COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE COLORADO MEDICAID DUR BOARD MEETING

Review of Proposed Criteria for Physician Administered Drugs (PAD)

March 23, 2021

Open Session

3:30 pm - 5:30 pm

Health First Colorado, Colorado Medicaid
Drug Utilization Review Board
Department of Health Care Policy and Financing

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 3:31 pm by A Blackmer, 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 seven voting members participating. Quorum is five members.

a. **Members present:** Allison Blackmer, PharmD (Chair); Alison Shmerling, MD, MPH (Vice Chair), Liza Claus, PharmD; Miroslav Anguelov, PharmD; Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; Scott VanEyk, MD
b. **Medicaid Pharmacy Staff:** Jeffrey Taylor, PharmD; Rachele Crane, PharmD
c. **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared these announcements:

- Today's meeting is being recorded.
- Speakers providing testimony who have signed up in advance will be unmuted by the meeting hosts at the appropriate times during review of the proposed criteria.

4. Department Updates

J Taylor provided these announcements from the Department:

- DUR Board Chair, Allison Blackmer, will be leaving the Board. The Department thanks Dr. Blackmer for her service to the State of Colorado and to Health First Colorado members. Good luck, Dr. Blackmer! You will be missed.

- The DUR Board is holding an interim meeting today to cover material that was deferred from the regular quarterly meeting in February due to time limitations. Today the Board will review criteria related to a new program HCPF is rolling out for medications that fall under the Medical Benefit. The next regular DUR Board meetings will take place in May and August.

- Thank you to Board members and all other attendees for participating in today's meeting.

R Crane provided these announcements from the Department:

- Rachele Crane introduced herself as the Department's pharmacist for physician administered drugs (PAD). PADs include drugs that are administered to members by a healthcare professional in a provider's office or clinic, and they are billed on the Medical Benefit.

- The Department has a new utilization management vendor, Keystone Peer Review Organization (KEPRO), that will begin managing Colorado PAD in the next couple of months. More information about KEPRO may be found on the Health First Colorado Prior Authorization Request page https://www.colorado.gov/hcpf/par, as well as in provider bulletins and newsletters. With KEPRO on board, HCPF will begin requiring prior authorization on a select number of PADs. This is part of an effort to align Health First Colorado medical and pharmacy benefits, curb inappropriate utilization, and encourage cost-effective utilization while caring for members.

- PAD prior authorizations will begin no sooner than June 1, 2021

5. Final Approval of Minutes from February 9, 2021 Meeting

A Blackmer, Chair, asked if there were any changes to propose for minutes from the February 2021 DUR Board meeting. With no discussion, a motion to approve the minutes as written made by L Claus, seconded by P Lanius. None opposed. 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 proposed. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers at the time they are speaking.

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

Registered speakers for today's meeting were verified.

The DUR Board has received input from others besides the DUR Boar, including providers and members of the public, regarding the proposed criteria being reviewed today. The DUR Board serves as an advisory Board, and all input will be considered by the Department before these criteria are finalized.

Open Session:

7. New Business (open for public testimony and board review)

Products included for review in this section are identified by HCPCS J Code billing codes. Information regarding specific product formulations included in a listed J Code is available by referencing Appendix X at https://www.colorado.gov/hcpf/billing-manuals#appendices)

Final, approved PAD prior authoirzation criteria will be available on Appendix Y: Physician Adminsitered Drug Medical Benefit Prior Authorization Procuedures and Criteria on the PAD Resource webpage.

New Proposed Prior Authorization Criteria for Medical Benefit Physician Administered Drug Products

1. Botox (onabotulinumtoxinA), J0585

Botox may be approved if the member meets ALL the following criteria:

a. If administered for Chronic Migraine, prophylaxis
   i. Member is 18 years of age or older AND
   ii. Member has a diagnosis of chronic migraine, which is defined as migraine attacks occurring 15 days or more monthly for at least 3 months, each attack lasting 4 hours or more AND
   iii. Member has trial and failure of topiramate AND
   iv. Dosing interval no sooner than every 12 weeks
   v. Reauthorization requests may be approved if member has shown a clinical reduction in number of migraine days per month

b. If administered for one of the following indications, member must meet the following age requirements and dosing must be no sooner than every 12 weeks
   i. Overactive Bladder
      1. Member is 18 years of age or older
   ii. Spasticity
      1. Member is 2 years of age or older
   iii. Cervical Dystonia
      1. Member is 16 years of age or older
   iv. Primary Axillary Hyperhidrosis
      1. Member is 18 years of age or older
   v. Blepharospasm and Strabismus
      1. Member is 12 years of age or older

2. Dysport (abobutulinumtoxinA), J0586

Dysport may be approved if the member meets ALL the following criteria for each indication:

a. If being administered for cervical dystonia
   i. Member has a diagnosis of cervical dystonia AND
   ii. Member is 18 years of age or older AND
   iii. Dosing interval is no sooner than every 12 weeks AND
   iv. Initial dose of 500 units followed by a maximum maintenance dose of 1000 units administered intramuscularly

OR

b. If being administered for spasticity
   i. Member is 2 years of age or older AND
   ii. Dosing interval is no sooner than every 12 weeks
   iii. Maximum dose is 1500 units administered intramuscularly

3. Myobloc (rimabotulinumtoxinB), J0587

Myobloc may be approved if the member meets ALL the following criteria:
- a. Member is 18 years of age or older AND
- b. If being administered for cervical dystonia
  - i. Member has a diagnosis of cervical dystonia AND
  - ii. Dosing interval is no sooner than every 12 weeks AND
  - iii. Maximum dose of 10,000 units

OR
- c. If being administered for chronic sialorrhea AND
  - i. Member has a diagnosis of chronic sialorrhea AND
  - ii. Dosing interval is no sooner than every 12 weeks AND
  - iii. Maximum Initial dose is 3,000 units

4. Xeomin (incobotulinumtoxinA), J0588

Xeomin may be approved if member meets ALL the following criteria for each indication:
- a. If being administered for one of the following indications:
  1. Blepharospasm
  2. Cervical dystonia
  - ii. Member is at least 18 years of age AND
  - iii. Dosing frequency is no sooner than every 12 weeks AND
  - iv. If administered for blepharospasm, maximum dose 100 units per treatment session
- b. If being administered for the chronic sialorrhea
  - i. Member is 2 years of age or older AND
  - ii. Member weighs more than 12 kg AND
  - iii. Dosing frequency is no sooner than every 16 weeks AND
  - iv. Maximum dose of 100 units
- c. If administered for the treatment of upper limb spasticity
  - i. Member is 2 years of age or older AND
  - ii. For members between 2 and 17 years of age, spasticity is not caused by cerebral palsy AND
  - iii. Dosing frequency is no sooner than every 12 weeks AND
  - iv. Maximum dose of 200 units per single upper limb, or 400 units total

Scheduled testimony presentations:

T Blair, Dysport, Imgen – relinquished her time
J Gianninoto, Botox, AbbVie
Letter – M Birlea, MD, Botox

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- A Blackmer offered that it would be good to have a process for members < age 18 years to receive these products for migraine headache.
- A Blackmer stated that health systems formularies might cause access issues to specific products above approved for specific conditions (such as sialorrhea). Institutions are unlikely to have all four of these products on their formularies.

- P Lanius asked about the grandfathering process for products in this class.
- R Crane and J Taylor clarified that providers who care for members who do not meet these criteria will have the opportunity to submit a request, with supporting documentation, that will be reviewed. Formal Court of Appeals and peer-to-peer processes are also available.
- Motion made by A Shmerling that (1) medications in this class be used somewhat interchangeably as "therapeutic equivalents" for FDA-labeled indications when a health system formulary prohibits availability of a specific FDA-labeled product, and (2) to consider grandfathering of these medications so that members who are currently using one of these products may continue to use the same product. Seconded by M Anguelov. Motion passed unanimously. None opposed.

5. Xgeva (denosumab), J0897

Xgeva may be approved if member meets ONE of the following indications:

a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastasis from solid tumors
b. Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
c. Hypercalcemia of Malignancy, refractory to bisphosphonate therapy

Scheduled testimony presentations:

M Faithe, Xgeva, Amgen – relinquished his time

Discussion

- No Board members reported a conflict of interest for this medication.
- Motion made by A Shmerling to consider adding a grandfathering clause so that members who are currently using Xgeva may continue to use the same product. Seconded by P Lanius. Motion passed unanimously. None opposed.

6. Nucala (mepolizumab), J2182

Nucala may be approved if member meets ALL the following criteria for the appropriate indication:

a. Initial approval if administered for asthma:

i. Member is 6 years of age or older AND
ii. Member has diagnosis of severe asthma with an eosinophilic phenotype AND
iii. Member has a blood eosinophil count of greater than or equal to 150 cells/mcL within 6 weeks of dosing or greater than or equal to 300 cells/mcL in the previous 12 months AND
iv. Member has had 2 or more asthma exacerbations requiring use of oral or systemic corticosteroids and/or hospitalizations and/or ER visits OR
v. Member requires daily use of oral corticosteroids AND

vi. Baseline FEV_1 and frequency of asthma exacerbations per month are provided
vii. For members 12 years of age and older, dose of 100mg once every 4 weeks OR for members between the ages of 6 and 11 years of age, dose of 40mg every 4 weeks

b. Reauthorization for asthma indication may be approved if member has shown clinical improvement as documented by one of the following
   i. Improvement in lung function, measured in FEV_1 OR
   ii. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits

c. If administered for eosinophilic granulomatosis with polyangiitis (EGPA)
   i. Member is 18 years of age or older AND
   ii. Member has been diagnosed with relapsing or refractory EGPA at least 6 months prior to request as demonstrated by ALL of the following:
      1. Member has a diagnosis of asthma AND
      2. Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL or a blood eosinophil level of 10% AND
      3. Member has the presence of two of the following EGPA characteristics:
         a. Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
         b. Neuropathy
         c. Pulmonary infiltrates
         d. Sinonasal abnormality
         e. Cardiomyopathy
         f. Glomerulonephritis
         g. Alveolar hemorrhage
         h. Palpable purpura
         i. Antineutrophil cytoplasmic antibody (ANCA) positive
   iii. Member is on a stable dose of corticosteroids for at least 4 weeks prior to request AND
   iv. Dose of 300 mg once every 4 weeks

d. If administered for hypereosinophilic syndrome (HES):
   i. Member is 12 years of age or older AND
   ii. Member has a diagnosis for HES for at least 6 months that is non-hematologic secondary HES AND
   iii. Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL AND
   iv. Member has a history of two or more HES flares (defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in therapy) AND
   v. Member has been on stable dose of HES therapy for at least 4 weeks, at

time of request, including at least one of the following: AND
1. Oral corticosteroids
2. Immunosuppressive therapy
3. Cytotoxic therapy

vi. Dose of 300 mg once every 4 weeks

Discussion

- No Board members reported a conflict of interest for this medication.
- Motion made by L Claus to approve criteria as written, with the addition of consideration to add a grandfathering clause so that members who are currently using Nucala may continue to use the same product. Seconded by P Lanius. Motion passed unanimously. None opposed.

7. Xolair (omalizumab), J2357

Xolair may be approved if member meets ALL the following criteria for the appropriate indication:

a. If administered for the treatment of asthma:
   i. Member is 6 years of age or older AND
   ii. Member has a diagnosis of moderate to severe asthma with one of the following:
      1. A pre-treatment IgE serum concentration greater than or equal to 30 IU per mL OR
      2. A positive skin test or in vitro reactivity to a perennial inhaled allergen
      AND
   iii. Member's symptoms remain uncontrolled despite adherence to concomitant treatment with a high-dose inhaled corticosteroids and long acting beta2-agonist AND
   iv. Xolair is not being used as a monotherapy AND
   v. Xolair will not be used concomitantly with other biologics indicated for asthma
   AND
   vi. Maximum dose of 750mg every 4 weeks

b. Reauthorization for asthma indication may be approved if member has shown clinical improvement as documented by one of the following
   i. Improvement in lung function, measured in FEV_1 OR
   ii. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits

c. If administered for the treatment of chronic idiopathic urticaria
   i. Member is 12 years of age or older AND
   ii. Member is diagnosed with chronic idiopathic urticaria AND
   iii. Member is symptomatic despite H1 antihistamine treatment AND

iv. Member has tried and failed a high-dose second-generation H1 antihistamine, H2 antihistamine, first-generation H1 antihistamine, a leukotriene receptor antagonist, and hydroxyzine or doxepin

Discussion

- No Board members reported a conflict of interest for this medication.
- Motion made by P Lanius for additional review of Xolair criteria section 7.c.iv by the Department to reconsider the number of medication trials/failures required in order to receive approval for Xolair for chronic idiopathic urticaria. Seconded by M Anguelov. Motion passed unanimously. None opposed.
- Motion made by A Shmerling to consider adding a grandfathering clause, appropriate for the indication, so that members who are currently using Xolair may continue to use the same product. Seconded by T Brubaker. Motion passed unanimously.

8. Cinqair (reslizumab), J2786

Cinqair may be approved if member meets all the following criteria:

a. Member is 18 years of age or older AND
b. Member has diagnosis of severe asthma with an eosinophilic phenotype AND
c. Member has a blood eosinophil count of greater than or equal to 400 cells/mcL AND
d. Cinqair is being used as a maintenance adjunctive therapy AND
e. Member's symptoms remain uncontrolled despite adherence to concomitant treatment with
   a medium to high-dose inhaled corticosteroids and long acting beta$_2$-agonist AND
f. Member has uncontrolled disease characterized by the following:
   i. Asthmatic symptoms occurring throughout the day
   ii. Nighttime awakenings occuring 7 times per week
   iii. Use of Short Acting Beta-Agonist for symptom control several times per day
   iv. Symptoms are causing extreme limitations of member's normal activity
   v. Lung Function, characterized by FEV1 is less than 60%
   vi. Asthma exacerbations requiring oral systemic corticosteroids, occurring more frequently and intensely than mild or moderate asthma
g. Baseline FEV_1 and frequency of asthma exacerbations per month are provided AND
h. Maximum dose of 3 mg/kg every 4 weeks
   i. Reauthorization may be approved if member meets one of the following:
   i. Improvement in lung function, measured in FEV_1 OR
   ii. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits

Discussion

- No Board members reported a conflict of interest for this medication.
- Motion made by P Lanius to delete criteria section 8.f.iv due to lack of a quantitative component. Seconded by A Shmerling. Motion passed unanimously.

- Motion made by P Lanius to consider adding a grandfathering clause, appropriate for the indication, so that members who are currently using Cinqair may continue to use the same product. Seconded by T Brubaker. Motion passed unanimously.

9. IV Immune Globulins

Gammaked, Gamunex-C, Gamunex, J1561
Octagam 5%, 10%, J1568
Gammagard Liquid, J1569
Privigen, J1459
Asceniv, Gammaplex, Panzyga, J1599
Bivigam, J1556
Flebogamma DIF, J1572
Gammagard S/D, J1566
Gammaplex, J1557

May be approved for members meeting one of the approved conditions listed and for doses not exceeding FDA-approved maximum (Table 1).

a. Approved Conditions for Immune Globulin Use:

i. Primary Humoral Immunodeficiency disorders including:

1. Common Variable Immunodeficiency (CVID)
2. Severe Combined Immunodeficiency (SCID)
3. X-Linked Agammaglobulinemia
4. X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
5. Wiskott-Aldrich Syndrome
6. Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm^3

ii. Neurological disorders including:

1. Guillain-Barré Syndrome
2. Relapsing-Remitting Multiple Sclerosis
3. Chronic Inflammatory Demyelinating Polyneuropathy
4. Myasthenia Gravis
5. Polymyositis and Dermatomyositis
6. Multifocal Motor Neuropathy

iii. Chronic Lymphocytic Leukemia (CLL)
iv. Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections
v. Autoimmune Hemolytic Anemia (AHA)
vi. Liver or Intestinal Transplant
vii. Immune Thrombocytopenia Purpura (ITP) including:

1. Requiring preoperative therapy for undergoing elective splenectomy with platelet count < 20,000
2. Members with active bleeding & platelet count <30,000
3. Pregnant members with platelet counts <10,000 in the third trimester
4. Pregnant members with platelet count 10,000 to 30,000 who are bleeding

Table 1: FDA-Approved Maximum Immune Globulin Dosing	
Gammaked	2 g/kg
Gamunex-C	2 g/kg
Octagam	2 g/kg
Gammagard Liquid	2.4 g/kg/month
Gammaplex 5% - IV Infusion	2 g/kg
Privigen - IV Infusion	2 g/kg
Asceniv	800 mg/kg every 3 weeks
Panzyga	2 g/kg
Bivigam	800 mg/kg every 3 weeks
Flebogamma DIF	600 mg/kg every 3 weeks
Gammagard S/D	1 g/kg

Discussion

- No Board members reported a conflict of interest for this therapeutic class.
- R Crane clarified that, although these proposed criteria for immune globulins mirror the criteria under the pharmacy benefit, the IVIG products included in this PAD class are covered when administered in a provider's office or clinic.
- T Brubaker stated that IV immune globulins are also used in pediatric hospital settings for Kawasaki disease (KD) and multisystem inflammatory syndrome in children (MIS-C), especially in the setting of COVID-19.
- Motion made by T Brubaker to request futher investigation to determine if Kawasaki disease and MIS-C need to be included on the list of approved conditions for immune globulin use above. Seconded by A Shmerling. Motion passed unanimously.
- Motion made by P Lanius to consider adding a grandfathering clause for this medication class. Seconded by T Brubaker. Motion passed unanimously.

10. Ocrevus (ocrelizumab), J2350

Ocrevus may be approved for initial therapy if the following criteria are met:

a. <u>If administered for Relapsing Forms of Multiple Sclerosis (MS)</u>

i. Member is 18 years of age or older AND

ii. Member has a relapsing form of multiple sclerosis AND

iii. Member has experienced one relapse within the prior year or two relapses within the prior two years AND

iv. Member has trial and failure of three preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication, Ocrevus (ocrelizumab), or Lemtrada (alemtuzumab). of the following agents: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Tysabri (Natalizumab) or Lemtrada (alemtuzumab). Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following:

1. One of the following on MRI: presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy
2. On clinical exam, signs and symptoms consistent with Functional limitations that last one month or longer OR

v. Member with highly active relapsing MS has trial and failure of two preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA labelled for use for the same prescribed indication, Ocrevus (ocrelizumab), or Lemtrada (alemtuzumab).

b. If administered for Primary Progressive Multiple Sclerosis

i. Member is 18 years of age or older AND

ii. Member is not concomitantly taking disease modifying therapies. : Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Tysabri (Natalizumab) or Lemtrada (alemtuzumab) AND

c. Member does not have active hepatitis B infection AND

d. Ocrevus is administered by or in conjunction consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis

e. Maximum maintenance dose: 600mg every 6 months

f. Grandfathering: If member is currently receiving and stabilized on Ocrevus, they may continue to receive prior authorization approval to continue.

11. Tysabri (natalizumab), J2323

Tysabri may be approved for initial therapy if the following criteria are met:

a. Medication is not currently being used in combination with immunosuppressants (azathioprine, 6 mercaptopurine, methotrexate) or TNF-alpha inhibitors (adalimumab, certolizumab pegol, infliximab) AND

b. If administered for induction of remission of moderate to severe Crohn's disease

i. The patient is ≥ 18 years of age AND

ii. Member has tried and failed Aminosalicylates AND

iii. Member has tried and failed Corticosteroids AND

iv. Member has tried and failed immunomodulators AND

v. Member has tried and failed two TNF-alpha inhibitors (e.g. adalimumab, certolizumab pegol, infliximab) AND

vi. Tysabri is administered by or in consultation with a gastroenterologist.

c. If administered for relapsing remitting multiple sclerosis (RRMS)

i. The patient is ≥ 18 years of age; AND

ii. Member has trial and failure of three preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication, Ocrevus (ocrelizumab), or Lemtrada (alemtuzumab). following agents: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Ocrevus (ocrelizumab) or Lemtrada (alemtuzumab). Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy indicated by one of the following:

1. One of the following on MRI: presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy
2. On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer OR

iii. Member with highly active relapsing MS has trial and failure of two preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication, Ocrevus (ocrelizumab), or Lemtrada (alemtuzumab).

d. Tysabri is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis

e. Grandfathering: If member is currently receiving and stabilized on Tysabri, they may continue receive prior authorization approval to continue.

Discussion

- No Board members reported a conflict of interest for Orcrevus or Tysabri.
- Motion made by S VanEyk to approve criteria for Ocrevus and Tysabri as written. Seconded by T Brubaker. Motion passed unanimously. None opposed.

The following section involves review of criteria for PADs that have previously been reviewed and approved by the DUR Board for the pharmacy benefit. The Department proposes using these same critiera for administering the medical benefit. The five following products will be included on a new document called Appendix Y.

1. Soliris (eculizumab), J1300

Soliris may be approved for members meeting all of the following criteria:

a. Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Mysthenia Gravis (gMG), or Neuromyleitis Optica Spectrum Disorder (NMOSD) AND

b. Member does not have a systemic infection AND

c. Member must be administered a meningococcal vaccine at least two weeks prior to initiation of Soliris therapy and revaccinated according to current medical guidelines for vaccine use AND

d. Prescriber is enrolled in the Soliris (eculizumab) Risk Evaluation and Mitigation Strategy (REMS) program AND

e. Medication is administered by or in conjunction with a hematologist for PNH and by or in conjunction with a hematologist or nephrologist for aHUS and by or in conjunction with a neurologist for gMG or NMOSD AND

f. Member meets criteria listed below based on specific diagnosis:

Paroxysmal Nocturnal Hemoglobinuria

- ❑ Member is 18 years of age or older AND
- ❑ Diagnosis of PHN must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND
- ❑ Member demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes) AND
- ❑ Member has one of the following indications for therapy:
    - ❑ Presence of a thrombotic event
    - ❑ Presence of organ damage secondary to chronic hemolysis
    - ❑ Patient is pregnant and potential benefit outweighs potential fetal risk
    - ❑ Patient is transfusion dependent
    - ❑ Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms

  AND
- ❑ Member has documented baseline values for one or more of the following:
    - ❑ Serum lactate dehydrogenase (LDH)
    - ❑ Hemoglobin level
    - ❑ Packed RBC transfusion requirement

Atypical Hemolytic Uremic Syndrome

- ❑ Member is 2 months or older AND
- ❑ Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by Evaluating ADAMTS13 level (ADAMTS-13 activity level > 10%); AND
- ❑ Shiga toxin E. coli related hemolytic uremic syndrome (STECHUS) has been ruled out; AND
- ❑ Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency AND
- ❑ Documented baseline values for one or more of the following:
- ❑ Serum lactate dehydrogenase (LDH)
- ❑ Serum creatinine/eGFR
- ❑ Platelet count
- ❑ Plasma exchange/infusion requirement

Generalized Myasthenia Gravis

- ❑ Member is 18 years or older AND
- ❑ Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND
- ❑ Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; AND
- ❑ Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; AND
- ❑ Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND
- ❑ Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)

Neuromyelitis Optica Spectrum Disorder

- ❑ Member is 18 years or older AND
- ❑ Member has a past medical history of one of the following:
- ❑ Optic neuritis
- ❑ Acute myelitis
- ❑ Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
- ❑ Acute brainstem syndrome
- ❑ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- ❑ Symptomatic cerebral syndrome with NMOSD-typical brain lesions AND
- ❑ Member has a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4- IgG)/NMP-IgG antibodies; AND
- ❑ Diagnosis of multiple sclerosis or other diagnoses have been ruled out AND
- ❑ Member has not failed a previous course of Soliris (eculizumab) therapy AND
- ❑ Member has a history of failure, contraindication, or intolerance torituximab therapy AND
- ❑ Member has at least one of the following:
    - ❑ History of at least two relapses during the previous 12 months prior to Initiating Soliris (eculizumab)
    - ❑ History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris (eculizumab) AND
- ❑ Member is not receiving Soliris in combination with any of the following:
    - ❑ Disease modifying therapies for the treatment of multiple sclerosis (such as Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab),etc.) OR
- ❑ Anti-IL6 therapy

Maximum dose: 900mg weekly for 4 weeks induction followed by 1200mg every 2 weeks maintenance dose

2. Fasenra (benralizumab), J0517

Fasenra may be approved for members meeting all of the following criteria:

a. Member is 12 years of age or older AND
b. Member has diagnosis of severe asthma with eosinophilic phenotype AND
c. Member has eosinophil count of at least 300 cells/µl AND
d. Fasenra is being administered as add-on therapy (not monotherapy) AND
e. Member is taking a high dose inhaled corticosteroids and a long-acting beta agonist AND
f. Member has had at least 2 asthma exacerbations requiring systemic corticosteroid therapy in the past 12 months

Maximum dose: 30mg subcutaneous injection every 4 weeks for 3 doses, then every 8 weeks thereafter

3. Prolia (denosumab), J0897

Prolia may be approved for members meeting all of the following criteria:

a. Member has one of the following diagnoses:
    i. Postmenopausal osteoporosis with high fracture risk
    ii. Osteoporosis
    iii. Bone loss in men receiving androgen deprivation therapy in prostate cancer
    iv. Bone loss in women receiving adjuvant aromatase inhibitor therapy for breastcancer

AND

b. Member has serum calcium greater than 8.5mg/dL AND
c. Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily

AND

d. Has trial and failure of preferred bisphosphonate for one year AND
    i. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
e. Member meets ANY of the following criteria:
    i. has a history of an osteoporotic vertebral or hip fracture
    ii. has a pre-treatment T-score of < -2.5
    iii. has a pre-treatment T-score of < -1 but > -2.5 AND either of the following:
        1. Pre-treatment FRAX score of > 20% for any major fracture
        2. Pre-treatment FRAX score of > 3% for hip fracture
    iv. Maximum dose of Prolia is 60mg every 6 months

4. Remicade (infliximab), J1745

a. May be approved with trial & failure of Renflexis® (infliximab abda) AND if meeting all the following criteria:
- Member has one of the following diagnoses:
  - o Crohn's disease and is 6 years or older
  - o Ulcerative colitis and is 6 years or older
  - o Rheumatoid arthritis and is 4 years or older
  - o Psoriatic arthritis in adults
  - o Ankylosing spondylitis in adults
  - o Juvenile idiopathic arthritis o Plaque psoriasis in adults

  AND
- Member has tried and failed‡ ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication.

** Members ≥ 50 years of age with an additional CV risk factor, will not need a trial and failure of Xeljanz IR.

5. Entyvio (vedolizumab), J3380

Entyvio may be approved for members meeting all of the following criteria:

a. Medication is 18 years of age or older AND
b. Member has a diagnosis of ulcerative colitis or Crohn's disease AND
c. For diagnosis of Crohn's disease, have trialed and failed Humira and Cimzia OR for a diagnosis of ulcerative colitis, have trialed and failed Humira and Simponi. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
d. Member has had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids AND
e. Member is not receiving Entyvio in combination with Humira, Simponi, or Tysabri AND
f. Medication is initiated and titrated per FDA-labeled dosing for Crohn's Disease and Ulcerative Colitis up to a maximum of 300mg IV infusion every 8 weeks

Scheduled testimony presentations:

M Faithe, Prolia, Amgen

Discussion

- No Board members reported a conflict of interest for these medications.
- T Brubaker commented that in the Soliris proposed criteria section regarding Atypical Hemolytic Uremic Syndrome (HUS), the bullet point related to ruling out other causes of HUS (such as coexisting oncological processes, *S. pneumo* infection, Shiga toxin E. coli

infection) may be clinically inappropriate because it lists many potential causes of atypical HUS. This results in a narrow definition for atypical HUS that only very few members would meet.

- Motion made by T Brubaker to either remove or further investigate the 4th bullet under Soliris/Atypical Hemolytic Uremic Syndrome (particularly S. *pneumoniae* and malignancy) as reasons for denying the approval of Soliris. Seconded by M Anguelov. Motion passed unanimously. None opposed.
- Motion made by L Claus to change Prolia criteria to (1) add glucocorticoid-induced osteoporosis (GIOP) to the diagnosis list under bullet 3.a, and (2) delete all of bullet point 3.d that begins "Has trial and failure of preferred bisphosphonate for one year…" Seconded by S VanEyk. Motion passed unaminmously.
- T Brubaker commented that 6 years may not be an absolute minimum age cut-off point for the use of Remicade. J Taylor mentioned that the Department is continuing to evaluate off-label uses and look at age ranges for the targeted immune modulators.

Adjournment

R Crane again thanked the Board members and guests for dedicating time to today's meeting and reviewing these criteria.

A Blackmer, Board Chair, reminded attendees that the next Board meeting is scheduled for May 11, 1:00 to 5:00 pm on Zoom, and also reminded Board members to delete the Adobe document binder that was distributed prior to today's meeting.

Motion to adjourn was made by T Brubaker, seconded by L Claus. The meeting was adjourned at 5:37 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD