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 7, 2023
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 1:02 pm by A Shmerling, 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 members.

   Members Present: Alison Shmerling, MD, MPH (Chair); Liza Claus, PharmD (Vice Chair); Brian Jackson, MD, MA; Shilpa Klocke, PharmD; Patricia Lanius, BSPharm, MHA; Ken MacIntyre, DO; Ingrid Pan, PharmD; Melissa Polvi, RN
   Members Absent: Todd Brubaker, DO
   HCPF Pharmacy Office: Jim Leonard, PharmD; Jeffrey Taylor, PharmD, Veronia Guirguis-Garcia, 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.
   - Speakers providing testimony and other meeting guests are asked to keep video and microphones turned off throughout the meeting so that Board members' votes can be easily seen and tracked. Stakeholders who have signed up in advance to provide testimony will be called upon at the appropriate times in the meeting agenda.
   - If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted, as that usually resolves the issue.

   Selection of New Board Chair and Vice Chair

   - A Shmerling facilitated the election process. Dr. Shmerling also announced that she will not pursue re-appointment to the DUR Board when her term expires at the end of March 2023.
   - 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 pharmacist serve as the Chair.
   - A Shmerling nominated L Claus to serve as Chair. Seconded by B Jackson. Motion passed unanimously.

- K MacIntyre nominated B Jackson to serve as Vice-Chair. Seconded by I Pan. Motion passed unanimously.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

- For products and drug classes currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud during the meeting.
- The current criteria on the PDL and Appendix P are available online for reference, as needed.
- The remining Board meetings in 2023 are tentatively scheduled for May 9, August 8 and November 14 from 1:00 to 5:00 pm.
- The Department extends its sincere thanks and gratitude to Dr. Alison Shmerling for her time, commitment and service on the DUR Board.
- Several public stakeholders reached out after the 24-hour registration deadline to provide verbal testimony or written input to the Board during today's meeting. Dr. Taylor reminded public stakeholders that the Department needs to receive these requests at least 24 hours in advance of each quarterly meeting. If any stakeholder input is received outside of the public meeting, the Department will still take that input into consideration as criteria changes are reviewed and evaluated internally.
- DUR Board meetings are held quarterly in the months of February, May, August and November. Drug classes reviewed each quarter will be the same as those reviewed in the prior month during the P&T Committee meeting. Each DUR Board meeting agenda is posted and available early in the month that precedes each DUR Board meeting at https://hcpf.colorado.gov/drug-utilization-review-board
- Stakeholders and members of the public are encouraged to look for those agendas prior to DUR Board meetings.
- Dr. Taylor thanked the members of the DUR Board for their time, service and commitment to participate on the Health First Colorado DUR Board. This public review process is extremely important and valuable to the Colorado Medicaid Program. It is important to acquire input regarding the appropriate, safe and effective use of therapies to be sure drug products are being managed appropriately and that we have access where needed for specific populations. The public process also helps the Department to be good stewards of Medicaid dollars, ensuring that funds are being used in the most appropriate and effective ways.
- A recent review of the Department's electronic prior authorization (ePA) statistics showed that there has been more than 50% uptake of the ePA system. The idea of this system is to create efficiencies for submission of PA requests and reduce burden on members and providers. The ePA system was implemented in June 2021 and there has been quite an increase in uptake.

5. Final Approval of Minutes from November 8, 2022 Meeting

New Board Chair L Claus asked the Board to review minutes from the November 8, 2022 meeting. With no discussion, K MacIntyre 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.

Melissa Polvi, RN, Industry Representative, disclosed her conflicts of interest related to employment by Swedish Orphan Biovitrum (Sobi), a rare disease company.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**

J Rawlings highlighted updates from the FDA Drug Approvals report prepared by Kelly Gaebel, DUR Intern. This quarter's Drug Safety Update included an FDA Communication regarding the risk of hypocalcemia in patients receiving Prolia (denosumab) while on dialysis.

- **Quarterly Clinical Modules**

R Page presented an update on last quarter's Quarterly Clinical Module, *Stimulant Medication Use among Pediatric and Adolescent Members of Health First Colorado*. This module, looking at data between July 1, 2021 and June 30, 2022 showed that the majority of Health First Colorado members who filled a stimulant prescription during the study period were between the ages of 18 and 59 years (approximately 60%). Concomitant use of stimulants and sedative agents and stimulants and buprenorphine products was also assessed. The percentage of medication claims for preferred agents in the stimulants class ranged between 90% and 93%.

Dr. Page also thanked members of the CO-DUR analytic team: Associate Professor Heather Anderson, PhD; biostatistician Garth Wright, MPH; and Vanessa Patterson, MPH/PhD Student, for their significant contributions to the DUR program.

The Colorado Evidence-based Drug Utilization Review team is currently working on clinical modules to evaluate the (1) use of gabapentin medications, and (2) evaluate the Health First Colorado Rx Review program and pharmacy interventions resulting from retrospective medication list reviews, particularly those related to the management of heart failure.

- **Retrospective DUR Report**

R Page presented the RDUR summary and referred Board members to the meeting binder for details.

- **Quarterly Drug Utilization Reports**

R Page presented highlights from this quarter's drug utilization reports. Board members were referred to these reports in the meeting binder for details.

8. New Business

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

- Board members will be asked if they have potential conflicts of interest to disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.
- For products and drug classes currently managed with posted DUR criteria, only proposed changes to the currently posted criteria will be read aloud.

- Time is permitted for stakeholder comment. All speakers have registered in advance, and each speaker will be given up to 3 minutes of time to present testimony.
- There will be an opportunity for Board discussion, motions and votes.

R Page proceeded with the review process of proposed criteria.

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

Red indicates proposed deleted text

Yellow indicates proposed new text

Conflict of Interest Check

No Board members reported a conflict of interest for any of the drug classes being reviewed today from the beginning of the therapeutic classes listed in the agenda up to the Mass Review section.

1. Opioids

a. Opioids, Short-acting

Preferred Agents

No PA Required* (if criteria and quantity limit is are met)

Codeine/acetaminophen 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, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200mg daily], voriconazole, delavirdine, and milk thistle) AND
    - Member meets <u>one</u> 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 50mg 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

<u>Quantity Limits</u>: 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).

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

Proposed Maximum Quantity Limit for opioid-containing liquid cough & cold preparations:

guaifenesin and codeine syrup – 180 mL/30 days
promethazine and codeine syrup – 180 mL/30 days
promethazine and dextromethorphan syrup– 180 mL/30 days
promethazine, phenylephrine and codeine syrup– 180 mL/30 days
hydrocodone polistirex/chlorpheniramine polistirex extended-release suspension– 120 mL/30 days

Discussion

- J Taylor clarified that the opioid-containing liquid cough & cold preparations are not included in the Short-acting Opioid PDL drug class. The new maximum quantity policy would be maintained on the Appendix P. There are no proposed changes to the content PDL criteria for the Short-acting Opioid therapeutic class.
- After some discussion, Board members recommended that new quantity limits for opioid-containing liquid cough & cold preparations apply only to members who are 12 years of age and older.
- B Jackson moved to accept the criteria as written. Seconded by I Pan. Motion passed unanimously.

b. Fentanyl preparations

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 A Shmerling. Motion passed unanimously.

c. Opioids, Long-acting

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

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

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

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

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

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

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

Reauthorization:
Reauthorization for a non-preferred agent may be approved if the following criteria are met:
Provider attests to continued benefit outweighing risk of opioid medication use AND

Member met original prior authorization criteria for this drug class at time of original authorization

Quantity/Dosing Limits:
Oxycontin, **Nucynta ER**, and **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).

Proposed Change for PDL Opioid Naïve Policy:
Members who have not filled a prescription for an opioid within the past 180 days will be identified as "opioid treatment naïve" and have the following limitations placed on the initial prescription(s):

The prescription is limited to short-acting opioid agents or Butrans (buprenorphine) 5 mcg patch. Use of other long-acting opioid agents will require prior authorization approval for members identified as opioid treatment naïve.

The days' supply of the first, second, and third prescription for an opioid will be limited to 7 days, the quantity will be limited to 8 dosage forms per day (tablets, capsules), maximum #56 tablets/capsules for a 7-day supply

The fourth prescription for an opioid will require prior authorization, filling further opioid prescriptions may require a clinical pharmacist review or provider to provider telephone consultation with a pain management physician (free of charge and provided by Health First Colorado).

If a member has had an opioid prescription filled within the past 180 days, then this policy would not apply to that member and other opioid policies would apply as applicable.

Discussion

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

2. Anticonvulsants, Oral

Preferred Agents

Barbiturates
Phenobarbital elixir, solution, tablet
Primidone tablet

Hydantoins
DILANTIN (phenytoin) 30 mg capsules
DILANTIN suspension
PHENYTEK (phenytoin ER)
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) IR tablet, chewable/dispersible tablet
LAMICTAL ODT (lamotrigine)
LAMICTAL dose titration kit (IR tablets)
LAMICTAL XR[BNR] (lamotrigine ER) tablet
Lamotrigine IR tablet, XR tablet, chewable/dispersible tablet

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

Brivaracetam/Levetiracetam
Levetiracetam IR tablet, ER tablet, solution

Other
FELBATOL[BNR] (felbamate) tablet, suspension
Lacosamide tablet, solution
Zonisamide capsule

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.

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 neurologist, or in consultation with a neurologist, and the following criteria are met:

- The prescription is being ordered by a practitioner who has sufficient education and experience to safely prescribe the non-preferred medication, AND
- If being prescribed in consultation with a neurologist, then t The prescription meets minimum age and the maximum dose limits listed in Table 1, AND
- For medications indicated for use as adjunctive therapy, the medication is being used in conjunction with another anticonvulsant medication, AND
- The prescription meets additional criteria listed for any of the following anticonvulsant products:

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

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

OXTELLAR XR (oxcarbazepine ER):
- Member is 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	2 years	40 mg per day
clobazam film (SYMPAZAN)	2 years	40 mg per day
clobazam suspension	2 years	40 mg per day
clonazepam (KLONOPIN)		20 mg per day
Brivaracetam/Levetiracetam		
brivaracetam (BRIVIACT)	1 month	200 mg per day
levetiracetam (KEPPRA)	1 month	3,000 mg per day
levetiracetam (SPRITAM)	4 years	3,000 mg per day
levetiracetam ER (ELEPSIA XR)	12 years	3,000 mg per day
levetiracetam ER (KEPPRA XR)	12 years	3,000 mg per day
Carbamazepine Derivatives		
carbamazepine (EPITOL)		1,600 mg per day
carbamazepine ER (EQUETRO)		1,600 mg per day
eslicarbazepine (APTIOM)	4 years	1,600 mg per day
oxcarbazepine ER (OXTELLAR XR)	6 years	2,400 mg per day
Hydantoins		
ethotoin (PEGANONE)		3,000 mg per day
phenytoin ER (DILANTIN) 100mg capsules, suspension, Infatab		1,000 mg loading dose 600 mg/day maintenance dose
Lamotrigines		
lamotrigine 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)		20 mg/kg/day
methsuximide (CELONTIN)		Not listed
Valproic Acid and Derivatives		
divalproex ER (DEPAKOTE ER)	10 years	60 mg/kg/day
Topiramates		
topiramate (TOPAMAX)	2 years	400 mg per day
topiramate ER (QUDEXY XR)	2 years	400 mg per day
topiramate ER (TROKENDI XR)	6 years	400 mg per day

Other		
cannabidiol (EPIDIOLEX)	1 year	20 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 ≥ 715 kg)	3,000 mg per day
tiagabine	12 years	64 56 mg per day
tiagabine (GABITRIL)	12 years	64 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
J Wilbanks, Aptiom - Sunovion
A Scurry, Briviact – UCB
M Aude – Vice President of Community Initiatives Epilepsy Foundation of Colorado & Wyoming
J Shear, Epidiolex - Jazz Pharmaceuticals
J Flatt, Ztalmy - Marinus

Written Testimony
Letter, Epilepsy Foundation of Colorado & Wyoming

Discussion

- J Taylor reminded the Board that the anticonvulsant drug class is an exception to the generic mandate policy. The brand version (preferred or non-preferred) of any generic preferred product will still be covered with an indication of DAW-1 on the prescription.
- S Klocke moved that the Anticonvulsants class be renamed Anti-Seizure Medications. Seconded by B Jackson. Motion passed unanimously.
- For consistency in the criteria, the Board discussed the proposed removal of minimum age requirements for non-preferred agents for treatment seizure disorder or convulsions and the proposed retention of minimum age requirements for non-preferred agents used to treat non-seizure disorders. J Taylor explained that the primary intent was to reduce restrictions for use of these agents being used specifically for the treatment of seizures. J Leonard added that the Department does not receive many requests for use of these agents in members younger than the minimum ages included in the current DUR criteria. To help condense the criteria in this drug class and make them more manageable, minimum ages could continue to be included in the table but not be included as part of the PA process for members with seizure disorders. There is an exception process in place for evaluation of individual patient cases, as necessary.
- S Klocke moved to accept the criteria as written. Seconded by A Shmerling. Motion passed unanimously.

3. Newer Generation Antidepressants

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

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

All non-preferred products not listed above may be approved for members who have failed adequate trial with three preferred newer generation anti-depressant products. If three preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication (failure is defined as lack of efficacy with 6-week trial, 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.**

Scheduled Speaker Testimony
C Wincott – Auvelity, Axcome

Discussion

- The Board supported the proposed decrease in preferred agent trials from *four* to *three* for Fetzima®, Trintellix®, and Viibryd®. There was also discussion regarding the potential length of time required for trial and failure of three preferred agents in this class before a non-preferred agent may be approved. Additional data that might support the earlier selection of non-preferred agents (such as pharmacogenomic testing results and head-to-head trial data) would be helpful when considering making changes to these criteria. Trial and failure of the number of preferred agents required for approval of a non-preferred product does not preclude adequate trials of additional preferred agents.
- K MacIntyre moved to change the language that requires trial and failure of *three* preferred newer generation antidepressants for approval of non-preferred agents in this class to say "adequate trial and failure of *two* preferred newer generation antidepressants" based on the standard failure definition. Seconded by B Jackson. Motion passed with five votes in favor. S Klocke opposed. L Claus abstained.

4. Neurocognitive Disorder Agents

Preferred Agents
***Must meet eligibility criteria**
*Donepezil 5mg, 10mg tablet
*Donepezil ODT
*Galantamine IR tablet
*Memantine IR, ER tablets
*Rivastigmine capsule, transdermal 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.

Discussion

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

5. Sedative Hypnotics

a. Non-benzodiazepines

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 < 18 years of age.

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

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

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

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

rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 AND
- Member does not have a diagnosis of narcolepsy

Dayvigo (lemborexant) may be approved for adult members that meet the following:
- Member has trialed and failed therapy with two preferred agents AND Belsomra (surovexant). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
- Member is not receiving strong inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 AND
- Member does not have a diagnosis of narcolepsy

Silenor (doxepin) may be approved if a for adult members that meets ONE of the following criteria:
- Contraindication toMember 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),see preferred drug list "Sedative Hypnotic" class for list of preferred products) OR
- Prescriber Provider attests to the medical necessity for use of prescribing individual doxepin doses of less than < 10 mg, OR
- Member's age is greater than ≥ 65 years

Hetlioz (tasimelteon) may be approved for members meeting the following criteria:
- Have Member has a documented diagnosis of non-24-hour sleep wake disorder (non-24 or N24) by a sleep specialist OR
- Have Member has a documented diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS)

AND
- For requests for the oral suspension formulation, member is 3 to 15 years of age and has difficulty swallowing or cannot take the solid oral dosage form.

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

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

Discussion
- K MacIntyre moved to remove the requirement that Hetlioz (tasimelteon) must be prescribed by a sleep specialist and instead insert "The prescription is being ordered by a practitioner who has sufficient education and experience to safely prescribe this non-preferred medication." Seconded by S Klocke. Motion passed with five votes in favor. P Lanius abstained.
- B Jackson moved to remove the phrase "is 3 to 15 years of age and" from the criteria for tasimelteon oral suspension and keep the more general language that the patient has difficulty swallowing or cannot take the solid oral dosage form. Seconded by K MacIntyre. Motion passed unanimously.
- A Shmerling moved to accept the criteria for this class as amended. Seconded by K MacIntyre. Motion passed unanimously.

b. Benzodiazepines

Preferred Agents

No PA Required* (unless age, dose, or duplication criteria apply)

Temazepam 15mg, 30mg capsule
Triazolam tablet

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

Temazepam 7.5 mg and 22.5 mg may be approved if the member has trialed and failed temazepam 15 mg or 30 mg 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 < 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	Generic	Maximum Dose
Non-Benzodiazepine		
Ambien CR	Zolpidem CR	12.5 mg/day
Ambien IR	Zolpidem IR	10 mg/day
Belsomra	Suvorexant	20 mg/day
Dayvigo	Lemborexant	10mg/day
Edluar	Zolpidem sublingual	10 mg/day
Intermezzo	Zolpidem sublingual	Men: 3.5mg/day Women: 1.75 mg/day
Lunesta	Eszopiclone	3 mg/day
Quviviq	Daridorexant	50 mg/day
- Sonata	Zaleplon	20 mg/day
Rozerem	Ramelteon	8 mg/day
Benzodiazepine		
Halcion	Triazolam	0.5 mg/day
Restoril	Temazepam	30 mg/day
-	Estazolam	2 mg/day
-	Flurazepam	30 mg/day
Doral	Quazepam	15 mg/day

Discussion

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

6. Skeletal Muscle Relaxants

Preferred Agents
No PA Required (if under 65 years of age)*
Baclofen tablet
Cyclobenzaprine 5 mg, 7.5 mg and 10 mg 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 5-17 years of age who have trialed and failed‡ one preferred agent and meet the following criteria:
Documentation of age-appropriate liver function tests AND

One of following diagnoses: Multiple Sclerosis, Cerebral Palsy, stroke, upper motor neuron disorder, or spinal cord injury

Dantrolene will be approved for the period of one year

If a member is stabilized on dantrolene at <18 years of age, they may continue to receive approval after turning 18 years of age

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

- The Board discussed the criteria limiting the use of dantrolene to members aged 5 to 17 years, as this agent is sometimes used in adults. R Page clarified that current criteria were written based on clinical data that was available at that time.
- There was a discussion about the word “acute” in the paragraph regarding carisoprodol authorization criteria. Since the FDA-approved product labeling for carisoprodol describes the indication for use as “acute, painful musculoskeletal conditions” no motions were offered.
- S Klocke moved to (1) remove “5-17 years of age,” (2) remove “If a member is stabilized on dantrolene at <18 years of age, they may continue to receive approval after turning 18 years of age,” and (3) requested that the Department evaluate current criteria for approval of dantrolene for appropriate age range and member access. Seconded by P Lanius. Motion passed unanimously.
- K MacIntyre moved to approve the criteria as amended. Seconded by A Shmerling. Motion passed unanimously.

7. 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
CONCERTA[BNR] (methylphenidate ER) tablet
DAYTRANA (methylphenidate) patch
Dexmethylphenidate IR tablet
Dexmethylphenidate ER capsule
Guanfacine ER tablet
Methylphenidate (generic Methylin/Ritalin) solution, tablet
Modafinil tablet
VYVANSE (lisdexamfetamine) capsule

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

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

- Prescription meets indication/age limitation criteria (Table 1) **AND**
- If member is ≥ 6 years of age:
  - Has documented trial and failure‡ with three preferred products in the last 24 months **AND**
  - For members unable to swallow solid oral dosage forms, two of the trials must include preferred products that may be administered without swallowing intact (whole) capsules (methylphenidate solution, dexmethylphenidate ER, Vyvanse, or Adderall XR)

  OR
- If member is 3-5 years of age:
  - Has documented trial and failure‡ with one preferred product in the last 24 months **AND**
  - For members unable to swallow solid oral dosage forms, the trial medication must include a preferred product that may be administered without swallowing intact (whole) capsules (methylphenidate solution, dexmethylphenidate ER, Vyvanse, or Adderall XR).

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

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

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

- Member is 18 years of age or older **AND**
- Member has diagnosis of narcolepsy and is experiencing excessive daytime sleepiness **AND**
- Member does not have end stage renal disease (eGFR <15 mL/minute) **AND**
- Member does not have severe hepatic impairment **AND**
- Member does not have a history of QT interval prolongation **AND**
- Member has trial and failure‡ of modafinil **AND** armodafinil **AND** one other agent in the stimulant PDL class **AND**

Member has been counseled that Wakix may reduce the efficacy of hormonal contraceptives and regarding use an alternative non-hormonal method of contraception during Wakix therapy and for at least 21 days after discontinuing treatment.

Maximum Dose (all products): See Table 2

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

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

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

Table 1: 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 (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 (DEXEDRINE)	ADHD (Age 6 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
Dextroamphetamine IR and ER (DEXTROSTAT)	ADHD and Narcolepsy (IR ≥ 3 years, ER ≥ 6 years)
Lisdexamfetamine dimesylate (**VYVANSE capsule**, Vyvanse chewable)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years)
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 (RITALIN LA)	ADHD (Age ≥ 6 years)
Methylphenidate ER (ADHANSIA XR)	ADHD (Age ≥ 6 years)
Non-Stimulants	
Atomoxetine (generic STRATTERA)	ADHD (Age ≥ 6 years)
Clonidine ER (KAPVAY)	ADHD (Age ≥ 6 years), Treatment of ADHD as monotherapy and as adjunctive therapy to stimulants
Guanfacine ER (generic INTUNIV)	ADHD (Age ≥ 6 years), Treatment of ADHD as monotherapy and as adjunctive therapy to stimulants
Viloxazine ER (QELBREE)	ADHD (Age ≥ 6 years)
Wakefulness-promoting Agents	
Armodafinil (generic NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD (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) (Age ≥ 18 years)
Pitolisant (WAKIX)	Excessive sleepiness associated with narcolepsy (Age ≥ 18 years)
Solriamfetol (SUNOSI)	Excessive sleepiness associated with narcolepsy, OSA (Age ≥ 18 years)
KEY: **ADHD**–attention-deficit/hyperactivity disorder, **OSA**–obstructive sleep apnea, **SWD**–shift work disorder	

Table 2: Maximum Dose	
Drug	**Maximum Daily Dose**
ADDERALL	60 mg
ADDERALL XR	60 mg
ADHANSIA XR	85 mg
ADZENYS XR ODT ADZENYS ER SUSPENSION	18.8 mg (age 6-12) 12.5 mg (age ≥ 13)
AMPHETAMINE SALTS	40 mg
APTENSIO XR	60 mg
CONCERTA	54 mg (age 6-12) or 72 mg (≥ age 13)
COTEMPLA XR-ODT	51.8 mg
DEXTROAMPHETAMINE ER	60 mg
DAYTRANA	30 mg/9 hour patch (3.3 mg/hr)
DESOXYN	25 mg
DEXEDRINE	40 mg60 mg
DEXTROSTAT	60 mg
DYANAVEL XR	20 mg

EVEKEO	60 mg
FOCALIN	20 mg
FOCALIN XR	40 mg
INTUNIV ER	4 mg (age 6-12) or 7 mg (age ≥ 13)
JORNAY PM	100 mg
KAPVAY ER	0.4 mg
METADATE CD	60 mg
METADATE ER	60 mg
METHYLIN	60 mg
METHYLIN ER	60 mg
METHYLIN SUSPENSION	60 mg
METHYLPHENIDATE	60 mg
METHYLPHENIDATE ER	60 mg
MYDAYIS ER	25 mg (age 13-17) or 50 mg (age ≥ 18)
NUVIGIL	250 mg
PROCENTRA	60 mg
PROVIGIL	400 mg
QELBREE	400 mg (age 6-17) or 600 mg((age ≥ 18)
QUILLICHEW ER	60 mg
QUILLIVANT XR	60 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
ZENZEDI	60 mg

Discussion

- J Taylor mentioned recent and ongoing shortages of products in the stimulants therapeutic class. The Department monitors drug shortages (FDA information, call center records, etc.) on an ongoing basis and makes product-related changes as needed outside of the quarterly review process.
- J Taylor confirmed that all preferred agents in this class are associated with age, maximum daily dose, and diagnosis requirements that must be met. Off-label, compendia supported indications for use are considered.
- K MacIntyre moved to (1) For consistently, include the same diagnoses and age limitations for both modafinil and armodafinil in Table 1, and (2) allow modafinil and armodafinil to be approved off-label for antipsychotic-related fatigue. Dr. MacIntyre clarified that the intent would be that modafinil would be initially selected over armodafinil in most cases. Seconded by S Klocke. Motion passed unanimously.
- The Board suggested further clarifying criteria language regarding approval of Sunosi (solriamfetol) and Wakix (pitolisant) for members who are unable to swallow solid oral dosage forms. The Department will follow up on this suggestion and try to make the criteria clearer for prescribers.
- K MacIntyre moved to accept the criteria as amended. Seconded by L Claus. Motion passed unanimously.

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

a. Oral agents

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

Quantity Limits for oral agents:

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

b. Non-oral agents

Preferred Agents

No PA Required (quantity limits may apply)

IMITREX[BNR] (sumatriptan) injection kit
IMITREX[BNR] (sumatriptan) nasal spray
MIGRANAL[BNR] (dihydroergotamine) 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.

Migranal (dihydroergotamine mesylate nasal spray and vial for injection) and other non-oral dihydroergotamine product formulations may be approved if meeting ALL of the following criteria:

- Member is not currently taking a potent CYP 3A4 inhibitor (for example, protease inhibitor, macrolide antibiotic) AND
- Member does not have uncontrolled hypertension or ischemic heart disease AND
- Product is being prescribed for cluster headache (vial only) or acute migraine treatment (vial and nasal spray) AND
- Non-oral dihydroergotamine product formulations (with exception of the generic vial) may be approved with adequate trial and failure of the generic dihydroergotamine vial. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions.
  AND
- If dihydroergotamine product is being prescribed for acute migraine treatment, member has adequate trial and/or failure of 2 triptan agents (for example sumatriptan, naratriptan)and 1 NSAID medication. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions.
  OR
- If dihydroergotamine product is being prescribed for cluster headaches, member has adequate trial and/or failure of 2 triptan agents. Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions.

Grandfathering:
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.

Maximum Dosing:
Migranal (dihydroergotamine) spray: 16mg per 28 days
Dihydroergotamine vial: 24mg per 28 days

Note: Cafergot (ergotamine/caffeine) tablet is covered without prior authorization.

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, documented inability to tolerate dosage form.

Quantity Limits for non-oral agents:

Product	**Maximum Quantity**
Dihydroergotamine mesylate vial 1mg/mL	24 mg/28 days24 vials/ 28 days
Imitrex (sumatriptan) injection	Max 4 injectors / 30 days
Imitrex (sumatriptan) nasal spray	Max 6 inhalers / 30 days
Migranal (dihydroergotamine mesylate) nasal spray	8 nasal spray devices/ 30 days
Onzetra Xsail (sumatriptan) nasal powder	Max 16 nosepieces / 30 days
Tosymra (sumatriptan) nasal spray	Max 12 nasal spray devices / 30 days
Zembrace Symtouch (sumatriptan) injection	Max 36mg / 30 days
Zomig (zolmitriptan) nasal spray	Max 6 inhalers / 30 days

Discussion

- J Taylor clarified that Migranal® (dihydroergotamine mesylate nasal spray) is going to become a preferred product on 4/1/2023, so the criteria in the paragraph related to Migranal should apply only to the injectable (vial) product. Migranal nasal spray will no longer require prior authorization.
- The Board discussed Trudhesa® a recently approved dihydroergotamine mesylate nasal spray. J Taylor confirmed that this product will continued to be covered by non-preferred criteria within this therapeutic class.
- S Klocke moved that the current criteria for Migranal nasal spray be amended so that they are more general and applicable to all non-preferred formulations of dihydroergotamine mesylate (including nasal spray and products for injection and excluding Migranal brand nasal spray, which will soon be a preferred agent). Seconded by P Lanius. Motion passed unanimously.
- L Claus moved to accept the criteria as amended. Seconded by S Klocke. Motion passed unanimously.

9. Multiple Sclerosis Therapies – Disease Modifying & Symptom Management

a. Disease Modifying Agents

Preferred Agents
No PA Required (unless indicated*)
*AUBAGIO (teriflunomide) tablet**2nd Line**
AVONEX (interferon beta 1a) injection
BETASERON (interferon beta 1b) injection kit
COPAXONE[BNR] (glatiramer) injection syringe, 20 mg and 40 mg
Dimethyl fumarate DR tablet (generic Tecfidera)
*GILENYA (fingolimod) 0.5 mg tablet**2nd Line**
*KESIMPTA (ofatumumab) pen**2nd Line**

*Second-line preferred agents (Gilenya, Aubagio, **Kesimpta (ofatumumab)** may be approved if meeting the following:
Member has a diagnosis of a relapsing form of multiple sclerosis confirmed on MRI by presence of new spinal lesions, cerebellar lesions, brain stem lesions, or change in brain atrophy AND
Medication is being prescribed by a neurologist or in consultation with a neurologist AND
Prescriber attests to shared decision making with respect to risks versus benefits of medical treatment AND
Additional safety criteria for prescribed agent are met (Table 1) AND
Member meets one of the following:
Mmember has trialed and failed treatment with one preferred agent. Avonex (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Copaxone (glatiramer) OR dimethyl fumarate. Failure is defined as intolerable side effects, contraindication to therapy, drug-drug interaction, or lack of efficacy. OR
Member has documented diagnosis of multiple sclerosis made by neurologist in the last 3 years OR member has history of diagnosis made by a neurologist > 3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of multiple sclerosis

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

- The requested medication is being prescribed by a neurologist or in consultation with a neurologist AND
- Member has a diagnosis of a relapsing form of multiple sclerosis AND
- 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 the prescribed agent is **Mayzent (siponimod)**, **Mavenclad (cladribine)**, **Vumerity (diroxemel fumerate)**, or **Bafiertam (monomethyl fumarate DR)**, then the
  - The safety criteria for prescribed agent are met (Table 1) AND
  - Aadditional criteria listed below for the respective prescribed agent are also met.

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

MAYZENT (siponimod):

- Member does not have diagnosis of macular degeneration **AND**
- Member has no evidence of relapse in the 3 months preceding initiation of therapy **AND**
- Member has previous trial and failure of three preferred agents, one of which must be Gilenya (fingolimod). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

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) **AND**
- Member is not currently on immune-suppressive or myelosuppressive therapy

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 (dimethyl fumarate) therapy (and no other reason for failure of Tecfidera is given), then the following additional criteria must be met:
  - Member has trialed a temporary dose reduction of Tecfidera (with maintenance dose being resumed within 4 weeks) **AND**
  - Member has trialed taking Tecfidera (dimethyl fumarate) with food **AND**
  - GI adverse events remain significant despite maximized use of gastrointestinal symptomatic therapies (such as calcium carbonate, bismuth subsalicylate, PPIs, H2 blockers, anti-bloating/anti-constipation agents, anti-diarrheal, and centrally acting anti-emetics) **AND**
  - Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of clinically significant reduction in GI adverse events.

Members currently stabilized on a preferred second-line or non-preferred product (with the exception of brand Tecfidera) may receive approval to continue therapy with that agent. Members currently stabilized on brand Tecfidera may use the preferred generic equivalent formulation.

Table 1: Safety Criteria for Initiating Multiple Sclerosis Disease Modifying Therapy								
Brand	**AUBAGIO**	**BAFIERTAM**	**GILENYA**	**KESIMPTA**	**MAYZENT**	**MAVENCLAD**	**TECFIDERA**	**VUMERITY**
Generic	**teriflunomide**	**monomethyl fumarate DR**	**fingolimod**	**ofatumumab**	**siponimod**	**cladribine**	**dimethyl fumarate**	**diroximel fumarate**
No active infections[a]	X	X	X	X	X	X	X	X
Baseline CBC w/diff	X	X			X	X[c,g]	X	X
Baseline ALT, AST, bilirubin ≤ 2x ULN[b]	X	X	X		X	X	X	X
Negative baseline pregnancy test	X	X			X	X	X	
Using highly effective contraception (if childbearing potential)	X	X	X	X	X	X	X	X
Other	Documented baseline blood pressure Skin or blood screening test for *M. tuberculosis*		No significant CV history[f] QTc interval < 500 ms No Class 1a or Class III antiarrhythmic use Baseline ocular coherence eye exam	Regular monitoring of immune globulin levels required Avoid live-attenuated and live vaccines Use is contra-indicated with active hepatitis B virus (HBV) infection Member counseled	No CYP2C9*3/*3 genotype No significant CV history[f] QTc interval < 500 ms Baseline eye evaluation that includes macula exam	No current evidence of malignancy No current immune-suppressive or myelosuppressive therapy	Member counseled regarding risks of anaphylaxis, angioedema and PML[e]	

				regarding risk of PML[e]				
Maximum dose	14 mg per day	190 mg twice a day	Age and weight based[d]	20 mg at weeks 0, 1 and 2, then 20 mg once monthly starting at Week 4	60 mg per 30 days	Not exceeding 3.5 mg/kg during full treatment course	240 mg twice a day	924 mg per day

a – including herpes zoster or other active serious infections (or chronic: such as hepatitis, tuberculosis, and HIV)
b – ULN - upper limit of normal
c – plus at 2 and 6 months post-initiation and periodically thereafter
d – GILENYA maximum dose: ≥ 10 years of age and > 40 kg body weight: 0.5 mg once daily; ≥ 10 years of age and ≤ 40 kg body weight: 0.25 mg once daily
e – PML - progressive multifocal leukoencephalopathy
f – No h/o MI, CVA, TIA, unstable angina, NYHA Class III-IV HF AND no Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
g – Lymphocytes must be within normal limits before initiating the first treatment course and ≥ 800 cells per microliter before initiating the second treatment course

Scheduled Speaker Testimony
K Bayo, Zeposia - Bristol Myers Squibb
A Hale, Ponvory - Janssen Scientific Affairs, LLC

Discussion

- J Taylor clarified that the overall goal this quarter was to simplify the management of products in this class. As of 4/1/2023, products on the preferred list, with the exception of Kesimpta (ofatumumab) which will continue its current status as a 2nd-line agent, will not require prior authorization.
- S Klocke moved to (1) add language that members should have a diagnosis of a relapsing form of multiple sclerosis in order to receive approval for Kesimpta (ofatumumab), and (2) In addition to the global drug class requirements regarding maximum doses and baseline pregnancy tests, add "If indicated in the product labeling, an ophthalmologic exam has been performed and documented prior to initiation of therapy." Seconded by P Lanius. Motion passed unanimously.
- S Klocke moved to accept the criteria as amended. Seconded by L Claus. Motion passed unanimously.

b. Multiple Sclerosis Symptom Management

Preferred Agents
Dalfampridine ER tablet

Ampyra (dalfampridine) prior authorization may be approved If the member is started on the generic equivalent drug but is unable to continue treatment on the generic drug, as determined by the prescriber. if all of the following criteria are met:

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

Reauthorization of Ampyra (dalfampridine) may be approved if medical record documentation indicates that member's symptoms are stable or there is improvement in ambulation (measured by T25FW assessment) or improvement in ADLs.

Discussion

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

10. Ophthalmics, Immunomodulators

Preferred Agents
RESTASIS[BNR] (cyclosporine 0.05%) unit-of-use droperettes

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
- L Claus moved to accept the criteria as written. Seconded by I Pan. 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.*

11. Non-opioid Analgesic Agents – Oral & Topical

a. Oral agents

Preferred Agents
Duloxetine 20 mg, 30 mg, 60 mg capsule (generic Cymbalta)
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.

b. Topical agents

Preferred Agents
LIDODERM[BNR] (lidocaine) patch
Lidocaine 5% patch

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

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

12. Non-steroidal Anti-inflammatory Drugs (NSAIDs) – Oral & Non-Oral

a. Oral agents

Preferred Agents

No PA Required
Celecoxib capsule
Diclofenac potassium tablet
Diclofenac sodium EC/DR tablet
Ibuprofen suspension, tablet (Rx)
Indomethacin capsule, ER capsule
Ketorolac tablet**
Meloxicam tablet
Nabumetone tablet
Naproxen DR/ER, tablet, suspension (Rx)
Naproxen EC* tablet (Rx) (*all manufacturers except *Woodward*)
Naproxen suspension* (*all manufacturers except *Acella*)
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
-

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

b. Non-oral agents

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.

FLECTOR (diclofenac) 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.

13. Monoamine Oxidase Inhibitors (MAOIs)

Preferred Agents
NONE

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

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

14. 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, solution

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

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

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

15. 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 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 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 (0.6mL) three times per day

KYNMOBI (apomorphine sublingual film) may be approved if meeting the following:
KYNMOBI (apomorphine) is being used for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease AND

Due to the risk of profound hypotension and loss of consciousness, member must not be concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron.

Maximum dose: 30mg five times per day

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

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

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, tablet, 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 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.

16. Benzodiazepines (non-sedative hypnotic)

Preferred Agents
(*may be subject to age limitations)
Alprazolam IR, ER tablet*
Chlordiazepoxide capsule*
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 Alprazolam ER tablet Alprazolam ODT XANAX (alprazolam) tablet XANAX XR (alprazolam ER) tablet Alprazolam Intensol oral concentrate 1 mg/mL	Adults ≥ 18 years: 10 mg/day	Total of 300 mg from all dosage forms per 30 days
Clorazepate tablet TRANXENE (clorazepate) T-Tab	>12 years: 90 mg/day Children 9-12 years: up to 60 mg/day	Total of 2,700 mg (adults) and 1,800 mg (children) from all tablet strengths per 30 days
Chlordiazepoxide capsule	Adults ≥ 18 years: 300 mg/day Children 6-17 years: up to 40 mg/day (pre-operative apprehension and anxiety)	Total of 9,000 mg (adults) and 120 mg (children, pre-op therapy) from all tablet strengths per 30 days
Diazepam Intensol oral concentrate 5 mg/mL Diazepam solution 5 mg/5 mL Diazepam tablet	Adults ≥ 18 years: 40 mg/day Children: N/A Adults ≥ 18 years: 40 mg/day Children Members age 6 months to 178 years: up to 10 mg/day	Total of 1200 mg from all dosage forms per 30 days Total of 1200 mg (adults) and 300 mg (pediatrics) from all dosage forms per 30 days
ATIVAN (lorazepam) Intensol concentrate 2 mg/mL ATIVAN (lorazepam) tablet Lorazepam oral concentrated soln 2 mg/mL Lorazepam tablet	Adults and children ≥ 128 years: 10 mg/day Children < 12 years: N/A	Total of 300 mg from all dosage forms per 30 days
Oxazepam capsule	Adults and children ≥ 128 years: 120 mg/day Children 6-128 years: absolute dosage not established	Total of 3600 mg from all dosage forms per 30 days

17. 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.

18. Atypical Antipsychotics - *pulled from Mass Review section (see page 40)*

19. Calcitonin Gene-related Peptide (CGRP) Inhibitors

Preferred Agents
*AIMOVIG (erenumab-aooe) auto-injector
*AJOVY (fremanezumab-vfrm) auto-injector, syringe
EMGALITY (galcanezumab-gnlm) pen, 120 mg syringe
*NURTEC (rimegepant) ODT

*Preferred agents (Aimovig, Ajovy, Nurtec 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 (Aimovig and Ajovy). 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 AND
  - 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 100mg: 19-65 years
All other products: ≥ 18 years

Maximum Dosing:
Aimovig (erenumab): 140mg per 30 days
Emgality 120mg (galcanezumab): 240mg once as first loading dose then 120mg monthly
Emgality 100mg (galcanezumab): 300mg per 30 days
Ajovy (fremanezumab): 225mg monthly or 675mg every three months
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)

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

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

20. Lithium Agents

Preferred Agents
Lithium carbonate capsule, tablet
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.

21. Ophthalmics, Allergy

Preferred Agents
- ALREX (loteprednol) 2%
- Cromolyn 4%
- Ketotifen 0.025% (OTC)
- 0.1% LASTACAFT (alcaftadine) 0.25% (OTC)
- Olopatadine 0.2% (OTC) (generic Pataday Once Daily)
- Olopatadine 0.1% (OTC) (generic Pataday Twice Daily)
- Olopatadine 0.1% (Rx)
- Olopatadine 0.2% (Rx) (all manufacturers except *Sandoz)*
- PAZEO (olopatadine) 0.7% (Rx)

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

22. Ophthalmics, Anti-inflammatories

Preferred Agents

NSAIDS
- Diclofenac 0.1%
- Flurbiprofen 0.03%
- ILEVRO (nepafenac) 0.3%
- Ketorolac 0.5%
- Ketorolac LS 0.4%
- NEVANAC (nepafenac) 0.1%

CORTICOSTEROIDS
- FLAREX (fluorometholone) 0.1%
- Fluorometholone 0.1% drops
- FML FORTE (fluorometholone) 0.25% drops
- LOTEMAX[BNR] (loteprednol) 0.5% drops
- LOTEMAX (loteprednol) 0.5% 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).

23. 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%

Prosataglandin analogue
Latanoprost 0.005%
LUMIGAN[BNR] (bimatoprost) 0.01%
TRAVATAN Z[BNR] (travoprost) 0.004%

Alpha-2 adrenergic agonists
ALPHAGAN P 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%
Dorzolamide/Timolol PF 2%-0.5% (*Akorn only)*

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha2-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.

Non-preferred combination products may be approved following trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the combination product being requested (if available) to establish tolerance. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.

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

Discussion regarding drug classes included in Mass Review

- L Claus recommended in the CGRP Inhibitors class to add Emgality® to the statement "*Preferred agents (Aimovig, Ajovy, Nurtec) may be approved if meeting the following criteria:"
- I Pan recommended in the Tricyclic Antidepressant class to delete the sentence "Silenor (doxepin 3mg, 6mg) approval criteria can be found on the Appendix P," as it is no longer applicable.
- S Klocke moved to accept all other criteria in Mass Review as written. Seconded by P Lanius. Motion passed unanimously.

18. Atypical Antipsychotics – Oral & Topical

c. Oral agents

Preferred Agents

No PA Required*

Aripiprazole tablet
Clozapine tablet

LATUDA[BNR] (lurasidone)[2nd line**]
Olanzapine tablet, ODT
Paliperidone ER tablet
Quetiapine IR tablet***
Quetiapine ER tablet
Risperidone tablet, ODT, oral solution
SAPHRIS[BNR] (asenapine) SL tablet
Ziprasidone

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

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

- Medication is being prescribed for an FDA-Approved indication AND
- Prescription meets dose and age limitations (Table 1) AND
- Member has history of trial and failure of three preferred products with FDA approval for use for the prescribed indication (failure defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing)

*Age Limits: All products including preferred products will require a PA for members younger than the FDA approved age for the agent (Table 1). Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for 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).

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

*****Quetiapine IR** when given at 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 < 150mg per day except for utilization (when appropriate) in members 65 years or older. PA will be approved for members 10-17 years of age with approved diagnosis (Table 1) stabilized on <150mg quetiapine IR per day.

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

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

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

- Member has history of adequate trial and failure of 5 preferred agents (one trial must include aripiprazole tablet). Failure is defined as lack of efficacy with 6-week trial on maximally tolerated dose, 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 can receive approval to continue therapy with that agent for one year.

Table 1 Atypical Antipsychotics – FDA Approved Indication, Age Range, Quantity and Maximum Dose					
Brand	**Generic**	**Approved Indications**	**Age Range**	**Maximum Daily Dose by Age/Indication**	**Quantity and Maximum Dose Limitations**
ABILIFY	aripiprazole	Schizophrenia Bipolar I Disorder 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 year ≥ 18 years	30 mg 30 mg 15 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 900mg per day
CAPLYTA	lumateperone	Schizophrenia Bipolar I Disorder Bipolar II Disorder	≥ 18 years	42 mg	Maximum dosage of 42mg per day
	clozapine	Treatment-resistant schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900mg 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 34mg per day
RISPERDAL	risperidone	Schizophrenia Schizophrenia Bipolar mania Irritability w/autistic disorder	≥ 18 years 13-17 years ≥ 10 years 5–17 years	12 mg 16 mg 6 mg 6 mg 3 mg	Maximum dosage of 12 16 mg/day
REXULTI	brexpiprazole	Schizophrenia Adjunctive treatment of MDD	≥ 13 years ≥ 18 years	4 mg 3 mg	Maximum of 3mg/day for MDD adjunctive therapy, Maximum of 4mg/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	≥ 18 years ≥ 18 years ≥ 18 years	6 mg 6 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
T Smith, PA-C - Vraylar, Colorado Mental Health Institute at Pueblo
(Mr. Smith was unable to present verbal testimony during today's meeting)

Discussion

- K MacIntyre moved to change criteria for non-preferred agents requiring "trial and failure of *three* preferred products with FDA approval for use for the prescribed indication to "trial and failure of *two* preferred products with FDA approval for use for the prescribed indication" with the same failure definition. Seconded by I Pan. Motion passed with three votes in favor. P Lanius and L Claus opposed. B Jackson and A Shmerling abstained.
- The Board discussed the content of Table 1 in this section. Indications, age ranges and maximum doses in the table are currently based on FDA-approved product labeling.
- K MacIntyre moved (1) that the Department evaluate dose information in Table 1, in particular for possibly increasing the maximum does of Geodon (ziprasidone) to 200 mg for both schizophrenia and bipolar I disorder, consolidating Seroquel® (quetiapine) indications and maximum doses, and considering a maximum dose for Zyprexa (olanzapine) of 30 mg to manage acute agitation, and consider removing "FDA approved" from the title of Table 1 and make table content adjustments as needed based on information from a combination of FDA labeling, other compendia, and expert evaluation, (2) that the Department to globally evaluate the paragraph related to Quetiapine IR given at subtherapeutic doses and also consider providing PA exceptions for subtherapeutic doses of quetiapine being prescribed by a psychiatrist (and possibly other prescriber types). Seconded by S Klocke. Motion passed with six votes in favor. A Shmerling abstained.
- K MacIntyre moved to accept the criteria for this class as amended. Seconded by L Claus. Motion passed unanimously. S Klocke abstained.

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

Conflict of Interest Check
No Board members reported a conflict of interest for any of the four non-PDL drug products being reviewed today.

- **DARTISLA (glycopyrrolate) orally disintegrating tablet (ODT)**

Dartisla (glycopyrrolate) ODT may be approved if the following criteria are met:

1. Member is ≥ 18 years of age AND
2. Member has a diagnosis of peptic ulcer disease AND
3. Member has been tested for *H. pylori* and received eradication therapy if appropriate, AND
4. Member has had an adequate trial of a generic glycopyrrolate tablet regimen at maximally tolerated recommended doses and has failed to achieve a clinically significant response AND
5. Dartisla ODT will be used as an adjunct treatment with a proton pump inhibitor (or H2 antagonist) and not as monotherapy

Initial approval: 6 months

Reauthorization: Prescriber attests that the member has experienced positive clinical response to therapy

Maximum dose: 6.8 mg/day

Quantity limit: 120 orally disintegrating tablets/30 days

Discussion

- L Claus moved to accept these criteria as written. Seconded by A Shmerling. Motion passed unanimously.

- **SPEVIGO (spesolimab) IV infusion**
  SPEVIGO (spesolimab) may be approved if the following criteria are met:

  1. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional **AND**
  2. Member is ≥ 18 years of age **AND**
  3. Member is experiencing a generalized pustular psoriasis (GPP) flare, **AND**
  4. Member has previously tried and failed† two of the following: oral cyclosporine, infliximab (brand/generic or biosimilar product), Humira (adalimumab), or Enbrel (etanercept)

  Dosing limit: up to two 900 mg doses per year

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

  Discussion

  - I Pan noted that biosimilar adalimumab products are expected to come out this year, and for the Department to consider those new biosimilar products as these criteria are finalized.
  - L Claus moved to accept these criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

- **TARPEYO (budesonide) delayed-release capsule**
  TARPEYO (budesonide) may be approved if the following criteria are met:

  1. Member is ≥ 18 years of age **AND**
  2. Member has proteinuria associated with primary immunoglobulin A nephropathy (IgAN) with a risk of rapid disease progression **AND**
  3. The diagnosis has been confirmed by biopsy, **AND**
  4. Most recent labs indicate a urine protein-to-creatinine ratio (UPCR) of ≥1.5 g/g, **OR** proteinuria > 0.75 g/day, **AND**
  5. Member has been receiving the maximum (or maximally tolerated) dose of either an ACE inhibitor **OR** angiotensin receptor blocker (ARB) for at least 90 days, **AND**
  6. Member has had an adequate trial of a generic oral budesonide regimen at maximally tolerated recommended doses and has failed to achieve a clinically significant response **AND**
  7. The medication is prescribed by or in consultation with a nephrologist **AND**
  8. Prescriber plans to reduce dosage from 16 mg/day to 8 mg/day during the final 2 weeks of the 9-month course of treatment
  9. Approval will be limited to 10 months for completion of 9-month course of therapy.

Maximum dose: 16 mg/day

Quantity limit: 120 4 mg capsules/30 days

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether delayed-release budesonide slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Schedule Stakeholder Testimony
Rowland Elwell, Tarpeyo - Calliditas NA Enterprises, Inc.

Discussion

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

- **RELYVRIO (sodium phenylbutyrate/taurursodiol)** powder for oral suspension

Relyvrio (sodium phenylbutyrate/taurursodiol) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member has a definite diagnosis of sporadic or familial ALS, as defined by the revised El Escorial (Airlie House) criteria, with symptom onset within the past 18 months (for new starts only), **AND**
3. ALS disease progression is recorded at baseline (prior to initiating Relyvrio) using the Revised ALS Functional Rating Scale (ALSFRS-R), **AND**
4. The requested medication is prescribed by or in consultation with a neurologist **AND**
5. Member has normal respiratory function, defined as having a forced vital capacity (FVC) ≥ 80% of predicted, **AND**
6. Due to the high sodium content of this product, provider attests that member does NOT have heart failure, hypertension, renal impairment or other salt-sensitive medical conditions.

Initial Approval: 6 months

Maximum dose: 2 packets (dissolved in water) per day

Quantity limit: 60 packets/30 days

Reauthorization: After 6 months, members may receive approval to continue therapy if the following criteria are met:

The member has shown no adverse events due to Relyvrio treatment AND

The member has demonstrated response to Relyvrio treatment by showing significant clinical improvement or no decline documented using the Revised ALS Functional Rating Scale (ALSFRS-R). Authorization may be reviewed every six months to confirm that current medical necessity criteria are met, and that the medication is effective based on improvement or no decline based on the ALSFRS-R score.

The above coverage criteria 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. If use outside of stated coverage standards is requested, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Discussion

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

C. Review of Proposed Changes to "High Cost Claims" Prior Authorization

- J Taylor presented information about the High Cost Claims section on Appendix P that was originally implemented in June 2018. Currently, any pharmacy claim that exceeds $19,999 will require prior authorization that simply verifies product use per product labeling.
- There are exceptions to this policy, including:
  - Drug products included on the preferred drug list (PDL) or Appendix P
  - Drug products for the management of HIV, hepatitis C, substance use disorder, multiple sclerosis or Fabry's disease
  - Oncology therapies
  - Long-acting injectable antipsychotics
  - Hemophilia products
- The Department proposes moving the dollar amount for prior authorization to $9,999. An evaluation was conducted to assess the effect of changing the dollar amount cutoff and the level of impact was determined to be low. In addition to usual types of high cost claims, the system also captures high cost claims for unmanaged drug products and probable prescription quantity errors. This system does not apply to claims submitted under the medical benefit. High Cost Claims are reviewed once weekly by the Department.
- A Shmerling moved to accept this policy change. Seconded by P Lanius. Motion passed unanimously.

9. Adjournment

Vice Chair B Jackson reminded attendees that the next Board meeting is scheduled for Tuesday, May 9, 2023, from 1:00 to 5:00 pm and also reminded Board members to delete their meeting binders at the conclusion of today's meeting.

R Page expressed appreciation to Dr. Alison Shmerling, on behalf of the University of Colorado Skaggs School of Pharmacy and the Colorado DUR group, for all of her years of dedication to the Health First Colorado DUR Board.

K MacIntyre moved to adjourn the meeting, Seconded by L Claus. Motion passed unanimously. The meeting was adjourned at 5:01 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD