P&T Committee Meeting Minutes
Medicaid
November 15, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonious, Pharm.D.	Jeremy Bennett, MD
Emily Antosh, Pharm.D.	Holly Bones, Pharm.D.
Kim Castelnovo, RPh	Alyssa Cilia, RPh
Kimberly Clark, Pharm.D.	Michael Evans, RPh
Michael Dubartell, MD	Jason Howay, Pharm.D.
Rajneel Farley, Pharm.D.	Mark Mowery, Pharm.D.
Kelly Faust Pharm.D.	Jonas Pearson, RPh
Tricia Heitzman, Pharm.D.	Angela Scarantino
Nichole Hossler, MD	William Seavey, Pharm.D.
Emily Hughes, Pharm.D.	Richard Silbert, MD
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Jamie Miller, RPh	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D	
Michael Shepherd, MD	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Luke Sullivan, MD	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Rachelle Moore (student)	
Prachi Trivedi (student)	

Call to Order:
Dr Yarczower called the meeting to order at 1:01 p.m., Tuesday, November 15, 2022

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Yarczower asked for a motion or approval to accept the September 20, 2022 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Amvuttra (vutrisiran)

Review: Amvuttra is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. Amvuttra is the third approved agent for the treatment of the polyneuropathy of hATTR, a rare, genetic, and progressive multi-organ disorder. Treatment options for hATTR have historically been limited to organ transplantation (liver, heart) or investigational agents. Vutrisiran is a double-stranded siRNA-GalNAc conjugate that causes degradation of mutant and wild-type transthyretin (TTR) mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Amvuttra joins Onpattro (patisiran), another small interfering ribonucleic acid (siRNA) treatment produced by the same manufacturer given as an IV infusion every 3 weeks as well as Tegsedi (inotersen), an antisense oligonucleotide (ASO) agent, self-administered as a weekly subcutaneous injection, as the third agent FDA approved for patients with polyneuropathy of hATTR. Both siRNA and ASO have similar mechanisms of action by targeting the mRNA of TTR, but differ by drug delivery, administration, efficacy, and safety. Currently there are two other agents in Phase 3 clinical trials being evaluated for the same indication. Amvuttra is a 25mg/0.5ml single-dose prefilled syringe administered by subcutaneous injection at a fixed dose of 25mg once every 3 months. Amvuttra should be administered by a healthcare professional. The FDA approval of Amvuttra is based on positive 9-month results from the Phase 3 HELIOS-A study (NCT03759379), a randomized, open-label, multicenter study of patients with polyneuropathy caused by hATTR amyloidosis. The trial included patients age 18-85 with a diagnosis of hATTR with a Neuropathy Impairment Score (NIS) of 5-130, and Polyneuropathy Disability (PND) score of <IIIb. Patients who received prior TTR-lowering treatment (Onpattro, Tegsedi) were excluded from the trial, however prior TTR stabilizer (Vyndamax, Vyndaqel) use was permitted, but therapy had to be discontinued prior to enrollment in the trial. The efficacy of Amvuttra was assessed by comparing the Amvuttra group in the HELIOS-A study with the placebo group from the Phase 3 APOLLO study (NCT01960348) of Onpattro. The primary endpoint was change from baseline to Month 9 in the modified neurologic impairment score + 7 (mNIS+7) and resulted in statistically significant improvements with the Amvuttra group having a 2.2 decrease in score from baseline compared to placebo group having a 14.8 increase in score from baseline (higher scores indicate severity of disease). The NIS objectively measures deficits in cranial nerve function, muscle strength, and reflexes, and the +7 assesses postural blood pressure, quantitative sensory testing, and peripheral nerve electrophysiology. Secondary endpoints evaluated in the trial included Change from baseline to Month 9 in the Norfolk quality of life-diabetic neuropathy (Norfolk QoL-DN) score, 10-meter walk test (10-MWT), and modified body mass index (mBMI), with statistically significant improvements seen in the Norfolk QoL-DN and 10-MWT scores for the Amvuttra group and the mBMI score nominally favoring the Amvuttra group. The most commonly reported adverse events in Amvuttra-treated patients included arthralgia (11%), dyspnea (7%), and vitamin A decrease (7%). A serious adverse reaction of atrioventricular (AV) block (heart block) occurred in 2 patients (1.6%) treated with Amvuttra, including one case of complete AV block. Injection site reactions were reported in 5 patients (4%) and were mild and transient. Because of the decrease in serum vitamin A levels, supplementation at the recommended daily allowance of vitamin A is advised for patients taking Amvuttra. Amvuttra has no black box warnings. Amvuttra has the convenience of a quarterly SC administration without the safety concerns and monitoring requirements of Tegsedi (REMS program for thrombocytopenia and glomerulonephritis) and given less frequently than the IV infused Onpattro. While

Tegsedi is self-administered, both Amvuttra and Onpattro have potential to be administered through Site of Care programs in the home by a healthcare professional. Thus, IPD Analytics anticipates Amvuttra will become a preferred product for the treatment of hATTR-PN. Amvuttra is also currently undergoing Phase 3 trials in the HELIOS-B study to evaluate it's effectiveness for treatment of patients with cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM), including both hATTR and wild-type ATTR (ATTRwt). Topline results are expected in early 2024.

Clinical Discussion: Dr Bret Yarczower recommended to update "geneticist" to "board certified medical geneticist". The committee voted unanimously to accept the amended recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Amvuttra will be covered as a medical benefit for GHP Family members and will be managed by GHP. It is recommended that Amvuttra require a prior authorization to ensure appropriate utilization. The following prior authorization criteria should apply.

- Prescription written by or in consultation with a neurologist, specialist at a hereditary transthyretin-mediated amyloidosis (hATTR) treatment center, or board certified medical geneticist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by all of the following:
    - Biopsy of tissue/organ to confirm amyloid presence AND
    - Immunohistochemistry or mass spectroscopy to differentiate ATTR amyloidosis from amyloid light-chain amyloidosis AND
    - Genetic testing to differentiate between hereditary and wild-type ATTR amyloidosis **AND**
- Medical record documentation of Amvuttra being used to treat polyneuropathy **AND**
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score of I, II, IIIA, or IIIB **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment

Note:
FAP stage:
1-unimpairmend ambulation
2- assistance with ambulation
3- wheelchair-bound or bedridden
Polyneuropathy disability score:
I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
IIIa- walking with 1 stick/crutch
IIIb- walking with 2 sticks/crutches
IV-wheelchair-bound or bedridden

Authorization Duration: Initial approval will be for 12 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 progresses to FAP stage 3 and/or polyneuropathy disability score IV (wheelchair-bound or bedridden).

Quantity Limit: 0.5 mL per 84 days to be coded in Darwin for claims processed through specialty vendor. Currently Amvuttra does not have a unique HCPCS code assigned to it and is billed with a miscellaneous Jcode when billed through medical. Alnylam Pharmaceuticals submitted an application to CMS in the 3rd quarter 2022 for a unique HCPCS code, these codes are expected to be released in January 2023. At that time a Facets RX count quantity limit should be added respective of the updated HCPCS code units to reflect a limitation of one 25mg (0.5ml) syringe every 3 months to policy quantity limit language.

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

Epsolay (benzoyl peroxide 5%)

Review: Epsolay is a recently approved topical cream for the treatment of inflammatory lesions of rosacea in adults. Epsolay is the only FDA-approved benzoyl peroxide product that is indicated for the treatment of inflammatory lesions of rosacea in adults. It is the first and only microencapsulated benzoyl peroxide product. The benzoyl peroxide is encapsulated within silica-based microcapsules which create a barrier between the skin and the medication. These microcapsules are designed to slowly release benzoyl peroxide over time which makes the product more tolerable and effective. It comes as a 5% cream in a 30-gram pump. Each gram of Epsolay contains 50 mg of benzoyl peroxide. Patients should prime the pump before use. It is recommended to apply a pea-sized amount once daily to each area of the face on clean and dry skin. Patients should avoid the eyes, lips, and mouth. Patients should wash hands after use and only use Epsolay for topical use. Epsolay was evaluated in two multicenter, randomized, double-blind, vehicle-controlled trials in subjects with moderate-to-severe papulopustular rosacea. These trials were conducted with 733 subjects who were all 18 years old or older. Patients were treated with either Epsolay or a vehicle cream for 12 weeks. Patients in the trial had to have a minimum of 15 to 70 inflammatory lesions and no more than 2 nodules. A nodule was defined as a papule or pustule greater than 5 mm in diameter. Patients also must have had an Investigator Global Assessment (IGA) score of 3 (moderate) or 4 (severe). IGA is a tool used to assess the severity of a patient's rosacea. There were two primary efficacy endpoints that were looked at in these trials. The first endpoint was based on the patient's IGA scores. A "treatment success" was defined as an IGA score of 0 (clear) or 1 (almost clear). The second endpoint was an absolute change in the number of inflammatory lesions when compared to baseline.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Epsolay is a pharmacy benefit and should not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of rosacea with inflammatory lesions AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

Formulary Alternatives: metronidazole (gel/cream/lotion), ivermectin 1% cream, azelaic acid gel

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

Priorix (Measles, Mumps, and Rubella Vaccine, Live)

Review: Priorix is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. Humoral immune responses against measles, mumps, and rubella viruses induced by Priorix were measured by enzyme-linked immunosorbent assays (ELISAs). IgG antibodies measured by the ELISAs used in clinical studies of Priorix have been shown to correlate with the presence of neutralizing antibodies that have been associated with protection**.**

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Priorix will be covered as a medical or pharmacy benefit and will not require prior authorization. Priorix will have an age limitation of 19 years of age or older for the pharmacy benefit. It is recommended that Priorix be added to the GHP Family formulary at the brand tier.

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

Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-replicating)

Review: Jynneos (Smallpox and Monkeypox Vaccine) was FDA approved in 2019 and is indicated for the prevention of smallpox and monkeypox infection in patients aged 18 years or older that are determined to be at high risk of contracting monkeypox or smallpox infection. Jynneos is currently not approved by the FDA for use in patients less than 18 years old, however, it is available for use, under an Emergency Use Authorization, indicating its use in adolescent and pediatric patients less than 18 years old. Under the EUA, it is recommended that children at risk/post-exposure prophylaxis (PEP) be considered for vaccination as young as 6 months. For a child younger than 6 months, the CDC recommends consulting with public health authorities for Jynneos use.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Jynneos will be both a medical and pharmacy benefit for subcutaneous administration for members aged 19 years or older. Jynneos will be a medical benefit only for intradermal administration. It will be added as a covered medication when commercially available

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

CaroSpir (spironolactone suspension)

Review: CaroSpir is available as a 25 mg/5 mL suspension (5 mg/mL). It is indicated for the treatment of Class III or IV heart failure and reduced ejection fraction, as add-on therapy for the treatment of hypertension, and for the management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restriction.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: CaroSpir is a pharmacy benefit and should not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Medical record documentation of an FDA approved indication AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary diuretics, one of which must be spironolactone tablets OR
- If the member has trouble swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to furosemide oral liquid OR
- If the member has trouble swallowing, medical record documentation of a diagnosis of heart failure.

Formulary Alternatives:
Loop diuretics: Bumetanide, Furosemide (tablets, solution), Torsemide
Potassium sparing diuretics: Spironolactone tablets, Spironolactone-hydrochlorothiazide, Eplerenone, Amiloride, Amiloride-hydrochlorothiazide, Triamterene-hydrochlorothiazide
Thiazide diuretics: Hydrochlorothiazide, Indapamide, Metolazone, Chlorthalidone

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

Line Extension Reviews 2022

MEDICATION	INDICATION	DOSAGE/ HOW SUPPLIED	FORMULARY ALTERNATIVES	RECOMMENDATIONS
ZILXI (minocycline topical foam)	Treatment of inflammatory lesions of rosacea in adults.	Apply a small amount of topical foam in a thin layer over all areas of the face. Each gram contains 15 mg of minocycline and is suppled in 30 gram of 1.5% foam in pressurized aluminum	metronidazole (gel/cream/lotion), ivermectin 1% cream, azelaic acid gel	Leave NF, Add to Epsolay Policy, • Medical record documentation of a diagnosis of rosacea with inflammatory lesions AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3)

		aerosol container		formulary alternatives
MINOLIRA ER (minocycline ER)	Treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older	Approximately 1 mg/kg once daily for 12 weeks. 105 and 135 mg tablets can be split along score lines and dosed according to patient body weight. 105 mg and 135 mg tablets in bottles of 30 tablets	Minocycline, doxycycline, tetracycline, azithromycin	Part of PDL and managed by DHS
CYSTADROPS (cysteamine ophthalmic)	Treatment of corneal cystine crystal deposits in adults and children with cystinosis.	One drop in each eye, four times daily during waking hours. Supplied as 5 mL sterile viscous solution in a 10 mL amber glass bottle	none	Leave NF, review with admin policy
EXSERVAN (riluzole oral film)	Treatment of amyotrophic lateral sclerosis (ALS)	50 mg twice daily, taken at least 1 hour before or 2 hours after a meal. 50 mg oral film, carton of 60 pouches	riluzole tablets, Tiglutik Suspension	Add to formulary, Add to Policy 1491.0F for Tiglutik

Outcome: The committee unanimously voted to accept the recommendations.

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

Updates

Benlysta

Recommendation: It is recommended to update the prior authorization criteria under systemic lupus erythematosus for medical benefit policy (MBP) 90.0 Benlysta and Medicaid Policy 1409.0F Benlysta Subcutaneous, to more closely align to the FDA-approved indication and to more closely reflect the regimens used in clinical trials.

Systemic Lupus Erythematosus:

- Medical record documentation of age ≥ 18 years
- Medical record documentation of active systemic lupus erythematosus **AND**
- Positive ANA and/or anti-dsDNA antibody **AND**
- ~~Concurrently receiving a stable treatment regimen with prednisone, NSAID, anti-malarial, or immunosuppressant~~ Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant) **AND**
- No CNS involvement **AND**
- Prescribed by a rheumatologist **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Lupus Nephritis:

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation of age greater than or equal to 18 **AND**
- Prescription written by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine) **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Outcome: The committee unanimously voted to accept the recommendation

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

Crysvita

Recommendation: It is recommended to update the prior authorization criteria and authorization duration for Crysvita to correctly reflect FDA-approved dosing recommendations and contraindications.

X-linked hypophosphatemia

- Medical record documentation that the patient is at least 6 months of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, geneticist, or nephrologist **AND**
- Medical record documentation of a diagnosis of X-linked hypophosphatemia as evidenced by one of the following:
    - Reduced TmP/GFR ratio **AND** Reduced or normal plasma concentration of 1,25-dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D [25(OH)D] **OR**
    - Genetic testing confirming a mutation in the PHEX (Phosphate regulating Endopeptidase on the X chromosome) gene

  AND

- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)

- Medical record documentation that the patient is at least 2 years of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, nephrologist, geneticist, or oncologist **AND**
- Medical record documentation of a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors **AND**
- Medical record documentation of an elevated serum level of FGF23 **AND**
- Medical record documentation that tumors cannot be curatively resected or localized **AND**
- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements.

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 and the following criteria are met:

- Medical record documentation that patient is being followed regularly by and receiving medication from an endocrinologist, nephrologist, geneticist or oncologist **AND**
- Medical record documentation that Crysvita is improving patient's disease as evidenced by normalized or improved serum phosphorus levels **AND**
- Medical record documentation that the patient is not concurrently using active Vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

Note: Per FDA labeling, supplementation with cholecalciferol or ergocalciferol is recommended to maintain 25-hydroxy vitamin D levels in the normal range for age.

Outcome: The committee unanimously voted to accept the recommendation

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

October ELECTRONIC VOTE

An electronic vote was held from October 17, 2022, to October 25, 2022. Responses were received from 32 members (out of 50 members) and all voted to approve. 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))

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.

No changes recommended to the formulary placement or authorization duration of Enhertu. 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:
    o Documentation of a prior anti-HER2 based therapy in the metastatic setting OR
    o 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 oh
• 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:
    o Documentation of a prior chemotherapy in the metastatic setting OR
    o 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

Imcivree (setmelanotide)

Updated Indication: Imcivree is now indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS). Previously, it was approved for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Pro-opiomelanocortic (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or Leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

In 2023, obesity will no longer be an excluded benefit. Imcivree will be non-formulary. It is recommended to add a prior authorization to Imcivree with the following criteria starting in 2023.

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:
    o For patients 16 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30kg/m2
    o 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) AND
• Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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:
    o For patients 18 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30 kg/m2
    o 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) AND
• Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved

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Raibni (rituximab-arrx)

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.

There are no changes recommended to the formulary placement or auth duration for Riabni. The following changes are recommended to the prior authorization criteria:

1. For Rheumatoid Arthritis:
All of the following criteria must be met:
• Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
• At least 18 years of age or older; **AND**
• Prescription written by a rheumatologist; **AND**
• Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
• Medical record documentation that Rituxan is not being used concurrently with a TNF blocker **AND**
• Physician documentation of an inadequate response to 12 weeks of therapy with Humira*, Rinvoq*, OR Xeljanz*

AND
• For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

AUTHORIZATION DURATION:
For Multiple Sclerosis: Initial approval will be for 12 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 and will require:
• Medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease **AND**
• For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

For all other indications: 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 and will require:
• Medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease **AND**
• For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima)

Meeting adjourned at 4:15 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on January 17th, 2023 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams