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

August 10, 2021
Open Session
1:00 pm – 5:00 pm

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:02 pm by L Claus, Board Chair.

2. Roll Call / Introductions

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

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

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

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

Reminders for Board Members:

- Board members should have very recently received an email reminder to submit their annual written Conflict of Interest (COI) disclosures. Please complete and return those documents to J Rawlings by August 31.
- Video and microphone for Board members will be turned ON. To facilitate the voting process, keeping your video turned on as much as possible during the meeting is encouraged.

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

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided several updates from the Department:

In a change from the posted agenda, the Ophthalmic Immunomodulator PDL drug class will be moved from the Mass Review section and be reviewed as the first item in the New Business section.

The Department is still working on system functionality for implementing prior authorization processing for select physician administered drugs (PAD) billed through the medical benefit. Implementation will occur no sooner than November 1, 2021. Updates will be made available on the Department's PAD web page at https://hcpf.colorado.gov/physician-administered-drugs

We will be continuing the format adopted during the last DUR Board meeting in May to read aloud only proposed additions and changes to DUR criteria currently posted on the PDL and Appendix P. For products and drug classes being newly managed and undergoing review, all proposed criteria will be read aloud during the meeting. For products and drug classes that are currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud. The current PDL and Appendix P are available on the Department's Pharmacy Resources page at https://hcpf.colorado.gov/pharmacy-resources

The Department's Prescriber Tool is now up and running. The tool, accessible through most electronic health record (EHR) systems, includes functionality for e-prescribing, electronic prior authorization, and allows registered prescribers to access the OpiSafe opioid risk module. More information is available eon the Department's web page https://hcpf.colorado.gov/prescriber-tool-project

The Department will be sending its Summer 2021 DUR Newsletter by email in the near future. The Newsletter will also be posted to the DUR Board web page at https://hcpf.colorado.gov/drug-utilization-review-board

The next Board meeting is tentatively scheduled to be held virtually on Tuesday, November 9, 2021, from 1:00 pm to 5:00 pm.

Dr. Laird disclosed his COIs as the Industry Representative so that he would not need to verbally disclose that information separately for each therapeutic class or product being reviewed during today's meeting.

5. Final Approval of Minutes from May 11, 2021 Meeting

Board Chair L Claus asked if there were any changes to propose for minutes from the May 11 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by B Jackson and seconded by P Lanius. The motion passed unanimously.

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

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

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting. Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers at the time they are speaking.

DUR Board Conflicts of Interest: DUR Board Members must verbally disclose any conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner. If a conflict of interest exists, members must recuse themselves from the applicable vote or discuss with the Board during the meeting whether the situation rises to the level of an actual conflict. If a Board member recuses, they should not participate in the discussion of the agenda item or any vote regarding that item.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**

DUR Intern Thao Anh Mai presented a summary of recent FDA drug approvals

DUR Intern Ryan Tran presented FDA Safety information from 2nd quarter 2021.

- **Retrospective DUR Reports**

  R Page presented the RDUR summary.

  - There was a slight uptick during 2Q2021 in the number of members <18 years of age who received two or more antipsychotic medications concomitantly for 45 or days or more.
  - The number of members who had two or more benzodiazepine claims concomitantly for 90 days or more remained fairly constant, with a slight decrease in 2Q2021 in both the number of providers and members.
  - The number of providers who have patients receiving an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly for 60 or more days (excluding individuals with cancer and with sickle cell disease) decreased slightly during the most recent quarter measured.
  - The number of members with claims for opioids exceeding an average of 200 MME in a 30-day period has continued to decline since 1Q2020. The number of prescribers increased very slightly in the most recent quarter measured.
  - A new RDUR intervention in 2021 looks at members with multiple claims for opioid prescriptions that total >150 MME (averaged over 30 days) and no naloxone fill within the 12 months prior to or during the current quarter. Between 1Q2021 and 2Q2021 the number of members in this intervention moved in a positive direction, from 358 to 331.

- **Quarterly Clinical Modules**

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

  - Opioid Utilization Among Health First Colorado Members with Migraine or Episodic Cluster Headaches *(final module submitted 6/30/2021)*
  - Hemophilia and Associated Treatment Among Health First Colorado Members *(draft module submitted 6/30/2021, final to be delivered by 9/30/2021)*

- HIV Prevention and Treatment *(draft module to be delivered by 9/30/2021)*
- Analysis of the First Health Colorado DUR Pain Management Consultation Service *(planned)*

- **Quarterly Drug Utilization Reports**
  Board members were referred to these reports in the meeting binder

9. New Business

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

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

R Page proceeded with the review process of proposed criteria

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

- **Ophthalmics, Immunomodulators** (moved out of today's Mass Review section)

  Preferred Agents

  RESTASIS (cyclosporine 0.05%) single-use vials

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

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

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

Scheduled testimony presentations:
Ana Lopez, OD – Greeley Eye Doctors

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

• Anticonvulsants, Oral

J Taylor introduced anticonvulsants by saying that this drug class has undergone multiple reviews over the years. The Department's goals with managing these products have been, and continue to be, to ensure that Health First Colorado members have access to appropriate treatment options and to be sensitive to stakeholder input from our provider community regarding how the Department is managing these products for members. Preferred products in this class do not require prior authorization. For any member currently receiving a non-preferred drug, the member will receive approval to continue on that medication. Additionally, non-preferred brand name drugs that have a generic equivalent that is preferred will not require prior authorization if the prescriber indicates Dispense as Written (DAW) on the prescription order.

Preferred Agents

Barbiturates
Phenobarbital elixir, solution, tablet
Primidone tablet

Benzodiazepines
Clonazepam tablet, ODT
Clobazam tablet

Brivaracetam/Levetiracetam
Levetiracetam IR, ER tablet, solution

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

Hydantoins
DILANTIN[BNR] (phenytoin ER) 30 mg capsules
DILANTIN[BNR] (phenytoin) suspension
PHENYTEK[BNR] (phenytoin ER)
Phenytoin suspension, chewable, ER capsule

Lamotrigines
LAMICTAL[BNR] (lamotrigine) *dispersible*/chewable tablet
Lamotrigine *IR* tablet, chewable/disperse tabs *dispersible/chewable tablet*

Succinamides
Ethosuximide capsule, solution

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

Topiramates
TOPAMAX[BNR] (topiramate) sprinkle capsule
Topiramate IR tablet, sprinkle capsule

Other
FELBATOL[BNR] (felbamate) tablet, suspension
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.

Prior Authorization for mMembers currently stabilized (in outpatient or acute care settings) on any non-preferred medication in this class will be approved may receive prior authorization approval to continue on that medication.

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

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

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

APTIOM (eslicarbazepine):
- Member has history of trial and failure‡ of any carbamazepine-containing product

BRIVIACT (brivaracetam):
- Member is ≥ 4 years of age **AND**
- Member has history of trial and failure‡ of any levetiracetam-containing product

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

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

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

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

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

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

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

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

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

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

Table 1: Non-preferred Anticonvulsant Products Table		
	Minimum Age**	**Maximum Dose****
Barbiturates		
primidone (MYSOLINE)		2,000 mg per day
Benzodiazepines		
clobazam (ONFI)	1 2 years	40 mg per day
clobazam film (SYMPAZAN)	2 years	40 mg per day
clobazam suspension	1 2 years	40 mg per day
clonazepam (KLONOPIN)		20 mg per day
Brivaracetam/Levetiracetam		
brivaracetam (BRIVIACT)	4 years	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, all *except* suspension (TEGRETOL)		Not listed
carbamazepine ER (CARBATROL ER)		1600 mg per day
carbamazepine ER (EQUETRO)		1,600 mg per day
carbamazepine ER (TEGRETOL XR)		Not listed
eslicarbazepine (APTIOM)	4 years	1,600 mg per day
oxcarbazepine (TRILEPTAL) suspension		Not listed
oxcarbazepine ER (OXTELLAR XR)	6 years	Not listed 2,400 mg per day
Hydantoins		
ethotoin (PEGANONE)		3,000 mg per day
phenytoin ER (DILANTIN) 100mg capsules, suspension, Infatab		1,000 mg loading dose 600 mg/day maintenance dose
Lamotrigines		
lamotrigine (LAMICTAL)	2 years	400 mg per day
lamotrigine (LAMICTAL ODT)	2 years	4500 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 DR	10 years	
divalproex DR (DEPAKOTE)	10 years	
divalproex DR (DEPAKOTE SPRINKLE)	10 years	
divalproex ER (DEPAKOTE ER)	10 years	60 mg/kg/day
valproic acid, including solution	10 years	
valproic acid (DEPAKENE)	10 years	
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)	12 years	20 mg/kg/day
cenobamate (XCOPRI)	18 years	400 mg per day
felbamate tablet, suspension	18 2 years	
fenfluramine (FINTEPLA)	2 years	26 mg per day
lacosamide (VIMPAT)	4 years	400 mg per day
perampanel (FYCOMPA)	4 years	12 mg per day
rufinamide (BANZEL) tablet and suspension	1 year	3,200 mg per day
stiripentol (DIACOMIT)	2 years	50mg/kg/day 3,000 mg per day
tiagabine	12 years	64 mg per day
tiagabine (GABITRIL)	12 years	64 mg per day
vigabatrin	1 month	3,000 mg per day
vigabatrin (SABRIL)	1 month	3,000 mg per day
vigabatrin (VIGADRONE) powder packet	1 month	3,000 mg per day
zonisamide (ZONEGRAN)	16 years	600 mg per day
**Limits based on data from FDA package insert. Approval for age/dosing that falls outside of the indicated range may be evaluated on a case-by-case basis.		

Stakeholder input:
Letter from G Mills, RN, BSN CNRN
Letter from Colorado combined epilepsy stakeholders
Letter from CU Anschutz Epilepsy Division
Letter from the Epilepsy Foundation of Colorado & Wyoming

Scheduled testimony presentations:
S Klein, Epilepsy Foundation of Colorado & Wyoming
R Sandhar, UCB Pharma – Vimpat
M Redmann, UCB Pharma – Briviact
B O'Neill, Sunovion - Aptiom
S Stern, SK Life Science – Xcopri
H Doshi, Blue Sky Neurology, Swedish & Sky Ridge Medical Centers
A Atwood, Department of Neurology, Epilepsy Division, CU Anschutz Medical Campus
D McDermott, Department of Neurology, Epilepsy Division, CU Anschutz Medical Campus

Discussion

- L Laird, as Industry Representative, reported a conflict of interest for this therapeutic class.
- B Jackson asked about how the phrase "consultation with a neurologist." J Taylor explained that the extent of verification for that requirement is "yes" or "no." B Jackson asked if these consultations could include solely telephone consultations or situations in which a member had seen a neurologist several years ago and was currently stable on medication. J Taylor confirmed that "in consultation" encompasses whatever the prescriber professionally considers to be appropriate consultation.
- A Shmerling commented that most primary care physicians are more familiar with products on the preferred agents list because they are generally less costly and also the medications they see the most in clinical practice. Because treatment of epilepsy is highly individualized and complex, primary care providers may feel less comfortable prescribing non-preferred agents that they do not commonly prescribe. There is value in keeping the "in consultation with a neurologist" statement.
- T Brubaker added that the current consultation requirement helps ensure patient safety and the best patient care and he is not in favor of taking out that requirement.

- S Klocke asked if the Department knows which medications are being used for new starts for Health First Colorado members, such as phenobarbital and other first-generation agents. R Page suggested that the topic could be explored as part of a future Clinical Module. S Klocke agreed that it would be helpful to have that level of data to better understand what the issues are.
- A Shmerling asked about the possibility of establishing a consultation service, similar to the service for hepatology previously offered by ECHO (https://echocolorado.org/) to help with anticonvulsant drug therapy, particularly medication new starts.
- A Shmerling asked about the lack of a specific time frame on a medication in order to assess efficacy prior to be considered a treatment failure. How long do patients need to be on a medication before the therapy is considered a failure? R Page explained that the Board has received feedback in the past that patients sometimes failure a particular medication fairly quickly, so the criteria have been left more open in that regard.
- L Claus noted that Briviact and Aptiom had specific failure criteria called out as far as trial and failure of preferred products.
- S Klocke also was in favor of having some level of consultation from a neurologist or epileptologist to support making appropriate epilepsy treatment decisions.
- Following an extended discussion for this therapeutic class, A Shmerling made a multi-element motion regarding the anticonvulsant therapeutic class:
  - Eliminate duplicate text in draft criteria (paragraph beginning, "Non-preferred brand name medications…") at the bottom of page 5.
  - Recommend that Medicaid in general increase access to neurology consults for its members, which might include a neurology consultation service for primary care providers
  - Recommend that the Department evaluate new starts of older anticonvulsant medications in this class to understand what drug utilization looks like, based on claims data from a variety of practice settings
  - Accept criteria for this class as written, with the exception of eliminating duplicate text as described in item #1 above
- Seconded by B Jackson. Motion passed unanimously.

- **Stimulants and Related Agents**

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

Preferred Agents

ADDERALL XR[BNR] (mixed amphetamine salts ER)
Armodafinil (generic NUVIGIL)
Atomoxetine (generic STRATTERA)
Mixed amphetamine salts (generic ADDERALL IR)
CONCERTA[BNR] (Methylphenidate ER) tablet
Dexmethylphenidate IR (generic FOCALIN)
Dexmethylphenidate ER (generic FOCALIN XR)
FOCALIN XR (dexmethylphenidate ER)
Guanfacine ER
Methylphenidate IR (generic RITALIN IR)
Modafinil (generic PROVIGIL)
VYVANSE (lisdexamfetamine) capsules, chewables

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

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

- Prescription meets indication/age limitation criteria (Table 1) **AND**
- Member meets one of the following:
  - If member is ≥ 6 years of age, has documented trial and failure‡ with three preferred products in the last 24 months **OR**
  - If members is 3 –5 years of age, has documented trial and failure‡ with one preferred product in the last 24 months

    AND
- For **DAYTRANA, METHYLIN** solution, **QUILLICHEW**, **QUILLIVANT XR** and **DYANAVEL XR**:
  - One of the preferred trials must include VYVANSE chewable tablet, FOCALIN XR, VYVANSE capsules, or ADDERALL XR **AND**
  - Member has a documented difficulty swallowing and is unable to utilize alternative dosing with preferred tablet and capsule formulations.

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

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

WAKIX (solriamfetol (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: Indications and Ages

- Approval for medically accepted indications not listed in Table 1 may be given with prior authorization review and may require submission of peer-reviewed literature or medical compendia showing safety and efficacy of the medication used for the prescribed indication.
- Preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis if meeting all other criteria for approval.
- **Bolded Drug names are preferred** (subject to preferential coverage changes for brand/generic equivalents)

Drug	Indication/Age
Stimulants - Immediate Release	
amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years)
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 methylphenidate IR may be approved for members ≥ 4 years for ADHD symptoms that have not significantly improved despite adequate behavior interventions AND there is moderate-to-severe continued disturbance in functioning AND provider has determined that the potential benefits of starting methylphenidate before the age of 6 years outweigh the potential harm of delaying treatment
methylphenidate XR ODT (CONTEMPLA XR ODT)	ADHD (Age ≥ 6 years to ≤ 17 years)
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 3 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 and VYVANSE chewable** and 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 ERrr (METADATE CD)	ADHD (Age ≥ 6 years)
methylphenidate ER (QUILLICHEW ER)	ADHD (Age ≥ 6 years ≤ 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)
methylphenidate ER (APTENSIO XR)	ADHD (Age ≥ 6 years)
methylphenidate XR ODT (CONTEMPLA XR ODT)	ADHD (Age ≥ 6 years to ≤ 17 years)
Methylphenidate ER (JORNAY PM)	ADHD (Age ≥ 6 years)
Non-Stimulants	
atomoxetine (generic STRATTERA)	ADHD (Age ≥ 6 years)
clonidine ER (KAPVAY)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
guanfacine ER (generic INTUNIV)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
viloxazine ER (QELBREE)	ADHD (Age ≥ 6 years to ≤ 17 years)
Wakefulness-promoting Agents	
armodafinil (generic NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD for age ≥ 18 years
modafinil (PROVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD) (Age ≥ 18 years)
pitolisant (WAKIX)	Excessive sleepiness or cataplexy 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	
Medication	**Maximum Daily Dose**
ADDERALL	60 mg
ADDERALL XR	60 mg
ADHANSIA XR	70 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
D-DEXTROAMPHETAMINE ER	40 60 mg
DAYTRANA	30 mg
DESOXYN	25 mg
DEXEDRINE	40 60 mg
DEXTROSTAT	40 60 mg

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

Discussion

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

- **Estrogen Agents**
  - **Injectable**

Preferred Agents

DELESTROGEN[BNR] (estradiol valerate) vial
DEPO-ESTRADIOL (estradiol cypionate) vial

Non-preferred injectable estrogen agents may be approved if member has had a trial and failure of one preferred injectable agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

- **Oral/Transdermal**

  Preferred Agents

  Estradiol tablet
  MINIVELLE [BNR] (estradiol) patch
  CLIMARA [BNR] (estradiol) patch
  VIVELLE-DOT [BNR] (estradiol) patch

Non-preferred oral estrogen agents may be approved if member has had a trial and failure of one preferred oral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Non-preferred transdermal estrogen agents may be approved if member has had a trial and failure of two preferred transdermal agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Maximum Dosing	
ALORA (estradiol) patch	2/week
CLIMARA (estradiol) patch	1/week
DOTTI (estradiol) patch	2/week
Estradiol patch (once weekly)	1/week
Estradiol patch (twice weekly)	2/week
LYLLANA (estradiol) patch	2/week
MENOSTAR (estradiol) patch	1/week
MINIVELLE (estradiol) patch	2/week
VIVELLE-DOT (estradiol) patch	2/week

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- P Lanius asked if lack of efficacy should apply to injectable products as part of the failure criteria.
- A Shmerling thinks the lack of efficacy requirement is sufficiently vague and supports keeping it as part of the failure criteria.
- A Shmerling asked for confirmation that products in this therapeutic class will be covered by Medicaid for gender-affirming care. J Taylor confirmed that the estrogen products in this class are not limited by indication and that they will be covered for gender-affirming care.
- L Claus asked for confirmation that vaginal estrogen products are unmanaged and not on the PDL. J Taylor confirmed.
- A Shmerling moved to accept criteria for this class as written. Seconded by L Claus. Motion passed unanimously.

- **Contraceptives**
  - **Oral**

Monophasic 28:
Altavera 28 0.15-30
Apri 28 0.15-30
Aubra 28 0.1-20
Aubra EQ-28 0.1-20
Aviane 28 0.1-20
Balziva 28 0.4-35
Cryselle 28 0.3-30
Cyclafem 28 1-35
Dasetta 28 1-35
Drosperinone-Eth Estradiol 28 3-30
Drosperinone-Eth Estradiol- Levomefolate 28 3-20
Drosperinone-Eth Estradiol- Levomefolate 28 3-30
Elinest 28 0.3-30
Enskyce 28 0.15-30
Estarylla 28 0.25-35
Ethynodiol-Eth Estra 28 1-50
Falmina 28 0.1-20
Femynor 28 0.25-35
Isibloom 28 0.15-30
Juleber 28 0.15-30
Kelnor 28 1-35
Kurvelo 28 0.15-30
Larissia 28 0.1-20
Lessina 28 0.1-20
Levonor-Eth Estrad 28 0.1-20
Levonor-Eth Estrad 28 0.15-30
Levora 28 0.15-30
Lillow 28 0.15-30
Low-Ogestrel 28 0.3-30
Lutera 28 0.1-20
Marlissa 28 0.15-30
Mili 28 0.25-35
Mono-Linyah 28 0.25-35
Necon 28 0.5-35
Norg-Ethin Estra 28 0.25-35
Nortrel 28 0.5-35
Nortrel 28 1-35
Ocella 28 3-30
Orsythia 28 1-20
Philith 28 0.4-35
Pirmella 28 1-35
Portia 28 0.15-30
Previfem 28 0.25-35
Sprintec 28 0.25-35
Sronyx 28 0.1-20
Syeda 28 3-30
Vienva 28 0.1-20
Vyfemla 28 0.4-35
Wera 28 0.5-35
Zarah 28 3-30

Monophasic 21:
Junel 21 1-20
Junel 21 1.5-30
Larin 21 1-20
Larin 21 1.5-30
Norethind-Eth estrad 21 1-20
Nortrel 21 1-35

Biphasic:
Azurette 28
Bekyree 28
Cyred 28
Desogest-Eth Estra 28
Emoquette 28
Kariva 28
Lo Loestrin FE 28 1-10
Mircette 28
Viorele 28

Triphasic:
Alyacen 7-7-7 28
Caziant 7-7-7 28
Cyclafem 7-7-7 28
Dasetta 7-7-7 28
Enpresse 28
Levonest 28
Levonor-Eth Estrad Triphasic 28
Norgestimate-Eth Estrad 0.18-0.215-0.25/0.025
Norgestimate-Eth Estrad 0.18-0.215-0.25/0.035
Nortrel Triphasic
Pirmella 7-7-7
Tri-Estarylla 28
Tri-Femynor 28
Tri-Linyah 28
Tri-Lo Estarylla 28
Tri-Lo Marzia 28
Tri-Lo-Mili
Tri-Lo Sprintec 28
Tri-Previfem 28
Tri-Sprintec 28
Tri-Vylibra Lo 28
Velivet 7-7-7 28

Continuous Cycle:
Aurovela FE 1-20
Aurovela FE 1.5-30
Blisovi FE 1-20
Blisovi FE 1.5-30
Camrese Lo 1-20
Gianvi 3-20
Hailey 1.5-30
Hailey FE 1-20
Jasmiel 3-20
Junel FE 1-20
Junel FE 1.5-30
Junel FE 24 1-20
Larin FE 1-20
Larin FE 24 1-20
Larin FE 1.5-30
LoJaimiess 1-20
Loryna 3-20
Microgestin FE 1-20
Nikki 3-20
Noreth-Eth Estrad-FE 24 1-20
Noreth-Eth Estrad-FE 1-20
Tarina FE 24 1-20
Tarina FE 1-20
Tarina FE 1-20 EQ

Extended Cycle:
Amethia 91 0.03 – 0.15 – 0.01
Ashlyna 91 0.15-10-30
Iclevia 91 0.15-30
Introvale 91 0.15-30
Jolessa 91 0.15-30
Levonorgest-Eth Estrad 0.09-20
Levonorgest-Eth Estrad 91 0.1-10-20
Levonorgest-Eth Estrad 91 0.15-0.03
Levonorgest-Eth Estrad 91 0.15-0.03-0.01
Levonorgest-Eth Estrad 91 0.15-20-25-30
Setlakin 91 0.15-30

Progestin (norethindrone) only:
Camila 28 0.35
Deblitane 28 0.35
Errin 28 0.35
Heather 28 0.35
Jencycla 28 0.35
Jolivette 28 0.35
Lyza 28 0.35
Norethindrone 28 0.35
Norlyda 28 0.35
Sharobel 28 0.35

All other rebateable prescription products are non-preferred

Non-preferred oral contraceptive products will may be approved if member fails one-month trial with four preferred agents **OR** if preferred products with medically necessary ingredients and/or doses are unavailable. (Failure is defined as allergy, intolerable side effects, or significant drug-drug interaction)

Initial fills may be dispensed for three-month supply to establish tolerance (i.e., lack of adverse effects, for example). After established tolerance on the same agent for 3 months, a 12-month supply (365 days) may be dispensed (as one fill).

Prescription Contraceptive Products 12 month supply (oral): Initial fills may be dispensed for up to a three-month supply to establish tolerance (lack of adverse events). If the prescribed medication is tolerated for at least three months of therapy, subsequent fills of that medication will be eligible to be filled for up to a twelve-month supply. Effective 01/20/2020, brand NUVARING is covered as favored product and claims for brand will pay with submission of DAW code 0, 1, or 9. Generic equivalent etonorgetstral/ethinyl estradiol vaginal ring products require prior authorization and may be approved based on prescriber verification that there is clinical necessity of use of the generic product. Depot and IUD formulations are billed through the medical benefit

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Shmerling mentioned that text related to Nuvaring on page 12 should be included in the non-oral contraceptive section rather than the oral contraceptive section. J Taylor acknowledged that the Department will make that correction in the final version of the criteria.

- S Klocke asked about language at the top of page 23 regarding failing a 1-month trial of an oral contraceptive and the initial 3-month supply language in the paragraph below. After discussion, the Board determined that it would be appropriate to dispense up to a 3-month supply because ideally members would initially try the product for 3 months; however, members who have severe side effects will not want to continue the therapy for 3 months.
- T Brubaker moved to accept criteria for this class with an amendment to remove language regarding Nuvaring coverage from the oral contraceptive section. Seconded by P Lanius. Motion passed unanimously.

- **Contraceptives**
  - **Non-Oral**

Preferred Agents

ANNOVERA (segesterone/ethinyl estradiol) vaginal ring
NUVARING [BNR] (etonorgestrel/ethinyl estradiol) vaginal ring
XULANE (norelgestromin/ethinyl estradiol) patch

Non-preferred non-oral contraceptive products may be approved if member has had a trial and failure of one preferred non-oral contraceptive product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

PHEXXI (lactic acid/citric acid/potassium) vaginal gel may be approved for members who meet all the following criteria:

1. Medication is being prescribed for the prevention of pregnancy **AND**
2. Member is unable to use any of the following methods of contraception due to failure, contraindication, intolerance, or preference:
   a. Injection (such as medroxyprogesterone acetate)
   b. Oral Contraceptive
   c. Transdermal Patch
   d. Vaginal Contraceptive Ring
   e. Diaphragm
   f. Cervical Cap
   g. Vaginal spermicide

   AND
3. PHEXXI (lactic acid/citric acid/potassium) is not being prescribed concomitantly with a vaginal ring product, **AND**
4. Provider attests that member has been counseled regarding a higher rate of pregnancy prevention with the use of other methods of contraception (such as injection, oral contraception, transdermal patch, vaginal ring) as compared to PHEXXI.

Prescription Contraceptive Products 12 month supply (topical patch and vaginal ring): Initial fills may be dispensed for up to a three-month supply to establish tolerance (lack of adverse events). If the prescribed medication is tolerated for at least three months of therapy, subsequent fills of that medication will be eligible to be filled for up to a twelve-month supply. Effective 01/20/2020, brand NUVARING is covered as favored product and claims for brand will pay with submission of DAW code 0, 1, or 9. Generic equivalent etonorgetstral/ethinyl estradiol vaginal ring products require prior authorization and may be approved based on prescriber verification that there is clinical necessity of use of the generic product. Depot and IUD formulations are billed through the medical benefit.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- J Taylor mentioned that text related to 12-month supply section on page 24 is not highlighted in yellow as an addition to criteria since it is current policy on Appendix P. The policy is now being added to the PDL
- L Claus proposed removing vaginal spermicide from the list of contraceptive methods since its efficacy in preventing pregnancy is inferior to that of Phexxi. B Jackson agreed.
- P Lanius proposed including less effective options in order make the contraceptive list more complete.
- B Jackson moved to remove vaginal spermicide from the list of contraceptive options. Seconded by A Shmerling. Seven aye votes. Opposed by P Lanius. Motion passed.
- L Claus moved to accept criteria as amended above. Seconded by P Lanius. Motion passed unanimously.

- **Diabetes Management Classes**

  - **GLP-1 Analogues**

Preferred Agents
***Must meet eligibility criteria**
*BYDUREON (exenatide ER) kit, pen
*BYETTA (exenatide)
*BYDUREON (exenatide ER)
*TRULICITY (dulaglutide)
*VICTOZA (liraglutide)

* Approval for preferred products requires a diagnosis of type 2 diabetes and a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of a GLP-1 analogue therapy.

Non-preferred products may be approved for members with a diagnosis of type 2 diabetes following trial and failure of a 3-month trial of metformin **AND** a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, limited dexterity resulting in the inability to administer doses of a preferred product, or a significant drug-drug interaction.

GLP-1 analogues will not be approved for obesity/weight loss in the absence of a diagnosis of type 2 diabetes.

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

GLP-1 Analogue	FDA Approved Maximum Dose in Adults
ADLYXIN (lixisenatide)	20 mcg per day
BYDUREON (exenatide)	2 mg weekly
BYDUREON BCISE (exenatide)	2 mg weekly
BYETTA (exenatide)	20 mcg per day
OZEMPIC (semaglutide)	1 mg weekly
RYBELSUS (semaglutide)	14 mg daily
TRULICITY (dulaglutide)	4.5 mg weekly
VICTOZA (liaglutide)	1.8 mg per day

Stakeholder input:
Trulicity Medical Value Summary

Scheduled testimony presentations:
J Chardoulias, Novo Nordisk – Ozempic
J Chardoulias, Novo Nordisk – Rybelsus
B Bentz, Trulicity – Eli Lilly

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- J Taylor shared that the Colorado state plan for Medicaid does not allow coverage of medications for weight loss; therefore, criteria concerning that indication in this medication sub-class have been added.
- S Klocke moved to accept criteria for this class as written. Seconded by M Anguelov. Motion passed unanimously.

- **Other Hypoglycemic Combinations**

  Preferred Agents

  NONE

Non-preferred products may be approved for members who have been stable on each of the individual ingredients in the requested combination for 3 months (including cases where the ingredients are taken as two separate 3-month trials or when taken in combination for at least 3 months).

Discussion

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

- **SGLT-2is & Combinations**

  Preferred Agents

  FARXIGA (dapagliflozin)
  INVOKANA (canagliflozin)
  JARDIANCE (empagliflozin)

FARXIGA (dapagliflozin), INVOKANA (canagliflozin) and JARDIANCE (empagliflozin) are contraindicated in members on dialysis. STEGLATRO (ertugliflozin) therapy is not recommended when eGFR is persistently 30 to less than 60 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

Non-preferred products may receive approval following trial and failure with two preferred products. Failure is defined as lack of efficacy with 3-month trial (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

- **SGLT-2i Combinations with Metformin**

  Preferred Agents
  INVOKAMET (canagliflozin/metformin)
  INVOKAMET XR (canagliflozin/metformin)
  XIGDUO XR (dapagliflozin/metformin)

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

INVOKAMET, INVOKAMET XR, SYNJARDY, SYNJARDY XR and XIGDUO XR are contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis. SEGLUROMET therapy is not recommended when eGFR is persistently 30 to less than 60 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- P Lanius asked if the word "persistently" within the phrase "persistently 30 to less than 60 mL/min/1.73 m^2" needed to be more clearly defined. J Rawlings explained that this word was used in some of the product labeling for this therapeutic class and that it is used here primarily to differentiate between acute renal injury and more chronic renal insufficiency. L Claus and B Jackson agreed.
- B Jackson moved to accept criteria for this class as written. Seconded by S Klocke. Motion passed unanimously.

- **Glucagon Agents**

  Preferred Agents
  No PA Required
  ***Must meet eligibility criteria**
  GLUCAGEN HYPOKIT
  Glucagon Emergency Kit (Fresenius) *(Novo Nordisk & Eli Lilly only)*
  GVOKE* Hypopen, Syringe

***GVOKE (glucagon)** may be approved following trial and failure of GLUCAGEN (glucagon) **OR** a preferred glucagon emergency kit. (Failure is defined as allergy to ingredients in product, intolerable side effects, or inability to administer dosage form)

Non-preferred products may be approved if the member has failed treatment with GVOKE (glucagon) **AND** one other preferred product. (Failure is defined as allergy to ingredients in product, intolerable side effects, or contraindication to dosing form)

Quantity limit for second-line preferred (GVOKE) and non-preferred products: 2 doses per year unless used / damaged / lost

Stakeholder input:
Baqsimi Medical Value Summary

Scheduled testimony presentations:
Tapan Patel, Xeris – Gvoke
B Bentz, Eli Lilly - Baqsimi

Discussion

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

- **Antiplatelet Agents**

Preferred Agents
AGGRENOX (ASA/dipyridamole) capsule
ASAAspirin/dipyridamole ER capsule
BRILINTA (tigacrelor) tablet
Cilostazol tablet
Clopidogrel tablet
Dipyridamole tablet
Pentoxifylline ER tablet
Prasugrel tablet

Patients taking **BRILINTA (ticagrelor)** must also be taking a maintenance dose of aspirin not exceeding 100 mg/day.

ZONTIVITY (vorapaxar) will may be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Patients must also be taking aspirin and/or clopidogrel concomitantly.

Non-preferred products without criteria will be reviewed on a case-by-case basis.

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- S Klocke expressed concerns, from a safety perspective, about the need to specify indications for use and appropriate length of therapy for some of the agents in this class (especially for ticagrelor and clopidogrel/aspirin dual antiplatelet therapy) and evaluating criteria for these aspects of drug use after acute ischemic stroke.
- L Claus expressed another safety concern about the potential to create additional prior authorization barriers for members who need to have these medications in a time-sensitive way upon release from the hospital. M Anguelov agreed and asked if some of the current anticoagulant criteria verbiage might also be applied here. J Taylor explained that some indications may be verified through ICD-10 codes during the prior authorization process.
- M Anguelov asked about duration of therapy limits for these products would be impacted when a member has a subsequent stroke after the initial event. If a situation warrants an extension of post-stroke therapy that needs to be taken into consideration.
- A Shmerling noted that many of these medications are started by acute care providers who are familiar with the standards of care in this area.

- B Jackson moved to request that the Department evaluate the duration of use for opportunity for quantity limits to help ensure safety for acute ischemic stroke, in particular related to the use of ticagrelor and clopidogrel/aspirin (in relation to diagnosis and timing of therapy) and also to approve criteria for this class with that amendment. Seconded by S Klocke. Six aye votes. A Shmerling abstained. P Lanius abstained. Motion passed.

- **Colony Stimulating Factors**

  Preferred Agents
  PA Required for all agents in this class*
  NEUPOGEN (filgrastim) vial, syringe
  UDENYCA (pegfilgrastim-cbqv)
  ZIEXTENZO (pegfilgrastim-bmez) syringe

  ***Prior authorization for preferred agents may be approved if meeting the following criteria:
  - Medication is being used for one of the following indications:
    - Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm^3 or the risk of neutropenia for the member is calculated to be greater than 20%)
    - Acute Myeloid Leukemia (AML) patients receiving chemotherapy
    - Bone Marrow Transplant (BMT)
    - Peripheral Blood Progenitor Cell Collection and Therapy
    - Hematopoietic Syndrome of Acute Radiation Syndrome
    - Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm^3)

    AND

    For **UDENYCA (pegfilgrastim-cbqv)** or **ZIEXTENZO (pegfilgrastim-bmez),** the member meets the following criteria:
    - Member has trial and failure of NEUPOGEN. Failure is defined as lack of efficacy, intolerable side effects, drug-drug interaction, or contraindication to NEUPOGEN therapy. Trial and failure of NEUPOGEN will not be required if meeting one of the following:
      - Member has limited access to caregiver or support system for assistance with medication administration **OR**
      - Member has inadequate access to healthcare facility or home care interventions.

  Prior authorization for non-preferred agents may be approved if meeting the following criteria:
  - Medication is being used for one of the following indications:
    - Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm^3 or the risk of neutropenia for the member is calculated to be greater than 20%)
    - Acute Myeloid Leukemia (AML) patients receiving chemotherapy
    - Bone Marrow Transplant (BMT)
    - Peripheral Blood Progenitor Cell Collection and Therapy
    - Hematopoietic Syndrome of Acute Radiation Syndrome
    - Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm^3)

    AND
  - Member has history of trial and failure of NEUPOGEN, AND UDENYCA, and

ZIEXTENZO. Failure is defined as a lack of efficacy with a 3-month trial, allergy, intolerable side effects, significant drug-drug interactions, or contraindication to therapy. Trial and failure of NEUPOGEN will not be required if meeting one of the following:

- Member has limited access to caregiver or support system for assistance with medication administration **OR**
- Member has inadequate access to healthcare facility or home care interventions.

Discussion

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

- **Newer Hereditary Angioedema (HAE) Products**

Preferred Agents
PA Required for all agents in this class

Prophylaxis:
HAEGARDA (C1 esterase inhibitor) vial

Treatment:
BERINERT (C1 esterase inhibitor) kit
ICATIBANT syringe (generic FIRAZYRBNR)

Medications Indicated for Routine Prophylaxis:
Members are restricted to coverage of one medication for routine prophylaxis at one time. Prior authorization approval will be for one year.

HAEGARDA (C1 esterase inhibitor (human) may be approved for members meeting the following criteria:

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member meets at least one of the following:
  - HAEGARDA is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
  - HAEGARDA is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥1 attacks per month resulting in documented ED admission or Hospitalization **OR**
    - History of laryngeal attacks **OR**
  - History of ≥2 attacks per month involving the face, throat, or abdomen **AND**
  - Member is not taking medications that may exacerbate HAE, including ACE inhibitors and estrogen-containing medications **AND**
  - Member has received hepatitis A and hepatitis B vaccination **AND**
  - Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Minimum Age: 10 years
Maximum Dose: 60 IU/kg

CINRYZE (C1 esterase inhibitor (human) may be approved for members meeting the following criteria:

- Member has history of trial and failure of HAEGARDA. Failure is defined as lack of efficacy allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member meets at least one of the following:
  - CINRYZE is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
  - CINRYZE is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥ 1 attacks per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥2 attacks per month involving the face, throat, or abdomen **AND**
    - Member is not taking medications that may exacerbate HAE, including ACE inhibitors and estrogen-containing medications **AND**
    - Member has received hepatitis A and hepatitis B vaccination **AND**
    - Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV.

Minimum age: 6 years
Maximum dose: 100 Units/kg

ORLADEYO (berotralstat) may be approved for members meeting the following criteria:

- Member has history of trial and failure of HAEGARDA. Failure is defined as lack of efficacy allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- ORLADEYO is prescribed by or in consultation with an allergist or immunologist **AND**
- Appropriate drug interaction interventions will be made for members using concomitant medications that may require dose adjustments (such as cyclosporine, fentanyl, pimozide, digoxin).
- Member meets at least one of the following:
  - **ORLADEYO** is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR**
  - **ORLADEYO** is being used for long-term prophylaxis and member meets one of the following:
    - History of ≥ 1 attack per month resulting in documented ED admission or hospitalization **OR**
    - History of laryngeal attacks **OR**
    - History of ≥ 2 attacks per month involving the face, throat, or abdomen **AND**
    - Member is not taking medications that may exacerbate HAE, including ACE inhibitors and estrogen-containing medications

Minimum age:12 years
Maximum dose: 150 mg once daily

TAKHZYRO (lanadelumab-flyo) may be approved for members meeting the following criteria:
- Member has history of trial and failure of HAEGARDA. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination.

Minimum age: 12 years
Maximum dose: The recommended starting dose is 300 mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well controlled (attack free) for more than 6 months.

Medications Indicated for Treatment of Acute Attacks:

Members are restricted to coverage of one medication for treatment of acute attacks at one time. Prior authorization approval will be for one year.

FIRAZYR (icatibant acetate) may be approved for members meeting the following criteria:
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications

Minimum age: 18 years
Maximum dose: 30 mg

BERINERT (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria:

- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND**
- Member has received hepatitis A and hepatitis B vaccination **AND**
- Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV

Minimum age: 6 years
Maximum dose: 20 IU/kg

RUCONEST (C1 esterase inhibitor (recombinant)) may be approved for members meeting the following criteria:

- Member has a history of trial and failure of FIRAZYR OR BERINERT. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND**
- Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND**
- Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**
- Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications AND o Member has received hepatitis A and hepatitis B vaccination **AND** Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV.

Minimum age: 13 years
Maximum dose: 4200 Units/dose

All other non-preferred agents may be approved if the member has trialed and failed at least two preferred agents with the same indicated role in therapy as the prescribed medication (prophylaxis or treatment). Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction.

Scheduled testimony presentations:
Lindsey Noble, Biocryst - Orladeyo

Discussion

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

- **Overactive Bladder (OAB) Agents**

Preferred Agents

GELNIQUE (oxybutynin) gel packets
Oxybutynin IR, ER tablets, syrup
Oxybutynin ER tablets *[duplicate listing]*
Solifenacin tablet
TOVIAZ (fesoterodine ER) tablet
MYRBETRIQ ER (mirabegron) tablet

Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Members with hepatic failure can receive approval for trospium (SANCTURA) or trospium extended release (SANCTURA XR) products without a trial on a preferred product.

Discussion

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

- **Bone Resorption Suppression and Related Agents**
  - **Bisphosphonates**

Preferred Agents
Alendronate 5 mg, 10 mg, 35 mg, 70 mg tablets
Alendronate oral solution 70 mg/75 mL
Ibandronate tablet

Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction.

ALENDRONATE 70mg/75ml oral solution may also be approved without trial of a preferred agent for members that cannot swallow solid oral dosage forms or members that have a feeding tube.

ETIDRONATE may also be approved without trial of a preferred agent for members with a diagnosis of heterotopic ossification.

