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 13, 2024
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 and Introductions

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

Members Present: Liza Claus, PharmD (Chair); Brian Jackson, MD, MA (Vice Chair); Todd Brubaker, DO; Shilpa Klocke, PharmD; Ken MacIntyre, DO; Ingrid Pan, PharmD

Members Absent: Patricia Lanius, BSPharm, MHA

HCPF Pharmacy Office Staff: Jim Leonard, PharmD; Jeffrey Taylor, PharmD, Veronia Garcia, PharmD, Rachele Poissant, PharmD

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
- Stakeholders who have signed up in advance will be invited to provide testimony at the appropriate time on the meeting agenda.
- If you experience technical difficulties, or if your connection is interrupted during the meeting, please leave the meeting and use the same Zoom link to be readmitted, as that usually resolves the issue.
- Video and microphone for Board members will be turned ON.
- Speakers providing testimony and our other meeting guests are asked to keep video turned off during the meeting so that we can more easily track Board member comments and votes.
- Board members should 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 today by the Chair or Vice Chair
- DUR/Population Health pharmacy interns D Lee, N DeLeon, M Harris, and Andy Rukavina will be presenting and/or assisting behind the scenes during our meeting this afternoon.

Selection of New Board Chair and Vice Chair

- L Claus facilitated the election process. The Chair and Vice Chair shall consist of one physician and one pharmacist. The officer positions alternate between a pharmacist and physician annually unless otherwise determined by the DUR Board members. This year, according to the usual schedule, the Board is to have a physician serve as the Chair.

- B Jackson nominated himself to serve as Chair. L Claus nominated herself to serve as Vice-Chair. There were no additional nominations. The Board voted to approve Dr. Jackson as Chair and Dr. Claus as Vice Chair until February 2025.

4. Colorado Department of Health Care Policy and Financing Updates

V Garcia provided updates from the Department:

- The Board recruits for new physician and pharmacist members on a rolling basis. There is currently an opening for a physician member of the Board. If you are interested in serving in this capacity, send an email with your current CV to the email address SSPPS.co-dur@cuanschutz.edu
- Since implementation of electronic prior authorization (ePA) requests in June 2021 for Health First Colorado member prescribers, ePA represents approximately 72%, and there is an approval rate of approximately 61% of all prior authorization (PA) requests as of January 2024.
- Per the National Asthma Education and Prevention Program guidelines, along with the American Lung Association, single maintenance and reliver therapy (SMART) dosing is covered for the Health First Colorado members when billed with appropriate day supply. For claim rejections related to dose/day supply frequencies, pharmacies can directly contact the Magellan helpdesk for an override.
- As a reminder, for products and drug classes currently managed with prior authorization criteria, only proposed changes to the currently posted criteria will be read aloud during today's meeting.

5. Final Approval of Minutes from the November 14, 2023 Meeting

- Chair B Jackson asked the Board to review minutes from the November 14, 2023 meeting.
- L Claus moved to approve the minutes as written. Seconded by S Klocke. 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. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting.

Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers.

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.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**
  A Rukavina, DUR Intern, presented this quarter's FDA Drug Approvals report that was prepared by R Sapasap, DUR Intern. This quarter's FDA Safety Update, prepared by J Hahn, DUR Intern, and presented by D Lee, DUR intern, included an FDA Communication from 11/28/2023 describing rare but serious cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with the use of levetiracetam and clobazam. A 1/11/24 communication provided an update on reports of suicidal thoughts or actions in patients being treated with GLP-1 receptor agonists. A 1/19/24 communicated information about a new Boxed Warning added to denosumab (Prolia®) about the risk of severe hypocalcemia in patients with advanced chronic kidney disease, particularly those on dialysis.

- **Quarterly Clinical Modules**
  R Page presented a summary of last quarter's Clinical Module, *Metabolic Drug Utilization among Health First Colorado Members,* delivered to the Department on December 31.

- **Retrospective DUR (RDUR) Report**
  R Page presented the quarterly RDUR summary. A new RDUR measure of members with concomitant opioid and benzodiazepine claims for greater than or equal to 30 days during the measurement quarter was recently added to this report.

- **Quarterly Drug Utilization Reports**
  R Page presented highlights from this quarter's drug utilization reports. Ventolin® HFA, gabapentin, amoxicillin, trazodone, sertraline, omeprazole, ondansetron ODT, cetirizine, atorvastatin and levothyroxine and were the top drug products by claim count during the 4th quarter of 2023. Humira®, Trulicity®, Biktarvy®, Trikafta®, Dupixent®, Stelara® and Taltz® were among the top product claims by cost. Board members were referred to utilization reports in the meeting binder for more details.

8. New Business

The New Business section of today's agenda covers the review of proposed criteria for the PDL Drug Classes scheduled for February review, along with several products being reviewed for addition to Appendix P (and/or Appendix Y).

J Rawlings described steps of the review process for this quarter's proposed DUR criteria:

- Board members will be asked if they have potential conflicts of interest to verbally disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.
- Time will be permitted for stakeholder comment. All of today's speakers have registered in advance and each will be given up to 3 minutes to provide testimony.
- There will be an opportunity for Board discussion.

R Page proceeded with the review process of proposed criteria and asked if any Board members had conflicts of interest to report related to the PDL therapeutic classes included on today's agenda up to the Mass Review section. No Board members reported potential conflicts.

A. Proposed Coverage Criteria for Preferred Drug List (PDL) Drug Classes

Red indicates proposed deleted text

Yellow indicates proposed new text

1. Non-Opioid Analgesic Agents

a. Non-Opioid Analgesic Agents – Oral

Preferred Agents
Duloxetine 20 mg, 30 mg, 60 mg capsule
Gabapentin capsule, tablet, solution
Pregabalin capsule
SAVELLA (milnacipran) tablet, titration pack

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 > 3600mg per day.

Discussion

- S Klocke moved to accept the criteria as written. Seconded by L Claus. Motion passed unanimously.

b. Topical Non-Opioid Analgesic Agents – Topical

Preferred Agents
Lidocaine patch
LIDODERM (lidocaine) patch

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

Lidocaine patch *(Puretek manufacturer only)* may be approved if the following criteria are met:

- Member is ≥ 18 years of age **AND**
- Member has had an adequate 8-week trial and failure of: gabapentin **AND** pregabalin **AND** duloxetine **AND** a preferred lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Prescriber has provided a justification of clinical necessity indicating that an alternative generic lidocaine patch formulation cannot be used.

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

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

2. **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**
    a. **Oral NSAIDs**

Preferred Agents

Celecoxib capsule
Diclofenac potassium 50 mg 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
Sulindac tablet

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

Diclofenac potassium 25 mg immediate-release tablets may be approved if the following criteria are met:

- Member is ≥ 18 years of age **AND**
- Member does not have any of the following medical conditions:
    - History of recent coronary artery bypass graft (CABG) surgery
    - History of myocardial infarction
    - Severe heart failure
    - Advanced renal disease
    - History of gastrointestinal bleeding

AND

- Member has trial and failure‡ of four preferred oral NSAIDs at maximally tolerated doses

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 limits: 5-day supply per 30 days and 20 tablets per 30 days

Discussion

- L Claus moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

b. NSAIDs – Non-Oral

Preferred Agents
Diclofenac 1.5% topical solution
Diclofenac sodium 1% gel (OTC/Rx)

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, 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.

Diclofenac topical 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

- T Brubaker moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

3. Opioids

a. Short-Acting Opioids

Preferred Agents
No PA Required*
(If criteria and quantity limit are met)
*Acetaminophen/codeine tablets
Hydrocodone/acetaminophen solution, tablet
Hydromorphone tablet
Morphine IR solution, tablet
**NUCYNTA (tapentadol) tablet
Oxycodone solution, tablet
Oxycodone/acetaminophen tablet
*Tramadol 50mg
*Tramadol/acetaminophen tablet

*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's BMI-for-age is not > 95th percentile per CDC guidelines **AND**
- Member 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's BMI-for-age is not > 95th percentile per CDC guidelines **AND**
  - Member 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 mL/min) **AND**
  - Member is not receiving strong inhibitors of CYP3A4 (such as erythromycin, clarithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200 mg daily], voriconazole, delavirdine, and milk thistle) **AND**
  - Member meets one of the following:
    - Member has trialed codeine or codeine-containing products in the past with no history of allergy or adverse drug reaction to codeine
    - 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."

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, 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.

- **Nucynta IR will have a maximum daily quantity of 6 tablets (180 tabs per 30 days).
- 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 2.5 mL 10 mg/mL package units per 30 days)

Discussion
- K MacIntyre moved to accept the criteria as written. Seconded by L Claus. Motion passed unanimously.

b. Fentanyl Preparations

▪ Fentanyl Preparations – buccal, transmucosal, sublingual)

Preferred Agents
NONE

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.

Discussion
- S Klocke moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

c. Long-Acting Opioids

Preferred Agents
No PA Required (*if doseUnless indicated by * or **)
*BELBUCA (buprenorphine) buccal film*2ND LINE*
BUTRANS^BNR (buprenorphine) transdermal patch
**Fentanyl 12 mcg, 25 mcg, 50 mcg, 7 5mcg, 100 mcg transdermal patch
Morphine ER (generic MS Contin) tablet
**NUCYNTA ER (tapentadol ER)
Tramadol ER (generic Ultram ER) tablet
XTAMPZA ER (oxycodone myristate) capsule

***Belbuca (buprenorphine) buccal film** may be approved for members who have trialed and failed‡ treatment with Butrans (buprenorphine) patch at a dose of 20 mcg/hr **OR** prescriber confirms that the maximum dose of Butrans 20 mcg/hr will not provide adequate analgesia. Quantity limit: 60 films/30 days

****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, intolerable application site skin reactions, 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, Nucynta ER, and Hydrocodone ER (generic Zohydro ER)** will only be approved for twice daily dosing.
- **Hysingla** 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 37 mcg/hr, 62 mcg/hr, and 87 mcg/hr, member must trial and fail two preferred strengths of separate patches that will provide the desired dose (such as 12 mcg/hr + 50 mcg/hr = 62 mcg/hr).

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

4. Anticonvulsants, Oral

Preferred Agents

Barbiturates
Phenobarbital elixir, solution, tablet
Primidone tablet

Hydantoins
DILANTIN (phenytoin) 30 mg capsule
DILANTIN INFATAB (phenytoin) 50 mg chewable tablet
DILANTIN (phenytoin) suspension
PHENYTEK (phenytoin ER) capsule
Phenytoin suspension, chewable, ER capsule

Succinamides
Ethosuximide capsule, solution

Benzodiazepines
Clobazam tablet, suspension
Clonazepam tablet, ODT

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

Carbamazepine Derivatives
Carbamazepine IR tablet, ER tablet, chewable, ER capsule, suspension
CARBATROL ER (carbamazepine) capsule
Oxcarbazepine tablet, suspension
TEGRETOL (carbamazepine) suspension, tablet
TEGRETOL XR (carbamazepine ER) tablet
TRILEPTAL (oxcarbazepine) suspension

Lamotrigines
LAMICTAL (lamotrigine) chewable/dispersible tablet, tablet
LAMICTAL[BNR] (lamotrigine) dose pack
Lamotrigine IR tablet, ER tablet, chewable/dispersible tablet, ODT

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

Brivaracetam/Levetiracetam
Levetiracetam IR tablet, ER tablet, solution

Other
FELBATOL[BNR] (felbamate) tablet, suspension
Lacosamide solution, tablet
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 the following criteria are met:

- The requested medication is being prescribed by a practitioner who has sufficient education and experience to safely manage treatment **AND**
- The request 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 medication indicated for treatment of seizure disorder/convulsions **AND**
- The request 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 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 has a diagnosis of seizures associated with tuberous sclerosis complex (TSC).

FINTEPLA (fenfluramine)
- Member has a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome

OXTELLAR XR (oxcarbazepine ER)
- 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, 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) suspension, tablet	2 years	40 mg per day
clobazam film (SYMPAZAN)	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		
phenytoin ER (DILANTIN) 100mg capsules, suspension, Infatab		1,000 mg loading dose 600 mg/day maintenance dose
Lamotrigines		
lamotrigine IR (LAMICTAL)	2 years	500 mg per day
lamotrigine (LAMICTAL ODT)	2 years	500 mg per day
lamotrigine ER (LAMICTAL XR)	13 years	600 mg per day
Succinamides		
ethosuximide (ZARONTIN)		25 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	25 mg/kg/day
cenobamate (XCOPRI)	18 years	400 mg per day
felbamate tablet, suspension	2 years	3,600 mg per day
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)	6 months (weighing ≥ 7 kg)	3,000 mg per day
tiagabine	12 years	56 mg per day
tiagabine (GABITRIL)	12 years	56 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.		

Scheduled Speaker Testimony
M Faithe, Epidiolex – Jazz Pharmaceuticals
C Wade, Xcopri – SK Life Science

Discussion
- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

5. Newer Generation Antidepressants

Preferred Agents
(If criteria are met)
Bupropion IR, SR, XL tablet
Citalopram tablet, solution
Desvenlafaxine succinate ER (generic Pristiq) tablet
Duloxetine (generic Cymbalta) capsule
Escitalopram tablet
Fluoxetine capsule, solution, 60 mg tablet

Fluvoxamine tablet
Mirtazapine tablet, ODT
Paroxetine IR tablet
Sertraline tablet, solution
Trazodone tablet
Venlafaxine IR tablet
Venlafaxine ER capsules

Non-preferred products may be approved for members who have failed adequate trial with two preferred newer generation anti-depressant products. If two 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, 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**

ZURZUVAE (zuranolone) may be approved if meeting the following criteria:

- Member is ≥ 18 years of age **AND**
- Member has a diagnosis of postpartum depression based on Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for a major depressive episode **AND**
- Member is not currently pregnant **AND**
- Prescriber attests that member has been counseled regarding use of effective contraception during zuranolone treatment and has been counseled regarding information from product package labeling that zuranolone may cause fetal harm **AND**
- Prescriber attests that the member has been counseled and has been engaged in shared decision-making with regard to the limited long-term safety data and potential risks for the breastfed child with use of zuranolone during lactation in conjunction with consideration for the favorable long-term safety data with use of SSRIs as first-line, recommended therapies for perinatal depressive disorders

by the American College of Obstetricians and Gynecologists (ACOG) or SNRIs as reasonable ACOG-recommended alternatives **AND**

- Member has ceased lactating or has agreed to refrain from providing breast milk to the infant prior to receiving the first dose until 7 days after the last dose **AND**
- Prescriber attests that the member has been counseled to refrain from engaging in potentially hazardous activities requiring mental alertness, including driving, for ≥ 12 hours after each zuranolone dose **AND**

- The member has been counseled to take the medication with 400 to 1,000 calories of food containing 25% to 50% fat **AND**
- If patient is taking another oral antidepressant medication, the dose has been stable for ≥ 30 days **AND**
- Prescriber verifies that concomitant medications have been assessed for potential drug interactions (CNS depressants, CYP3A4 inhibitors, CYP3A4 inducers) and any needed dosage adjustments for zuranolone have been made in accordance with package labeling **AND**
- Baseline renal and hepatic function have been assessed and prescriber verifies that dosing is appropriate in accordance with package labeling.

Quantity Limit: One time fill of 28 capsules/14 days

Maximum dose: 50 mg (2 capsules) once daily

Duration of Approval: Approval will allow for one 14-day course of treatment per postpartum period

Scheduled Speaker Testimony
R Finch, Zurzuvae – Biogen
S Hammond, Auvelity – Axsome Therapeutics

Written Testimony
H Nelson, Zurzuvae – Sr. Policy Analyst, Colorado Children's Campaign

Discussion

- After some discussion regarding the bullet point that begins, "Member has ceased lactating or has agreed to refrain…" K MacIntyre moved to delete that entire bullet point (#6). Seconded by L Claus. Motion passed unanimously.
- K MacIntyre moved to incorporate the content of the bullet (#4) that begins, "Prescriber attests that member has been counseled regarding use of effective contraception…" into the bullet point below it (#5) in order to consolidate the counseling and shared decision-making topics. Seconded by B Jackson. Motion passed with five votes in favor. L Claus opposed.
- After discussion about possibly including some language about the risk of suicide upon initiation of therapy with zuranolone, the Board decided to not pursue that option, at least until more data are available for this new agent.
- K MacIntyre moved to accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

6. Atypical Antipsychotics – Oral and Topical

Preferred Agents
*Aripiprazole tablet
Clozapine tablet
Lurasidone tablet
Olanzapine tablet, ODT

Paliperidone ER tablet
Quetiapine IR tablet*
Quetiapine ER tablet
Risperidone tablet, ODT, oral solution
SAPHRIS[BNR] (asenapine) SL tablet
***Vraylar (cariprazine) capsule[*2nd line*]
Ziprasidone capsule

***Vraylar (cariprazine)** may be approved for members after 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, or known interacting genetic polymorphism that prevents safe preferred product dosing.

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 two 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 approval.
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).

****Quetiapine IR** when given at subtherapeutic 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 < 150 mg 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 <150 mg quetiapine IR per day.

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

Nuplazid (pimavanserin tartrate) may be approved for the treatment of hallucinations and delusions associated with Parkinson's Disease psychosis **AND** following trial and failure of therapy with quetiapine or clozapine (failure 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, allergy, intolerable side effects, significant drug-drug interactions **AND**
- Information is provided regarding adherence measures being recommended by provider and followed by member (such as medication organizer or digital medication reminders) **AND**
- Member has history of adequate trial and failure of 3 long-acting injectable formulations of atypical antipsychotics, one of which must contain aripiprazole (failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, significant drug-drug interactions) **AND**
- Abilify MyCite is being used with a MyCite patch and member is using a compatible mobile application
  AND
- Medication adherence information is being shared with their provider via a web portal or dashboard.

Quantity Limits: Quantity limits 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.

Members currently stabilized on a non-preferred atypical antipsychotic may 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 Bipolar I Disorder Irritability w/autistic disorder Tourette's disorder Adjunctive treatment of MDD	≥ 13 years ≥ 18 years 10-17 years 6-17 years 6-18 years ≥ 18 years	30 mg 30 mg 30 mg 15 mg 20 mg (weight-based) 15 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 900 mg per day
CAPLYTA	lumateperone	Schizophrenia Bipolar I Disorder Bipolar II Disorder	≥ 18 years	42 mg	Maximum dosage of 42 mg per day
-	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 Schizophrenia Bipolar I disorder Bipolar I disorder	≥ 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 160mg for schizophrenia, then max 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 Schizophrenia Bipolar mania Irritability w/autistic disorder	≥ 18 years 13-17 years ≥ 10 years 5–17 years	16 mg 6 mg 6 mg 3 mg	Maximum dosage of 16 mg/day (4 tablet/day limitation applied in claims system to allow for dose escalation and tapering)

REXULTI	brexpiprazole	Schizophrenia Adjunctive treatment of MDD Agitation associated with Alzheimer's disease (AD)	≥ 13 years ≥ 18 years	4 mg 3 mg 3 mg	Maximum of 3 mg/day for MDD adjunct therapy and agitation due to AD Maximum of 4 mg/day for schizophrenia
SAPHRIS	asenapine	Schizophrenia Bipolar mania or mixed episodes	≥ 18 years ≥ 10 years	20 mg 20 mg	Maximum two tablets per day
SECUADO	asenapine patch	Schizophrenia	≥ 18 years	7.6 mg/ 24 hours	Maximum 1 patch per day
SEROQUEL	quetiapine	Schizophrenia Schizophrenia Bipolar I mania or mixed Bipolar I mania or mixed Bipolar I depression 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 Bipolar I mania Bipolar I mania Bipolar I depression 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 300mg & 400mg tablets max 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 (18mg olanzapine/75mg fluoxetine)
VRAYLAR	cariprazine	Schizophrenia Acute manic or mixed episodes with Bipolar I disorder Depressive episodes with Bipolar I disorder Adjunctive treatment of MDD	≥ 18 years ≥ 18 years ≥ 18 years ≥ 18 years	6 mg 6 mg 3 mg 3 mg	Maximum dosage of 6mg/day
ZYPREXA ZYPREXA ZYDIS	olanzapine	Schizophrenia Acute manic or mixed episodes with Bipolar I disorder	≥ 13 years	20 mg	Maximum one tablet per day

Scheduled Speaker Testimony
B Skoog, Nuplazid – Acadia Pharmaceuticals
K Barry, Lybalvi – Alkermes
G Mark, APRN – provider stakeholder
M Shurtleff, Rexulti – Otsuka
H Freml, Vraylar – AbbVie *(yielded speaking time)*

Written Testimony
B Skoog, Nuplazid – Acadia Pharmaceuticals

Discussion
- After some Board discussion, K MacIntyre moved to remove the trial and failure steps of quetiapine or clozapine in order to receive approval for Nuplazid (pimavanserin) for a diagnosis of Parkinson's Disease psychosis. Seconded by B Jackson. Motion passed with five votes in favor. Opposed by S Klocke.
- I Pan moved to include the word "contraindication" to the failure definitions. Seconded by T Brubaker. Motion passed unanimously.
- K MacIntyre moved to accept the criteria as amended. Seconded by L Claus. Motion passed unanimously.

7. Calcitonin Gene-Related Peptide Inhibitors (CGRPis)

Preferred Agents

Migraine Treatment
PA Required for all agents
*NURTEC (rimegepant) ODT
*UBRELVY (ubrogepant) tablet

Migraine Prevention
PA Required for all agents
*AIMOVIG (erenumab-aooe) auto-injector
*AJOVY (fremanezumab-vfrm) auto-injector, syringe
*EMGALITY (galcanezumab-gnlm) 120 mg pen, 120 mg prefilled syringe
*NURTEC (rimegepant) ODT

*Preferred agents may be approved if meeting the following criteria:

Preferred Medications for Migraine Prevention (must meet all of the following):
- The requested medication is being used as preventive therapy for episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura **AND**
- Member has tried and failed 2 oral preventive 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 **OR**
- If the prescribed medication is Nurtec, the member has tried and failed two preferred injectable product formulations. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Preferred Medications for Acute Migraine Treatment (must meet all of the following):
- The requested medication is being used as acute treatment for migraine headache **AND**
- Member has history of trial and failure of two triptans (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

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

- The requested medication is being used as preventive therapy for episodic or chronic migraine **AND**
- Member has diagnosis of migraine with or without aura **AND**
- Member has tried and failed two oral preventive 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**
- The requested medication is not being used in combination with another CGRP medication **AND**
- The member has history of adequate trial and failure of 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).

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

- Member is 18 years of age or older AND
- Medication is being prescribed to treat migraine headache with moderate to severe pain **AND**
- The requested medication is not being used in combination with another CGRP medication **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):
    - Two triptans **AND**
    - One NSAID agent **AND**
    - One preferred agent indicated for acute migraine treatment

Non-Preferred Medications for Treatment of Episodic Cluster Headache (must meet all of the following):

- Member is 19-65 years of age **AND**
- Member meets diagnostic criteria for episodic cluster headache (has had no more than 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the week prior to this medication being prescribed) **AND**
- Member is not taking other preventive 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 to therapy, allergy, intolerable side effects, or significant drug-drug interaction):
    - Oxygen therapy **AND**
    - Sumatriptan subcutaneous or intranasal **OR** zolmitriptan intranasal

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

Table 1. Calcitonin Gene-Related Peptide Inhibitor Quantity Limits	
Drug Name	**Maximum Dosing**
Aimovig (erenumab)	one 140 mg autoinjector per 30 days
Ajovy (fremanezumab)	one 225 mg autoinjector or syringe per 30 days monthly or three 225 mg autoinjectors or syringes 675 mg every 90 days three months
Emgality 100mg (galcanezumab)	300 mg three 100 mg prefilled syringes per 30 days
Emgality 120 mg (galcanezumab)	two 120 mg pens or prefilled syringes 240 mg once as first loading dose then one 120 mg pen or prefilled syringe per 30 days monthly
Nurtec (rimegepant)	Prevention: 16 tablets/30 days; Acute Treatment: 8 tablets/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)
ZAVZPRET (zavegepant)	6 unit-dose nasal spray devices per 30 days

Members with current prior authorization approval on file for a preferred agent may receive approval for continuation of therapy with the preferred agent.

Scheduled Speaker Testimony
S Dolzani, Nurtec – Pfizer
T Miller, Nurtec – Advanced Neurology of Colorado (Fort Collins)
M Sohal, Ajovy – Teva Pharmaceuticals
C O'Brien, CGRP inhibitors - Department of Neurology and Headache/Epilepsy Clinical Professor, University of Colorado Hospital Anschutz Outpatient Pavilion
H Freml, Qulipta - AbbVie *(yielded speaking time)*
H Freml, Ubrelvy - AbbVie *(yielded speaking time)*

Written Testimony
T Miller, Nurtec – Advanced Neurology of Colorado (Fort Collins)

Discussion
- S Klocke moved to add language to the paragraph that begins, "If the prescribed medication is Nurtec…" to clarify that it is currently FDA approved for prevention of episodic migraine but not chronic migraine. Proposed language was "If the prescribed medication is Nurtec, it is being used for prevention of episodic migraine…" Seconded by L Claus. Motion passed unanimously.
- I Pan moved to accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

8. Sedative Hypnotics

a. Non-Benzodiazepine Sedative Hypnotics

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

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

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

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

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

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

- Member has trialed and failed therapy with two preferred agents (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
  AND
- Member is not receiving strong CYP3A4 inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or strong CYP3A4 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 CYP3A4 inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or strong CYP3A4 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

Hetlioz (tasimelteon) capsules may be approved for members meeting the following criteria:

- Member is ≥18 years of age and has a documented diagnosis of Non-24-hour sleep wake disorder (Non-24) **OR**
- Member is ≥16 years of age and has a documented diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS)
  AND
- The requested medication is being prescribed by a sleep specialist or a practitioner who has sufficient education and experience to safely prescribe tasimelteon

Hetlioz LQ (tasimelteon) oral suspension may be approved for members meeting the following criteria:

- Member is 3 to 15 years of age and has a documented diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) **AND**
- The requested medication is being prescribed by a sleep specialist or a practitioner who has sufficient education and experience to safely prescribe tasimelteon.

Silenor (doxepin) may be approved for adult members that meet ONE of the following criteria:

- Member has tried and failed two preferred oral sedative hypnotics (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
- Provider attests to the medical necessity of prescribing individual doxepin doses of less than 10 mg, **OR**
- Member's age is ≥ 65 years

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

b. Benzodiazepine Sedative Hypnotics

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

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

Temazepam 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, allergy, intolerable side effects, or significant drug-drug interaction).

Temazepam 7.5 mg may be approved if provider attests to the medical necessity of prescribing individual temazepam doses of less than 15 mg.

Children: Prior authorization will be required for all sedative hypnotic agents when prescribed for children members < 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.

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 Name	**Generic Name**	**Maximum Dose**
Non-Benzodiazepine		
Ambien CR	Zolpidem CR	12.5 mg/day
Ambien IR	Zolpidem IR	10 mg/day
Belsomra	Suvorexant	20 mg/day
Dayvigo	Lemborexant	10 mg/day
Edluar	Zolpidem sublingual	10 mg/day

-	Zolpidem sublingual	Men: 3.5 mg/day Women: 1.75 mg/day
Hetlioz	Tasimelteon capsule	20 mg/day
Hetlioz LQ	Tasimelteon liquid	≤ 28 kg: 0.7 mg/kg/day > 28 kg: 20 mg/day
Lunesta	Eszopiclone	3 mg/day
Quviviq	Daridorexant	50 mg/day
-	Zaleplon	20 mg/day
Rozerem	Ramelteon	8 mg/day
Benzodiazepine		
Doral	Quazepam	15 mg/day
Halcion	Triazolam	0.5 mg/day
Restoril	Temazepam	30 mg/day
Silenor	Doxepin	6 mg/day
-	Estazolam	2 mg/day
-	Flurazepam	30 mg/day

Discussion

- S Klocke moved to accept the criteria as written. Seconded by T Brubaker. Motion passed unanimously.

9. Skeletal Muscle Relaxants

Preferred Agents
No PA Required
(*if under 65 years of age)
Baclofen tablet
Cyclobenzaprine tablet
Methocarbamol tablet
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.

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 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, they may continue to receive approval

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

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

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by B Jackson. Motion passed unanimously.

10. Stimulants and Related Agents

Preferred Agents
***No PA Required (if age, max daily dose, and diagnosis met)**
ADDERALL XR[BNR] (mixed amphetamine salts ER) capsule
Amphetamine salts, mixed (generic Adderall) tablet
Armodafinil tablet
Atomoxetine capsule
Clonidine ER tablet
CONCERTA[BNR] (methylphenidate ER) tablet
DAYTRANA[BNR] (methylphenidate) patch
Dexmethylphenidate IR tablet
Dexmethylphenidate ER capsule
Guanfacine ER tablet
Methylphenidate (generic Methylin/Ritalin) solution, tablet
Modafinil tablet
VYVANSE[BNR] (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**
- If member is ≥ 6 years of age:
  - Has documented trial and failure‡ with three preferred products in the last 24 months **AND**
  - If the member is unable to swallow solid oral dosage forms, two of the trials must be methylphenidate solution, dexmethylphenidate ER, Vyvanse, Adderall XR, or any other preferred product that can be taken without the need to swallow a whole capsule.

OR

- If member is 3–5 years of age:
  - Has documented trial and failure‡ with one preferred product in the last 24 months **AND**
  - **If the member is unable to swallow** solid oral dosage forms, the trial must be methylphenidate solution, dexmethylphenidate ER, Vyvanse, Adderall XR, or any other preferred product that can be taken without the need to swallow a whole capsule.

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 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: Diagnosis 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	**Diagnosis and Age Limitations**
Stimulants - Immediate Release	
Amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years)
Dextroamphetamine IR tablet (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. †Prior Authorization for members 3-6 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)
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)
Dexmethylphenidate ER (generic FOCALIN XR)	ADHD (Age ≥ 6 years)
Dextroamphetamine ER Spansule (DEXEDRINE)/ER capsule	ADHD (Age 6 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
Dextroamphetamine IR and ER	ADHD and Narcolepsy (IR ≥ 3 years, ER ≥ 6 years)
Dextroamphetamine ER patch (XELSTRYM)	ADHD (Age ≥ 6 years)
Lisdexamfetamine dimesylate (**VYVANSE capsule**, Vyvanse chewable)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years)
Methylphenidate ER OROS **(CONCERTA)**	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA
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 (RELEXXI ER)	ADHD (Age 6 to 65 years)
Methylphenidate ER (RITALIN LA)	ADHD (Age ≥ 6 years)
Methylphenidate ER (ADHANSIA XR)	ADHD (Age ≥ 6 years)
Methylphenidate ER (JORNAY PM)	ADHD (Age ≥ 6 years)
Methylphenidate XR (APTENSIO XR)	ADHD (Age ≥ 6 years)
Methylphenidate XR ODT (COTEMPLA XR-ODT)	ADHD (Age 6 to 17 years)
Serdexmethylphenidate/dexmethylphenidate (AZSTARYS)	ADHD (Age ≥ 6 years)
Non-Stimulants	
Atomoxetine (generic STRATTERA)	ADHD (Age ≥ 6 years)
Clonidine ER (KAPVAY)	ADHD as monotherapy or adjunctive therapy to stimulants (Age ≥ 6 years)
Guanfacine ER (generic INTUNIV)	ADHD as monotherapy or adjunctive therapy to stimulants (Age ≥ 6 years)
Viloxazine ER (QELBREE)	ADHD (Age ≥ 6 years)
Wakefulness-promoting Agents	
Armodafinil (generic NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD) (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), antipsychotic medication-related fatigue (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
AZSTARYS	52.3 mg serdexmethylphenidate and 10.4 mg dexmethylphenidate
CLONIDINE ER	0.4 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/9 hour patch (3.3 mg/hr)
DESOXYN	25 mg
DEXEDRINE	60 mg
DYANAVEL XR	20 mg
EVEKEO	60 mg
FOCALIN	20 mg
FOCALIN XR	40 mg
GUANFACINE ER	4 mg (age 6-12) or 7 mg (age ≥ 13)
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 (age 6-17) or 600 mg (age ≥ 18)
QUILLICHEW ER	60 mg
QUILLIVANT XR	60 mg
RELEXXII	72 mg
RITALIN IR	60 mg
RITALIN SR	60 mg
RITALIN LA	60 mg
STRATTERA	1.4 mg/kg or 100mg, whichever is less (age ≥ 6 years with weight < 70 kg) or 100mg (adults and children/adolescents with weight > 70 kg)
SUNOSI	150 mg
VYVANSE CAPSULES AND CHEWABLE TABLETS	70 mg
WAKIX	35.6 mg
XELSTRYM ER PATCH	18 mg/9 hours
ZENZEDI	60 mg

Scheduled Speaker Testimony
S Hammond, Sunosi – Axsome Therapeutics
J Li, Qelbree – Supernus Pharmaceuticals

Discussion
- S Klocke moved to accept the criteria as written. Seconded by B Jackson. Motion passed unanimously.

11. Insulins

a. Rapid-Acting Insulin

Preferred Agents
HUMALOG (insulin lispro) 100U/mL, vial
HUMALOG[BNR] (insulin lispro) KwikPen, cartridge
HUMALOG Jr.[BNR] (insulin lispro) KwikPen[BNR]
Insulin aspart cartridge, pen, vial
Insulin lispro vial
NOVOLOG (insulin aspart) cartridge, vial, FlexTouch pen

Non-preferred products may be approved following trial and failure of treatment with two preferred products, one of which is the same rapid-acting insulin analog (lispro or aspart) as the non-preferred product being requested. (Failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects).

Afrezza (human insulin) may be approved if meeting the following criteria:
- Member is 18 years or older **AND**
- Member has trialed and failed treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, or angioedema] or intolerable side effects) **AND**
- Member must not have chronic lung disease such as COPD or asthma **AND**
- If member has type 1 diabetes, must use in conjunction with long-acting insulin **AND**
- Prescriber acknowledges that Afrezza is not recommended in patients who smoke or have recently stopped smoking.

b. Short-Acting Insulin

Preferred Agents
HUMULIN R U-100 (insulin regular) vial (OTC)
NOVOLIN R U-100 (insulin regular) FlexPen (OTC)

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

c. Intermediate-Acting Insulin

Preferred Agents
HUMULIN N U-100 (insulin NPH) vial (OTC)
NOVOLIN N U-100 (insulin NPH) FlexPen (OTC)

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

d. Long-Acting Insulin

Preferred Agents
LANTUS (insulin glargine) vial, Solostar
LEVEMIR (insulin detemir) vial, FlexTouch

TRESIBA (insulin degludec) may be approved for members who have trialed and failed‡ Lantus.

All other non-preferred products may be approved if the member has tried and failed‡ treatment with Levemir AND Lantus **AND** Tresiba.

(f‡Failure is defined as lack of efficacy, allergy, or intolerable side effects).

Non-preferred products may be approved if the member has failed treatment with Levemir AND Lantus (failure is defined as lack of efficacy, allergy or intolerable side effects).

e. Insulin Mixtures

Preferred Agents
HUMALOG MIX 50/50 Kwikpen, vial
HUMALOG MIX 75/25 Kwikpen[BNR], vial
HUMULIN 70/30 (OTC) Kwikpen, vial
Insulin aspart protamine/insulin aspart 70/30 FlexPen, vial (generic Novolog Mix)
NOVOLOG MIX 70/30 FlexPen, vial

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

f. Concentrated Insulin

Preferred Agents
HUMULIN R U-500 (insulin regular) concentrated vial, Kwikpen

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

Scheduled Speaker Testimony
S Hanson, Tesiba – NovoNordisk

Discussion

- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

12. Multiple Sclerosis Therapies

a. Disease-Modifying Therapies for Multiple Sclerosis

Preferred Agents
No PA Required
(Unless indicated*)
AVONEX (interferon beta 1a) injection
BETASERON (interferon beta 1b) injection
COPAXONE[BNR] (glatiramer) injection
Dimethyl fumarate tablet, starter pack

*KESIMPTA (ofatumumab) pen**2nd Line**
Teriflunomide tablet
Fingolimod 0.5mg capsule

*Kesimpta (ofatumumab) may be approved if member has trialed and failed treatment with one preferred agent (failure is defined as intolerable side effects, contraindication to therapy, drug-drug interaction, or lack of efficacy).

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

- Member has a diagnosis of a relapsing form of multiple sclerosis **AND**
- Member has previous trial and failure with three preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Prescribed dose does not exceed the maximum FDA-approved dose for the medication being ordered **AND**
- If indicated in the product labeling, a negative pre-treatment pregnancy test has been documented, **AND**
- If indicated in the product labeling, an ophthalmologic examination has been performed and documented prior to medication initiation, **AND**
- The request meets additional criteria listed for any of the following:

Mayzent (siponimod):

- 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.

Mavenclad (cladribine):

- 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)

Vumerity (diroximel fumarate) or **Bafiertam (monomethyl fumarate DR)**:

- 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, significant drug-drug interactions, intolerable side effects (if GI adverse events, must meet additional criteria below) **AND**
- If the requested medication is being prescribed due to GI adverse events with Tecfidera 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 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.

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

b. Symptom Management Therapies for Multiple Sclerosis

Preferred Agents
Dalfampridine ER tablet

Non-preferred products may be approved with prescriber attestation that there is clinical rationale supporting why the preferred brand/generic equivalent product formulation is unable to be used.

Maximum Dose:
Ampyra (dalfampridine) 10 mg twice daily

Scheduled Speaker Testimony
L Finseth, Multiple Sclerosis Agents/Disease Modifying Therapies – National MS Society, Denver, CO

Discussion

- S Klocke moved to delete this bullet point for Mayzent (siponimod): "Member has no evidence of relapse in the 3 months preceding initiation of therapy." Seconded by I Pan. Motion passed unanimously.
- S Klocke moved to accept the criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

13. Ophthalmics, Immunomodulators

Preferred Agents
RESTASIS[BNR] (cyclosporine 0.05%) vials

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, 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

Discussion

- B Jackson moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously

14. Ophthalmics, Anti-inflammatories

a. NSAIDs

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

b. Corticosteroids

Preferred Agents
FLAREX (fluorometholone) 0.1%
Fluorometholone 0.1% drops
FML FORTE (fluorometholone) 0.25% drops
LOTEMAX[BNR] (loteprednol) 0.5% drops, gel, ointment
MAXIDEX (dexamethasone) 0.1%
PRED MILD (prednisolone) 0.12%
Prednisolone acetate 1%

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 to therapy, 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, intolerable side effects, or significant drug-drug interaction).

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

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 to therapy, 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, 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

Verkazia (cyclosporine ophthalmic emulsion) may be approved if the following criteria are met:
- Member is ≥ 4 years of age **AND**
- Verkazia is being used for the treatment of vernal keratoconjunctivitis (VKC) **AND**
- Member has trialed and failed therapy with three agents from the following pharmacologic categories: preferred dual-acting mast cell stabilizer/antihistamine from the Ophthalmics-Allergy PDL class, oral antihistamine, preferred topical ophthalmic corticosteroid from the Ophthalmics-

Anti-inflammatories PDL class. Failure is defined as lack of efficacy with 2-week trial, allergy, contraindication to therapy, intolerable side effects, or significant drug-drug interaction

- Quantity limit: 120 single-dose 0.3 mL vials/15 days

All other non-preferred products may be approved with trial and failure of three preferred agents (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction).

Discussion

- S Klocke moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously

15. Ophthalmics, Glaucoma

Preferred Agents

Beta Blockers
Levobunolol 0.5%
Timolol (generic Timoptic) 0.25%, 0.5%

Carbonic Anhydrase Inhibitors
AZOPT[BNR] (brinzolamide) 1%
Dorzolamide 2%

Prostaglandin Analogues
Latanoprost 0.005%
LUMIGAN (bimatoprost) 0.01%
TRAVATAN Z[BNR] (travoprost) 0.004%

Alpha-2 Adrenergic Agents
ALPHAGAN P [BNR] 0.1% (brimonidine)
ALPHAGAN P [BNR] 0.15% (brimonidine)
Brimonidine 0.2%

Other ophthalmic, glaucoma and combinations
COMBIGAN[BNR] 0.2%-0.5% (brimonidine/timolol)
Dorzolamide/Timolol 2%-0.5%
RHOPRESSA (netarsudil) 0.02%
ROCKLATAN (netarsudil 0.02%/latanoprost 0.005%)

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha$_2$-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.
Non-preferred combination products may be approved following trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the combination product being requested (if available) to establish tolerance. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.

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

Discussion

- K MacIntyre moved to accept the criteria as written. Seconded by B Jackson. 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. 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 that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

17. Tricyclic Antidepressants (TCAs)

Preferred Agents
Amitriptyline tablet
Clomipramine capsule
Desipramine tablet
Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule
Doxepin oral concentrate
Imipramine HCl tablet
Nortriptyline capsule

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 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.**

18. Anti-Parkinson's Agents

a. Dopa decarboxylase inhibitors, dopamine precursors and combinations

Preferred Agents
Carbidopa/Levodopa IR, ER tablet
Carbidopa/Levodopa/Entacapone tablet

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

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

Non-preferred medications that are not prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval for other FDA-labeled indications 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.

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

b. MAO-B Inhibitors

Preferred Agents
- Rasagiline tablet
- Selegiline capsule
- Selegiline tablet

Non-preferred agents may be approved with adequate trial and failure of selegiline capsule or tablet (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Non-preferred medications that are not prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval for other FDA-labeled indications 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.

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

c. Dopamine Agonists

Preferred Agents
- Pramipexole IR tablet
- Ropinirole IR tablet

Non-preferred agents may be approved with adequate trial and failure of ropinirole IR AND pramipexole IR (failure is defined as lack of efficacy with 4-week trial, documented 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 (0.6 mL) 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 for other FDA-labeled indications 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.

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

d. Other Parkinson’s Agents

Preferred Agents
Amantadine capsule, solution/syrup
Benztropine tablet
Trihexyphenidyl tablet, elixir

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, documented 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 for other FDA-labeled indications 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.

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

19. Benzodiazepines, Non-Sedative Hypnotic

Preferred Agents
No PA Required
(*may be subject to age limitations)
Alprazolam IR, ER tablet*
Chlordiazepoxide capsule*
Clonazepam tablet, ODT
Clorazepate tablet*
Diazepam tablet*, solution
Lorazepam tablet*, oral concentrate
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.

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	Adults ≥ 18 years: 10 mg/day	Total of 300 mg from all dosage forms per 30 days
Alprazolam ER tablet		
Alprazolam ODT		
XANAX (alprazolam) tablet		
XANAX XR (alprazolam ER) tablet		
Alprazolam Intensol oral concentrate 1 mg/mL		
Clorazepate tablet	>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
TRANXENE (clorazepate) T-Tab		
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	Adults ≥ 18 years: 40 mg/day Members age 6 months to 17 years: up to 10 mg/day	Total of 1200 mg (adults) and 300 mg (pediatrics) from all dosage forms per 30 days

Diazepam solution 5 mg/5 mL Diazepam tablet		
ATIVAN (lorazepam) Intensol concentrate 2 mg/mL ATIVAN (lorazepam) tablet Lorazepam oral concentrated solution 2 mg/mL Lorazepam tablet	Adults ≥ 18 years: 10 mg/day Children: N/A	Total of 300 mg from all dosage forms per 30 days
Oxazepam capsule	Adults ≥ 18 years: 120 mg/day Children 6-18 years: absolute dosage not established	Total of 3,600 mg from all dosage forms per 30 days

20. 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.

21. Lithium Agents

Preferred Agents
Lithium carbonate capsule, tablet
Lithium citrate solution
Lithium ER tablet

Non-preferred products may be approved with trial and failure of one preferred agent (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, intolerance to dosage form).

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

22. Neurocognitive Disorder Agents

Preferred Agents
***Must meet eligibility criteria**
*Donepezil 5mg, 10mg tablet
Donepezil ODT
*Galantamine IR tablet
*Memantine IR tablet, dose pack
*Memantine ER capsule
*Rivastigmine capsule, patch

***Eligibility criteria for Preferred Agents** – Preferred products may be approved for a diagnosis of neurocognitive disorder (eligible for AutoPA automated approval).

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.

23. Triptans, Ditans and Other Migraine Treatments

a. Triptans, Ditans and Other Migraine Treatments – Oral

Preferred Agents
(Quantity limits may apply)
Eletriptan tablet (generic Relpax)
Naratriptan tablet (generic Amerge)
Rizatriptan tablet, ODT (generic Maxalt)
Sumatriptan tablet (generic Imitrex)
Zolmitriptan tablet

Non-preferred oral 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, documented contraindication to therapy, intolerable side effects, or significant drug-drug interaction.

Note: There is limited information available regarding Tthe 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)	9 tabs/30 days
Treximet (sumatriptan/naproxen)	9 tabs/30 days
Axert (almotriptan) and Relpax (eletriptan)	6 tabs/30 days
Maxalt (rizatriptan)	12 tabs/30 days
Reyvow (lasmiditan)	8 tabs/30 days

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

Preferred Agents
(Quantity limits may apply)
IMITREX[BNR] (sumatriptan) nasal spray
IMITREX[BNR] (sumatriptan) cartridge, pen injector
MIGRANAL[BNR] (dihydroergotamine) nasal spray
Sumatriptan nasal spray
Sumatriptan vial
Zolmitriptan nasal spray *(Amneal only)*

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, 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 trialed 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, allergy, intolerable side effects or significant drug-drug interactions, or documented inability to tolerate dosage form.

Quantity Limits:

Dihydroergotamine mesylate vial 1mg/mL	24 vials/ 28 days
Imitrex (sumatriptan) injection	4 injectors / 30 days
Imitrex (sumatriptan) nasal spray	6 inhalers / 30 days
Migranal (dihydroergotamine mesylate) nasal spray	8 nasal spray devices/ 30 days
Onzetra Xsail (sumatriptan) nasal powder	16 nosepieces / 30 days
Tosymra (sumatriptan) nasal spray	12 nasal spray devices / 30 days
Zembrace Symtouch (sumatriptan) injection	36mg / 30 days
Zomig (zolmitriptan) nasal spray	6 inhalers / 30 days

Members currently utilizing a non-oral dihydroergotamine product formulation (based on recent claims history) may receive one year approval to continue therapy with that medication.

24. Ophthalmics, Allergy

Preferred Agents
- ALREX[BNR] (loteprednol) 0.2%
- Azelastine HCl 0.05%
- Cromolyn 4%
- Ketotifen 0.025% (OTC)
- LASTACAFT (alcaftadine) 0.25% (OTC)
- Olopatadine 0.1%, 0.2% (OTC) (generic Pataday Once Daily)

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).

Discussion
- S Klocke noted that both Kynmobi (apomorphine sublingual film) and Imitrex brand sumatriptan nasal spray have been discontinued.
- S Klocke moved to accept criteria in the Mass Review section of the agenda as written. Seconded by T Brubaker. Motion passed unanimously.

Proposed Coverage Criteria for Non-PDL Products
Managed Under the Pharmacy Benefit

R Page proceeded with the review process of proposed criteria for Non-PDL Products and asked if any Board members had conflicts of interest related to the seven products on today's agenda. No Board members reported a potential conflict of interest for the ten products included in this section of the agenda.

To better accommodate today's speakers, products were reviewed in the following order: Zilbrysq, Vyvgart and Vyvgart Hytrulo, Amondys 45, Roctavian, Agamree, Fabhalta, Pombiliti and Opfolda, Tavneos.

1. Zilbrysq (zilucoplan) subcutaneous injection

Zilbrysq (zilucoplan) may be approved if the following criteria are met:
1. Member is ≥ 18 years of age **AND**
2. The requested medication is being prescribed for treatment of generalized myasthenia gravis that is anti-acetylcholine receptor (AChR) antibody positive **AND**
3. The requested medication is being prescribed by or in consultation with a neurologist or rheumatologist **AND**
4. Provider will perform a myasthenia gravis functionality score (such as the MGADL or QMG) at baseline.

Maximum Dose: 32.4 mg/day

Quantity Limit 28 single-dose prefilled syringes/28 days

Reauthorization: Additional one year approval may be granted with provider attestation that a follow-up myasthenia gravis functionality assessment indicates stable symptoms or clinical improvement.

Discussion
- S Klocke moved to (1) limit use of zilucoplan to myasthenia gravis (MGFA) clinical classes II to IV (and not class I, which indicates ocular weakness only), and (2) remove "rheumatologist" from the list of prescribers in bullet point 3. Seconded by I Pan. Motion passed unanimously.

2. Vyvgart (efgartigimod alfa) IV infusion and Vyvgart Hytrulo (efgartigimod alfa/ hyaluronidase-qvfc) subcutaneous injection

Vyvgart (efgartigimod alfa) or Vyvgart Hytrulo (efgartigimod alfa/ hyaluronidase-qvfc) may be approved if the following criteria are met:
1. Member is ≥ 18 years of age **AND**
2. The requested medication is being prescribed for treatment of generalized myasthenia gravis that is anti-acetylcholine receptor (AChR) antibody positive **AND**
3. The requested medication is being prescribed by or in consultation with a neurologist or rheumatologist **AND**
4. Provider will perform a myasthenia gravis functionality score (such as the MGADL or QMG) at baseline.

Maximum Dose:
IV formulation: 1,200 mg weekly for 4 weeks
Subcutaneous formulation: 1,008 mg weekly for 4 weeks

Quantity Limit:
IV formulation: Twelve 400 mg/20 mL single-dose vials per 28 days
Subcutaneous formulation: Four 1,008 mg/5.6 mL single-dose vials per 28 days

Reauthorization: Additional one year approval may be granted with provider attestation that a follow-up myasthenia gravis functionality assessment indicates stable symptoms or clinical improvement

Discussion

- R Poissant presented this set of criteria and noted that it has already been reviewed by the DUR Board and currently exists on Appendix P. Today a secondary review is being conducted in order to add the same set of criteria to Appendix Y for the medical benefit.
- S Klocke moved to (1) limit use of Vyvgart and Vyvgart Hytrulo to myasthenia gravis (MGFA) clinical classes II to IV (and not class I, which indicates ocular weakness only), and (2) remove "rheumatologist" from the list of prescribers in bullet point 3. Seconded by T Brubaker. Motion passed unanimously.

3. Agamree (vamorolone) oral suspension

Agamree (vamorolone) may be approved when the following criteria are met:

1. Member is ≥ 2 years of age **AND**
2. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) and is ambulatory, **AND**
3. A baseline assessment of ambulatory function using the Time to Stand Test (TTSTAND) has been documented prior to initiating Agamree (vamorolone) therapy **AND**
4. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a neurologist or physical medicine and rehabilitation physician), **AND**
5. Member requires use of long-term corticosteroid therapy with Agamree (vamorolone) due to an inability to tolerate therapy with traditional corticosteroids, **AND**
6. Member has received all appropriate immunizations according to current ACIP guidelines at least two weeks prior to (at least 4 to 6 weeks prior for live-attenuated or live vaccines) Agamree initiation **AND**
7. Provider attests that member will be monitored for corticosteroid-related effects (such as Cushing's syndrome, hyperglycemia, behavioral/mood disturbances, or adrenal insufficiency after Agamree therapy is withdrawn), **AND**
8. Provider attests that the dose of Agamree will be appropriately reduced per product labeling for members who are concurrently taking strong CYP3A4 inhibitors (such as itraconazole, ketoconazole diltiazem, ritonavir).

† Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction

Quantity limit: 225 mL/30 days

Initial Approval: 6 months

Reauthorization: After 6 months of treatment with Agamree (vamorolone), the member may receive approval to continue therapy for one year if the following criteria are met:

- Member has shown no clinically significant or intolerable adverse effects related to vamorolone treatment **AND**
- Member demonstrates response to vamorolone treatment with clinical improvement in trajectory from baseline assessment in ambulatory function as measured by the Time to Stand Test (TTSTAND)

Discussion

- S Klocke moved to (1) remove the second "neurologist" reference in bullet point 4, and (2) add "pulmonologist" to bullet point 4. Seconded by B Jackson. Motion passed unanimously.
- B Jackson moved to increase the initial authorization period for vamorolone from 6 months to one year. Seconded by T Brubaker. Motion passed unanimously.

- I Pan moved to recommend that the Department draft criteria for DMD medications that come to market with (1) the same set of prescriber subspecialties (neurologist, pulmonologist, physical medicine and rehabilitation physician) and (2) an initial approval period of one year. Seconded by B Jackson. Motion passed unanimously.
- B Jackson moved to accept the criteria as amended. T Brubaker seconded. Motion passed unanimously.

4. Amondys 45 (casimersen) IV infusion

Amondys 45 (casimersen) may be approved for members meeting the following criteria:

- Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) **AND**
- Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 45 skipping **AND**
- Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a pediatric neurologist, cardiologist, or pulmonary specialist) **AND**
- Provider attests that serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) and glomerular filtration rate (GFR) will be measured prior to initiation of and that the member will be monitored periodically for kidney toxicity during treatment **AND**
- The member must be on corticosteroids at baseline or prescriber provides clinical rationale for not using corticosteroids **AND**
- If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale or Forced Vital Capacity (FVC) documented **AND**
- Provider and patient or caregiver are aware that continued US FDA approval of Amondys 45 (casimersen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Reauthorization: After 24 weeks of treatment with Amondys 45 (casimersen), the member may receive approval to continue therapy for one year if the following criteria are met:

- Member has shown no intolerable adverse effects related to Amondys 45 (casimersen) treatment at a dose of 30mg/kg IV once a week **AND**
- Member has normal renal function or stable renal function if known impairment **AND**
- Member demonstrates response to Amondys 45 (casimersen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC).

Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.

Maximum Dose: 30 mg/kg per week

Scheduled Speaker Testimony
S Kennedy, Amodys- Sarepta Therapeutics

Written Testimony
A Stratton, Amodys – Assoc. Professor, University of Colorado; Pediatric Physical Medicine and Rehabilitation, Children's Hospital Colorado

Discussion

- R Poissant presented this set of criteria and noted that it has already been reviewed by the DUR Board and currently exists on Appendix P. Today a secondary review is being conducted in order to add the same set of criteria to Appendix Y for the medical benefit.
- B Jackson moved to (1) remove one of the "neurologist" references in bullet point 3 and also add "physical medicine and rehabilitation," (2) increase the initial authorization period from 6 months to one year, and (3) accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

5. Roctavian (valoctocogene roxaparvovec-rvox) single-dose IV infusion

Roctavian (valoctocogene roxaparvovec-rvox) may be approved if the member meets ALL the following criteria:

1. Member is 18 years of age or older **AND**
2. Member has documented diagnosis of severe hemophilia A defined by all of the following:
    a. Factor VIII deficiency with factor VIII activity < 1 IU/dL **AND**
    b. Member has ≥ 10 bleeding events requiring factor replacement therapy per year **AND**
3. Member has had a minimum of 150 exposure days per year to a factor VIII agent **AND**
4. Member is currently using factor VIII prophylaxis therapy or emicizumab **AND**
5. Member is adeno-associated virus serotype 5 negative as determined by an FDA approved test **AND**
6. Member must have completed Bethesda assay results of < 0.6 Bethesda Units (BU) within the prior 12 months **AND**
7. Prescribed by or in consultation with a hematologist **AND**
8. Member has documented liver health assessments completed including:
    a. Hepatic ultrasound and elastography
    b. Liver function tests (ALT, AST, GGT, ALP, total bilirubin and INR)

    AND
9. Member does not have any of the following:
    a. Hepatic fibrosis or significant liver dysfunction including but not limited to cirrhosis
    b. Active infection, either acute or chronic including but not limited to hepatitis B, hepatitis C, or uncontrolled HIV
    c. History of detectable factor VIII inhibitor
    d. History of arterial or venous thromboembolic events
    e. Prior treatment with gene therapy for the treatment of hemophilia A

Approval will be placed to allow for one treatment course

Scheduled Speaker Testimony
I Ma, Roctavian – BioMarin Pharmaceuticals

Discussion

- S Klocke moved to accept the criteria as written. Seconded by B Jackson. Motion passed unanimously.

6. Fabhalta (iptacopan) oral capsules

Fabhalta (iptacopan) may be approved if the following criteria are met:

1. Member is ≥18 years of age **AND**
2. Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high-sensitivity flow cytometry **AND**
3. Member has an eGFR ≥30 mL/min **AND**
4. Member does not have severe hepatic disease (Child-Pugh Class C) **AND**
5. Member does not have any active infections caused by an encapsulated bacteria (such as *Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type b)* **AND**
6. Member has received vaccination against encapsulated bacteria (such as *Streptococcus pneumoniae, Neisseria meningitidis,* and *Haemophilus influenzae type b*) at least 2 weeks prior to initiation of Fabhalta (iptacopan) therapy. If urgent iptacopan therapy is indicated in a patient who is not up-to-date with vaccines, or the vaccines were administered within the last 2 weeks, prescriber attests that the member will receive appropriate antibacterial drug prophylaxis and the vaccines will be administered as soon as possible **AND**
7. Requested product is being prescribed by or in consultation with a hematologist, immunologist or nephrologist **AND**
8. Member has residual anemia (hemoglobin < 10 g/dL) despite a stable regimen of anti-C5 treatment for at least 6 months **AND**
9. Fabhalta (iptacopan) is not being used in combination with another anti-C5 complement inhibitor that is used to treat PNH, **AND**
10. Member's medication profile does not indicate any clinically significant interactions with CYP2C8 inducers (such as rifampicin, phenobarbital, phenytoin) or strong CYP2C8 inhibitors (such as gemfibrozil, clopidogrel, fluticasone) **AND**
11. Prescriber is enrolled in the Fabhalta Risk Evaluation and Mitigation Strategy (REMS) program

†Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Initial Approval: Six months

Reauthorization: Prescriber attests that member's hemoglobin has increased by ≥ 2 g/dL from baseline while on Fabhalta (iptacopan) therapy

Maximum dose: 400 mg/day

Quantity limit: 60 capsules/30 days

Discussion

- S Klocke moved to (1) remove the word "another" from bullet point 9. Seconded by I Pan. Motion passed unanimously.
- S Klocke moved to accept the criteria as amended. B Jackson seconded. Motion passed unanimously.

7. Pombiliti (cipaglucosidase alfa-atga) IV infusion and **Opfolda (miglustat) oral capsule**

Pombiliti (cipaglucosidase alfa-atga) **AND** Opfolda (miglustat) may be approved when the following criteria are met:

- For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND**
- Member is ≥18 years of age **AND**
- Member has an actual body weight of ≥40 kg **AND**
- Member has a definitive diagnosis of late-onset Pompe disease confirmed by one of the following:
  - Deficiency of acid alpha-glucosidase (GAA) enzyme activity
    OR
  - Detection of biallelic pathogenic variants in the GAA by molecular genetic testing

  AND
- Reqested product is being prescribed by a provider specializing in the treatment of Pompe disease **AND**
- Member has tried and failed† Lumizyme (alglucosidase alfa) or Nexviazyme (avalglucosidase-ngpt) **AND**
- Pombiliti (cipaglucosidase alfa-atga) and Opfolda (miglustat) will be used in combination according to the approved product labeling **AND**
- The requested medications will not be used in combination with other lysosomal acid alpha-glucosidase (GAA) enzyme replacement therapies **AND**
- More frequent monitoring of vital signs will be performed during Pombiliti infusion for members who are susceptible to fluid volume overload and those with acute underlying respiratory illness or compromised cardiac or respiratory function, **AND**
- Member is not pregnant or breastfeeding, and member and partners have been counseled on appropriate use of contraception **AND**
- Member has documented baseline age-appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted forced vital capacity (FVC), and 6-minute walk test (6MWT) **AND**
- Prescriber acknowledges consideration for administering antihistamines, antipyretics, and/or corticosteroids prior to Pombiliti (cipaglucosidase alfa) administration to reduce the risk of severe infusion-associated reactions

†Failure is defined as lack of efficacy or intolerable side effects

Initial approval: one year

Reauthorization: Pombiliti (cipaglucosidase alfa) and Opfolda (miglustat) may be approved for one year if member met initial approval criteria at the time of initiation of therapy **AND** meets the following:

- Member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT
  AND
- Member is being monitored for antibody formation and hypersensitivity

Maximum Dose
Members ≥40 kg: 20 mg/kg administered every 2 weeks

Discussion

- B Jackson moved to accept the criteria as written. Seconded by S Klocke. Motion passed unanimously.

8. Tavneos (avacopan) oral capsule

Tavneos (avacopan) may be approved when the following criteria are met:
1. Member is ≥18 years of age **AND**
2. Severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis **AND**
3. Member did not achieve sustained remission with one year of treatment with glucocorticoid therapy **AND**
4. Member is currently receiving, and will continue to be on a standard care plan for ANCA-associated vasculitis that includes a glucocorticoid **AND**
5. Member does not have active, untreated and/or uncontrolled chronic liver disease (such as chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis and cirrhosis) **AND**
6. A baseline liver panel (ALT, AST, alkaline phosphatase, total bilirubin) will be obtained before initiating Tavneos (avacopan), then every 4 weeks after start of therapy for the first 6 months of treatment and as clinically indicated thereafter **AND**
7. Labs to screen for Hepatitis B infection (HBsAg and anti-HBc) have been evaluated prior to initiation of Tavneos (avacopan) therapy **AND**
8. Member is not currently taking a strong CYP3A4 inducer (such as carbamazepine, phenytoin, rifampin, phenobarbital) **AND**
9. If member is on concurrent therapy with a strong CYP3A4 inhibitor (such as itraconazole, ketoconazole, diltiazem, ritonavir), Tavneos (avacopan) dose will be adjusted according to the approved product labeling

Initial Approval: one year

Reauthorization: Tavneos (avacopan) may be approved for one year if:
- Member met initial approval criteria at the time of initiation of therapy **AND**
- Provider attests that sustained remission was achieved on Tavneos (avacopan) therapy within the previous 12 months

Maximum dose: 60 mg/day

Quantity limit: 180 capsules/30 days

Continuation of therapy: Members who are currently stabilized on Tavneos (avacopan) therapy may receive approval to continue that medication.

Discussion
- I Pan moved to remove bullet point 3, "Member did not achieve sustained remission with one year of treatment with glucocorticoid therapy" because defining a specific time period for glucocorticoid therapy prior to initiating avacopan would be challenging clinically. Seconded by T Brubaker. Motion passed unanimously.
- K MacIntyre moved accept the criteria as amended. Seconded by I Pan. Motion passed unanimously.

C. Adjournment

Board Chair Claus reminded attendees that the next Board meeting is tentatively scheduled for Tuesday, May 7, 2024, from 1:00 to 5:00 pm. She also reminded Board members to delete their meeting binders and associated emails at the conclusion of today's meeting.

I Pan moved to adjourn the meeting, Seconded by S Klocke. Motion passed unanimously and the meeting was adjourned at 4:21 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD