P&T Committee Meeting Minutes
Commercial, Exchange, & CHIP
October 2022 e-vote

Fast Facts

BEOVU (brolucizumab-dbll)

Updated indication: Beovu is now indicated for the treatment of diabetic macular edema (DME). The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every six weeks (approximately every 39-45 days) for the first five doses, followed by 6 mg (0.05 mL) by intravitreal injection once every 8-12 weeks.

Current formulary status: Medical benefit requiring prior authorization.

Recommendation: Recommend adding the following prior authorization criteria for the Beovu MBP 251.0 for the diagnosis of diabetic macular edema:

- Medical record documentation of a diagnosis of diabetic macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

DUPIXENT (dupilumab)

Updated indication: Dupixent is an interleukin-4 receptor alpha antagonist that is now indicated for the treatment of atopic dermatitis in pediatric patients aged six months and older, eosinophilic esophagitis in adults and pediatric patients aged 12 years and older weighing at least 40 kg, and prurigo nodularis in adult patients.

Previously, Dupixent was only indicated for the treatment of atopic dermatitis (AD) in adults and pediatric patients aged 6 years and older, moderate-to-severe asthma in patients aged 6 years and older, and chronic rhinosinusitis with nasal polyposis in adult patients.

Current formulary status: Pharmacy benefit on the specialty tier or brand non-preferred tier for members with a three tier benefit requiring prior authorization.

Recommendation: No changes are recommended to the formulary placement or authorization duration of Dupixent. It is recommended that the following prior authorization criteria be added to Commercial Policy 457.0 to incorporate the updated population and new indications:

Atopic Dermatitis

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 6 ~~years~~ months **AND**

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure* on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
    - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable (use on sensitive areas, age between 2 and 15 years): Therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

#NOTE:

Atopic Dermatitis

Dosage in Adults (2.3):

Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W).

Dosage in Pediatric Patients 6 Months to 5 Years of Age (2.3):

Body Weight	Initial and Subsequent Dosage
5 to less than 15 kg	200 mg (one 200 mg injection) every 4 weeks (Q4W)
15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks (Q4W)

Dosage in Pediatric Patients 6 Years to 17 Years of Age (2.3):

Body Weight	Initial Loading Dose	Subsequent Dosage[a]
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg Q4W
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg Q2W
60 kg or more	600 mg (two 300 mg injections)	300 mg Q2W

[a] Q2W – every other week; Q4W – every 4 weeks

QUANTITY LIMIT

- **Initial Approval**
    - 600 mg once, followed by 300 mg every other week
        1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
        2. In PA Hub: Add PA, OQL, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
            - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
    - 600 mg once, followed by 300 mg every four weeks
        1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
        2. In PA Hub: Add PA, OQL, and max quantity dispensed 2 with a start date 1 day after the loading dose ends for the remainder of the authorization.

- QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 2 mL per 28 days

- 400 mg once, followed by 200 mg every other week
  1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 4.56, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
  2. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28 with a start date 1 day after the loading dose ends for the remainder of the authorization.
     - QL FOR LETTER: Loading dose: 4.56 mL per 42 days, Maintenance dose: 2.28 mL per 28 days
- 200 mg every four weeks
  1. In PA Hub: Add PA, OQL, and max quantity dispensed 1.14.
     - QL FOR LETTER: 1.14 mL per 28 days
- 300 mg every four weeks
  1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.
     - QL FOR LETTER: 2 mL per 28 days

- **Renewal –**
  - 300 mg every other week
    - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 4.
      - QL FOR LETTER: 4 mL per 28 days
  - 300 mg every four weeks
    - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.
      - QL FOR LETTER: 2 mL per 28 days
  - 200 mg every other week
    - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28.
      - QL FOR LETTER: 2.28 mL per 28 days
  - 200 mg every four weeks
    - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 1.14
      - QL FOR LETTER: 1.14 mL per 28 days

Eosinophilic Esophagitis

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of weight ≥40 kg **AND**
- Medical record documentation of a diagnosis of eosinophilic esophagitis **AND**
- Medical record documentation of ≥15 intraepithelial eosinophils per high-power field (eos/hpf)
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on a proton pump inhibitor **AND**
- Medical record documentation that the member is experiencing chronic symptoms of esophageal dysfunction (i.e. dysphagia, food impaction, food refusal, abdominal pain, heartburn, regurgitation, chest pain, odynophagia) **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on a swallowed inhaled respiratory glucocorticoid **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

#**NOTE:** Recommended dosage for patients aged 12 years and older is 300 mg given once weekly. No loading dose is required.

QUANTITY LIMIT

- 300 mg once weekly
  1. In PA Hub: Add PA, OQL, and max quantity dispensed 8.
     - QL FOR LETTER: 8 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

FORMULARY ALTERNATIVES:
Proton pump inhibitors: omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole
Inhaled respiratory glucocorticoids: budesonide inhalation suspension, Flovent HFA

Prurigo Nodularis

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of prurigo nodularis **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of a failure on a very-high potency topical corticosteroid (i.e. clobetasol dipropionate 0.05% ointment) **OR** calcineurin inhibitor (i.e. tacrolimus) if topical corticosteroids are not advisable **OR**
  - Medical record documentation of widespread or recalcitrant disease **AND** contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND** systemic therapy (including methotrexate and/or cyclosporine) **AND**
- Medical record documentation that the member is receiving an appropriate dose# based on patient's age and weight

#**NOTE:** Recommended dosage for adults is 600 mg once, followed by 300 mg given every other week.

QUANTITY LIMIT

- **Initial Approval**
  - 600 mg once, followed by 300 mg every other week
    - 1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
    - 2. In PA Hub: Add PA, OQL, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
      - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
- **Renewal –**
  - 300 mg every other week
    - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 4.
      - QL FOR LETTER: 4 mL per 28 days

FORMULARY ALTERNATIVES:

- Systemic Therapies: cyclosporine, methotrexate
- Topical Therapies: Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*, Eucrisa

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)
*prior authorization required

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ENHERTU (fam-trastuzumab deruxtecan-nxki)

Updated Indication: Enhertu is now indicated for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy and for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. The NSCLC indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Enhertu was previously indicated for the following:

- treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy.
- treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.

Current formulary status: Medical benefit requiring prior authorization. When processed at a specialty pharmacy, it is on the specialty tier or brand non preferred tier.

Recommendation: No changes recommended to the formulary placement or authorization duration of Enhertu at this time. However, it is recommended to update policy Medical Benefit Policy 208 to include the following highlighted changes:

Breast Cancer

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic HER2-positive breast cancer AND
- Medical record documentation of one of the following:
    - Documentation of a prior anti-HER2 based therapy in the metastatic setting OR
    - Documentation of a prior anti-HER2 based therapy in the neoadjuvant or adjuvant setting AND documentation of disease recurrence during or within 6 months of completing therapy

OR

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND

- Medical record documentation of unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer AND
- Medical record documentation that Enhertu will be used as a single agent AND
- Medical record documentation of one of the following:
    - Documentation of a prior chemotherapy in the metastatic setting OR
    - Documentation of disease recurrence during or within 6 months of completing adjuvant chemotherapy

Gastric Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma AND
- Medical record documentation of one or more prior trastuzumab-based therapies

Non-Small Cell Lung Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic non-small cell lung cancer (NSCLC) AND
- Medical record documentation of tumors that have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test AND
- Medical record documentation that Enhertu will be used as a single agent AND
- Medical record documentation of a prior systemic therapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

EVRYSDI (risdiplam)

Updated Indication: Evrysdi (risdiplam) was first FDA approved for the treatment of spinal muscle atrophy (SMA), a hereditary disease that results in destruction of motor neurons leading to muscle weakness and atrophy, in patients 2 months of age and older on August 7, 2020. Risdiplam now has an updated approval to include pediatric patients from newborn to 2 months of age who have a diagnosis of spinal muscular atrophy. The label extension is based on interim efficacy and safety data from the RAINBOWFISH study.

Current formulary status: Pharmacy benefit on the specialty tier or brand non-preferred tier for members with a three tier benefit requiring prior authorization.

Recommendation: Update prior authorization criteria by removing the following:

- Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist **AND**
- ~~Medical record documentation of age greater than or equal to 2 months **AND**~~
- Medical record documentation of one of the following:
    - A confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:

        - Homozygous exon 7 gene deletion **OR**
        - Homozygous exon 7 conversion mutation **OR**
        - Compound heterozygous exon 7 mutation **OR**
    - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g., Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g., Spinraza)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

RIABNI (rituximab-arrx)

Updated Indication: Riabni (rituximab-arrx) is biosimilar to Rituxan (rituximab). Riabni, in combination with methotrexate, is now indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis (RA) who have had an inadequate response to one or more TNF antagonist therapies. Previously, Riabni was approved for the treatment of adult patients with Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Granulomatosis with Polyangiitis (GPA) (also called Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

Current formulary status: Medical benefit requiring prior authorization. When processed at a specialty pharmacy, it is on the specialty tier or brand non preferred tier.

Recommendation: No changes are recommended to the formulary placement of Riabni. No changes are recommended to Medical Benefit Policy 48.0 and Part D Policy 369.0D as indication of RA for Riabni is already addressed and appropriate.

Discussion: No comments or questions

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

IMCIVREE (setmelanotide)

Clinical Summary: Ultomiris is now FDA approved for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody–positive. This is the only long-acting component 5 (C5) complement inhibitor approved for the treatment of gMG. Previously, Ultomiris was approved for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) and Atypical Hemolytic Uremic Syndrome (aHUS).

Current formulary status: Pharmacy benefit excluded from Commercial, Exchange, and GHP Kids. For certain TPA clients that request this benefit (weight loss), Imcivree will process at the Specialty Tier or Brand Non-Preferred tier for members with a three tier benefit with an approved prior authorization.

Recommendation: There are no changes to formulary status or quantity limits at this time. However, it is recommended to update the prior authorization criteria to the following:

Obesity due to Bardet-Biedl Syndrome

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
    - For patients 16 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30kg/m^2 **OR**
    - For patients 6 years to less than 16 years: Medical record documentation of weight greater than or equal to 97th percentile using growth chart assessments **AND**
- Medical record documentation of obesity due to Bardet-Biedl syndrome (BBS)*

Obesity due to POMC, PCSK1, or LEPR deficiency

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
    - For patients 18 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30 kg/m^2 **OR**
    - For patients age 6 years to less than 18 years: Medical record documentation of weight greater than or equal to 95th percentile using growth chart assessments

AND

- Medical record documentation of a proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **AND**
- Medical record confirmation of genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)*

*NOTE: Imcivree is not indicated for treatment of:

- Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

NUBEQA (darolutamide)

Updated Indication: Nubeqa is now indicated for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. Previously, Nubeqa was approved for non-metastatic castration resistant prostate cancer (nmCRPC).

Current Formulary Status: Pharmacy benefit on the oral oncology brand non preferred tier requiring prior authorization with a quantity limit.

Recommendation: There are no changes recommended to the formulary placement or authorization duration for Nubeqa. The following changes are recommended to the prior authorization criteria in Commercial Policy 585.0:

- Medical record documentation that Nubeqa is prescribed by an oncologist or urologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - a diagnosis of non-metastatic, castration-resistant prostate cancer **OR**
    - a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** Nubeqa is being used in combination with docetaxel
- Medical record documentation that members is receiving GnRH analog(s) concurrently **OR** that member has had a bilateral orchiectomy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

OLUMIANT (baricitinib)

Updated Indication: Olumiant is newly indicated for the treatment of severe alopecia areata in adult patients. The original indication for Olumiant was rheumatoid arthritis

Current formulary status: Olumiant is a pharmacy benefit currently available at the Specialty tier. For 2023, Olumiant will be non-formulary. Currently, Olumiant requires prior authorization.

Recommendation: Coverage of Olumiant for the treatment of alopecia areata is not a covered service under the pharmacy benefit. It is also recommended that Olumiant 4 mg tablets are excluded under the pharmacy benefit.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SKYRIZI (risankizumab-rzaa)

Update Indication: Skyrizi is now indicated for moderately to severely active Crohn's disease in adults. Previously, Skyrizi was approved for psoriatic arthritis in adults and for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Current formulary status: Skyrizi 150 mg/ ml prefilled syringe, Skyrizi 150 mg/ ml auto-injector, Skyrizi 75 mg/0.83 ml prefilled syringe-Pharmacy benefit requiring prior authorization; Specialty Tier or Brand non preferred for members with a 3- Tier Benefit

Recommendation: Add Skyrizi 360 mg/ 2.4 mL to Specialty Tier or Brand Non-Preferred Tier for members with a 3- Tier benefit. Prior authorization required for new starts only. Update policy 580.0 for Skyrizi to include the following:

For Crohn's Disease (CD):

1. Prescription must be written by a gastroenterologist AND
2. Medical record documentation that the patients is at least 18 years of age AND
3. Medical record documentation of a diagnosis of moderately to severely active Crohn's Disease
4. Medical record documentation that medication is not being used concurrently with a TNF blocker or other biologic agent AND
5. Medical record documentation of one of the following:
    a. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and immunomodulators (e.g. azathioprine and 6 mercaptopurine) OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy OR
    b. Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/ or penetrating behavior.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 360 mg/ 2.4 mL; 2.4 milliliters per 56 days

RE-AUTHORIZATION CRITERIA**:** Skyrizi is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 -day break in therapy.

Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

Medical Benefit Policy:

Skyrizi 600 mg /10 mL intravenous is a medical benefit and should be added to the medical benefit cost share list. If processed at a specialty pharmacy, Skyrizi 600 mg /10 mL should process at the Specialty tier or Brand Non-Preferred tier for members with a 3- tier benefit

Create a new medical benefit policy for Skyrizi for Crohn's Disease

1. Prescription must be written by a gastroenterologist AND
2. Member must be at least 18 years of age AND
3. Medical record documentation of moderately to severely active Crohn's disease AND
4. Medical record documentation that Skyrizi is not being used concurrently with a TNF blocker or other biologic agent AND
5. Medical record documentation of one of the following:
    a. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and immunomodulators (e.g., azathioprine and 6

mercaptopurine) OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy OR

b. Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/ or penetrating behavior.

6. Medical record documentation of Skyrizi 600 mg/ 10 mL vials for IV infusion is being prescribed for induction therapy at weeks 0, 4, and 8.

Auth duration: Initial: 3-month auth (to allow 3 loading dose administration); remainder of initial 6-month authorization will be entered as a pharmacy auth x 3 months. (Quantity limit: 2.4 ml per 56 days)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

UPDATES

INTRAVITREAL VEGF INHIBITOR QUANTITY LIMIT UPDATE

Background: It was brought to our attention from Regeneron that Eylea can be administered "every 4 weeks (approximately every 25 days, monthly). Our current quantity limits allow for one injection per each eye every month (30 days). Regeneron asked that we update our quantity limit to allow up to every 25 day administration. We discussed this with Dr. Benjamin Hale. He mentioned they typically do injections every 4 weeks (every 28 days). This may be +/- a few days. He said there should not be restriction on how many days we have to wait to repeat an injection. He said every 25 day dosing is not unreasonable. There is no harm in giving an injection at day 25 vs. 28 vs. 30 and it may be beneficial to the patient. He would be in favor of us removing the quantity limit.

Recommendations: It is recommended to update the quantity limits as follows:

- Beovu
  - For Darwin: 0.1mL per 25 days
  - For Facets: J0179 (1 mg): 12 per 25 days
- Eylea:
  - For Darwin: 0.1 mL per 25 days
  - For Facets: J0178 (1 mg): 4 per 25 days
- Lucentis:
  - For Darwin: 0.1 mL per 28 days
  - For Facets: J2278 (0.1 mg): 10 per 28 days
- Vabysmo:
  - For Darwin: 0.1 mL per 21 days
  - For Facets: 12 mg every 21 days
- Susvimo:
  - For Darwin:
    - GPI-14 86655060002040: 0.2 mL (2 vials) per 24 weeks
    - GPI-14 86655060002042: 0.2 mL (2 vials) per 24 weeks
    - GPI-14 97604040002340: 2 implants (1 implant per eye) per lifetime
  - For Facets:
    - GPI-14 86655060002040: 20 mg (2 vials) per 24 weeks
    - GPI-14 86655060002042: 20 mg (2 vials) per 24 weeks
    - GPI-14 97604040002340: 2 implants (1 implant per eye) per lifetime

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

PRALUENT AND REPATHA

Background: It was brought to our attention that the requirement of Zetia prior to a PCSK9 inhibitor is not clinically appropriate for all patients. Zetia has been shown to improve CV outcomes in combination with a statin, specifically Simvastatin, in the IMPROVE-IT trial. I had a discussion with Nathan Sauers regarding Zetia use. He believes patients should not be required to try Zetia prior to a PSCK9 inhibitor. He mentioned how the IMPROVE-IT trial used simvastatin, which is not a high intensity statin, so to

require Zetia when target dose of atorvastatin or rosuvastatin is not sufficient to get to goal does not make sense. He mentioned how Zetia only reduces the LDL slightly, so for many of these patients adding Zetia to atorvastatin 80 mg or rosuvastatin 40 mg will not be potent enough. He also mentioned for familial hypercholesterolemia or ASCVD, the target LDL is < 70 and sometimes < 50, and it would benefit patients to go right to the PSCK9 inhibitor instead of requiring Zetia or use a combination of PSCK9 inhibitor and Zetia. For primary prevention, the use of Zetia makes more sense. It also depends on the patient's LDL in terms of whether Zetia should be considered.

Recommendations: It is recommended to update the Zetia criterion to the following for both the Praluent (policy 392.0) and Repatha policies (393.0):

- Medical record documentation of one of the following:
    - The patient is currently on and adherent to (taking at least 90% of the prescribed doses over the past three months) ezetimibe in combination with a maximally tolerated dose of a statin and LDL-C remains above goal **OR**
    - Intolerance or contraindication to ezetimibe **OR**
    - The patient is currently on and adherent to (taking at least 90% of prescribed doses over the past three months) a maximally tolerated dose of a statin **OR** the patient is statin-intolerant **AND** an LDL-C is more than 20% above goal

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

RADICAVA ORS QUANTITY LIMIT UPDATE

Background: Radicava ORS is available as a 105 mg/5mL oral suspension, supplied in bottles of 35 mL and 50 mL. The recommended dose of Radicava ORS is 105 mg (5 mL). It is administered as an initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period. Subsequent cycles are daily dosing for 10 days out of 14-day periods, followed by a 14-day drug-free period.

At September P&T, I recommended coding the quantity limit at 50 mL per 28 days and entering a one-time override for 70 mL per 28 days for the loading dose. It was brought to my attention that we can code the quantity limit for the loading dose, even though they have the same GPI.

Recommendations: It is recommended to update the quantity limit to the following:
For NDC 70510232101 & 70510232102: 70 mL per 180 days (to allow for the loading dose)
For NDC 70510232201: 50 mL per 28 days

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Voting responses were received from 32 of 50 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on November 15th, 2022 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.