For members who have a low risk of fracture, discontinuation of bisphosphonate therapy and drug holiday should be considered following 5 years of treatment. Low risk is defined as having a bone mineral density, based on the most recent T-score, of greater than (better than) -2.5 **AND** no history of low trauma or fragility fracture.

  - **Non-Bisphosphonates**

Preferred Agents
NONE

CALCITONIN SALMON (nasal) may be approved if the member meets the following criteria:
- Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of -2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
- Member cannot swallow solid oral dosage forms or has a feeding tube.

Quantity limit: One spray daily

RALOXIFENE may be approved if the member meets the following criteria:
- Diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

Maximum dose: 60 mg daily

FORTEO (teriparatide) or generic teriparatide may be approved if the member meets the following criteria:
- Member has one of the following diagnoses:
  - Osteoporosis, (BMD T-scores of -2.5 or less) primary or hypogonadal in men
  - Osteoporosis due to corticosteroid use
  - Postmenopausal osteoporosis

  AND
- Member has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (FORTEO and TYMLOS) shall not exceed two years

Maximum dose: 20mcg daily

TYMLOS (abaloparatide) may be approved if the member meets the following criteria:

- Member has a diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (FORTEO and TYMLOS) shall not exceed two years.

Maximum dose: 80 mcg daily

All other non-preferred non-bisphosphonates may be approved for members who have failed treatment with one preferred bisphosphonate product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction.

*Note: Prior authorization criteria for **PROLIA (denosumab)** is listed on Appendix P.*

Discussion

- No Board members reported a conflict of interest for this therapeutic class that was pulled from Mass Review.
- L Claus commented that there are new recommendations in the 2020 AACE/ACE Guideline update to not require trial and failure of an oral bisphosphate for post-menopausal women with a very high baseline risk of fracture and to start with injectable therapy. This could impact criteria for Forteo and Tymlos (plus zoledronic acid and denosumab on Appendix P)
- L Claus moved to request that the Department review criteria for use of Forteo, Tymlos, zoledronic acid and denosumab, given 2020 updates to the AACE/ACE Guidelines for treatment of post-menopausal osteoporosis. Seconded by B Jackson. Motion passed unanimously.

Mass review drug classes*

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

- **Diabetes Management Classes**
  - **Amylin**

Preferred Agents
NONE

SYMLIN (pramlintide) may be approved following trial and failure of metformin **AND** trial and failure of a DPP4-inhibitor or GLP-1 analogue. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1c goal despite adherence to regimen) following three month trial, allergy, intolerable side effects, or a significant drug-drug interaction. Prior authorization may be approved for SYMLIN (pramlintide) products for members with a diagnosis of diabetes mellitus Type 1 without requiring trial and failure of other products.

Maximum Dose: Prior authorization will be required for doses exceeding FDA-approved dosing listed in product package labeling.

- **Biguanides**

Preferred Agents

Metformin 500 mg, 850 mg, 1,000 mg tablets
Metformin ER tablets 500 mg, 750 mg (generic GLUCOPHAGE XR)

Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Liquid metformin may be approved for members who meet one of the following:

- Member is under the age of 12 with a feeding tube **OR**
- Prescriber confirms that member has difficulty swallowing

- **DPP-4is & Combinations**

Preferred Agents

***Must meet eligibility criteria**

*JANUMET (sitagliptin/metformin)
*JANUMET XR (sitagliptin/metformin)
*JANUVIA (sitagliptin)
*TRADJENTA (linagliptin)

*Approval for preferred products require a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy.

Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of metformin AND a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Maximum Dose:
Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table:

	FDA Approved Maximum Dose (mg/day)
Alogliptin (generic NESINA)	25 mg/day
JANUVIA (sitagliptan)	100 mg/day
NESINA (alogliptan)	25 mg/day
ONGLYZA (saxagliptan)	5 mg/day
TRADJENTA (linagliptan)	5 mg/day

- **Insulins & Related Agents**

Preferred Agents

Rapid acting

NOVOLOG (insulin aspart) cartridge, vial, FlexTouch
HUMALOG (insulin lispro) cartridge, vial, KwikPen
HUMALOG Jr. (insulin lispro) KwikPen

Non-preferred products may be approved following trial and failure of treatment with two preferred products. Failure is defined as allergy (hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema) or intolerable side effects.

AFREZZA (human insulin) may be approved if meeting the following criteria:

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

Short acting

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

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

Intermediate acting

HUMULIN N (insulin NPH) vial (OTC)
NOVOLIN N (insulin NPH) FlexPen, vial (OTC)

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

Long acting

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

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

Mixtures

HUMALOG MIX 50/50 Kwikpen, vial
HUMALOG MIX 75/25 Kwikpen, vial
HUMULIN 70/30 Kwikpen, vial (OTC)
NOVOLOG MIX 70/30 FlexPen, vial

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

- **Meglitinides & Combinations**

  Preferred Agents
  NONE

  Non-preferred products may be approved for members who have failed treatment with one sulfonylurea. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.

  Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

- **TZDs & Combinations**

  Preferred Agents
  Pioglitazone

Non-preferred agents may be approved following trail and failure of metformin AND trial and failure of one preferred product. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) with a 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction.

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

- **GI Motility, Chronic**

  Preferred Agents
  PA Required for all agents in this class
  AMITIZA[BNR] (lubiprostone) capsule
  LINZESS (linaclotide) capsule
  MOVANTIK (naloxegol) tablet

  All agents will only be approved for FDA labeled indications and up to FDA approved maximum doses listed below.

  Preferred agents may be approved if the member meets the following criteria:
  - Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain **AND**
  - Member does not have a diagnosis of GI obstruction **AND**
  - For indication of OIC, member opioid use must exceed 4 weeks of treatment
  - For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (polyethylene glycol, docusate or bisocodyl, for example). Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction).
    - If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisocodyl enema)
  - For indication of IBS-D, must have documentation of adequate trial with loperamide **AND** dicyclomine **OR** hyoscamine. Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

Non-preferred agents may be approved if the member meets the following criteria:
- Member meets all listed criteria for preferred agents **AND**
- Member has trialed and failed two preferred agents
    - If indication OIC caused by methadone, then non-preferred agent may be approved after trial of MOVANTIK. Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction, **AND**
    - Member meets additional criteria for the agents listed below

VIBERZI (eluxadoline) may be approved for members who meet the following criteria:
- Has diagnosis of Irritable Bowel Syndrome – Diarrhea (IBS-D) **AND**
- Member has a gallbladder **AND**
- Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas **AND**
- Member does not drink more than 3 alcoholic drinks per day **AND**

LOTRONEX (alesotron alosetron) and **generic alesotron alosetron** may be approved for members who meet the
following criteria:
- Member is a female with Irritable Bowel Syndrome – Diarrhea (IBS-D) with symptoms lasting 6 months or longer **AND**
- Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation or ischemic colitis, hypercoagulable state, Crohn's disease or ulcerative colitis, or known mechanical gastrointestinal obstruction

- **Anticoagulants**
    - **Oral**

Preferred Agents
ELIQUIS (apixaban) tablet, starter pack
PRADAXA (dabigatran) capsule
Warfarin tablet
XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg tablet, dose pack

EVYXXA (betrixaban) may be approved if all the following criteria have been met:
- The member has trialed and failed therapy with two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction, **AND**
- Member is not on dialysis **AND**
- The member is need of prophylaxis for DVT following hospitalization for an acute medical illness who are at risk for thromboembolic events due to limited mobility **AND**
- The member does not have a mechanical prosthetic heart valve

ELIQUIS (apixaban) may be approved if the following criteria have been met:
- The member is on dialysis or has chronic renal failure **OR**
- The member has failed therapy with one preferred agent. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If the member is on dialysis or has chronic renal failure, trial and failure of preferred agents is not required **AND**
- The member does not have a mechanical prosthetic heart valve **AND**
- Eliquis (apixaban) is being prescribed for one of the following indications:
    - Deep vein thrombosis (DVT) **OR**
    - In need of DVT prophylaxis following knee or hip replacement surgery **OR**
    - Pulmonary embolism (PE) **OR**

- Non-valvular atrial fibrillation **OR**
- Venous thromboembolism (VTE) in the setting of malignancy

SAVAYSA (edoxaban) may be approved if all the following criteria have been met:
- The member has 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 on dialysis **AND**
- Member does not have CrCl > 95 ml/min **AND**
- The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
- The member has a diagnosis of non-valvular atrial fibrillation **AND**
- The member does not have a mechanical prosthetic heart valve

XARELTO 2.5 mg (rivaroxaban) may be approved for members meeting all of the following criteria:
- Xarelto 2.5 mg is being prescribed to reduce major CV events in members diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease **AND**
- Xarelto 2.5 mg is being taken twice daily and in combination with aspirin 75-100 mg daily **AND**
- Member must not be receiving dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or other oral anticoagulant **AND**
- Member must not have had an ischemic, non-lacunar stroke within the past month
  AND
- Member must not have had a hemorrhagic or lacunar stroke at any time

All other non-preferred oral agents require trial and failure of two preferred oral agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Continuation of Care: Members with current prior authorization approval on file for a non-preferred oral anticoagulant medication may continue to receive approval for that medication

- **Parenteral Anticoagulants**

  Preferred Agents

  Enoxaparin syringe
  Enoxaparin vial

Non-preferred parenteral anticoagulants may be approved if member has trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

ARIXTRA (fondaparinux) may be approved if the following criteria have been met:
- Member is 18 years of age or older **AND**
- Member has a CrCl > 30 mL/min **AND**
- Member weighs > 50 kg **AND**
- Member has a documented history of heparin induced-thrombocytopenia **OR**
- Member has a contraindication to enoxaparin

Grandfathering: Members currently stabilized on fondaparinux (ARIXTRA) and or dalteparin (FRAGMIN) may receive prior authorization approval to continue on that medication.

- **Erythropoiesis Stimulating Agents (ESAs)**

  Preferred Agents
  PA Required for all agents in this class*
  RETACRIT (epoetin alfa-epbx)

*Prior Authorization is required for all products and may be approved if meeting the following:

- Medication is being administered in the member's home or in a long-term care facility **AND**
- Member meets one of the following:
  - A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower **OR**
  - A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL **OR**
  - A diagnosis of hepatitis C, currently taking Ribavirin and failed response to a reduction of Ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic). **OR**
  - A diagnosis of HIV, currently taking Zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500mUnits/mL or less **OR**
  - Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood pre-operatively

  AND

  - For any non-preferred product, member has trialed and failed treatment with one preferred product. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

† Hemoglobin results must be from the last 30 days.

- **Prenatal Vitamins/Minerals**

  Preferred Agents
  ***Must meet eligibility criteria**
  COMPLETE NATAL DHA tablet
  M-NATAL PLUS tablet
  NESTABS tablet
  PNV 29-1 tablet
  PRENATAL VITAMIN PLUS LOW IRON tablet
  PREPLUS CA-FE 27 mg-FA 1 mg tablet
  SE-NATAL 19 chewable tablet
  PROVIDA OB capsule
  THRIVITE RX tablet
  TRINATAL RX 1 tablet
  TRUST NATAL DHA
  VITAFOL gummies
  VOL-PLUS tablet
  VP-PNV-DHA softgel
  WESTAB PLUS tablet

All other rebateable prescription products are non-preferred

*Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to get pregnant.

Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.

Discussion

- No Board members reported a conflict of interest for drug classes included in Mass Review.
- Ophthalmic Immunomodulators were moved from Mass Review and reviewed at the beginning of today's meeting. Bisphosphonates were also pulled from Mass Review and reviewed separately at the request of L Claus.
- B Jackson moved to accept remaining criteria in the Mass Review section as written. Seconded by T Brubaker. Motion passed unanimously.

Proposed ProDUR and Prior Authorization Criteria for Other Selected Products

No Board members reported a conflict of interest for the eight products being reviewed in this section of the agenda.

1. **ADUHELM (aducanumab-avwa)**

   ADUHELM (aducanumab-avwa) may be approved if the member meets ALL of the following criteria:

   1. Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials as evidenced by all of the following:
      a. Positron Emission Tomography (PET) scan positive for amyloid beta plaque
      b. Clinical Dementia Rating global score (CDR-GS) of 1
      c. Mini-Mental State Examination (MMSE) score of 24-30
   2. Member is ≥ 50 years of age
   3. The prescriber attests that member has been counseled on the approval and safety status of ADUHELM being approved under accelerated approval based on reduction in amyloid beta plaques
   4. Prior to initiation of ADUHELM, the prescriber attests that the member meets ALL of the following:
      a. Member has had a brain MRI within the prior one year to treatment initiation, showing no signs or history of localized superficial siderosis, ≥ 10 brain microhemorrhages, and/or brain hemorrhage > 1 cm
      b. Attestation that MRI will be completed prior to the 7th (1st dose at 10 mg/kg) and 12th (6th dose at 10 mg/kg) infusion
   5. Member does not have any of the following:
      a. Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive impairment including, but not limited to stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus.
      b. Contraindications to PET, CT scan, or MRI
      c. History of or increased risk of amyloid related imaging abnormalities (ARIA)- edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H)

   d. History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, Transient Ischemic Attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of ADUHELM
   e. History of a stroke or Transient Ischemic Attack (TIA) or unexplained loss of consciousness in the past 1 year prior to initiation of ADUHELM
6. ADUHELM (aducanumab-avwa) is prescribed by or in consultation with a neurologist or geriatrician
7. Dose
   a. Dosing must match FDA-approved labeling:
      i. Infusion 1 and 2: 1 mg/kg over approximately 1 hour every 4 weeks
      ii. Infusion 3 and 4: 3 mg/kg over approximately 1 hour every 4 weeks
      iii. Infusion 5 and 6: 6 mg/kg over approximately 1 hour every 4 weeks
      iv. Infusion 7 and beyond: 10 mg/kg over approximately 1 hour every 4 weeks
8. To bill for aducanumab-avwa under the Pharmacy Benefit, the medication must be administered in the member's home or in a long-term care facility

Maximum approval period: 6 months

Maximum dose: 10 mg/kg IV every 4 weeks

The above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If request is for use outside of stated coverage standards, 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).

Stakeholder input:
Aduhelm Summary of Clinical information

Scheduled testimony presentations:
Y Zabar, Biogen

Discussion

- J Taylor clarified that the proposed criteria for Aduhelm will apply to both the pharmacy benefit and the medical benefit (once the PAD prior authorization is in place).
- S Klocke offered four recommendations for the Board's consideration:
  1. There are relatively few PET scanners in the U.S. Consider including lumbar puncture as an alternative method to confirm the presence of amyloid beta plaque
  2. Recommend removal of the CDR-GS tool, as it is not frequently used in clinical practice
  3. Administration of the MMSE requires licensure and not all physicians have one. Consider including the Montreal Cognitive Assessment (moCA) Test score between 17 and 30 (mild cognitive impairment and dementia) as an alternative to the MMSE.
  4. Per study exclusion criteria, recommend adding that the member does not have any bleeding abnormalities or be on any form of anticoagulation therapy
- S Klocke moved to accept criteria for Aduhelm with the amendments above. Seconded by L Claus. Seven aye votes. B Jackson abstained. Motion passed.

2. CABLIVI (caplacizumab-yhdp)

CABLIVI (caplacizumab-yhdp) may be approved if all the following criteria have been met:

1. Member is 18 years or older **AND**
2. Member has a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
3. Member is undergoing plasma exchange and is receiving immunosuppressive therapy **AND**
4. CABLIVI (capliacizumab) is being prescribed by or in consultation with a hematologist
5. Prescriber is aware that concomitant use of CABLIVI with any anticoagulant or underlying coagulopathy may increase the risk of severe bleeding, including epistaxis and gingival hemorrhage
6. Member has not experienced more than 2 recurrences of aTTP while on CABLIVI
7. To bill for CABLIVI (caplacizumab-yhdp) under the Pharmacy Benefit, the medication must be administered in the member's home or in a long-term care facility

Maximum dose:
- First day of treatment: 11 mg prior to plasma exchange, followed by 11 mg after plasma exchange
- Subsequent days during treatment period: 11 mg once daily

Discussion

- A Shmerling moved to accept criteria for Cablivi as written. Seconded by B Jackson. Motion passed unanimously.

3. INGREZZA (valbenazine)

INGREZZA (valbenazine) may be approved if all the following criteria have been met:
1. Member is 18 years or older **AND**
2. Member has been clinically diagnosed with tardive dyskinesia **AND**
3. Has a recorded baseline Abnormal Involuntary Movement Scale (AIMS) score **AND**
4. If there is no improvement after 6 weeks of therapy according to an AIMS test, approval for INGREZZA (valbenazine) will be discontinued

Maximum dose: 80 mg/day
Quantity limit: 60 capsules per 30 days

Discussion

- A Shmerling moved to accept criteria for Ingrezza as written. Seconded by P Lanius. Motion passed unanimously.

4. MYFEMBREE (relugolix, estradiol hemihydrate, norethindrone acetate)

MYFEMBREE (relugolix, estradiol hemihydrate, norethindrone acetate) may be approved for members when the following criteria are met:
1. Member is 18 years of age or older **AND**
2. Member is pre-menopausal **AND**
3. Member has a confirmed diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
4. Member has tried and failed treatment with an estrogen-progestin contraceptive (oral tablets, vaginal ring, transdermal patch) OR a progestin releasing intrauterine device (IUD). Failure is

defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy

AND

5. The medication is prescribed by or in consultation with an obstetrician/gynecologist **AND**
6. Member does not have a high risk of arterial, venous thrombotic, or thromboembolic disorder, including:
    a. Women over 35 years of age who smoke **OR**
    b. Women with a past or current history of the following:
        i. DVT, PE, or cerebrovascular disease (such as cerebrovascular disease, coronary artery disease, peripheral vascular disease) **OR**
        ii. Thrombogenic valvular or thrombogenic rhythm diseases of the heart (such as subacute bacterial endocarditis with valvular disease, or atrial fibrillation) **OR**
        iii. Inherited or acquired hypercoagulopathies **OR**
        iv. Uncontrolled hypertension **OR**
        v. Headaches with focal neurological symptoms OR migraine headaches with aura if over age 35

AND

7. Member is not pregnant or breastfeeding **AND**
8. Member does not have known osteoporosis **AND**
9. Member does not currently have, or have a history of, breast cancer or other hormonally-sensitive malignancies **AND**
10. Member does not have known liver impairment or disease **AND**
11. Member will not receive MYFEMBREE in combination with any medication that is contraindicated or not recommended per FDA labeling **AND**
12. Member has not previously received treatment with ORLISSA (elagolix) 150 mg or ORIAHNN (elagolix/estradiol/norethindrone acetate) for more than 24 months, or previous treatment with ORLISSA (elagolix) 200 mg for more than 6 months
13. Member has been counseled that that MYFEMBREE does not prevent pregnancy **AND**
14. Member has been instructed that only non-hormonal contraceptives should be used during MYFEMBREE therapy and for at least 1 week following discontinuation **AND**
15. Prescriber acknowledges that assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter, and discontinuation of MYFEMBREE should be considered if the risk associated with bone loss exceeds the potential benefit of treatment.

Reauthorization: Members with a current 6-month prior authorization approval on file may receive an additional 6-month approval to continue therapy.

Prior authorization requests for MYBEMFREE will take into account exposure to all GnRH receptor antagonist medications (such as elagolix and relugolix) and will not be approved for a total exposure that exceeds 24 months.

Maximum dose: 1 tablet daily (relugolix 40 mg, estradiol 1 mg, norethindrone acetate 0.5 mg)
Maximum approval period: 6 months

Scheduled testimony presentations:
R Dufour, Myovant

Discussion

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

5. EMPAVELI (pegcetacoplan)

EMPAVELI (pegcetacoplan) may be approved if the member meets ALL the following criteria:

1. Member is 18 years of age or older **AND**
2. Medication is being administered in the member's home or in a long-term care facility by a healthcare professional **AND**
3. Member is not pregnant **AND**
4. Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high-sensitivity flow cytometry **AND**
5. Member has received vaccination against encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of EMPAVELI therapy, unless treatment cannot be delayed **OR** if the vaccines were administered within the last 2 weeks, member has received 2 weeks of antibacterial drug prophylaxis **AND**
6. Member does not have any active infections caused by encapsulated bacteria (such as Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and *Haemophilus influenzae* type b) **AND**
7. Member has a baseline lactate dehydrogenase result available and is being monitored by prescriber **AND**
8. EMPAVELI is not being used in combination with SOLIRIS (eculizumab), ULTOMIRIS (ravulizumab-cwvz), or other medications to treat PNH **AND**
9. EMPAVELI is being prescribed by, or in consultation with, a hematologist, immunologist, or nephrologist **AND**
10. Prescriber is enrolled in the EMPAVELI Risk Evaluation and Mitigation Strategy (REMS) program
11. To bill for EMPAVELI (pegcetacoplan) under the Pharmacy Benefit, the medication must be administered in the member's home or in a long-term care facility

Maximum dose: 1,080 mg (1 single-dose vial) every three days

Approval period: 12 months

Scheduled testimony presentations:
J Tobitt, Apellis

Discussion

- B Jackson noted that bullet points 2 and 11 are duplicates (eliminate one from final criteria)
- B Jackson moved to accept criteria for this class as amended above. Seconded by S VanEyk. Motion passed unanimously.

6. XOLAIR (omalizumab)

Injectable omalizumab is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.

For self-administration, XOLAIR (omalizumab) may be approved for members when the following criteria are met:

1. The prescriber acknowledges that the member has been safely established on Xolair (omalizumab) therapy following initiation in a healthcare setting, **AND**
2. The prescriber has determined that self-administration of XOLAIR (omalizumab) by the member or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and implementation of mitigation strategies

Maximum dose: 600 mg every two weeks

7. ZOKINVY (lonafarnib)

ZOKINVY (lonafarnib) may be approved if the member meets ALL the following criteria:

1. Member is one year of age or older
2. Member has a body surface age of 0.39 m^2 or greater
3. Member has one of the following diagnoses:
    a. Hutchinson-Gilford Progeria Syndrome (HGPS) confirmed by genetic testing for the pathogenic variant in the LMNA gene that results in production of progerin
    b. Processing-deficient progeroid laminopathy confirmed by genetic testing for heterozygous LMNA mutation with progerin-like protein accumulation **OR** for homozygous or compound heterozygous ZMPSTE24 mutations
4. Member is not taking lovastatin, simvastatin, or atorvastatin
5. Member, parent, or legal guardian has been, or will be, counseled that ZOKINVY (lonafarnib) may impact pubertal development and impair fertility
6. ZOKINVY is being prescribed or in consultation with a specialist in the area of the patient's diagnosis (such as a cardiologist or geneticist)

Maximum dose: 300 mg/day

Approval period: 12 months

8. VERQUVO (vericiguat)

VERQUVO (vericguat) may be approved if the member meets ALL the following criteria:

1. Member is 18 years of age or older
2. Member is not pregnant
3. Member has a diagnosis of heart failure with reduced ejection fraction (LVEF <45%)
4. Member is NOT concurrently taking long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, or transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil or tadalafil)
5. Member had a trial and failed ONE agent from EACH of the following drug classes. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions):
    a. ACE inhibitor (such as enalapril or lisinopril) **OR** ARB (such as valsartan or candesartan) **OR** angiotensin receptor-neprilysin inhibitor [ARNI] (such as sacubitril/valsartan)
    b. Beta blocker (bisoprolol, carvedilol, metoprolol succinate)
    c. Aldosterone antagonist (spironolactone or eplerenone)
    d. SGLT-2 inhibitor: FARXIGA (dapagliflozin), JARDIANCE (empagliflozin) or INVOKANA (canagliflozin)

Maximum dose: 10 mg/day

Discussion

- B Jackson commented that since Xolair is indicated for age 6 and up, that information should possibly be included in the drug use criteria.

- B Jackson also proposed adding to the criteria, per product labeling for Xolair, a requirement to "establish safety by administering at least 3 doses in a monitored setting prior to allowing home administration."
- Proposed criteria for Xolair (omalizumab), Zokinvy (lonafarnib) and Verquvo (vericiguat) were reviewed by the Board in one grouping.
- S Brubaker moved to accept criteria for these three products, with the two amendments for Xolair recommended above. Seconded by B Jackson. Motion passed unanimously.

10. Adjournment

L Claus reminded the Board that the next meeting is scheduled for Tuesday, November 9, from 1:00 to 5:00 pm on Zoom. Dr. Claus also reminded all Board members to delete the meeting binder immediately after today's meeting.

J Taylor thanked all of the Board members for their time and participation in today's meeting.

L Claus moved to adjourn the meeting, seconded by B Jackson. Motion passed unanimously. The meeting was adjourned at 5:11 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD