.
- Stakeholders who have signed up in advance to provide testimony will have their microphones unmuted at the appropriate time.
- Speakers providing testimony, and other meeting guests, are asked to keep video turned off throughout the meeting so that we can more easily see and track Board members votes

Reminders for Board Members:

- Video and microphone for Board members will be turned ON. To facilitate the voting process, keeping your video turned on as much as possible during the meeting is encouraged.

- If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted, as that usually resolves the issue.
- An updated meeting binder was sent to Board members this morning. A reminder to use the icon on the left that looks like a ribbon to pull up links that will allow you to quickly navigate to specific documents.
- Shaded rows on the market share tables indicate the current preferred products on the PDL.
- An important reminder to all Board members to DELETE the meeting binder immediately following this meeting
- Voting may be conducted by raising your hand and/or by verbal "ayes" and "nays," abstentions, and recusals as determined by the Board Chair and/or Vice-Chair.

4. Election of Board Chair and Vice Chair

For this year's officer election, the Chair will be a physician and the Vice Chair will be a pharmacist.

L Claus nominated A Shmerling for Board Chair. S VanEyk seconded the nomination. Motion passed, with Dr. Shmerling abstaining. A Shmerling nominated L Claus for Board Vice-Chair. B Jackson seconded the nomination. Motion passed, with Dr. Claus abstaining.

5. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

During today's meeting, new proposed criteria for specific products and therapeutic drug classes currently managed with DUR criteria on the Preferred Drug List (PDL) and Appendix P will be read aloud. For products currently included on the PDL and Appendix P, the team may summarize only proposed additions and changes to the currently-posted criteria. The current PDL and Appendix P documents are available on the Department's Pharmacy Resources page at https://hcpf.colorado.gov/pharmacy-resources

It is possible that items included in the mass review section of today's agenda may be moved out of mass review. Two classes to be moved out of mass review for full review today will be the Short-Acting Opioids and Long-Acting Opioids.

The remaining Board meetings for 2022 are tentatively scheduled to be held virtually on May 10, August 9, and November 8. All meetings will be held on Zoom from 1:00 to 5:00 pm. Board members will receive calendar invitations for these dates within the next two weeks.

Thank you to Dr. Laird, as this is his final Board meeting for his term of service as the DUR Board's Industry Representative. If any industry representatives are interested in applying to serve in this role in the future, please email jeffrey.taylor@state.co.us and provide a CV/resume with your request.

5. Final Approval of Minutes from November 8, 2021 Meeting

Vice Chair L Claus asked if there were any changes to propose for minutes from the November 8 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by B Jackson and seconded by S Klocke. The motion passed unanimously.

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

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. Presenters 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, they should not participate in the discussion of the agenda item or any vote regarding that item.

Dr. Laird, Industry Representative, disclosed his conflicts of interest regarding psychiatry topics (including schizophrenia, bipolar disorder and antidepressants), neurology topics including anticonvulsants used in Parkinson's Disease, along with respiratory products, and sedative-hypnotics.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**

DUR Intern Thao Anh Mai presented a summary of recent FDA drug approvals, noting that the generic name for Livtencity® should be corrected to maribavir in the Board's FDA document.

DUR Intern Ryan Tran presented FDA Safety information (01/12/2022) about a significant risk of dental problems associated with buprenorphine products dissolved in the mouth.

- **Quarterly Clinical Modules**

  R Page presented an update on Quarterly Clinical Modules, complex clinical modules created by the CO-DUR team based on the needs of the Department and to assist with policy development.

  - HIV Prevention and Treatment
    (final module delivered 12/30/2021)
  - Analysis of the First Health Colorado DUR Pain Management Consultation Service
    (draft module to be delivered by 12/31/2021)
  - Analysis of Targeted Immune Modulators (TIMs)
    (draft module to be delivered by 3/31/2022)

- **Quarterly Drug Utilization Reports**

  Board members were referred to these reports in the meeting binder. R Page highlighted that the top drugs in 4Q2021 by number of claims were Proair HFA, gabapentin, amoxicillin, sertraline, omeprazole, trazodone and ibuprofen. Top drugs by cost were Humira®, Trikafta®, Biktarvy®, Trulicity®, Latuda®, Novolog®, Enbrel® and ProAir® HFA.

- **Retrospective DUR Reports**

  R Page presented the RDUR summary.

  - There was a slight increase during 4Q2021 in the number of members <18 years of age who received two or more antipsychotic medications concomitantly for 45 or days or more.
  - Data regarding the number of members who had two or more benzodiazepine claims concomitantly for ≥ 90 days remained fairly constant in both the number of providers and members between 3Q2021 and 4Q2021.
  - The number of members who received an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly for 60 or more days (excluding individuals with a diagnosis of cancer or sickle cell disease) remained fairly constant between 3Q2021 and 4Q2021.
  - The number of members and providers associated with claims for opioids exceeding an average of 200 MME in a 30-day period declined from 3Q2021 to 4Q2021.
  - Members with multiple claims for opioid prescriptions that total >150 MME (averaged over 30 days) and no naloxone fill within the 12 months prior to or during the current quarter leveled off with the inclusion of 4Q2021 data. J Rawlings noted that some prescribers have provided feedback to CO-DUR that some patients are obtaining naloxone through community resources other than CO Medicaid, so the related graph may not reflect the full scope of naloxone availability for members in our state.

9. New Business

J Rawlings referred Board members to the proposed DUR criteria section of the Meeting Binder and described the steps of the review process:

- Board members will be asked if they have potential conflicts of interest to disclose prior to reviewing the therapeutic drug classes listed in the meeting agenda.
- For products and drug classes being newly managed and undergoing review, all proposed criteria will be read aloud during the meeting. For products and drug classes that are currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud.
- Time is permitted for stakeholder comment. All speakers have registered in advance, and each will be given up to 3 minutes of speaking time.
- There will be an opportunity for Board discussion
- Then we will capture for the minutes all motions made by the Board:
  - Name of the member who makes the motion
  - Name of the member who 2nds the motion
  - Abstentions, recusals, and voting results
  - To facilitate recordkeeping for this meeting, a reminder to Board members to please clearly and state your name when making motions and offering seconds

R Page proceeded with the review process of proposed criteria.

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) – Oral & Non-Oral

Preferred Agents - Oral

CAMBIA (diclofenac potassium) powder packet
Celecoxib capsule
Diclofenac potassium tablet
Diclofenac sodium EC/DR tablet
Ibuprofen suspension, tablet (RX)
Indomethacin capsule, ER capsule
Ketorolac tablet**
Meloxicam tablet
Nabumetone tablet
Naproxen DR/ER tablet (RX)
Naproxen EC* tablet (RX)
*(all manufacturers except *Woodward*)
Naproxen suspension*
*(all manufacturers except *Acella*)
Sulindac tablet

Preferred Agents – Non-oral

Diclofenac 1.5% topical solution
Diclofenac 1% gel (OTC/RX)
Diclofenac sodium 1% (generic Voltaren) gel (Rx)
VOLTAREN (diclofenac) 1% gel (Rx)

DUEXIS (ibuprofen/famotidine) or **VIMOVO (naproxen/esomeprazole)** may be approved if the member meets the following criteria:

- Trial and failure‡ of all preferred NSAIDs at maximally tolerated doses **AND**
- Trial and failure‡ of three preferred proton pump inhibitors in combination with NSAID within the last 6 months **AND**
- Has a documented history of gastrointestinal bleeding

All other non-preferred oral agents may be approved following trial and failure‡ of four preferred agents.

‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

**Ketorolac tablets quantity limitsations: 5-day supply per 30 days and 20 tablets per 30 days

SPRIX (ketorolac) may be approved if meeting the following criteria:

- Member is unable to tolerate, swallow or absorb oral NSAID formulations **OR**
- Member has trialed and failed three preferred oral or topical NSAID agents (failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions)
- Quantity limit: 5-single day nasal spray bottles per 30 days

All other non-preferred topical agents may be approved for members who have trialed and failed one preferred agent. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

FLECTOR (diclofenac) patch Quantity Limit: 2 patches per day

Diclofenac 3% gel (generic SOLARAZE) prior authorization criteria can be found in the Antineoplastic Agents, Topical, section of the PDL.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- B Jackson moved to accept the proposed criteria as written. Seconded by L Claus. Motion passed unanimously.

2. Beta-Blockers & Combinations

Preferred Agents – Beta Blockers, Single Agent

1st generation (non- selective)
Nadolol tablet
Pindolol tablet
Propranolol IR tablet, solution
Propranolol ER capsule

2nd generation (ß1 selective)
Acebutolol capsule
Atenolol tablet
Bisoprolol tablet
Metoprolol tartrate tablet
Metoprolol succinate ER tablet

3rd generation (non-selective with ancillary properties)
Carvedilol IR tablet
Carvedilol ER capsule
Labetalol tablet

3rd generation (ß1 selective with ancillary properties)
BYSTOLIC (nebivolol) tablet

Preferred Agents – Beta Blockers, Anti-Arrhythmics
Sotalol tablet

Preferred Agents – Beta Blockers, Combinations
Atenolol/Chlorthalidone tablet
Bisoprolol/HCTZ tablet
Metoprolol/HCTZ tablet

Beta-Blockers, Single Agent

Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, 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.
Maximum dose: 1.7 mg/kg twice daily

KAPSPARGO SPRINKLE (metoprolol succinate) extended-release capsule may be approved for members ≥ 6 years of age that have difficulty swallowing or require medication administration via a feeding tube.
Maximum dose: 200mg/day (adult); 50mg/day (pediatric)

Grandfathering: Members currently stabilized on 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		
Nebivolol	X			
Pindolol	X	X		X
Propranolol	X	X		

Beta-Blockers, Anti-Arrhythmics

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 **OR** members that have trialed and failed therapy with one preferred product. (Failure is defined as allergy or intolerable side effects.)

Maximum dose: 320 mg/day

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke moved to accept the proposed criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. Anticonvulsants, Oral

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

Preferred Agents, Barbiturates
Phenobarbital elixir, soln, tab
Primidone tablet

Preferred Agents, Hydantoins
DILANTIN (phenytoin) 30 mg Kapseal
DILANTIN Infatab
DILANTIN suspension
PHENYTEK (phenytoin ER)
Phenytoin suspension, chewable, ER capsule

Preferred Agents, Succinamides
Ethosuximide capsule, solution

Preferred Agents, Benzodiazepines
Clobazam tablet
Clonazepam tablet, ODT

Preferred Agents, Valproic Acid and Derivatives
DEPAKOTE (divalproex DR) sprinkle capsule, tablet
Divalproex capsule, DR tablet, ER tablet
Valproic acid capsule, solution

Preferred Agents, Carbamazepine Derivatives
Carbamazepine IR tablet, ER tablet, chewable, ER capsule, suspension
CARBATROL ER (carbamazepine) capsule
Oxcarbazepine tablet, suspension
TEGRETOL (carbamazepine) suspension

TEGRETOL (carbamazepine) tablet
TEGRETOL XR (carbamazepine ER) tablet
TRILEPTAL (oxcarbazepine) suspension

Preferred Agents, Lamotrigines
LAMICTAL (lamotrigine) chewable/dispertab
LAMICTAL (lamotrigine) tablet
LAMICTAL XR[BNR] (lamotrigine ER) tablet
LAMICTAL ODT [BNR] (lamotrigine)
Lamotrigine tablet, chewable/disperse tabs

Preferred Agents, Topiramates
TOPAMAX (topiramate) sprinkle capsule
Topiramate tablet, sprinkle capsule

Preferred Agents, Brivaracetam/Levetiracetam
Levetiracetam IR tablet, ER tablet, solution

Preferred Agents, Other
FELBATOL[BNR] (felbamate) tablet, suspension
Zonisamide capsule

Members currently stabilized (in outpatient or acute care settings) on any non-preferred medication in this class may receive prior authorization approval to continue on that medication.

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.

Non-Preferred Products Newly Started for Treating Seizure Disorder or Convulsions:

- Non-preferred medications newly started for members with a diagnosis of seizure disorder/convulsions may be approved if meeting the following criteria:
  - The medication is being prescribed by a neurologist **OR**
  - The medication is in consultation with a neurologist and meets the following:
    - The prescription meets minimum age and maximum dose limits listed in Table 1 **AND**
    - For medications indicated for use as adjunctive therapy, the medication is being used in conjunction with another anticonvulsant medication

    AND
  - The prescription meets additional criteria listed for any of the following:

APTIOM (eslicarbazepine):

- Member has history of trial and failure‡ of any carbamazepine-containing product

BRIVIACT (brivaracetam):
- Member is ≥1 month of age **AND**
- Member has history of trial and failure‡ of any levetiracetam-containing product

DIACOMIT (stiripentol):
- Member is concomitantly taking clobazam **AND**
- Member has diagnosis of seizures associated with Dravet syndrome

ELEPSIA XR (levetiracetam ER) tablet:
- Member has history of trial and failure‡ of levetiracetam ER (KEPPRA XR)

EPIDIOLEX (cannabidiol):
- Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet Syndrome **OR**
- Member is ≥ 1 year of age and has a diagnosis of seizures associated with tuberous sclerosis complex (TSC).

FINTEPLA (fenfluramine):
- Member is ≥ 2 years of age AND has a diagnosis of seizures associated with Dravet syndrome

ONFI (clobazam) oral suspension:
- Member is ≥2 years of age **AND**
- Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) **AND**
- Member has documented swallowing difficulty due to young age and/or a medical condition, and is unable to use preferred tablet and capsule formulations **AND**
- Member is not taking a concomitant opioid (or concomitant opioid therapy has been determined to be clinically appropriate due to inadequacy of alternative treatment options)

OXTELLAR XR (oxcarbazepine ER):
- Member is ≥ 6 years of age **AND**
- Member is being treated for partial-onset seizures **AND**
- Member has history of trial and failure‡ of any carbamazepine or oxcarbazepine-containing product

SPRITAM (levetiracetam) tablet for suspension
- Member has history of trial and failure‡ of levetiracetam solution

SYMPAZAN (clobazam) film:
- Member has history of trial and failure‡ of clobazam tablet or solution **OR**
- Provider attests that member cannot take clobazam tablet or solution

Non-Preferred Products Newly Started for Non-Seizure Disorder Diagnoses:

- Non-preferred medications newly started for non-seizure disorder diagnoses may be approved if meeting the following criteria:
  - Member has history of trial and failure‡ of two preferred agents **AND**
  - The prescription meets minimum age and maximum dose limits listed in Table 1.

‡Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or documented contraindication to therapy, or inability to take preferred formulation. Members identified as HLA-B*15:02 positive, carbamazepine and oxcarbazepine should be avoided per Clinical Pharmacogenetics Implementation Consortium Guideline. This may be considered a trial for prior authorization approvals of a non-preferred agent.

Table 1: Non-preferred Product Minimum Age and Maximum Dose

	Minimum Age**	**Maximum Dose****
Barbiturates		
primidone (MYSOLINE)		2,000 mg per day
Benzodiazepines		
clobazam (ONFI)	2 years	40 mg per day
clobazam film (SYMPAZAN)	2 years	40 mg per day
clobazam suspension	2 years	40 mg per day
clonazepam (KLONOPIN)		20 mg per day
Brivaracetam/Levetiracetam		
brivaracetam (BRIVIACT)	1 month	200 mg per day
levetiracetam (KEPPRA)	1 month	3,000 mg per day
levetiracetam (SPRITAM)	4 years	3,000 mg per day
levetiracetam ER (ELEPSIA XR)	12 years	3,000 mg per day
levetiracetam ER (KEPPRA XR)	12 years	3,000 mg per day
Carbamazepine Derivatives		
carbamazepine (EPITOL)		1,600 mg per day
carbamazepine ER (EQUETRO)		1,600 mg per day
eslicarbazepine (APTIOM)	4 years	1,600 mg per day
oxcarbazepine ER (OXTELLAR XR)	6 years	2,400 mg per day
Hydantoins		
ethotoin (PEGANONE)		3,000 mg per day
phenytoin ER (DILANTIN) 100mg capsules, suspension, Infatab		1,000 mg loading dose 600 mg/day maintenance dose
Lamotrigines		
lamotrigine (LAMICTAL ODT)	2 years	500 mg per day
lamotrigine ER (LAMICTAL XR)	13 years	600 mg per day
Succinamides		
ethosuximide (ZARONTIN)		20 mg/kg/day
methsuximide (CELONTIN)		Not listed
Valproic Acid and Derivatives		
divalproex ER (DEPAKOTE ER)	10 years	60 mg/kg/day

Topiramates		
topiramate (TOPAMAX)	2 years	400 mg per day
topiramate ER (QUDEXY XR)	2 years	400 mg per day
topiramate ER (TROKENDI XR)	6 years	400 mg per day
Other		
cannabidiol (EPIDIOLEX)	1 year	20 mg/kg/day
cenobamate (XCOPRI)	18 years	400 mg per day
felbamate tablet, suspension	2 years	
fenfluramine (FINTEPLA)	2 years	26 mg per day
lacosamide (VIMPAT)	1 month	400 mg per day
perampanel (FYCOMPA)	4 years	12 mg per day
rufinamide (BANZEL) tablet and suspension	1 year	3,200 mg per day
stiripentol (DIACOMIT)	2 years	3,000 mg per day
tiagabine	12 years	64 mg per day
tiagabine (GABITRIL)	12 years	64 mg per day
vigabatrin	1 month	3,000 mg per day
vigabatrin (SABRIL)	1 month	3,000 mg per day
vigabatrin (VIGADRONE) powder packet	1 month	3,000 mg per day
zonisamide (ZONEGRAN)	16 years	600 mg per day
**Limits based on data from FDA package insert. Approval for age/dosing that falls outside of the indicated range may be evaluated on a case-by-case basis.		

Stakeholder input:

Letter, Epilepsy Foundation of Colorado & Wyoming
Letter, National MS Society/Epilepsy Foundation of CO & WY, Rocky Mountain Multiple Sclerosis Center, Parkinson Association of the Rockies
Written testimony, Briviact – UCB Pharma
Written testimony, Vimpat – UCB Pharma
Letter, E Maa, MD – Denver Neurology Clinic
Letter, G Mills – Swedish Medical Center

Scheduled testimony presentations:

M Aude – Epilepsy Foundation of Colorado & Wyoming
A Scurry – UCB Pharma, Vimpat
A Scurry – UCB Pharma, Briviact
E Maa – Denver Neurology Clinic
G Mills – Swedish Medical Center
M Maruscak - Fintepla

Discussion

- L Laird reported a conflict of interest for this therapeutic class.
- L Claus asked about the possibility of offering neurology consults for CO Medicaid providers, as discussed during the last review of this drug class. J Taylor stated that although such a plan has been discussed by the Department, there are no plans at this time to implement that type of service within Medicaid.
- The Board had a lengthy discussion about the pros and cons of requiring neurologist subspecialty consultations within the PDL criteria for this class.
- S VanEyk asked for the Board's input regrading removing requirements to fail a similar medication in order to meet requirements for a brand-name product (for example, failing a trial of carbamazepine in order to receive PA approval for eslicarbazepine). A consultation with a neurologist is required and may lessen the need for such trials/failures. S Klocke

mentioned the lack of head-to-head studies to compare outcomes between similar products is a significant consideration.
- J Taylor clarified that branded multisource agents will not require prior authorization with inclusion of a Dispense as Written (DAW-1) designation, with no coverage restrictions. This is related to the generic mandate exception policy for the anticonvulsant therapeutic class.
- B Jackson moved to change the language regarding non-neurologists consulting with neurologists to, "Consultation with a neurologist is required at the time of prescribing and, as long as the patient remains stable, the medication may continue to be prescribed by the non-neurologist." Seconded by T Brubaker. Motion passed unanimously.
- S Klocke moved that, for conciseness, minimize ages be included either within PDL bulleted criteria for this class or in the Minimum Age chart (Table 1), but not both. Seconded by B Jackson. Six aye votes. A Shmerling and S VanEyk abstained. Motion passed.
- S Klocke moved to ask for a re-review of the studies by the Department for similar medications within this class. Seconded by L Claus. Seven aye votes. P Lanius abstained. Motion passed.
- T Brubaker moved to accept the proposed criteria as amended. Seconded by S Klocke. Motion passed unanimously.

4. Newer Generation Antidepressants

Preferred Agents
Bupropion IR, SR, XL tablet
Citalopram tablet, solution
Desvenlafaxine succinate ER (generic Pristiq) tablet
Duloxetine (generic Cymbalta) capsule
Escitalopram tablet
Fluoxetine capsule, solution
Fluvoxamine tablet
Mirtazapine tablet, ODT
Paroxetine IR tablet
Sertraline tablet, solution
Trazodone tablet
Venlafaxine IR tablet
Venlafaxine ER capsule

Prior authorization for **FETZIMA, TRINTELLIX, or VIIBRYD** may be approved for members who have failed an adequate trial with four preferred newer generation anti-depressant products (failure is defined as lack of efficacy with 6-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

All non-preferred products not listed above may be approved for members who have failed adequate trial with three preferred newer generation anti-depressant products. If three preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication (failure is defined as lack of efficacy with 6-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Citalopram doses higher than 40mg/day for ≤60 years of age and 20mg/day for >60 years of age will require prior authorization. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information.

Members currently stabilized on a Non-preferred newer generation antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

Discussion

- L Laird reported a conflict of interest for this therapeutic class.
- B Jackson moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed unanimously.

5. Anti-Parkinson's Agents

Preferred Agents, Dopa decarboxylase inhibitors, dopamine precursors and combinations
Carbidopa/Levodopa IR, ER tablet
Carbidopa/Levodopa/Entacapone tablet

Preferred Agents, MAO-B Inhibitors
Selegiline capsule
Selegiline tablet

Preferred Agents, Dopamine Agonists
Pramipexole IR tablet
Ropinirole IR tablet

Preferred Agents, Other Parkinson's Agents
Amantadine capsule, tablet, solution/syrup
Benztropine tablet
Trihexyphenidyl tablet, elixir

Dopa decarboxylase inhibitors, dopamine precursors and combinations

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, contraindication to therapy, 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.

MAO-B Inhibitors

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, contraindication to therapy, 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.

Dopamine Agonists

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, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions).
APOKYN (apomorphine subcutaneous cartridge) 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 AND
- 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: 30 mg 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.

Other Parkinson's Agents

Non-preferred agents may be approved with adequate trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, 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.

Stakeholder input:

Letter, National MS Society/Epilepsy Foundation of CO & WY, Rocky Mountain Multiple Sclerosis Center, Parkinson Association of the Rockies

Discussion

- L Laird reported a conflict of interest for this therapeutic class.
- L Claus moved to accept the proposed criteria as written. Seconded by P Lanius. Motion passed unanimously.

6. Benzodiazepines (Non-Sedative Hypnotic)

Preferred Agents, Benzodiazepines
(*may be subject to age limitations)
Alprazolam IR, ER tablet*
Chlordiazepoxide capsule*
Clorazepate tablet*
Diazepam tablet*, solution
Lorazepam tablet*, oral concentrate solution
Oxazepam capsule*

Non-preferred products 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 agents when prescribed for children <18 years of age (with the exception of oral solution products) and may be approved with prescriber verification of necessity of use for member age.

Diazepam Intensol may be approved following trial and failure of the preferred 5 mg/5 mL oral solution. Failure is defined as intolerable side effects, drug-drug interaction, or lack of efficacy.

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

Grandfathering: Continuation of therapy:

- Members < 65 years of age who are currently stabilized on a non-preferred benzodiazepine medication may receive approval to continue that medication.
- Members < 18 years of age who are currently stabilized on a non-preferred oral solution product may receive authorization to continue that medication.

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

Table 1 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 6-17 years: up to 40 mg/day (pre-operative apprehension and anxiety)	Total of 9,000 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 5 mg/5 mL	Adults ≥ 18 years: 40 mg/day Children: N/A	Total of 1,200 mg from all dosage forms per 30 days

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	Adults ≥ 18 years: 10 mg/day Children: N/A	Total of 300 mg from all dosage forms per 30 days
ATIVAN (lorazepam) tablet		
Lorazepam oral concentrated soln 2 mg/mL		
Lorazepam tablet		
Oxazepam capsule	Adults ≥ 18 years: 120 mg/day Children 6-18 years: absolute dosage not established	Total of 3600 mg from all dosage forms per 30 days

Discussion
- No Board members reported a conflict of interest for this therapeutic class.
- P Lanius moved to accept the proposed criteria as written. Seconded by B Jackson. Motion passed unanimously.

7. Atypical Antipsychotics – Oral & Topical

For injectable Atypical Antipsychotics please see Appendix P for criteria

Preferred Agents, Oral
Aripiprazole tablet
Clozapine tablet
LATUDA (lurasidone) **2nd line****
Olanzapine tablet, ODT
Quetiapine IR tablet***
Quetiapine ER tablet
Risperidone tablet, ODT, oral solution
Ziprasidone

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.

Non-preferred products may be approved for members meeting all of the following:
- Medication is being prescribed for an FDA-Approved indication AND
- Prescription meets dose and age limitations (Table 1) AND
- Member has history of trial and failure of three preferred products with FDA approval for use for the prescribed indication (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 1). 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 consult 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 (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day except for utilization (when appropriate) in members 65 years or older. PA will be approved for members 10-17 years of age with approved diagnosis (Table 1) stabilized on <150mg 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 will be 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, contraindication to therapy, 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, contraindication to therapy, 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 will be applied to all products (Table 1). In order to receive approval for off-label dosing, the member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen.

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

Table 1 Atypical Antipsychotics - FDA Approved Indication, Age Range, Quantity and Maximum Dose					
Brand	**Generic**	**Approved Indications**	**Age Range**	**Maximum Daily Dose by Age/Indication**	**Quantity and Maximum Dose Limitations**
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	Maximum one tablet per day (maximum of two tablets per day allowable for members < 18 years of age to accommodate for incremental dose changes)
CLOZARIL	clozapine	Treatment-resistant schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900mg per day
CAPLYTA	lumateperone	Schizophrenia Bipolar I Disorder Bipolar II Disorder	≥ 18 years	42 mg	Maximum dosage of 42 mg per day
FAZACLO	clozapine	Treatment-resistant Schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900 mg per day
FANAPT	iloperidone	Schizophrenia	≥ 18 years	24 mg	Maximum two tablets per day
GEODON	ziprasidone	Schizophrenia Bipolar I Disorder	≥ 18 years ≥ 18 years	200 mg 160 mg	Maximum two capsules per day
INVEGA	paliperidone	Schizophrenia & schizoaffective disorder	≥ 12 years and weight ≥ 51 kg ≥ 12 years and weight < 51 kg	12 mg 6 mg	Maximum one capsule per day
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	Maximum one tablet per day (If dosing 160 mg for schizophrenia, then maximum of two tablets per day)
NUPLAZID	pimavanserin	Parkinson's disease psychosis	≥ 18 years	34 mg	Maximum dosage of 34 mg per day

RISPERDAL	risperidone	Schizophrenia (adult) Schizophrenia (adolescents) Bipolar mania (adult & peds) Irritability w/autistic disorder	≥ 18 years 13-17 years ≥ 10 years 5-17 years	12mg 6 mg 6 mg 3 mg	Maximum dosage of 12 mg/day
REXULTI	brexpiprazole	Schizophrenia (adult) Adjunctive treatment of MDD (adult)	≥ 13 years ≥ 18 years	4 mg 3 mg	Maximum of 4 mg/day for schizophrenia (≥ 13 years of age) Maximum of 3 mg/day for MDD adjunctive therapy
SAPHRIS	asenapine	Schizophrenia (adult) Bipolar mania or mixed episodes	≥ 18 years ≥ 10 years	20 mg 20 mg	Maximum two tablets per day
SECUADO	asenapine patch	Schizophrenia (adult)	≥ 18 years	7.6 mg/ 24 hours	Maximum 1 patch per day
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	Maximum three tablets per day
SEROQUEL XR	quetiapine ER	Schizophrenia (adult/adolescent) Bipolar I mania (adult) Bipolar I mania (peds) Bipolar I depression (adults) Adjunctive treatment of MDD	≥ 13 years ≥ 18 years 10-17 years ≥ 18 years ≥ 18 years	800 mg 800 mg 600 mg 300 mg 300 mg	Maximum one tablet per day (for 300 mg & 400 mg tablets, maximum of 2 tablets per day)
SYMBYAX	olanzapine/ fluoxetine	Acute depression in Bipolar I Disorder Treatment resistant depression (MDD)	≥ 10 years	12 mg olanzapine/ 50 mg fluoxetine	Maximum three capsules per day (18 mg olanzapine/75 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	Maximum dosage of 6 mg/day
ZYPREXA ZYPREXA ZYDIS	olanzapine	Schizophrenia Acute manic or mixed episodes with Bipolar I Disorder	≥ 13 years	20 mg	Maximum one tablet per day

Stakeholder input:
Written testimony, Rexulti - Otsuka

Scheduled testimony presentations:
M Lands, Caplyta – Intra-Cellular Therapeutics
M Shurtleff, Rexulti - Otsuka
L Hill, Vraylar - AbbVie

Discussion
- L Laird reported a conflict of interest for this therapeutic class.
- S VanEyk moved to accept the proposed criteria as written. Seconded by B Jackson. Seven aye votes. S Klocke abstained. Motion passed.

8. Calcitonin Gene-Related Peptide Inhibitors (CGRPIs)

Preferred Agents, Monoclonal Antibodies
PA Required for all agents (quantity limits may apply)
*AIMOVIG (erenumab-aooe) auto-injector
*AJOVY (fremanezumab-vfrm) auto-injector, syringe
*EMGALITY 120mg (galcanezumab-gnlm) pen, syringe

Preferred Agents, Gepants
PA Required for all agents (quantity limits may apply)
**NURTEC (rimegepant) ODT

*Preferred agents (Aimovig, Ajovy, Nurtec Emgality) may be approved if meeting the following criteria: Migraine Prevention Criteria below.

Preferred Medications for Migraine Prevention Prior Authorization Criteria (must meet all of the following):
- Member is 18 years of age or older AND
- Member is in need of The requested medication is being used as preventative therapy for episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura 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 has tried and failed two oral preventative pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
- If the prescribed medication is Nurtec, the member has tried and failed two preferred injectable product formulations (Aimovig and Ajovy). Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.
- 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 taking 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

- 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)

Preferred Medications for Acute Migraine Treatment (must meet all of the following):

- Member is 18 years of age or older AND
- The requested medication is being prescribed for used as acute treatment for 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 two triptans all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).:
  - Three triptans
    AND
  - Two NSAID agents

Non-Preferred Medications for Migraine Prevention (must meet all of the following):

- Member is 18 years of age or older AND
- Member is in need of The requested medication is being used as preventative therapy for episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura 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 has tried and failed two oral preventative pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction 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
- Medication is not prescribed for chronic migraine with medication overuse headache AND
- The member has history of adequate trial and failure of Emgality 120mg AND Aimovig therapy. all preferred products indicated for preventive therapy (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).
- 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)

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 (must meet all of the following) or Cluster Headache Treatment:
Non-preferred medications for acute migraine treatment may be approved for members meeting the following criteria:

- 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 with all of the following (failure is defined as lack of efficacy with 4-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction):
    - Three Two triptans AND
    - Two NSAID agents AND
    - One preferred agent indicated for acute migraine treatment

Non-Preferred Medications for Treatment of Episodic Cluster Headache (must meet all of the following):
Non-preferred medications for treatment of cluster headache may be approved for members meeting all of the following:

- Member is 19 to 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.

Age Limitations:
Emgality 100mg: 19-65 years
All other products: ≥ 18 years

Maximum Dosing:
Aimovig (erenumab): 140 mg per 30 days
Ajovy (fremanezumab): 225 mg monthly or 675 mg every three months
Emgality 120 mg (galcanezumab): 240 mg once as first loading dose, then 120 mg monthly
Emgality 100 mg (galcanezumab): 300 mg per 30 days
Nurtec (rimegepant): Prevention: 15 16 tablets/30 days; Acute Treatment: 8 tablets/30 days (1,125 mg per 30 days)

Qulipta (atogepant): 30 tablets/30 days
Ubrelvy 50 mg (ubrogepant): 16 tablets/30 days (800 mg per 30 days)
Ubrelvy 100 mg (ubrogepant): 16 tablets/30 days (1,600 mg per 30 days)

Members with current prior authorization approval on file for Emgality (galcanezumab) 120mg may receive one-year approval for an alternative preferred injectable product formulation (Aimovig or Ajovy) without needing to meet criteria listed above.

Scheduled testimony presentations:

J Shear, Ajovy – Teva (yielded time)
C Johnson, Aimovig – Amgen
L Hill, Ubrelvy – AbbVie (yielded time)
L Hill, Qulipta - AbbVie

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke recommended that the language regarding cardiovascular risk, headache count, and medication overuse headache be consistent in criteria for both preferred and non-preferred agents in this class, and perhaps those statement should be removed for both preferred and non-preferred agents. J Taylor clarified that the intent was to remove some criteria for preferred products.
- S Klocke also noted that for prophylactic migraine therapy, specific headache counts are not required and there is some controversy associated with rather arbitrary numbers of headaches being used to guide clinical management. A member may experience less frequent, but more severe, headaches, for example.
- L Claus recommended that because two different NSAIDs used at equivalent doses are considered to provide the same pain relief benefit, and also that members may use OTC NSAIDs not captured in prescription data, the trial and failure of two NSAIDs in the "Non-Preferred Medications for Acute Migraine Treatment" be reduced to trial and failure of one NSAID instead of two.
- S Klocke stated that adequate safety evidence is not yet available to support the use of two monoclonal antibody CGRP inhibitors concomitantly for both prophylaxis and acute treatment, and therefore she would support retaining the bullet point, "Member is not receiving an injectable form of CGRP medication for any indication."
- S Klocke recommended removing these four bullet points under cluster headache treatment:
    1. Member is not prescribed this medication for medication overuse headache AND
    2. Member does not have ECG abnormalities compatible with acute cardiovascular event or conduction delay AND
    3. 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
    4. 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
- S Klocke moved to accept the proposed criteria for *prophylactic* use of CGRP inhibitors, with an amendment to delete cardiovascular exclusions, headache counts and medication overuse headache language from proposed criteria for non-preferred agents. Seconded by B Jackson. Motion passed unanimously.
- S Klocke moved to accept the proposed criteria for *treatment* with CGRP inhibitors, with amendments to:
    1. either remove the 2-NSAID failure requirement for non-preferred acute treatment or reduce it to trial/failure of 1 NSAID, and
    2. retain the bullet point "Member is not receiving an injectable form of CGRP medication for any indication" in the Preferred Medications for Acute Migraine Treatment section.

  Seconded by T Brubaker. Motion passed unanimously.

- S Klocke moved to delete four bullet points in the cluster headache section of criteria as described above. Seconded by B Jackson. Motion passed unanimously.
- S Klocke moved to accept all other criteria in this therapeutic class, as amended. Second by A Shmerling. Motion passed unanimously.

9. Triptans, Ditans and Other Migraine Treatments – Oral & Non-Oral

Preferred Agents, Oral Triptans
(quantity limits may apply)
Eletriptan tablet (generic Relpax)
Naratriptan tablet (generic Amerge)
Rizatriptan tablet, ODT (generic Maxalt)
Sumatriptan tablet (generic Imitrex)

Preferred Agents, Non-Oral Triptans
(quantity limits may apply)
IMITREX[BNR] (sumatriptan) nasal spray
Sumatriptan vial
Zolmitriptan nasal spray (*Amneal only)*

Preferred Agents, Ditans
None

Oral agents

Non-preferred oral triptan products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4-week trial, allergy, contraindication to therapy, intolerable side effects, contraindication to therapy or significant drug-drug interaction.

Note: The safety, tolerability, and efficacy of coadministering lasmiditan with a triptan or a gepant has not been assessed.

Quantity Limits:

Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan), Zomig (zolmitriptan)	Max 9 tabs/30 days
Treximet (sumatriptan/naproxen)	Max 9 tabs/30 days
Axert (almotriptan) and Relpax (eletriptan)	Max 6 tabs/30 days
Maxalt (rizatriptan)	Max 12 tabs/30 days
Reyvow (lasmiditan)	Max 8 tabs/30 days

Non-oral agents

Zembrace Symtouch injection, Tosymra nasal spray, or Onzetra Xsail nasal powder may be approved for members who have trialed and failed one preferred non-oral triptan products AND two oral triptan agents with different active ingredients. Failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, significant drug-drug interaction, or documented inability to take alternative dosage form.

All other non-preferred products may be approved for members who have trailed and failed one preferred non-oral triptan product AND one preferred oral triptan product. Failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects or

significant drug-drug interactions, documented inability to tolerate dosage form.

Quantity Limits:

Imitrex (sumatriptan) injection	Max 4 injectors / 30 days
Imitrex (sumatriptan) nasal spray	Max 6 inhalers / 30 days
Onzetra Xsail (sumatriptan) nasal powder	Max 16 nosepieces / 30 days
Tosymra (sumatriptan) nasal spray	Max 12 nasal spray devices / 30 days
Zembrace Symtouch (sumatriptan) injection	Max 36 mg / 30 days
Zomig (zolmitriptan) nasal spray	Max 6 inhalers / 30 days

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke and L Claus recommended editing the first sentence in the non-preferred oral agents section to simply" non-preferred products" or "non-preferred tripan and ditan products."
- B Jackson recommends revisiting the note about the safety, tolerability, and efficacy of coadministering lasmiditan with a triptan or a gepant during the next review of this drug class (or within a reasonable period of time) to consider removing it from these criteria in the future.
- L Claus favors adding a separate section of criteria specifically related to non-preferred ditan products that states "Non-preferred ditan products may be approved for members who have tried and failed three preferred products OR have a contraindication to therapy, intolerable side effects (etc.) to triptan products." A Shmerling moved to adopt this proposed language. Seconded by S Klocke. Motion passed unanimously.
- B Jackson moved to accept criteria in this class as amended. T Brubaker seconded. Motion passed unanimously.

10. Stimulants and Related Agents

Preferred Agents

***No PA Required (if age, maximum daily dose, and diagnosis met)**

ADDERALL XR[BNR] (mixed amphetamine salts ER)
Amphetamine salts, mixed (generic Adderall) tablet
Armodafinil tablet
Atomoxetine capsule
CONCERTA[BNR] (methylphenidate ER) tablet
Dexmethylphenidate IR tablet
Dexmethylphenidate ER capsule
Guanfacine ER tablet
Methylphenidate (generic Ritalin) oral solution
Methylphenidate (generic Ritalin) tablet
Modafinil tablet
VYVANSE (lisdexamfetamine) capsule

*Preferred medications may be approved through AutoPA for indications listed in Table 1 (preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis).

Non-preferred medications may be approved for members meeting the following criteria (for Sunosi (solriamfetol) and Wakix (pitolisant), refer to specific criteria listed below):

- Prescription meets indication/age limitation criteria (Table 1) AND
- Member meets one of the following:
  - If member is ≥ 6 years of age, has documented trial and failure‡ with three preferred products in the last 24 months OR

- If member is 3 to 5 years of age, has documented trial and failure‡ with one preferred product in the last 24 months

AND

- For members unable to swallow solid oral dosage forms, **Daytrana**, **Methylin solution**, **Quillichew**, **Quillivant XR** and **Dyanavel XR**: Onetwo of the trials must include preferred products that may be administered without swallowing whole (methylphenidate solution, dexmethylphenidate ER, Vyvanse, or Adderall XR) AND
- Member has a documented difficulty swallowing and is unable to utilize alternative dosing with preferred tablet and capsule formulations.

SUNOSI (solriamfetol) prior authorization may be approved if member meets the following criteria:

- Member is 18 years of age or older AND
- Member has diagnosis of either narcolepsy or obstructive sleep apnea (OSA) and is experiencing excessive daytime sleepiness AND
- Member does not have end stage renal disease AND
- If Sunosi is being prescribed for OSA, member has 1 month trial of CPAP AND
- Member has trial and failure‡ of modafinil AND armodafinil AND one other agent in stimulant PDL class.

WAKIX (pitolisant) prior authorization may be approved if member meets the following criteria:

- Member is 18 years of age or older AND
- Member has diagnosis of narcolepsy and is experiencing excessive daytime sleepiness AND
- Member does not have end stage renal disease (eGFR <15 mL/minute) AND
- Member does not have severe hepatic impairment AND
- Member does not have a history of QT interval prolongation AND
- Member has trial and failure‡ of modafinil AND armodafinil AND one other agent in the stimulant PDL class AND
- Member has been counseled that Wakix may reduce the efficacy of hormonal contraceptives and regarding use an alternative non-hormonal method of contraception during Wakix therapy and for at least 21 days after discontinuing treatment.

Maximum Dose (all products): See Table 2

Exceeding Max Dose: Prior authorization may be approved for doses that are higher than the listed maximum dose (Table 2) for members meeting the following criteria:

- Member is taking medication for indicated use listed in Table 1 AND
- Member has 30-day trial and failure‡ of three different preferred or non-preferred agents at maximum doses listed in Table 2 AND
- Documentation of member's symptom response to maximum doses of three other agents is provided AND
- Member is not taking a sedative hypnotic medication (such as temazepam, triazolam, or zolpidem from the Sedative Hypnotic PDL class).

‡Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Table 1: Indication and Age Limitations	
• Approval for medically accepted indications not listed in Table 1 may be given with prior authorization review and may require submission of peer-reviewed literature or medical compendia showing safety and efficacy of the medication used for the prescribed indication. • Preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis if meeting all other criteria for approval. • **Bolded drug names are preferred** (subject to preferential coverage changes for brand/generic equivalents)	
Drug	**Indication/Age**
Stimulants-Immediate Release	
Amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years), adjunct therapy to manage fatigue associated with multiple sclerosis
Dextroamphetamine IR (ZENZEDI)	ADHD (Age 3 to≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine solution (PROCENTRA)	ADHD (Age 3 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Methamphetamine (DESOXYN)	ADHD (Age ≥ 6 years)
methylphenidate IR (generic METHYLIN, RITALIN)	ADHD (Age ≥ 6 years†), Narcolepsy (Age ≥ 6 years), OSA, adjunct therapy to manage fatigue associated with multiple sclerosis †Prior Authorization for members 4 to 6 years of age with a diagnosis of ADHD may be approved with prescriber attestation to the following: • Member's symptoms have not significantly improved despite adequate behavior interventions AND • Member experiences moderate-to-severe continued disturbance in functioning AND • Prescriber has determined that the potential benefits of starting methylphenidate before the age of 6 years outweigh the potential harm of delaying treatment.
Mixed amphetamine salts IR (generic ADDERALL)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years), adjunct therapy to manage fatigue associated with multiple sclerosis
Stimulants -Extended-Release	
Amphetamine ER (ADZENYS XR-ODT and ADZENYS ER suspension)	ADHD (Age ≥ 6 years)
Amphetamine ER (DYANAVEL XR)	ADHD (Age ≥ 6 years)
Mixed-amphetamine salts ER (**ADDERALL XR**)	ADHD (Age ≥ 6 years), adjunct therapy to manage fatigue associated with multiple sclerosis
Dexmethylphenidate ER (generic Focalin XR)	ADHD (Age ≥ 6 years)
Dextroamphetamine ER (DEXEDRINE)	ADHD (Age 6 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
Dextroamphetamine IR and ER (DEXTROSTAT)	ADHD and Narcolepsy (IR ≥ 3 years, ER ≥ 6 years)
Lisdexamfetamine dimesylate (**VYVANSE capsule**, Vyvanse chewable)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years), adjunct therapy to manage fatigue associated with multiple sclerosis

Methylphenidate ER OROS **(CONCERTA)**	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA, adjunct therapy to manage fatigue associated with multiple sclerosis
Methylphenidate patch (DAYTRANA)	ADHD (Age ≥ 6 years)
Methylphenidate SR (METADATE ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (METADATE CD)	ADHD (Age ≥ 6 years)
Methylphenidate ER (QUILLICHEW ER)	ADHD (Age 6 years to ≤ 65 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (QUILLIVANT XR)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (RITALIN LA)	ADHD (Age ≥ 6 years)
Methylphenidate ER (ADHANSIA XR)	ADHD (Age ≥ 6 years)
Non-Stimulants	
Atomoxetine (generic STRATTERA)	ADHD (Age ≥ 6 years), adjunct therapy to manage fatigue associated with multiple sclerosis
Clonidine ER (KAPVAY)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
Guanfacine ER (generic INTUNIV)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants, adjunct therapy to manage fatigue associated with multiple sclerosis
Viloxazine ER (QELBREE)	ADHD (Age 6 years to ≤ 17 years)
Wakefulness-promoting Agents	
Armodafinil (generic NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD, adjunct therapy to manage fatigue associated with multiple sclerosis (all Age ≥ 18 years)
Modafinil (PROVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD), adjunct therapy to manage fatigue associated with multiple sclerosis (all Age ≥ 18 years)
Pitolisant (WAKIX)	Excessive sleepiness associated with narcolepsy (Age ≥ 18 years)
Solriamfetol (SUNOSI)	Excessive sleepiness associated with narcolepsy, OSA (Age ≥ 18 years)
KEY: **ADHD**-attention-deficit/hyperactivity disorder, **OSA**-obstructive sleep apnea, **SWD**-shift work disorder	

Table 2: Maximum Dose

Drug	Maximum Daily Dose
ADDERALL	60 mg
ADDERALL XR	60 mg
ADHANSIA XR	85 mg
ADZENYS XR ODT ADZENYS ER SUSPENSION	18.8 mg (age 6-12) 12.5 mg (age ≥ 13)
AMPHETAMINE SALTS	40 mg
APTENSIO XR	60 mg
CONCERTA	54 mg (age 6-12) or 72 mg (≥ age 13)

COTEMPLA XR-ODT	51.8 mg
DEXTROAMPHETAMINE ER	60 mg
DAYTRANA	30 mg
DESOXYN	25 mg
DEXEDRINE	60 mg
DEXTROSTAT	60 mg
DYANAVEL XR	20 mg
EVEKEO	60 mg
FOCALIN	20 mg
FOCALIN XR	40 mg
INTUNIV ER	4 mg (age 6-12) or 7 mg (age ≥ 13)
JORNAY PM	100 mg
KAPVAY ER	0.4 mg
METADATE CD	60 mg
METADATE ER	60 mg
METHYLIN	60 mg
METHYLIN ER	60 mg
METHYLIN SUSPENSION	60 mg
METHYLPHENIDATE	60 mg
METHYLPHENIDATE ER	60 mg
MYDAYIS ER	25 mg (age 13-17) or 50 mg (age ≥ 18)
NUVIGIL	250 mg
PROCENTRA	60 mg
PROVIGIL	400 mg
QELBREE	400 mg
QUILLICHEW ER	60 mg
QUILLIVANT XR	60 mg
RITALIN IR	60 mg
RITALIN SR	60 mg
RITALIN LA	60 mg
STRATTERA	100 mg
SUNOSI	150 mg
VYVANSE CAPSULES AND CHEWABLE TABLETS	70 mg
WAKIX	35.6 mg
ZENZEDI	60 mg

Scheduled testimony presentations:

L Lewis, Corium - Azstarys

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling moved to accept the proposed criteria as written. Seconded by B Jackson. Motion passed unanimously.

11. Growth Hormones

Preferred agents

No PA Required (if diagnosis and dose met)

GENOTROPIN cartridge, Miniquick pen
NORDITROPIN Flexpro pen

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 (i.e., 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 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 Max Dosing (age < 18 years)	Adult Max Dosing (age ≥ 18 years)
Genotropin	0.33 mg/kg/week	0.08 mg/kg/week
Humatrope	0.375 mg/kg/week	0.0875 mg/kg/week
Norditropin Flexpro	0.47 mg/kg/week	0.112 mg/kg/week
Nutropin AQ Nuspin	0.357 mg/kg/week	0.175 mg/kg/week for ≤35 years of age

		0.0875 mg/kg/week for >35 years of age
Omnitrope	0.33 mg/kg/week	0.08 mg/kg/week
Saizen	0.18 mg/kg/week	0.07 mg/kg/week
Serostim	Not Indicated	42 mg/week for cachexia with HIV only (in combination with antiretroviral therapy)
Zomacton	0.375 mg/kg/week	0.0875 mg/kg/week
Zorbtive	Not Indicated	8 mg/28 days for short bowel syndrome only
*Based on FDA labeled indications and dosing		

Discussion

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

12. Bile Salts

Preferred Agents
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 product (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 age must be greater than 3 weeks old AND
  - Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3ß-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 age must be greater than 3 weeks old 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 titer of 1:40 or higher
    - Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND
- Due to risk of serious liver injury, member does not have Primary Biliary Cholangitis with advanced cirrhosis, AND
- Member has failed treatment with a preferred ursodiol product for at least 1 year with an inadequate response OR
- Member has had intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations.

Scheduled testimony presentations:

B Peck, Albireo Pharma - Bylvay
A Chi, Livmarli – Mirum Pharmaceuticals

Discussion

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

13. Multiple Sclerosis Agents

Preferred Agents, Disease Modifying Therapies
No PA Required (unless indicated*)
*AUBAGIO (teriflunomide) tablet**2nd Line**
AVONEX (interferon beta-1a) injection
BETASERON (interferon beta-1b) injection
COPAXONE[BNR] (glatiramer) 20 mg injection
Dimethyl fumarate DR capsule (generic Tecfidera)
*GILENYA (fingolimod) 0.5 mg tablet (30-ct bottle)**2nd Line**
*KESIMPTA (ofatumumab) pen**2nd Line**
*TECFIDERA[BNR] (dimethyl fumarate) tablet **2nd Line**

Preferred Agents, Symptom Management Therapies
None

*Second-line preferred agents **(Gilenya, Tecfidera, Aubagio, Kesimpta)** may be approved if meeting the following:

- Member has documented diagnosis of multiple sclerosis made by neurologist in the last 3 years OR member has history of diagnosis made by a neurologist > 3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of multiple sclerosis AND
- Documentation is provided by prescribing neurologist (or name of neurologist consulted may be indicated) supporting marked functional decline as demonstrated by MRI or medical record documentation supporting increased burden of disease AND

- Prescriber attests to shared decision making with respect to risks versus benefits of medical treatment AND
- Additional safety criteria for prescribed agent are met (Table 1).

For members NOT meeting above criteria, sSecond-line preferred agents **(Gilenya, Tecfidera, Aubagio, Kesimpta)** may be approved if meeting all of the following:

- 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 consultation with a neurologist AND
- Prescriber attests to shared decision making with respect to risks versus benefits of medical treatment AND
- On clinical exam, member has signs and symptoms consistent with functional limitations due to multiple sclerosis that have lasted one month or longer AND
- Additional safety criteria for prescribed agent are met (Table 1)
- Member meets one of the following:
    - Member has trialed and failed treatment with Avonex (interferon beta-1a) OR Betaseron (interferon beta-1b) OR with Copaxone (glatiramer) OR dimethyl fumarate. Failure is defined as intolerable side effects, contraindication to therapy, drug-drug interaction, or lack of efficacy, ANDOR
    - Member has documented diagnosis of multiple sclerosis made by neurologist in the last 3 years OR member has history of diagnosis made by a neurologist > 3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of multiple sclerosis

Non-Preferred Products:

Non-preferred products may be approved following trial and failure with three preferred products. **Mayzent** (simponimod), **Mavenclad** (cladribine), **Vumerity** (dioroxemel fumerate), and **Bafiertam** (monomethyl fumarate DR) must meet specific criteria listed for those agents below. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

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 no evidence of relapse in the 3 months preceding initiation of therapy AND
- Member has previous trial and failure of three preferred agents, one of which must be Gilenya (fingolimod). Failure is defined as lack of efficacy, 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) may be approved with provider attestation that member's symptoms are stable or there is documented clinical improvement.

Mavenclad (cladribine) 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 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 prescribed agent are met (Table 1)

Vumerity (diroximel fumarate) or **Bafiertam (monomethyl fumarate DR)** 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
- Additional safety criteria for prescribed agent are met (Table 1) AND
- Member has previous trial and failure of three preferred agents, one of which must be Tecfidera (dimethyl fumarate). Failure is defined as lack of efficacy, allergy, intolerable side effects [if GI adverse events, must meet additional criteria below], or significant drug-drug interactions) AND
- If Vumerity (diroximel fumarate) or 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 Vumerity (diroximel fumarate) therapy or Bafiertam (monomethyl fumarate DR).

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

Table 1: Safety Criteria for Initiating Multiple Sclerosis Disease Modifying Therapy							
Brand	**AUBAGIO**	**BAFIERTAM**	**GILENYA**	**MAYZENT**	**MAVENCLAD**	**TECFIDERA**	**VUMERITY**
Generic	**teriflunomide**	**monomethyl fumarate DR**	**fingolimod**	**siponimod**	**cladribine**	**dimethyl fumarate**	**dioroxemel fumarate**
No active infections[a]	X	X	X	X	X	X	X
Baseline CBC w/diff	X	X		X	X[c, g]	X	X
Baseline ALT, AST, bilirubin ≤ 2x ULN[b]	X	X	X	X	X	X	X
Negative baseline pregnancy test	X	X		X	X	X	
Using highly effective contraception (if childbearing potential)	X	X	X	X	X	X	X
Other	• Documented baseline blood pressure • Skin or blood screening test for *M. tuberculosis*		• No significant CV history[f] • QTc interval <500 ms • No Class 1a or Class III antiarrhythmic use • Baseline ocular coherence eye exam	• No CYP2C9*3/*3 genotype • No significant CV history[f] • QTc interval <500 ms • Baseline eye evaluation that includes macula exam	• No current evidence of malignancy • No current immunosuppressive or myelosuppressive therapy	Member counseled regarding risks of anaphylaxis, angioedema and PML[e]	
Maximum dose	14 mg per day	190 mg twice a day	Age and weight based[d]	60 mg per 30 days	Not exceeding 3.5mg/kg during full treatment course	240 mg twice a day	924 mg per day

a – including herpes zoster or other active serious infections (or chronic: such as hepatitis, tuberculosis and HIV)
b – ULN - upper limit of normal
c – plus at 2 and 6 months post-initiation and periodically thereafter
d – GILENYA 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
e – PML - progressive multifocal leukoencephalopathy
f – No h/o MI, CVA, TIA, unstable angina, NYHA Class III-IV HF **AND** no Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
g – Lymphocytes must be within normal limits before initiating the first treatment course and ≥ 800 cells per microliter before initiating the second treatment course

Stakeholder input:

Letter, National MS Society/Epilepsy Foundation of CO & WY, Rocky Mountain Multiple Sclerosis Center, Parkinson Association of the Rockies
Kespimta Clinical Summary – Novartis Pharmaceuticals

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke suggested removing the bullet point, "Member has trialed taking Tecfidera (dimethyl fumarate) with food AND" since this seems more like a patient counseling point and not a specific medical intervention. P Lanius offered that the phrase offers a checkpoint to help ensure that members are taking their medication properly. L Claus added that it was a more subjective phrase that is not generally added to criteria for other medications that should be taken with food. A Shmerling moved to delete the bullet point. Seconded by S Klocke. P Lanius was opposed the edit. Motion passed with seven aye votes.
- S Klocke moved to accept the criteria as amended. T Brubaker seconded. Motion passed unanimously.

14. Ophthalmics, Anti-Inflammatory Agents

Preferred Agents, NSAIDs
Diclofenac 0.1%
Flurbiprofen 0.03%
ILEVRO (nepafenac) 0.03%
Ketorolac 0.5%, Ketorolac LS 0.4%

Preferred Agents, Corticosteroids
FLAREX (fluorometholone) 0.1%
Fluorometholone 0.1% drops
FML FORTE (fluorometholone) 0.25% drops
LOTEMAX (loteprednol) 0.5% drops[BNR], 0.5% ointment
MAXIDEX (dexamethasone) 0.1%
PRED MILD (prednisolone) 0.12%
Prednisolone acetate 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, contraindication to therapy, 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 prednisolone acetate 1% (failure is defined as lack of efficacy, 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, contraindication to therapy, allergy, contraindication, intolerable side effects, or significant drug-drug interaction).

Lotemax SM (loteprednol etabonate) or **Inveltys (loteprednol etabonate)** may be approved if meeting all of the following:

- Member is ≥ 18 years of age AND
- Lotemax SM or Inveltys (loteprednol etabonate) is being used for the treatment of post-operative

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, contraindication to therapy, 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

Eysuvis (loteprednol etabonate) may be approved if meeting all of the following:
- Member is ≥ 18 years of age AND
- Eysuvis (loteprednol etabonate) is being used for short-term treatment (up to two weeks) of the signs and symptoms of dry eye disease AND
- Member has failed treatment with one preferred product in the Ophthalmic Immunomodulator therapeutic class. Failure is defined as lack of efficacy with a 3-month trial, contraindication to therapy, allergy, 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

Quantity limit: one bottle/15 days

Scheduled testimony presentations:

K Godfrey, OD – Front Range Family Eye Care

Discussion
- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke moved to accept the proposed criteria as written. Seconded by A Shmerling. Motion passed unanimously.

15. Opioids – Short-Acting, Fentanyl Preparations & Long-Acting

Preferred Agents, Short-acting
No PA Required* (if criteria and quantity limits is are met)
Codeine/acetaminophen tablet*
Hydrocodone/acetaminophen solution, tablet
Hydromorphone tablet
Morphine IR solution, tablet
NUCYNTA (tapentadol) tablet
Oxycodone solution, tablet
Oxycodone/acetaminophen tablet
Tramadol 50 mg tablet*
Tramadol/acetaminophen tablet*

Preferred Agents, Short-acting fentanyl preparations
(*buccal, intranasal, transmucosal, sublingual)*
None

Preferred Agents, Long-acting
No PA Required (*if dose met)
BUTRANS[BNR] (buprenorphine) transdermal patch
*Fentanyl 12 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg transdermal patch
Morphine ER (generic MS Contin) tablet
NUCYNTA ER (tapentadol ER) tablet
Tramadol ER (generic Ultram ER) tablet

Short-acting agents

*Preferred codeine and tramadol products do not require prior authorization for adult members (18 years of age or greater) if meeting all other opioid policy criteria. Preferred codeine or tramadol products prescribed for members < 18 years of age must meet the following criteria:

- **Preferred tramadol and tramadol-containing products** may be approved for members < 18 years of age if meeting the following:
  - Member is 12 years to 17 years of age AND
  - Tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND
  - Member is not obese (BMI-for-age > 95th percentile per CDC guidelines) and does not have obstructive sleep apnea or severe lung disease
    OR
  - For members < 12 years of age with complex conditions or life-limiting illness who are receiving care under a pediatric specialist, tramadol and tramadol-containing products may be approved on a case-by-case basis

- **Preferred Codeine and codeine-containing products** will receive prior authorization approval for members meeting the following criteria may be approved for members < 18 years of age if meeting the following:
  - Member is 12 years to 17 years of age AND
  - Codeine is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND
  - Member is not obese (BMI-for-age > 95th percentile per CDC guidelines) and does not have obstructive sleep apnea or severe lung disease AND
  - Member is not pregnant or breastfeeding AND
  - Renal function is not impaired (GFR > 50 m/min) AND
  - Member is not receiving strong inhibitors of CYP3A4 (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200mg daily], voriconazole, delavirdine, and milk thistle) AND
  - Member meets one of the following:
    1. Member has trialed codeine or codeine-containing products in the past with no history of allergy or adverse drug reaction to codeine
    2. Member has not trialed codeine or codeine-containing products in the past and the prescriber acknowledges reading the following statement: “Approximately 1-2% of the population metabolizes codeine in a manner that exposes them to a much higher potential for toxicity. Another notable proportion of the population may not clinically respond to codeine. We ask that you please have close follow-up with members newly starting codeine and codeine-containing products to monitor for safety and efficacy.”

Nucynta® IR (tapentadol) may be approved for members who meet the following criteria:
- Member has history of trial/failure of 7-days utilization of preferred product(s) in the last 21 days OR
- If member does not meet the above criteria, prior authorization approval for Nucynta IR will require trial and failure of three preferred agents. Failure is defined as lack of efficacy, intolerable side effects, significant drug-drug interaction, allergy‡, or significant adverse drug reaction.

Non-preferred tramadol products may be approved following trial and failure of generic tramadol 50 mg tablet AND generic tramadol/acetaminophen tablet.

All other non-preferred short-acting opioid products may be approved following trial and failure of three preferred products. Failure is defined as allergy‡, lack of efficacy, contraindication to therapy, intolerable side effects, or significant drug-drug interaction.

‡Allergy: hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema

Quantity Limits: Short-acting opioids will be limited to a total of 120 tablets per 30 days (4/day) per member for members who are not included in the opioid treatment naive policy. Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. For members who are receiving more than 120 tablets currently and who do not have a qualifying exemption diagnosis, a 6-month prior authorization can be granted via the prior authorization process for providers to taper members. Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. There may be allowed certain exceptions to this limit for acute situations (for example: post-operative surgery, fractures, shingles, car accident).

Maximum Doses:
Tramadol: 400 mg/day
Codeine: 360 mg/day
Butorphanol intranasal: 10 mL per 30 days (four 2.5mL 10mg/mL package units per 30 days)

The maximum quantity for Nucynta IR will have a maximum daily quantity of is 6 tablets per day (180 tablets per 30 days).

Short-acting fentanyl preparations

Fentanyl buccal, intranasal, transmucosal, and sublingual products:

Prior authorization approval may be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The prior authorization may be granted for up to 4 doses per day. For patients in hospice or palliative care, prior authorization will be automatically granted regardless of the number of doses prescribed.

Long-acting agents

***Nucynta ER or Oxycontin** may be approved for members who have trialed and failed‡ treatment with TWO preferred agents.

All other non-preferred products may be approved for members who have trialed and failed‡ three preferred products.

‡Failure is defined as lack of efficacy with 14-day trial due to allergy (hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema), intolerable side effects, or significant drug-drug interaction.

Methadone: Members may receive 30-day approval when prescribed for neonatal abstinence syndrome without requiring trial and failure of preferred agents or opioid prescriber consultation.

Methadone Continuation:
Members who have been receiving methadone for pain indications do not have to meet non-preferred criteria. All new starts for methadone will require prior authorization under the non-preferred criteria listed above.

If a prescriber would like to discuss strategies for tapering off methadone or transitioning to other pain management therapies for a Health First Colorado member, consultation with the Health First Colorado pain management physician is available free of charge by contacting the pharmacy call center helpdesk and requesting an opioid prescriber consult.

Reauthorization:
Reauthorization for a non-preferred agent may be approved if the following criteria are met:

- Provider attests to continued benefit outweighing risk of opioid medication use AND
- Member met original prior authorization criteria for this drug class at time of original authorization

Quantity/Dosing Limits:

- **Oxycontin, Opana ER, Nucynta ER**, and **Zohydro ER** will only be approved for twice daily dosing.
- **Hysingla ER** will only be approved for once daily dosing.
- **Fentanyl patches** will require a PA for doses of more than 15 patches/30 days (if using one strength) or 30 patches for 30 days (if using two strengths). For fentanyl patch strengths of 37mcg/hr, 62mcg/hr, and 87mcg/hr, member must trial and fail two preferred strengths of separate patches that will provide the desired dose (such as 12mcg/hr + 50mcg/hr = 62mcg/hr).

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke moved to remove the phrase “Member is not obese” that appears twice in this therapeutic class and revising the wording of those two statements. Seconded by A Shmerling. Motion passed unanimously.
- S Klocke moved to accept the proposed criteria as amended. Seconded by P Lanius. Motion passed unanimously.

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.*

16. Non-Opioid Analgesia Agents – Oral & Topical

Preferred Agents, Oral
Duloxetine capsule (generic Cymbalta)
Gabapentin capsule, tablet, solution
Pregabalin capsule
SAVELLA (milnacipran) tablet, titration pack

Preferred Agents, Topical
LIDODERM[BNR] (lidocaine) patch
Lidocaine patch *(Par only)*

Oral products

Non-preferred oral non-opioid analgesic agents may be approved if member meets all of the following criteria:

- Member has trialed and failed duloxetine (20mg, 30mg, or 60mg) AND has trialed and failed gabapentin OR pregabalin capsule (Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Prior authorization will be required for Lyrica (pregabalin) capsule dosages > 600mg per day (maximum of 3 capsules daily) and gabapentin dosages > 3,600mg per day.

Topical products

Non-preferred topical products require a trial/failure with an adequate 8-week trial of gabapentin AND pregabalin AND duloxetine AND lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Prior authorization will be required for lidocaine patch quantities exceeding 90 patches per 30 days (maximum of 3 patches daily).

17. Alpha Blockers & Calcium Channel Blockers

Preferred Agents, alpha blockers
Prazosin capsule

Preferred Agents, calcium channel blockers, dihydropyridines (DHPs)
Amlodipine tablet
Felodipine ER tablet
Nifedipine IR capsule
Nifedipine ER tablet

Preferred Agents, calcium channel blockers, Non-dihydropyridines (Non-DHPs)
Diltiazem IR tablet
Diltiazem ER capsule
Verapamil IR, ER tablet
Verapamil ER 120 mg, 180 mg, 240 mg capsule

Alpha blockers

Non-preferred products may be approved following trial and failure of one preferred product (failure is defined as lack of efficacy with 4-week trial, allergy or intolerable side effects).

Calcium channel blockers, Dihydropyridines (DHPs)

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

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

Non-preferred products 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.

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 if meeting the following:
- The member has a feeding tube or confirmed difficulty swallowing solid oral dosage forms AND
- For members < 6 years of age, the prescriber confirms that the member has already been receiving the medication following initiation in a hospital or other clinical setting

18. Lipotropics - Bile Acid Sequestrants, Fibrates, Other

Preferred Agents, Bile Acid Sequestrants
Colesevelam tablet
Colestipol tablet
Cholestyramine packet (sucrose)
Cholesytramine light packet (aspartame)

Preferred Agents, Fibrates
Fenofibrate capsule, tablet (generic Lofibra/Tricor)
Gemfibrozil tablet

Preferred Agents, Other
Ezetimibe tablet
Niacin ER tablet
*Omega-3 ethyl esters capsule (generic Lovaza)

Non-preferred bile acid 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).

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

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).

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

***Omega-3 ethyl esters (generic Lovaza)** 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 (e.g., 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

19. Statins & Combinations

Preferred Agents
Atorvastatin tablet
Lovastatin tablet
Pravastatin tablet
Rosuvastatin tablet
Simvastatin tablet

Statins

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 < 8 years of age.

Statin Combinations

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:

- VYTORIN (ezetimibe/simvastatin) will not be approved for members < 18 years of age.
- CADUET (amlodipine/atorvastatin) will not be approved for members < 10 years of age.

20. Monoamine Oxidase Inhibitors (MAOIs)

Preferred Agents

None

Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred anti-depressant products. If three preferred anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred anti-depressant products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Members currently stabilized on a Non-preferred MAOi antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

21. Tricyclic Antidepressants

Preferred Agents

Amitriptyline tablet
Desipramine tablet
Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule
Doxepin solution
Imipramine HCl tablet
Nortriptyline capsule, solution

Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred tricyclic products. If three preferred products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all tricyclic preferred products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Members currently stabilized on a non-preferred TCA tricyclic antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

Silenor (doxepin 3mg, 6mg) approval criteria can be found on the Appendix P.

22. Anxiolytics, Non-Benzodiazepine

Preferred Agents
Buspirone tablet

Non-preferred products 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.

23. Lithium Agents

Preferred Agents
Lithium carbonate capsule
Lithium carbonate tablet
Lithium ER tablet

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.

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.

24. Neurocognitive Disorder Agents

Preferred Agents
***Must meet eligibility criteria**
*Donepezil 5mg, 10mg tablet, ODT
Galantamine IR tablet
*Memantine IR tablet
*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 that 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)

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.

25. Sedative Hypnotics – Non-Benzodiazepine & Benzodiazepine

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

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

Non-benzodiazepine Sedative Hypnotics

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:
- Members 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 (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

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).

Benzodiazepine Sedative Hypnotics

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 7.5 mg 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 trial 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 member's ≥ 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	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	10mg/day
Edluar	zolpidem sublingual	10 mg/day
Intermezzo	zolpidem sublingual	Men: 3.5mg/day Women: 1.75 mg/day
Lunesta	eszopiclone	3 mg/day
Quviviq	daridorexant	50 mg/day
Rozerem	ramelteon	8 mg/day
Sonata	zaleplon	20 mg/day
Benzodiazepine		
Halcion	triazolam	0.5 mg/day
Restoril	temazepam	30 mg/day
-	estazolam	2 mg/day
-	flurazepam	30 mg/day
Doral	quazepam	15 mg/day

26. Skeletal Muscle Relaxants

Preferred Agents
No PA Required (if under 65 years of age)*
Baclofen (generic Lioresal)
Cyclobenzaprine (generic Flexeril) 5mg and 10mg tablet
Methocarbamol
Tizanidine tablet

All agents in this class will require a PA for members 65 years of age and older. The maximum allowable approval will be for a 7-day supply.

Non-preferred skeletal muscle relaxants may be approved for members who have trialed and failed‡ three preferred agents.

Authorization for any **CARISOPRODOL** product will be given for a maximum 3-week one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products within the last 6 months.

***Dantrolene** may be approved for members 5-17 years of age who have trialed and failed‡ one preferred agent and meet the following criteria:

- Documentation of age-appropriate liver function tests AND
- One of following diagnoses: Multiple Sclerosis, Cerebral Palsy, stroke, upper motor neuron disorder, or spinal cord injury
- Dantrolene will be approved for the period of one year
- If a member is stabilized on dantrolene at <18 years of age, they may continue to receive approval after turning 18 years of age

‡Failure is defined as: lack of efficacy with 14 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.

27. Hemorrhoidal, Anorectal, and Related Topical Anesthetic Agents

Preferred Agents, Hydrocortisone single agent
ANUSOL-HC (hydrocortisone) 2.5% cream
CORTIFOAM (hydrocortisone) 10% aerosol
Hydrocortisone 1% cream with applicator
Hydrocortisone 2.5% cream with applicator
Hydrocortisone enema
PROCTO-MED HC (hydrocortisone) 2.5% cream
PROCTO-PAK (hydrocortisone) 1% cream
PROCTOSOL-HC 2.5% (hydrocortisone) cream
PROCTOZONE-HC 2.5% (hydrocortisone) cream

Preferred Agents, Lidocaine single agent
Lidocaine 5% ointment

Preferred Agents, Other and Combinations
Lidocaine-Hydrocortisone 3-0.5% cream with applicator
Lidocaine-Prilocaine Cream
PROCTOFOAM (hydrocortisone-pramoxine)

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).

28. Ophthalmics, Allergy Agents

Preferred Agents
ALREX (loteprednol) 2%
Cromolyn 4%
Ketotifen 0.025% (OTC)
LASTACAFT (alcaftadine) 0.25%
Olopatadine 0.2% (Generic Pataday Once Daily) (OTC)
Olopatadine 0.1%, (Generic Pataday/Patanol) 0.2% (RX)
PAZEO (olopatadine) 0.7% (RX)

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).

29. Ophthalmics, Immunomodulators

Preferred Agents
RESTASIS (cyclosporine 0.05%)

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

- Member is 18 years and older AND
- Member has a diagnosis of chronic dry eye AND
- Member has failed a 3-month trial of one preferred product. Failure is defined as a lack of efficacy, contraindication to therapy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions AND
- Prescriber is an ophthalmologist, optometrist or rheumatologist

Maximum Dose/Quantity:
60 single use containers for 30 days
5.5 mL/20 days for Restasis Multi-Dose

30. Ophthalmics, Glaucoma Agents

Preferred Agents, Beta blockers
Levobunolol
Timolol (generic Timoptic)

Preferred Agents, Carbonic anhydrase inhibitors
AZOPT[BNR] (brinzolamide)
Dorzolamide

Preferred Agents, Prostaglandin analogue
Latanoprost 0.005%
LUMIGAN[BNR] (bimatoprost) 0.01%
TRAVATAN Z[BNR] (travoprost)

Preferred Agents, Alpha-2 adrenergic agonists
ALPHAGAN P 0.1% (brimonidine)
ALPHAGAN P[BNR] 0.15% (brimonidine)
Brimonidine 0.2%

Preferred Agents, Other ophthalmic, glaucoma and combinations
COMBIGAN[BNR] (brimonidine/timolol)
Dorzolamide/Timolol
Dorzolamide/Timolol PF

Beta-blockers

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, contraindication to therapy, 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 agents in the Mass Review section of criteria.
- B Jackson moved to accept the criteria as written. A Shmerling seconded. Motion passed unanimously.

Prior Authorization and Utilization Management Criteria for other Selected Products

1. XOLAIR (omalizumab) subcutaneous injection

XOLAIR (omalizumab) may be approved for members when the following criteria are met for the appropriate indication:

1. The prescriber has determined that self-administration of XOLAIR (omalizumab) by the member or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and implementation of mitigation strategies.
2. If administered for the treatment of asthma:
   - Member is 6 years of age or older AND
   - Member has a diagnosis of moderate to severe asthma with one of the following:
     1. A pre-treatment IgE serum concentration greater than or equal to 30 IU per mL, OR
     2. A positive skin test or in vitro reactivity to a perennial inhaled allergen AND
   - Member's symptoms remain uncontrolled despite adherence to concomitant treatment with a high-dose inhaled corticosteroids and a long acting beta2-agonist AND
   - Xolair is not being used as a monotherapy AND
   - Xolair will not be used concomitantly with other biologics indicated for asthma AND
   - Maximum dose for asthma is 375 mg subcutaneously every 2 weeks.

b. Reauthorization for asthma indication may be approved if member has shown clinical improvement as documented by one of the following:

- Improvement in lung function, measured in FEV1, OR
- Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits

c. If administered for the treatment of chronic idiopathic urticaria (CSU)
- Member is 12 years of age or older AND
- Member is diagnosed with chronic idiopathic urticaria AND
- Member is symptomatic despite H1 antihistamine treatment AND
- Member has tried and failed at least three of the following:
    1. high-dose second generation H1 antihistamine
    2. H2 antihistamine
    3. first-generation antihistamine
    4. leukotriene receptor antagonist
    5. hydroxyzine or doxepin (must include)
- Member who is currently stable on Xolair for chronic idiopathic urticaria may continue to receive prior authorization approval to continue Xolair therapy.
- Maximum dose for chronic idiopathic urticaria is 300 mg subcutaneously every 4 weeks
- The appropriate duration of Xolair therapy for CSU has not been evaluated. Prescriber attests that the need for continued therapy will be periodically reassessed.

d. If administered for the treatment of chronic rhinosinusitis with nasal polyps
- Member has a concomitant diagnosis of asthma or chronic idiopathic urticaria and meets one of the following:
    1. For asthma
        a. member's symptoms remain uncontrolled despite adherence to concomitant treatment with a high-dose inhaled corticosteroids and a long acting beta2-agonist
    2. For chronic idiopathic urticaria:
        a. Member is symptomatic despite H1 antihistamine treatment AND
        b. Member has tried and failed at least three of the following:
            i. high-dose second generation H1 antihistamine
            ii. H2 antihistamine
            iii. first-generation antihistamine
            iv. leukotriene receptor antagonist
            v. hydroxyzine or doxepin (must include)

  AND
- Member is 18 years of age or older AND
- Member has diagnosis of chronic rhinosinusitis with nasal polyps AND
- Member has a pre-treatment IgE level greater than or equal to 30 IU per mL AND
- Member has tried and failed at least two intranasal corticosteroids (see Intranasal Rhinitis Agents PDL class). Failure is defined as lack of efficacy with a 2-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction
  AND
- Member is *currently* adherent to intranasal corticosteroid therapy AND
- Member has a baseline bilateral endoscopic nasal polyps score indicating the need for treatment
- Xolair is being prescribed by or in conjunction with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist
- Maximum dose for nasal polyps is 600 mg subcutaneously every 2 weeks.

e. Reauthorization for chronic rhinosinusitis with nasal polyps indication may be approved if member has shown clinical improvement as documented by one of the following:
   - Initial approval criteria were met at the time of initiation of therapy AND
   - Provider attests that member has documented improvement in bilateral endoscopic nasal polyps score, AND
   - Provider attests that member is being periodically reassessed for need for continued therapy based on disease severity and/or level of symptom control

Quantity Limits:

For asthma:
- one 75 mg/0.5 mL pre-filled syringe/14 days
- two 150 mg/mL pre-filled syringes or single-dose vials/14 days

For chronic spontaneous urticaria:
- two 150mg/mL pre-filled syringes or single-dose vials/30 days

For nasal polyps:
- four 150 mg/mL pre-filled syringes or single-dose vials/14 days

Scheduled testimony presentations:

M Puyear, Xolair - Genentech

Discussion

- J Taylor reminded Board members that Xolair (omalizumab) is managed on both the pharmacy benefit and the medical benefit. The proposed changes will be an updated to the current criteria and potentially impact both benefit types.
- P Lanius moved to modify bullet point 2.d.viii to say, "Xolair is being prescribed by or in conjunction with a specialist (such as a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist). Seconded by S Klocke. Motion passed unanimously.
- L Claus moved to remove the required the section of criteria related to members having a concomitant diagnosis of asthma or chronic idiopathic urticaria in order to meet PA criteria for a diagnosis of chronic rhinosinusitis with nasal polyps. Seconded by B Jackson. Motion passed unanimously.
- B Jackson moved to accept the proposed criteria for Xolair as amended. Seconded by S Klocke. Motion passed unanimously.

2. LIVTENCITY (maribavir) oral tablets

LIVTENCITY (maribavir) may be approved if the following criteria are met:

1. Member is ≥ 12 years of age and weighs ≥ 35 kg, AND
2. Member has a diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet AND
3. Prescriber confirms that potentially significant drug-drug interactions (such as those with digoxin, anticonvulsants, rosuvastatin, strong CYP3A4 inducers, rifampin, and immunosuppressants) will be carefully evaluated prior to initiating therapy with LIVTENCITY (maribavir), based on the current product labeling.

Maximum Dose:
- Usual dose: 800 mg/day
- If co-administered with carbamazepine: 1,600 mg/day
- If co-administered with phenytoin or phenobarbital: 2,400 mg/day

Quantity Limits:
- Usual dose: 120 tablets/30 days
- If co-administered with carbamazepine: 240 tablets/30 days
- If co-administered with phenytoin or phenobarbital: 360 tablets/30 days

Scheduled testimony presentations:

D Cram – Takeda Pharmaceutical Co. (relinquished time)

Discussion
- No Board members reported a conflict of interest for Livtencity (maribavir).
- T Brubaker moved to accept the proposed criteria as written. Seconded by B Jackson. Motion passed unanimously.

3. NEXVIAZYME-ngpt (avalglucosidase alpha) IV infusion

NEXVIAZYME-ngpt (avalglucosidase alpha) may be approved if the following criteria are met:

1. NEXVIAZYME-ngpt (avalglucosidase alpha) is being administered by a healthcare professional in the member's home or in a long-term care facility AND
2. Member is ≥ 1 year of age AND
3. NEXVIAZYME is being prescribed for late-onset Pompe disease (lysosomal acid alpha-glucosidase deficiency) AND
4. Prescriber will consider administering antihistamines, antipyretics, and/or corticosteroids prior to NEXVIAZYME administration to reduce the risk of severe infusion-associated reactions

4. VOXZOGO (vosoritide) subcutaneous injection

VOXZOGO (vosoritide) may be approved if the following criteria are met:
1. Member is ≥ 5 years of age AND
2. Member has a genetically-confirmed diagnosis of achondroplasia with open epiphyses AND
3. Prescriber acknowledges that in order to reduce the risk of low blood pressure the member should have adequate food intake and drink 240 to 300 mL of fluid in the hour prior to Voxzogo administration.
4. Prescriber agrees to monitor body weight, growth, and physical development every 3 to 6 months, and to permanently discontinue Voxzogo (vosoritide) upon confirmation of no further growth potential, indicated by closure of epiphyses.
5. Provider and patient or caregiver are aware that continued US FDA approval of VOXZOGO (vosoritide) for achondroplasia with open epiphyses may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Maximum Dose: 0.8 mg/day

Quantity Limit: Three 10-packs of 0.4 mg, 0.56 mg, or 1.2 mg vials/30 days

Initial Authorization: 6 months

Reauthorization for Voxzogo (vosoritide) for 12 months may be approved if linear growth is improving and closure of epiphyses has not yet occurred

5. SAPHNELO (anifrolumab-fnia) IV infusion

SAPHNELO (anifrolumab) may be approved if the following criteria are met:
1. SAPHNELO (anifrolumab) is being administered by a healthcare professional in the member's home or in a long-term care facility, AND
2. Member is ≥ 18 years of age with active, autoantibody-positive, moderate to severe systemic lupus erythematosus (SLE) AND is receiving standard therapy
   AND
3. SAPHNELO (anifrolumab) is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus
4. Member has had incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND
5. Member will maintain standard therapy for SLE while receiving SAPHNELO (anifrolumab) therapy

Maximum Dose: 300 mg IV every 4 weeks

Quantity Limit: one 300 mg vial/30 days

6. TYRVAYA (varenicline) nasal spray

TYRVAYA (varenicline) may be approved if the following criteria are met:
1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of chronic dry eye disease AND
3. Member has failed a 3-month trial of one preferred product in the Ophthalmic Immunomodulator class on the current Preferred Drug List. Failure is defined as a lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions, AND
4. Prescriber is an ophthalmologist, optometrist or rheumatologist

Maximum Dose: 4 sprays/day

Discussion
- Nexviazyme-ngpt, Voxzogo (vosoritide), Saphnelo (anifrolumab-fnia), Tyrvaya (varenicline) were reviewed as one section.
- No Board members reported a conflict of interest for these products.
- B Jackson moved to accept the proposed criteria for these four products, along with one edit to limit prescribing of Nexviazyme to a subspecialist (such as a metabolic specialist, genetic cardiologist, or neurologist). Seconded by S Klocke. Motion passed unanimously.

Adjournment

L Claus reminded the Board that the next meeting is scheduled for Tuesday, May 10, from 1:00 to 5:00 pm on Zoom. Dr. Claus also reminded all Board members to delete the meeting binder at the conclusion of today's meeting.

L Claus moved to adjourn the meeting, seconded by T Brubaker. Motion passed unanimously. The meeting was adjourned at 5:14 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD