PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

This is the January 1, 2021 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

The Provider Alert, Prior Authorization Requirements, and Medical policies are all available on ProvLink and through the link above.

Number 255

January 1, 2021

We are searching for a handful of physicians to consider joining Oregon Region Pharmacy & Therapeutics Committee (ORPTC). This expert panel, comprised of practicing physicians, nurses, and pharmacists across various clinical specialties, reviews and evaluates the utilization and coverage for medications in the region. Additionally, ORPTC establishes the Providence Health Plan formularies and medication use policies to promote the clinically appropriate and cost-effective use of medications to improve the health of our population.

The meetings occur virtually every other month on the first Friday from 7:00 – 10:00 am. They start and finish on time to be respectful of your commitments outside of the ORPTC. Also, remuneration is provided to compensate for the time commitment to cover the meetings attendance.

Members are appointed to the committee by both the Oregon Region and the Providence Health Plan Chief Medical Officers. This is a great leadership opportunity! If you are interested in joining, or would like to nominate a physician, please contact:

Reina Natero
Email: Reina.natero@providence.org
t: (503) 574-6496

and/or
Lisa Hofmann,
Email: lisa.hofmann@providence.org
T: (503) 574-6497

Please feel free to distribute this information to potential candidates. Early career doctors are also welcome!
We look forward to hearing about your interest in a membership with the Oregon Region Pharmacy & Therapeutics Committee.

Here's what's new from the following policy committees:

MEDICAL POLICY COMMITTEE

Effective February 1, 2021

Colorectal Cancer Screening	**Interim update** Change age of routine screening for colorectal cancer with fecal immunochemical tests and fecal DNA testing to age 45 years or older (previously 50 years or older), based on new 2020 guidance from USPSTF.

Effective March 1, 2021

Skin and Tissue Substitutes
 	
MED378
	Annual Update
	• **Criterion X:** Medically necessary criteria was added for the use of skin substitutes to prevent Frey's Syndrome after parotidectomy, based on clinical recommendation.
	• **Criterion XI: recommend** adding the clarifying statement: "Repeat treatment *(i.e. any additional applications after the initial 12-week treatment period outlined in criteria VI. And VII. above)*" to specify that repeat treatment does not refer to the 5 applications mentioned in criteria VI and VII.
	• Add "Alloderm for complex nasal reconstruction" to Criterion XI (investigational indications), based on clinical recommendation
	• Add three products as investigational to Criterion XII: ENDURAGen, GalaFLEX Scaffold, and Stravix
	• The definition of code Q4133 was revised by AMA, therefore recommend changing the language in the CPT Code section.
	• **CMS:** Add two Medicare guidances. Neither has codes and both are in line with our policy:
	  ○ National Coverage Determination (NCD) for Porcine SKIN and Gradient Pressure Dressings (270.5)
	  ○ Local Coverage Article: Use of Amniotic Membrane Derived SKIN SUBSTITUTEs (A56156)
	Codes/PA:
	• Add Codes C1763 and C1781 with no PA, corresponding to the investigational products added to criteria.

VENDOR UPDATES

Updates to AIM Advanced Imaging of the Heart Clinical Appropriateness Guideline

Effective for dates of service on and after **March 14, 2021**, the following updates will apply to the AIM Advanced Imaging of the Heart Clinical Appropriateness Guidelines.

Evaluation of patients with cardiac arrhythmias

- Updated repeat TTE criteria
- Added restrictions for patients whose initial echocardiogram shows no evidence of structural heart disease, and follow-up echocardiography is not appropriate for ongoing management of arrhythmia.

Evaluation of signs, symptoms, or abnormal testing

- Added restrictions for TTE in evaluation of palpitation and lightheadedness based on literature.

For questions related to guidelines, please contact AIM via email at aim.guidelines@aimspecialtyhealth.com. Additionally, you may access and download a copy of the current and upcoming guidelines here.

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting December 4, 2020

Go-Live Date: Monday, February 01, 2021, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Berotralstat (Orladeyo) Capsule**
   a. **Indication**: Prophylactic treatment against angioedema attacks in hereditary angioedema
   b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**

Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	Yes	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	1 capsule per day	1 capsule per day	1 capsule per day
Audit			
Formulary Alternatives: Cinryze (plasma-derived nanofiltered C1 INH IV), Haegarda (plasma-derived nanofiltered C1INH SC), Takhzyro (lanadelumab SC)			

c. Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Cinryze, Haegarda, Takhzyro
MEDICATION NAME	Orladeyo (berotralstat)
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	Combination prophylaxis therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®
REQUIRED MEDICAL INFORMATION	All of the following must be met: 1. Documentation of **one** of the following clinical criteria: a. Self-limiting, noninflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or c. Recurrent laryngeal edema **AND** 2. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (eg. estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary **AND** 3. One of the following: a. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show: i. C4 is less than 50 percent of the lower limit of normal **AND** ii. **one** of the following: a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or

	b. C1-INH function is less than 50 percent of the lower limit of normal b. For HAE with normal C1-INH or HAE Type III: i. Confirmed Factor 12 (FXII) , ANGPT1, PLG, KNG1 gene mutation **OR** ii. Positive family history for HAE **AND** attacks lack response with high dose antihistamines or corticosteroids. For coverage of Cinryze®: Documentation of trial and failure or contraindication to Haegarda®. REAUTHORIZATION: Documentation must be provided showing benefit of therapy with reduction of frequency and severity of HAE attack episodes by greater than or equal to 50% from baseline.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an immunologist or an allergist.
COVERAGE DURATION	Initial prior authorization will be approved for 3 months. Reauthorization may be approved for one year.

d. Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	CINRYZE/HAEGARDA/TAKHZYRO
MEDICATION NAME	Orladeyo (berotralstat)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Combination prophylaxis therapy with Cinryze®, Haegarda®, or Takhzyro®
REQUIRED MEDICAL INFORMATION	All of the following must be met: 1. Diagnosis of Hereditary Angioedema (HAE) Type I, II or III. 2. One of the following: A. For HAE Type I and Type II, documentation of a complement study that shows: i. C4 less than 50 percent of the lower limit of normal AND ii. One of the following: C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal or C1-INH function is less than 50 percent of the lower limit of normal. B. For HAE with normal C1-INH or HAE Type III, one of the following: i. Confirmed Factor 12 (FXII) mutation OR ii. Positive family history for HAE AND attacks that lack response with high dose antihistamines or corticosteroids. 3. Dosing regimens are within FDA labeled dosing outlined in package insert or sufficient evidence-based rationale is provided for increased dosing and/or frequency.

	4. For coverage of Cinryze: Documentation of trial and failure or contraindication to Haegarda. Reauthorization requires documentation of benefit of therapy with reduction of frequency and severity of HAE attacks.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an immunologist or an allergist.
COVERAGE DURATION	Initial prior authorization will be approved for 3 months. Reauthorization may be approved for one year.

2. Roxadustat (Evrenzo)

a. **Indication**: Not FDA approved in the United Stated. Undergoing FDA review with an anticipated decision expected at the end of the 2020 year.

b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-Formulary	Non-Formulary	Part D: Non-Formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: epoetin alfa (Epogen®/Procrit®/Retacrit®), darbepoetin alfa (Aranesp®), methoxy polyethylene glycol-epoetin beta (Mircera®)			

c. **Proposed Prior Authorization Criteria for Commercial/Medicaid Decision:**

PA PROGRAM NAME	Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitors
MEDICATION NAME	Roxadustat (Evrenzo)
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA	Patients with uncontrolled hypertension
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy, AND 2. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% For reauthorization: 1. Documentation of continued medical necessity (e.g. ongoing chronic kidney disease), AND 2. Documented HGB levels of less than or equal to 12g/dl within previous 30 days
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Medication must be prescribed by, or in consultation with, a hematologist/oncologist or nephrologist
COVERAGE DURATION	Initial authorization and reauthorization will be for one (1) year

d. **Proposed Prior Authorization Criteria for Medicare Part D if FDA approval is granted:**

PA PROGRAM NAME	HIF-PH Inhibitors
MEDICATION NAME	Roxadustat (Evrenzo)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Patients with uncontrolled hypertension
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy, AND 2. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% For reauthorization: 1. Documentation of continued medical necessity (e.g. ongoing chronic kidney disease), AND 2. Documented HGB levels of less than or equal to 12g/dl within previous 30 days

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization and reauthorization will be for one (1) year

3. Belantamab mafodotin-blmf (Blenrep) Vial

a. **Indication**: Treatment of adults with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
- This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Audit			
Formulary Alternatives: None			

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B:** Add to Injectable Anti-cancer Medications policy

4. Decitabine-cedazuridine (Inqovi) Tablet

a. Indication: Treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

b. Decision:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Formulary

Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: lenalidomide, IV azacitidine, IV decitabine			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Add to oral anti-cancer agents policy
d. **Prior Authorization Criteria for Medicare Part D:** Add to anti-cancer agents program

5. Tafasitamab-cxix (Monjuvi) Vial

a. **Indication**: Adult patients with diffuse large B-cell lymphoma, relapsed or refractory, including disease arising from low-grade lymphoma, and not eligible for autologous stem cell transplant, in combination with lenalidomide

b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Part D: Non-Formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Audit			
Formulary Alternatives:			

c. **Prior Authorization Criteria**: Add to injectable anti-cancer medications policy

6. Pralsetinib (Gavreto) Capsule

a. Indication: Treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)

b. Decision:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-Preferred Specialty	Specialty	Specialty

Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: selpercatinib (Retevmo™) oral capsule			

c. **Prior Authorization Criteria for Commercial/Medicaid:** Add to oral anti-cancer medications policy
d. **Prior Authorization Criteria for Medicare Part D**: Add to anti-cancer agents program

7. Viltolarsen (Viltepso) Vial

a. **Indication**: Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
   - This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with viltolarsen. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Part D: Non-Formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Audit			
Formulary Alternatives: prednisone, deflazacort (Emflaza®)			

c. **Prior Authorization Criteria**: Add to Exon-Skipping Therapies For Duchenne Muscular Dystrophy policy

PA PROGRAM NAME	Exon-Skipping Therapies For Duchenne Muscular Dystrophy
MEDICATION NAME	Exondys® 51 (eteplirsen vial), Vyondys® 53 (golodirsen vial), Viltepso® (vitolarsen vial)

POLICY	Eteplirsen (Exondys® 51), golodirsen (Vyondys® 53) and vitolarsen (Viltepso®) are not considered medically necessary and will not be covered due to the lack of clinical evidence of improved outcomes and safety.

8. Monomethyl fumarate (Bafiertam) Capsule DR

a. **Indication**: Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

b. **Decision**: Effective 1/1/2021

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Step Therapy	Step Therapy	N/A
Quantity Limit			
Audit			
Formulary Alternatives: dimethyl fumarate, Rebif®, Gilenya®, Avonex®, Aubagio®			

c. **Prior Authorization Criteria**:

PA PROGRAM NAME	Non-preferred fumarate products
MEDICATION NAME	Bafiertam
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Documented trial or contraindication to dimethyl fumarate
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

9. Amisulpride (Barhemsys) Vial

a. **Indication**: Indicated in adults for prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class or for treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.
b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
Audit			
Formulary Alternatives: PONV prevention: ondansetron, dexamethasone, scopolamine, metoclopramide; PONV treatment: ondansetron, prochlorperazine, metoclopramide			

c. **Prior Authorization Criteria**: N/A

10. Risdiplam (Evrysdi) Soln Recon
a. **Indication**: Treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.
b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	N/A	N/A	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: None			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Evrysdi
MEDICATION NAME	Risdiplam powder for oral solution
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	1. Use in combination with Spinraza (nusinersen) therapy 2. Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)
REQUIRED MEDICAL INFORMATION	Initial authorization 1. The patient has a diagnosis, confirmed by genetic testing, of Spinal Muscular Atrophy (SMA) type 1, 2, or 3 2. Patient does not require invasive ventilation or tracheostomy 3. Baseline assessment with an age appropriate tool that establishes baseline motor ability must be submitted (e.g., HINE-2, HFSME, CHOP-INTEND, MFM-32) 4. Requested dose is within FDA labeling Reauthorization: 1. Documentation of response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (e.g., stabilization or improvement in motor function test scores performed at baseline) 2. Requested dose is within FDA labeling
AGE RESTRICTIONS	May be covered for patients aged 2 months and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for 12 months.

d. **Prior Authorization Criteria for Medicare Part D**:

PA PROGRAM NAME	Evrysdi
MEDICATION NAME	Risdiplam powder for oral solution
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	1. Use in combination with Spinraza (nusinersen) therapy 2. Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)

REQUIRED MEDICAL INFORMATION	Initial authorization 1. The patient has a diagnosis, confirmed by genetic testing, of Spinal Muscular Atrophy (SMA) 2. Baseline assessment with an age appropriate tool that establishes baseline motor ability must be submitted (i.e. HINE-2, HFSME, CHOP-INTEND, MFM-32) 3. Requested dose is within FDA labeling Reauthorization: 1. Documentation of response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (e.g., stabilization or improvement in motor function test scores performed at baseline) 2. Requested dose is within FDA labeling
AGE RESTRICTIONS	May be covered for patients aged 2 months or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for 12 months.

New Drug Strengths and Formulations:

1. **Oxymetazoline hcl-pf (Upneeq) Droperette**
   a. **Indication**: Treatment of acquired belpharoptosis in adults.
   b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	Brand	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	One droperette/day	One droperette/day	One droperette/day
Audit			
Formulary Alternatives: None			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Upneeq
MEDICATION NAME	Upneeq 0.1% eye drops
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	Congenital ptosis, Horner syndrome, myasthenia gravis, mechanical ptosis, or visual field loss from any cause other than ptosis
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Documentation of acquired blepharoptosis 2. Documentation of a superior visual field deficit [e.g. inability to detect at least 8 of 17 points in the top 2 rows on the Leicester Peripheral Field Test (LPFT)] 3. Marginal reflex distance 1 (MRD-1) of less than or equal to 2 mm Reauthorization requires documentation of improvement in visual field deficit
AGE RESTRICTIONS	N/A if none
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an ophthalmologist
COVERAGE DURATION	Initial authorization will be for 6 months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

d. **Prior Authorization Criteria for Medicare Part D**:

PA PROGRAM NAME	Upneeq
MEDICATION NAME	Upneeq 0.1% eye drops
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Congenital ptosis, Horner syndrome, myasthenia gravis, mechanical ptosis, or visual field loss from any cause other than ptosis
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Documentation of acquired blepharoptosis

	2. Documentation of a superior visual field deficit [e.g. inability to detect at least 8 of 17 points in the top 2 rows on the Leicester Peripheral Field Test (LPFT)] 3. Marginal reflex distance 1 (MRD-1) of less than or equal to 2 mm Reauthorization requires documentation of improvement in visual field deficit
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an ophthalmologist
COVERAGE DURATION	Initial authorization will be for 6 months. Reauthorization will be approved until no longer eligible with the plan

2. Octreotide acetate (Mycapssa) Capsule DR

a. **Indication**: Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	4 capsules/day	4 capsules/day	4 capsules/day
Audit			
Formulary Alternatives:			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Oral Octreotide
MEDICATION NAME	Octretide (Mycapssa) Capsule DR
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Confirmed diagnosis of acromegaly, AND

	2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation, AND 3. Patient has been maintained (for at least 6 months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy. Reauthorization required documentation of a positive clinical response to therapy (e.g. reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization and reauthorization for 12 months

d. **Prior Authorization Criteria for Medicare Part D**:

PA PROGRAM NAME	Oral Octreotide
MEDICATION NAME	Octretide (Mycapssa) Capsule DR
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Confirmed diagnosis of acromegaly, AND 2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation, AND 3. Patient has been maintained (for at least 6 months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy. Reauthorization requires documentation of a positive clinical response to therapy (e.g. reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization and reauthorization for 12 months

3. Ofatumumab (Kesimpta Pen) Pen Injctr

a. **Indication**: Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

b. **Decision**:

Health Plan			
	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
Audit			
Formulary Alternatives: dimethyl fumerate, Aubagio®, Gilenya®			

c. **Prior Authorization Criteria**: N/A

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Fluticasone propionate/salmeterol xinafoate (Airduo Digihaler) AER PW BAS	New Inhalation Device. • Commercial/Medicaid: Non-Formulary, Quantity Limit (1 inhaler per 30 days) • Medicare Part D: Non-Formulary	N/A
Fluticasone propionate (Armonair Digihaler) AER PW BAS	New dosage form. • Commercial/Medicaid: Non-Formulary, Quantity Limit (1 inhaler per 30 days) • Medicare Part D: Non-Formulary	N/A
Dolasetron (Anzemet) tablets	Remove from Commercial formulary as drug is now obsolete	N/A
Budesonide/glycopyrrolate/formoterol fumarate (Breztri Aerosphere) HFA AER AD	New combination. • Non-Formulary for all lines of business	N/A
Arformoterol tartrate (Brovana) Vial-Neb	Remove from Specialty for Commercial and Medicaid	N/A

	• Commercial: Formulary, Tier 4, Quantity Limit (4 vials/day) • Medicaid: Non-Formulary	
Cysteamine hcl (Cystadrops) Drops	Add to formulary • Commercial: Formulary, Tier 6, Quantity Limit (20 ml per 28 days) • Medicaid: Formulary, Quantity Limit (20 ml per 28 days) • Medicare Part D: Formulary, Tier 5, Quantity Limit (20 ml per 28 days)	N/A
Metoclopramide hcl (Gimoti) Tablet	New Route (Nasal), Dosage Form (Spray/Pump), and Strength (15mg). • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (9.8 ml per 28 days [1 bottle per 28 days]) • Medicaid: Non-Formulary, Quantity Limit (9.8 ml per 28 days [1 bottle per 28 days]) • Medicare Part D: Non-Formulary, FDA Max (9.8 ml per 28 days [1 bottle per 28 days])	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Imatinib mesylate (Gleevec) 100 mg and 400 mg Tablet	Commercial/Medicaid (Brand only): Add Prior Authorization Effective 03/01/2021	Commercial/Medicaid: Brand Over Generic
Dimethyl fumarate (Tecfidera) 120 mg and 240 mg Capsule DR	Commercial/Medicaid (Brand only): Add Prior Authorization Effective 03/01/2021	Commercial/Medicaid: Brand Over Generic
Heparin Flush/Lock	Medicaid: Remove from Formulary, Medical Benefit	N/A
Heparin sodium, porcine 5000/ml and 20000/ml Vial	Add to Commercial formulary; • Standard: Formulary, Tier 2 • Cost-Based: Formulary, Tier 4	N/A
Heparin sodium, porcine 5000/ml Syringe	Add to formulary for Medicare Part D: Formulary, Tier 3	N/A
Heparin sodium, porcine/PF 5000/ml Syringe	Add to formulary for Commercial and Medicare Part D:	N/A

	• Standard: Formulary, Tier 2 • Cost-Based: Formulary, Tier 4 • Medicare Part D: Formulary, Tier 3	
Heparin sodium, porcine/PF 50000/ml Vial	Add to Commercial and Medicare Part D formulary; • Standard: Formulary, Tier 2 • Cost-Based: Formulary, Tier 4 • Medicare Part D: Formulary, Tier 3	N/A

Heparin sodium, porcine/PF 5000/0.5ml Syringe	Add to formulary;
	• Commercial:
	  ○ Standard: Formulary, Tier 2
	  ○ Cost-Based: Formulary, Tier 4
	• Medicaid: Formulary
	• Medicare Part D: Formulary, Tier 3
		N/A

Heparin sodium, porcine 1000/ml Vial	Medicaid: Remove from Formulary, Medical Benefit	N/A
Heparin sodium, porcine/PF 1000/ml Vial	Medicaid: Remove from Formulary, Medical Benefit	N/A
Immediate-release opioids: • **Hydromorphone** • **Morphine Sulfate** • **Oxaydo** • **Oxycodone hcl** • **Oxymorphone hcl** • **Roxybond**	Commercial: Remove Quantity Limits, as high-doses will be evaluated with cumulative 90MME edit Effective 01/01/2021	N/A
Budesonide (Ortikos) Capsule ER	New Strength (6mg), Dosage Form (ER Capsule). • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Travoprost Drops	Add to Medicaid formulary	N/A
Diroximel fumarate (Vumerity) Capsule DR	• Commercial: Change from Tier 5 to Tier 6, add Step Therapy through dimethyl fumarate (Tecfidera®) • Medicaid: Remove from formulary Effective 01/01/2021	• Commercial: Vumerity • Medicaid: N/A

Zoster vaccine live/pf (Zostavax) Vial	Remove from Medicare Part D formulary as drug is no longer being manufactured in the U.S.	N/A
Darifenacin hydrobromide (Enablex) Tab ER 24H	Add to Medicaid formulary: Formulary, Step Therapy	Overactive Bladder Medications
Fesoterodine fumarate (Toviaz) Tab ER 24H	Add to Medicaid formulary: Formulary, Step Therapy	Overactive Bladder Medications
Solifenacin succinate (Vesicare) Tablet	Remove step therapy for Commercial and Medicaid. Change tiers for Commercial and Medicare Part D • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	• Commercial/Medicaid: Overactive Bladder Medications • Medicare Part D: N/A
Fidaxomicin (Dificid) Tablet	• Commercial: Change from Tier 6 to Tier 4 • Medicaid: Remove from Specialty Tier	Dificid
Atovaquone (Mepron) Oral Susp	Commercial: Remove from Specialty tier • Standard: Formulary, Tier 2, Prior Authorization • Cost-Based: Formulary, Tier 4, Prior Authorization	Mepron
Posaconazole (Noxafil) Oral Susp/Tablet DR	Remove from Specialty for Commercial and Medicaid • Commercial: Formulary, Tier 4, Prior Authorization • Medicaid: Formulary, Prior Authorization	Antifungal Agents
Sinecatechins (Veregen) Ointment	Remove from Specialty for Commercial and Medicaid	Veregen

	• Commercial: Formulary, Tier 4, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization	

The formulary status for the following drugs was line extended in accordance with Providence Health Plan Pharmacy Operational Policy ORPTCOPS062

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Dulaglutide (Trulicity) Pen Injctr	New Strengths (3mg/0.5ml; 4.5mg/0.5ml). Line extend with Trulicity; • Commercial: Formulary, Tier 3, Quantity Limit (2 ml per 28 days), Step Therapy • Medicaid: Formulary, Quantity Limit (2 ml per 28 days), Step Therapy • Medicare Part D: Formulary, Tier 3	• Commercial: GLP-1 Receptor Agonists • Medicaid: GLP-1 Receptor Agonists – Medicaid • Medicare Part D: N/A
Meningococcal vaccine a,c,y and w-135,conj tetanus toxoid/pf (Menquadfi) Vial	New formulation. Line extend with Menhibrix vaccine; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Formulary, Tier 3	N/A
Polatuzumab vedotin-piiq (Polivy) Vial	New Strength (30mg). Line extend with Polivy 140mg; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Injectable Anti-Cancer Medications
Fluticasone furoate/umeclidinium bromide/vilanterol trifenat (Trelegy Ellipta) Blst w/Dev	New Strength (200-62.5-25). Line extend with Trelegy Ellipta 100-62-5.25; • Commercial/Medicare Part D: Formulary, Tier 3 • Medicaid: Formulary, Step Therapy	• Commercial/Medicare Part D: N/A • Medicaid: Trelegy Ellipta Step Therapy

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Emtricitabine Capsule	First Generic (Emtriva). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Peg 3350/sodium sulfate/sod chloride/kcl/ascorbate sod/vit c Powd Pack	First generic (Moviprep). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Sapropterin dihydrochloride Tablet Sol	First generic (Kuvan). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Kuvan
Diclofenac submicronized (Diclofenac) Capsule	First generic (Zorvolex). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Tobramycin Ampul-Neb	First generic (Bethkis). Line extend as generic; Medical Benefit for all lines of business	N/A

Efavirenz/lamivudine/tenofovir disoproxil fumarate Tablet	First generic (Symfi/Symfi Lo). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Deferiprone Tablet	First Generic (Ferriprox). Line extend as generic; • Commercial: Formulary, Tier 6 • Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary	N/A
Lapatinib ditosylate Tablet	First Generic (Tykerb). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Dimethyl fumarate Capsule DR	First Generic (Tecfidera Starter Pack). Line extend as generic; • Commercial: Formulary, Tier 5, Quantity Limit (2 capsules per day) • Medicaid: Formulary, Quantity Limit (2 capsules per day) • Medicare Part D: Formulary, Tier 5	N/A
Fosfomycin tromethamine Packet	First Generic (Monurol). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A

Efavirenz/emtricitabine/tenofovir disoproxil fumarate Tablet	First Generic (Atripla). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Emtricitabine/tenofovir disoproxil fumarate Tablet	First Generic (Truvada). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Tolvaptan Tablet	First Generic (Samsca). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Tolvaptan • Medicare Part D: Samsca/Jynarque

Clinical Policy Changes:

Policy Name	Summary of Change
Actinic Keratosis Agents	Removed exclusion criteria of use for pain. This was an exclusion for diclofenac 3%, which is no longer on this policy.
Aczone	Removed mention of Medicaid from this policy as this policy does not apply to Medicaid. Medicaid review should be based on line status and non-formulary review.

Albenza, Emverm	Updated covered uses to include all medically accepted indications to help address requests for off label, but clinically appropriate cases. All indications, except pinworms, will require infectious disease prescriber or that the diagnosis is confirmed by laboratory testing.
Alinia	Updated covered uses to include all medically accepted indications to help address requests for off label, but clinically appropriate cases. Indications which are not FDA approved will require infectious disease physician or gastroenterologist prescriber.
Antifungal Agents	• Treatment of blastomycosis or histoplasmosis: Added posaconazole to coverage option for treatment to align with recommendations from the Infectious Disease Society of America (IDSA) and Sanford Guide for Antimicrobial Stewardship. • For Prophylaxis of Aspergillus or Candida infections: Updated coverage statement for from specific covered conditions to those who are severely immunocompromised. This to allow for more prescriber and pharmacist discretion on appropriate therapy and to better align with IDSA recommendations. • For dermatomycosis: Added option of trial and failure of topical therapy in addition to current criteria of topical agents not practical. • For mucromycosis: added posaconazole as covered option to align with treatment recommendations from the European Society of Clinical Microbiology and Infectious Diseases Fungal Infection Study Group; European Confederation of Medical Mycology and the European Conference on Infections in Leukemia (ECIL).
Antimalarial Agents	Removal of pyrimethamine coverage for treatment of acute malaria. Indication for treatment of malaria removed from FDA label (6/21/2017) and use not supported by either Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO) for treatment of malaria.
Arikayce	Removal of criteria for requirement of IV aminoglycosides and inhaled amikacin sulfate. Updated practice guidelines issued by the American Thoracic Society, the European Respiratory Society, the European Society of Clinical Microbiology and Infectious Diseases and the Infectious Diseases Society of America (ATS/ERS/ESCMID/IDSA) recommend amikacin liposome inhalation suspension for those who remain Mycobacterium avium complex (MAC) positive after 6 months of guideline directed therapy (i.e., triple drug plus IV aminoglycoside therapy initially if indicated). They support liposome formulation over parenteral formulation for inhalation unless liposome inhalation suspension is not available.
Botulinum Toxin	Updated criteria for anal fissures to clarify exclusions of combination therapy. In addition, a new indication for Xeomin® was added.
Brand Over Generic	New Policy – this policy was created to aid in the review of medical necessity for the use of brand name formulations when a generic therapeutically equivalent formulation is available.
Cholbam	Updated criteria to require baseline liver function tests (LFTs) with initiation and LFTs for reauthorization to assess efficacy.

Continuous Glucose Monitors for Personal Use - Medicaid	The criteria were updated to align with medical policy for all advanced diabetes medical technology. The hope is to have consistent criteria across all products and place of service.
Continuous Glucose Monitors for Personal Use	The criteria were updated to align with medical policy for all advanced diabetes medical technology. The hope is to have consistent criteria across all products and place of service.
Denavir, Sitavig, Xerese, Zovirax	Quantity Limit added to only allow two treatments per year (or two doses) as these medications are not intended for use as suppressive agents. The coverage duration was recently extended, so this is being implemented to prevent misuse.
Disposable Insulin Pumps	The criteria were updated to align with medical policy for all advanced diabetes medical technology. The hope is to have consistent criteria across all products and place of service.
Doptelet, Mulpleta	Added other thrombopoietin receptor agonists (e.g., eltrombopag or romiplostim) as options for prerequisite therapies to align with the American Society of Hematology 2019 guidelines for immune thrombocytopenia.
Dronabinol	Add Syndros® (dronabinol oral solution) to policy. Coverage of Syndros® will require documentation that patient cannot take oral capsules. Criteria also updated to clarify prerequisite therapies available on formulary.
Enstilar, Taclonex, Taclonex Scalp	Simplified criteria. Requiring use of calcipotriene cream or solution and betamethasone (as separate products) as these are the most cost effective. Calcipotriene & betamethasone aerosol foam (Enstilar®) is the most expensive product and will also requires use of a Taclonex product prior to approval. Added criteria for Medicaid to align with Oregon Health Authority guidance.
Eucrisa	Added criteria for Medicaid that requires mild to moderate severity for coverage based on Oregon Health Authority guidance.
Givlaari	Criteria related to prophylactic hemin use was updated so patients currently on prophylactic hemin are eligible for treatment, even without attacks within the last year. In addition, criteria related to concomitant use of hemin and appropriate dosing were added.
Hepatitis C - Direct Acting Antivirals	Updated criteria to remove genotype requirement unless patient is cirrhotic, treatment-experienced or is using a DAA that is not pangenotypic.
Hepatitis C - Direct Acting Antivirals - Medicaid	Remove pregnancy testing requirement to match Medicaid fee-for-service PA criteria (updated on September 1 2020) to comply with the Hep C Risk Corridor Contract.
Immune Gamma Globulin (IGG)	Criteria updated for primary immunodeficiency to allow for more subtypes and updated with IgG laboratory values based on guidelines. Criteria also updated for B-cell chronic lymphocytic leukemia and post-stem cell transplantation.
Lotronex	Updated trial and failure criteria to align with recommendations from the American Gastroenterological Association, World Gastroenterology Organization and American College of

	Gastroenterology. Updated duration of approval for initial authorization and reauthorization. In addition, added prior authorization and policy criteria to Medicaid line of business.
Medical Nutrition Medicare Part B	Updated to align with CMS National Coverage Determinations, as all Local Coverage Determinations were retired. Added exclusions to policy that are already excluded from coverage based upon CMS coding and billing guidelines. In-line digestive enzyme cartridge (Relizorb) no longer excluded from coverage.
Mepron	Prevention or treatment of pneumocystis pneumonia (PCP) will be covered until the patient is no longer eligible with the health plan.
New Medications and Formulations without Established Benefit	Gimoti (metoclopramide nasal spray) is added to this policy. Exception is allowed if there is documentation that patient cannot take medication by mouth.
Non-Preferred ARBs	Medicaid was removed from this policy and these agents will remain non-formulary to align with Oregon Health Authority.
Ocaliva	Removed specific criteria to assess a failure of treatment with ursodiol. Inadequate response will be left to assessment by the prescribing physician.
Overactive Bladder Agents	Solifenacin (generic Vesicare) will no longer require prerequisite therapy, as it is available as a low-cost generic medication. Solifenacin was added as a prerequisite therapy requirement for other branded, less cost-effective agents.
Oxbryta	Covered Uses section was updated to outline this medication will only be covered for sickle cell disease at this time.
Promacta	Increase initial coverage duration to 6 months and reauthorization to 12 months for both chronic immune thrombocytopenia and severe aplastic anemia as long-term therapy often appropriate.
Reblozyl	Criteria for myelodysplastic syndromes was updated to align with National Comprehensive Cancer Network (NCCN) guidelines.
Serotonin Antagonists	Removed Anzemet from policy and changed formulary status to non-formulary for Commercial and Medicaid as drug is now obsolete.
Soliris	Updated criteria for compliment mediated hemolytic uremic syndrome to include an option for medical rationale explaining why plasma therapy is not appropriate. For neuromyelitis optica spectrum disorder updated criteria to exclude coverage when used in combination with other drug classes that treat the condition such as other complement inhibitors, IL-6 inhibitor, anti-cd19 therapy. For all indications, added criteria to both initial and reauthorization criteria requiring that the dose and frequency requested is within the FDA label recommendations.
Sublingual Immunotherapy with Allergen-specific Pollen Extracts (SLIT)	Updated start time of Oralair from 14 weeks to 16 weeks prior to start of allergy season to match labeling.

Therapeutic Immunomodulators (TIMs) - Commercial	Updates to preferred products based on new cost-positioning contracts available starting 1/1/21
Topical Antibiotics	Change to a step therapy policy and update to authorization until no longer eligible with the plan.
Total Parenteral Nutrition (TPN) - Medicare Part B	Updated to align with CMS National Coverage Determinations as Local Coverage Determinations retired.
Uceris	Policy updated to include criteria for off-label diagnosis of microscopic colitis for Uceris® tablets.
Ultomiris	Updated criteria for compliment mediated hemolytic uremic syndrome to include an option for medical rationale explaining why plasma therapy is not appropriate. For all indications, added criteria to both initial and reauthorization criteria requiring that the dose and frequency requested is within the FDA label recommendations.
Viberzi	Updated trial and failure criteria to align with recommendations from the American Gastroenterological Association, World Gastroenterology Organization and American College of Gastroenterology. Reauthorization criteria has been removed as the duration of approval has been changed until no longer eligible with the plan. In addition, policy criteria and prior authorization has been applied to the Medicaid line of business.
Xiaflex	The policy was update to allow criteria for coverage of Xiaflex® for Peyronie's Disease. This indication was previously excluded, but will now be allowed if patient meets criteria outlined in the American Urological Association guidelines and has a functional impairment.
Xifaxan	Updated trial and failure criteria to align with recommendations from the American Gastroenterological Association, World Gastroenterology Organization and American College of Gastroenterology. In addition, removed requirement of trial of dietary modification as criteria almost always met but causes significant operational burden to obtain the information.
Zinplava	Updated policy initial and reauthorization criteria based on FDA approved label, Infectious Disease Society of America guideline, and infectious disease expert opinion. A follow-up extension study for the MODIFY II trial was published and evaluated.

New Indications:

a. **SPRAVATO®**
ESKETAMINE

New indication approved 07/31/2020:

- **in conjunction with an oral antidepressant, for the treatment of:**
  - **Treatment-resistant depression (TRD) in adults.**

- **Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial and Medicare Part B policy will be updated as follows:

PA PROGRAM NAME	**Spravato**
MEDICATION NAME	Spravato (esketamine nasal spray)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	• Concomitant use with another dissociative agent • Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation • History of intracerebral hemorrhage • Current or prior DSM-5 diagnosis of a psychotic disorder or MDD with psychosis, bipolar or related disorders, comorbid obsessive compulsive disorder, intellectual disability, autism spectrum disorder, borderline personality disorder, antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder • Current or recent history (i.e. within the last 6 months) of moderate or severe substance or alcohol use disorder
REQUIRED MEDICAL INFORMATION	For initial authorization for treatment resistant depression (TRD) <u>all</u> of the following criteria must be met: 1. Individual has been diagnosed with treatment-resistant depression (TRD) by a psychiatrist within the previous 3 months. Clinical documentation must be provided that outlines the patient evaluation, plan for on-going management, and treatment options reviewed. 2. Baseline score from one of the following standardized depression rating scales confirming severe depression: a. HAMD17 b. QIDS-C16 c. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28 3. Individual has tried and failed three oral antidepressants in at least two different therapeutic classes for at least 8 weeks of treatment at the highest tolerable dose or the FDA-approved maximum dose for the medication 4. Individual has tried and failed augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly) 5. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy

6. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For reauthorization, **all** of the following criteria must be met:
1. Documentation of clinical improvement in depression symptoms as measured by a clinically significant decrease in baseline depression rating scores
2. Documentation of on-going management with a psychiatrist at minimum of every three (3) months
3. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For initial authorization for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior all of the following criteria must be met:
1. Individual has been diagnosed with depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior by a psychiatrist
2. Baseline score from one of the following standardized depression rating scales confirming severe depression:
    a. MADRS total score of at least 28
    b. HAMD 17
    c. QIDS-C 16
3. Individual received standard of care treatment including one of the following:
    a. Initiation of an antidepressant; or
    b. Optimized oral antidepressant; or
    c. Added augmentation therapy to current antidepressant
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For continuation of care post initiation in inpatient setting **all** of the following criteria must be met:
1. Documentation of the number of doses provided in the inpatient setting
2. Documentation of clinical improvement in depression symptoms as measured by a clinically significant decrease in baseline (upon admission) depression rating scores
3. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

	Note: Approval will be limited to completion of one month of therapy, inclusive of doses received as inpatient. Continuation of therapy beyond this will require satisfying the criteria for TRD outlined above.
AGE RESTRICTIONS	Approved for 18 years and older
PRESCRIBER RESTRICTIONS	Prescribed by or in consultation with a psychiatrist
COVERAGE DURATION	For treatment resistant depression: Initial authorization will be approved for three months. Reauthorization will be approved for 6 months For Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior: Initial authorization will be approved for one month, inclusive of doses received as inpatient. Reauthorization will only be approved if treatment resistant depression criteria are met.

b. XEOMIN®
INCOBOTULINUMTOXINA
New indication approved 08/18/2020:
Treatment or improvement of:
- **Chronic sialorrhea in adults**
- **Upper limb spasticity in adults**
- **Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy**
- **Cervical dystonia in adults**
- **Blepharospasm in adults**

RECOMMENDATION: Inform prescribers via MD alert. The Botulinum Toxin policies will be updated to reflect these new indications. Coverage will be allowed for upper limb spasticity in children, regardless of cause.

c. DARZALEX®
DARATUMUMAB
New indication approved 08/20/2020:
- **treatment of adult patients with multiple myeloma in combination with carfilzomib and dexamethasone in patients who have received one to three prior lines of therapy**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

d. SUPREP BOWEL PREP KIT®
SODIUM ULFATE, POTASSIUM SULFATE, MAGNESIUM SULFATE
New indication approved 08/05/2020:

- **cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older**

RECOMMENDATION: Inform prescribers via MD alert.

e. **DOVATO®**
DOLUTEGRAVIR AND LAMIVUDINE

New indication approved 08/06/2020:

- **Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.**

RECOMMENDATION: Inform prescribers via MD alert.

f. **MIRENA®**
LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM

New indication approved 08/20/2020:

- **Prevention of pregnancy for up to 6 years**
- **Treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception for up to 5 years**

RECOMMENDATION: Inform prescribers via MD alert.

g. **KYPROLIS®**
CARFILZOMIB

New indication approved 08/20/2020:

- **For the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with**
  - **Lenalidomide and dexamethasone; or**
  - **Dexamethasone; or**
  - **Daratumumab and dexamethasone.**
- **As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) therefore no updates to the policy are warranted.

h. **ULTRAVATE®**
HALOBETASOL PROPIONATE LOTION

New indication approved 08/27/2020:

- **Topical treatment of plaque psoriasis in patients 12 years of age and older.**

RECOMMENDATION: Inform prescribers via MD alert.

i. **NUCALA®**
MEPOLIZUMAB

New indication approved 9/12/20 and 9/25/20:

- **Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.**
- **The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).**
- **The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.**

RECOMMENDATION: Inform prescribers via MD alert. Update Commercial, Medicare Part B, and Medicaid policy and Medicare Part D policy as follows:

PA PROGRAM NAME	**IL-5 INHIBITORS**
MEDICATION NAME	Nucala (mepolizumab)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
REQUIRED MEDICAL INFORMATION	For initial authorization, must meet all of the following criteria: **For eosinophilic asthma:** 1. Documentation of eosinophilic asthma by **one** of the following: a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids 2. Documentation of treatment with maximally tolerated dose of medium to high –dose inhaled corticosteroid plus a long-acting inhaled β2-agonist and has been compliant to therapy in the past 3 months (*this may be verified by pharmacy claims information*) 3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as **one** of the following: a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5 b. At least two (2) asthma exacerbations requiring oral systemic corticosteroids in the last 12 months c. At least one (1) asthma exacerbation requiring hospitalization, emergency room or urgent care visit

For Eosinophilic Granulomatosis with Polyangiitis (EGPA):

1. Request is for Nucala®
2. History or presence of asthma
3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter
4. At least two of the following clinical findings:
    a. Biopsy evidence of eosinophilic vasculitis
    b. Motor deficit or nerve conduction abnormality
    c. Pulmonary infiltrates
    d. Sinonasal abnormality
    e. Cardiomyopathy
    f. Glomerulonephritis
    g. Alveolar hemorrhage
    h. Palpable purpura
    i. Positive test for ANCA
5. Documentation of one of the following
    a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous 2 years while receiving at least 7.5 mg/day prednisone (or equivalent)
    OR
    b. Failure to achieve remission following a standard induction regimen administered for at least 3 months OR recurrence of symptoms of EGPA while tapering of glucocorticoids
        i. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

For Hyperesosinophilic Syndrome (HES)

1. Request is for Nucala®
2. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
3. Blood eosinophil count of 1,000 cells/mcL or higher for at least 6 months
4. Documentation of use of HES therapy including one of the following in the past for the past 12 months:
    a. chronic or episodic oral corticosteroids
    b. immunosuppressive therapy
    c. cytotoxic therapy

	5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)
AGE RESTRICTIONS	Nucala®: Approved for 6 years of age or older for eosinophilic asthma and approved for 12 years of age and older for HES Cinqair®: Approved for 18 years of age or older Fasenra®: Approved for 12 years of age or older
PRESCRIBER RESTRICTIONS	For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist) For Eosinophilic Granulomatosis with Polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist For hypereosinophilic syndrome (HES): must be prescribed by or in consultation with hematologist, immunologist, pulmonologist, cardiologist, or neurologist.
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

Medicare Part D Policy:

PA PROGRAM NAME	IL-5 Inhibitors
MEDICATION NAME	Nucala and Fasenra
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
REQUIRED MEDICAL INFORMATION	For initial authorization, must meet all of the following criteria: For eosinophilic asthma: 1. Documentation of eosinophilic asthma by one of the following: a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids 2. Documentation of treatment with maximally tolerated dose of medium to high–dose inhaled corticosteroid plus a long-acting inhaled beta2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information) 3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following: a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5 b. At least two (2) asthma exacerbations requiring oral systemic corticosteroids in the last 12 months c. At least one (1) asthma exacerbation requiring hospitalization, emergency room or urgent care visit. For eosinophilic granulomatosis with polyangiitis (EGPA): 1. Request is for mepolizumab (Nucala®) 2. History or presence of asthma 3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter 4. At least two of the following clinical findings: a. Biopsy evidence of eosinophilic vasculitis b. Motor deficit or erve conduction abnormality c. Pulmonary

	infiltrates d. Sinonasal abnormality e. Cardiomyopathy f. Glomerulonephritis g. Alveolar hemorrhage h. Palpable purpura i. Positive test for ANCA 5. Documentation of one of the following a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous 2 years while receiving at least 7.5 mg/day prednisone (or equivalent) OR b. Failure to achieve remission following a standard induction regimen administered for at least 3 months OR recurrence of symptoms of EGPA while tapering of glucocorticoids. Standard treatment regimens include: prednisone (or equivalent) dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil. Reauthorization documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses For Hyperesosinophilic Syndrome (HES): 1. Request is for Nucala® 2.Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma 3. Blood eosinophil count of 1,000 cells/mcL or higher for at least 6 months 4. Documentation of use of HES therapy including one of the following in the past for the past 12 months: a. chronic or episodic oral corticosteroids (OCS) b. immunosuppressive therapy c. cytotoxic therapy 5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist). For eosinophilic granulomatosis with polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist. For hypereosinophilic syndrome (HES): must be prescribed by or in consultation with hematologist, immunologist, pulmonologist, cardiologist, or neurologist.
COVERAGE DURATION	Initial authorization will be approved for 6 months, reauthorization will be approved for 1 year

j. <u>SIMPONI ARIA®</u>
GOLIMUMAB

New indication approved 09/29/2020:

- **Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate**
- **Active Psoriatic Arthritis (PsA) in patients 2 years of age and older**
- **Adult patients with active Ankylosing Spondylitis (AS)**
- **Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older**

RECOMMENDATION: Inform prescribers via MD alert.

k. NITYR®
NITISINONE
New indication approved 09/02/2020:
- **treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.**

RECOMMENDATION: Inform prescribers via MD alert.

l. TRELEGY®
FLUTICASONE FUROATE, UMECLINDINIUM BROMIDE, VILANTEROL TRIFENATATE
New indication approved 09/09/2020:
- **maintenance treatment of asthma in patients aged 18 years and older**

RECOMMENDATION: Inform prescribers via MD alert. Medicaid Step Therapy policy reviewed and no policy updates were necessary.

m. ERAXIS®
New indication approved 09/22/2020:
- **Candidemia and other forms of Candida infections (intra-abdominal abscess and peritonitis) in adults and pediatric patients (1 month of age and older)**
- **Esophageal candidiasis in adults**

RECOMMENDATION: Inform prescribers via MD alert.

n. KALYDECO®
New indication approved 09/24/2020:
- **treatment of cystic fibrosis (CF) in patients age 4 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data**

RECOMMENDATION: Inform prescribers via MD alert.

o. XELJANZ®
TOFACITINIB
New indication approved 09/25/2020:
- **Polyarticular Course Juvenile Idiopathic Arthritis: treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.**

RECOMMENDATION: Inform prescribers via MD alert. The Therapeutic Immunomodulator policy for Commercial is policy is being updated with the current December P&T cycle. No policy criteria changes are warranted for Medicaid at this time.

p. FETROJA®
CEFIDEROCOL SULFATE TOSYLATE

New indication approved 09/25/2020:

- **patients 18 years of age or older for the treatment of the following infections caused by susceptible Gram-negative microorganisms:**
  - **Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)**

RECOMMENDATION: Inform prescribers via MD alert.

Drug Safety Monitoring:

1. **National Action Network Alert: Tranexamic Acid**
   [Posted 9/23/2020]
   ISSUE:
   After several recent wrong-route errors, the National Alert Network (NAN) issued a warning earlier this month for the antifibrinolytic tranexamic acid due to container mix-ups that led to accidental spinal injection of the medication. The blue caps on tranexamic acid vials resemble the caps on anesthesia drugs such as bupivacaine and ropivacaine. In three cases, patients scheduled for surgeries experienced seizures after receiving tranexamic acid instead of an anesthetic.

   Recommendation: Notify via MD alert

2. **Invokana, Invokamet, Invokamet XR (canagliflozin): MedWatch Safety Alert - Boxed Warning about Risk of Leg and Foot Amputations Removed**
   [Posted 8/26/2020]
   ISSUE: Based on FDA's review of new data from three clinical trials, the boxed warning about amputation risk from the diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) was removed from the prescribing information.
   FDA reviews of new clinical trial data demonstrated additional heart- and kidney-related benefits, which led to additional approved uses. Specifically, in 2018, canagliflozin was approved to reduce the risk of major heart-related events such as heart attack, stroke, or death in patients with type 2 diabetes who have known heart disease; and, in 2019, it was approved to reduce the risk of end-stage kidney disease, worsening of kidney function, heart-related death, and being hospitalized for heart failure in certain patients with type 2 diabetes and diabetic kidney disease.
   Collectively, these newly identified effects of canagliflozin on heart and kidney disease show significantly enhanced benefit of this medicine. Safety information from recent clinical trials also suggests that the risk of amputation, while still increased with canagliflozin, is lower than previously described, particularly when appropriately monitored. Based upon these considerations, FDA has concluded that the boxed warning should be removed.

   FDA RECOMMENDATION:

Health care professionals and patients should continue to recognize the importance of preventative foot care and monitor for new pain, tenderness, sores, ulcers, and infections in the legs and feet. Risk factors that may predispose patients to the need for amputation should be considered when choosing antidiabetic medicines.

Recommendation: Notify via MD alert

3. **Benzodiazepine Drug Class: Drug Safety Communication - Boxed Warning Updated to Improve Safe Use**
[Posted 9/23/2020]
ISSUE: The FDA is requiring the Boxed Warning, FDA's most prominent warning, be updated by adding other information to the prescribing information for all benzodiazepine medicines. This information will describe the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions consistently across all the medicines in the class. The FDA is also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.
Other changes are also being required to several sections of the prescribing information, including to the Warnings and Precautions, Drug Abuse and Dependence, and Patient Counseling Information sections.

FDA RECOMMENDATION:
- Consider the patient's condition and the other medicines being taken, and assess the risk of abuse, misuse, and addiction.
- Limit the dosage and duration of each medicine to the minimum needed to achieve the desired clinical effect when prescribing benzodiazepines, alone or in combination with other medicines.
- Use a gradual taper to reduce the dosage or to discontinue benzodiazepines to reduce the risk of acute withdrawal reactions.
- Take precautions when benzodiazepines are used in combination with opioid addiction medications.

Recommendation: Notify via MD alert

4. **Benadryl (diphenhydramine): Drug Safety Communication - Serious Problems with High Doses of the Allergy Medicine**
[Posted 9/24/2020]
ISSUE: FDA is warning that taking higher than recommended doses of the common over-the-counter (OTC) allergy medicine Benadryl (diphenhydramine) can lead to serious heart problems, seizures, coma, or even death. FDA is aware of news reports of teenagers ending up in emergency rooms or dying after participating in the "Benadryl Challenge" encouraged in videos posted on the social media application TikTok.

FDA RECOMMENDATION:
Health care professionals should be aware that the "Benadryl Challenge" is occurring among teens and alert their caregivers about it. Encourage teens and caregivers to read and follow the Drug Facts label. In the event of an overdose, health care professionals should attempt to determine whether a patient with a suspected overdose took diphenhydramine.

Recommendation: Notify via MD alert