PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 241

November 1, 2019

This is the November 1, 2019 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-and-provider-information/

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

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

MEDICAL POLICY COMMITTEE

New Policies and/or Major Criteria Changes

Effective January 1, 2020

Percutaneous Ultrasonic Ablation for Tendinopathy SUR445	**New Policy** This policy has been created to address a new, investigational tendinopathy treatment: percutaneous ultrasonic ablation (i.e., The Tenex Health TX® System). **Codes:** • The manufacturer's website states the codes for Tenex are the general tenotomy or fasciotomy codes. However, this technology involves an ultrasonic ablation component that tenotomy/fasciotomy does not. Therefore, an unlisted code should be billed for this procedure. • Billing guideline note added to state that if a tenotomy/fasciotomy code is billed for this procedure it is considered investigational and not covered. **Evidence/Practice Guidelines:** There is insufficient high-quality, published evidence to evaluate the safety, efficacy, and clinical utility of percutaneous ultrasonic ablation for tendinopathy. Larger, higher-quality studies (i.e., randomized controlled trials) are required to validate the findings of the current body of literature. Additional studies should also compare percutaneous ultrasonic ablation with other established surgical treatments of tendinopathy.
Myoelectric Upper Limb Prosthesis DME239 *(previously titled: Hand/Arm-Artificial Myoelectric Limb)*	**Annual Update** No change to criteria designating myoelectric upper limb prostheses as medically necessary. Partial-hand myoelectric prostheses have been added as an investigational indication, per evidence review and payer consensus. **Codes/PA:** Myoelectric prosthesis will continue to require PA. L6026 (partial-hand myoelectric prostheses) will now deny investigational.

Effective November 1, 2019

Diabetes: Continuous Glucose Monitors (All Lines	**Annual Update** • No change to criteria designating short-term CGMs as medically necessary. • Long-term CGMs:

of Business Except Medicare) **DME207**	○ *Criterion III.A.C. (liberalization):* removed the pre-gestational diabetes requirement for pregnant individuals with type 1 or type 2 diabetes ○ *Criterion I.V. (liberalization)* The following non covered criteria were removed: ▪ Type 1 diabetics not on insulin or taking only basal or bid insulin ▪ Long-term CGMs as a convenience item ▪ Individuals with gestational diabetes mellitus (GDM) ▪ Individuals with compliance issues ○ No change: Long-term CGM remain investigational for non-pregnant adults with Type 2 diabetes. • No change: CGM devices with an implantable sensor remain investigational. • Upgrade/replacement criteria (*criterion VII. liberalization*): ○ Removed "upgrade" language. Criteria now only address replacements ○ Removed criterion VIII.B. "evaluation by a health care provider managing the diabetes within the last 6 months that includes a recommendation supporting continued use of a continuous glucose monitor." **Codes/PA:** No coding or PA changes. CGMs will continue to require prior authorization.
Diabetes: Continuous Glucose Monitors (Medicare Only) **DME392**	**Annual Update** No change to applicable Medicare criteria. **Codes/PA:** No coding or PA changes. CGMs will continue to require prior authorization. **CMS:** • Local Coverage Determination (LCD): Glucose Monitors Devices (L33822) • Local Coverage Article (LCA): Glucose Monitor (A52464)
Urine Drug Testing for Therapeutic or Substance Abuse Monitoring (All Lines of Business Except Medicare) **LAB361**	**Interim Update** • We will now allow for presumptive UDT (80305-80307) performed at any place of service. • We will only allow for definitive UDT (G0480-G0481) when: ○ Performed at an independent lab or outpatient hospital *(payment policy)*; and ○ When preceded by presumptive testing *(medical policy)*. Note: There will be an edit in place to deny a definitive drug testing claim if there is not a presumptive claim on file. ○ Definitive testing will also have a quantity limit of 14 tests in a 12-month period *(payment policy)*
Lower Limb Prosthesis **DME322**	**Annual Update** Policy continues to follow Medicare guidance for all lines of business. No changes to relevant guidance. **Codes/PA:** No coding or PA changes **CMS:** • Local Coverage Determination (LCD): Lower Limb Prostheses (L33787) • Local Coverage Article (LCA) Lower Limb Prostheses (A52496)
Rhinoplasty (All Lines of Business Except Medicare)	**Annual Update**

SUR337	No change to criteria designating functional, non-cosmetic rhinoplasty as medically necessary and covered as a treatment of nasal airway obstruction. Note added to top of criteria that policy does not address rhinoplasty for patients under 17 (with or without cleft lip and/or palate) which may be considered medically necessary. **Codes/PA:** No coding changes; 6 codes will continue to PA. Removing PA from 2 codes addressing rhinoplasty for nasal deformity secondary to cleft lip and/or palate (30460, 30462).
Rhinoplasty (Medicare Only) SUR444	**New Policy** New Medicare only policy due to slight differences in coverage criteria: The Medicare criteria are rather vague and only allow for rhinoplasty when billed with specific diagnosis codes. **Codes/PA:** 6 codes pay when billed with dx codes included in billing guidelines. Removing PA from 2 codes addressing rhinoplasty for nasal deformity secondary to cleft lip and/or palate (30460, 30462). **CMS:** Local Coverage Determination (LCD): Plastic Surgery (L37020)

VENDOR UPDATES

AIM Speciality Health

Effective February 9, 2020

AIM Specialty Health© (AIM) is pleased to provide enhancements to the AIM Clinical Appropriateness Guidelines. The following updates, part of the annual review of AIM's Radiology Program guidelines, enhance the guideline text related to Advanced Imaging of the Abdomen and Pelvis. As always, these enhancements are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services. These enhancements are scheduled to be effective on February 9, 2020.

Imaging of the Abdomen and Pelvis Guideline contains updates to the following:

- Foreign body (Pediatric only), Gastrointestinal bleeding, Henoch-Schonlein purpura, Hematoma or hemorrhage – intracranial or extracranial, Perianal fistula/abscess (fistula in ano), Ascites, Biliary tract dilatation or obstruction, Cholecystitis, Choledocholithiasis, Focal liver lesion, Hepatomegaly, Jaundice, Azotemia, Adrenal mass, indeterminate, Hematuria, Renal mass, Urinary tract calculi, Adrenal hemorrhage, Adrenal mass, Lymphadenopathy, Splenic hematoma, Undescended testicle (cryptorchidism)
- Abdominal and/or pelvic pain
  - Combined pelvic pain with abdominal pain criteria in new "abdominal and/or pelvic pain" indication
  - Required ultrasound or colonoscopy for select adult patients based on clinical scenario
  - Ultrasound-first approach for pediatric abdominal and pelvic pain
- Lower extremity edema
  - Added requirement to exclude DVT prior to abdominopelvic imaging
- Splenic mass, benign, Splenic mass, indeterminate, Splenomegaly

- Added new indications for diagnosis, management, and surveillance of splenic incidentalomas following the ACR White Paper (previously reviewed against "tumor, not otherwise specified")

- Pancreatic mass
  - Separated criteria for solid and cystic pancreatic masses
  - Defined follow up intervals for cystic pancreatic masses
- Diffuse liver disease
  - Added criteria for MR elastography
- Inflammatory bowel disease
  - Limited requirement for upper endoscopy to patients with relevant symptoms
  - New requirement for fecal calprotectin or CRP to differentiate IBS from IBD
- Enteritis or colitis, not otherwise specified
  - Incorporated Intussusception (pediatric only), and Ischemic bowel
- Prostate cancer
  - Moved this indication to Oncologic Imaging Guideline

PHARMACY & THERAPEUTICS COMMITTEE

Oregon Region P&T Committee Meeting October 11, 2019
Go-Live Date: Wednesday, January 01, 2020, unless otherwise noted

New Drugs and Combinations:

Brexanolone (Zulresso) Vial
Indication: Treatment of post-partum depression in adults. **Formulary Alternatives:** While brexanolone injection is the only treatment with an FDA approval for PPD, oral antidepressants can be utilized in treatment per current guidelines.
• Commercial: Medical Benefit, Prior Authorization • Medicaid: Non-Formulary • Medicare: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization

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Prior Authorization Criteria:
Authorization will be approved for 1 month for a one-time infusion. Treatment is limited to one infusion per pregnancy. Re-authorization for the same post-partum period will not be permitted. Authorization for subsequent pregnancies may be allowed when criteria outlined in the policy is met.

1. Patient has a confirmed diagnosis of postpartum depression (PPD)
2. The patient had an onset of depressive symptoms no sooner than the third trimester of pregnancy and no later than within 4 weeks after delivery
3. The patient is less than 6 months postpartum
4. Negative pregnancy test result
5. Patient has documentation of severe postpartum depression based on the Hamilton Rating Scale for Depression (HAM-D) or another standardized, validated depression tool or documentation of suicidal ideation
6. Individual has failed at least 6 weeks of oral anti-depressant therapy or documentation that a trial would be inappropriate or cause harm

Darolutamide (Nubeqa) Tablet Effective 10/30/2019

Indication:
Darolutamide is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC).

Formulary Alternatives:
Erleada, Xtandi

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization
- Medicaid: Formulary, Specialty, Prior Authorization
- Medicare Part D: Formulary, Specialty, Prior Authorization

Prior Authorization Criteria:
Added to Oral Anti-Cancer Medications policy

Romosozumab-aqqg (Evenity) Syringe

Indication:

Treatment of:

- Osteoporosis in postmenopausal women at high risk for fracture, defined as history of osteoporotic fracture, or multiple risk factors for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

Formulary Alternatives:

teriparatide (Forteo), abaloparatide (Tymlos)

- Commercial: Medical Benefit, Prior Authorization
- Medicaid: Medical Benefit, Prior Authorization
- Medicare Part D: Non-Formulary
- Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria:

1. One of the following criteria:
    a. Documented clinical diagnosis of osteoporosis [defined as a non-traumatic, non-pathologic spinal fracture OR spine, or hip bone mineral density (BMD) T-score less than or equal to -2.5].
    OR
    b. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and –2.5) AND meeting one of two risk assessments
        A. one of the following risk factors: i. previous fracture ii. history of hip or spine fracture in first degree relative iii. low body weight (less than127 lbs. for women) iv. smoking, excess alcohol intake v. secondary osteoporosis (e.g. rheumatoid arthritis) vi. history of falls
        OR
        B. Fracture Risk Assessment (FRAX) Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%
    OR
    c. One of the following chronic glucocorticosteroid use:
        A. greater than 20 mg/day for longer than 1 month
        B. 5-20 mg/day for longer than 3 months in post-menopausal women not on estrogen
        C. 5-20 mg/day for longer than 3 months AND T-score less than-1.5

AND

2. Documentation of one of the following:
    a. Failure of bisphosphonate therapy, defined as a new fracture or worsening bone mineral density while adherent to bisphosphonate therapy
    b. Adverse effects, other than gastrointestinal effects, or contraindication to use of oral or IV bisphosphonate therapy.

c. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy

AND

3. Documentation of trial and failure or contraindication/intolerance to Prolia® (denosumab). Failure is defined as a new fracture or worsening
bone mineral density while adherent to Prolia® (denosumab).

Selinexor (Xpovio) Tablet Effective 10/11/2019

Indication:

Selinexor is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization
- Medicaid: Formulary, Specialty, Prior Authorization
- Medicare Part D: Formulary, Specialty, Prior Authorization

Prior Authorization Criteria:

Added to Oral Anti-Cancer Medications policy

Bevacizumab-awwb (Mvasi) Vial Effective 11/1/2019

Indication:

- Metastatic Colorectal Cancer
- First-Line Non-Squamous Non-Small Cell Lung Cancer
- Recurrent Glioblastoma
- Metastatic Renal Cell Carcinoma
- Persistent, Recurrent, or Metastatic Cervical Cancer

Formulary Alternatives:

bevacizumab (Avastin®)

- Commercial: Medical Benefit, Prior Authorization
- Medicaid: Medical Benefit, Prior Authorization

- Medicare Part D: Non-Formulary
- Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria:
Added to Injectable Anti-Cancer Medications policy

Trastuzumab-anns (Kanjinti) Vial Effective 11/1/2019

Indication:
Adjuvant breast cancer, metastatic breast cancer, metastatic gastric cancer.

Formulary Alternatives:
trastuzumab (Herceptin®)

- Commercial: Medical Benefit, Prior Authorization
- Medicaid: Medical Benefit, Prior Authorization
- Medicare Part D: Non-Formulary
- Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria:
Added to Injectable Anti-Cancer Medications policy

Pexidartinib hydrochloride (Turalio) Capsule Effective 11/1/2019

Indication:
Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) that is not amenable to improvement with surgery and is associated with severe morbidity or functional limitations.

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization
- Medicaid: Formulary, Preferred Specialty, Prior Authorization
- Medicare Part D: Formulary, Preferred Specialty, Prior Authorization

Prior Authorization Criteria:
Added to Oral Anti-Cancer Medications policy

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Entrectinib (Rozlytrek) Capsule Effective 11/1/2019

Indication:

- Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive
- Treatment of adult and pediatric patients 12 years of age and older with solid tumors that:
  - have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
  - are metastatic or where surgical resection is likely to result in severe morbidity, and
  - have either progressed following treatment or have no satisfactory alternative therapy

Formulary Alternatives:

For Solid Tumors with the NTRK mutation: larotectinib (Vitrakvi®)
For NSCLC with ROS1 mutation: crizotinib (Xalkori ®)

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization
- Medicaid: Formulary, Preferred Specialty, Prior Authorization
- Medicare Part D: Formulary, Preferred Specialty, Prior Authorization

Prior Authorization Criteria:

Added to Oral Anti-Cancer Medications policy

Fedratinib dihydrochloride (Inrebic) Capsule

Indication:

Treatment of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis in adult patients.

Formulary Alternatives:

ruxolitinib (Jakafi®)

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (4 capsules per day)
- Medicaid: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (4 capsules per day)
- Medicare Part D: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (4 capsules per day)

Prior Authorization Criteria:

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Added to Oral Anti-Cancer Medications policy

Triclabendazole (Egaten) Tablet
Indication: Treatment of fascioliasis in patients 6 years of age and older. **Formulary Alternatives:** nitazoxanide (Alinia®)
• Commercial: Non-Formulary • Medicaid: Non-Formulary • Medicare Part D: Non-Formulary

Drospirenone (Slynd) Tablet
Indication: An oral progestin-only contraceptive for use by female patients of reproductive potential to prevent pregnancy. **Formulary Alternatives:** Norethindrone 0.35 mg tablet; Medical drugs: Levonorgestrel IUD, etonogestrel implant, copper IUD, depot medroxyprogesterone acetate IM injection

• Commercial: Non-Formulary, Prior Authorization
• Medicaid: Non-Formulary, Prior Authorization
• Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization
 	
Prior Authorization Criteria for Commercial/Medicaid:
For initial authorization:
• Use must be for a FDA approved indication
• Patient with chronic medical condition(s) who should avoid estrogen-containing contraceptives due to increased risk of thromboembolism, such as:
  ○ Diabetes with vascular disease
  ○ Diabetes and age greater than 20 years

- Migraines with aura
- Uncontrolled hypertension (SBP greater or equal to 160 mmHg or DBP greater or equal 100 mmHg
- Obesity (BMI greater or equal to 30 kg/m^2) with other risk factors for thromboembolism (e.g. smoking, age 35 years or older)
- Postpartum women with one of the following:
  - Less than 21 days postpartum
  - With risk factors for thromboembolism (e.g. preeclampsia, smoking, age 35 years and older)
- History of stroke
- Systemic lupus erythematosus

- One of the following:
  - Documented intolerance or contraindication to norethindrone tablets ("mini-pills")
  - Patient unable to maintain strict adherence of norethindrone tablets ("mini-pills") due to unpredictable daily schedule (e.g. variable work schedule)

For reauthorization: Documentation that patient continues to have increased risk of thromboembolism and should avoid estrogen-containing contraceptives

Prior Authorization Criteria for Medicare Part D:
For initial authorization:

- Use must be for a FDA approved indication
- Patient with chronic medical condition(s) who should avoid estrogen-containing contraceptives due to increased risk of thromboembolism, such as:
- One of the following:
  - Documented intolerance or contraindication to norethindrone tablets ("mini-pills")
  - Patient unable to maintain strict adherence of norethindrone tablets ("mini-pills") due to unpredictable daily schedule (e.g., variable work schedule, cognitive dysfunction)

For reauthorization: Documentation that patient continues to have increased risk of thromboembolism and should avoid estrogen-containing contraceptives

Segesterone acetate-ethinyl estradiol (Annovera) Vag Ring
Indication:

A reusable contraceptive vaginal ring for pregnancy prevention in female patients of reproductive potential for up to 13 cycles.

Formulary Alternatives:
etonogestrel/EE vaginal ring (NuvaRing®), oral low-dose monophasic contraceptives (e.g. levonorgestrel/EE, norethindrone/EE, norgestrel/EE), norelgestromin/EE transdermal patch (e.g. Xulane®), progestin-only oral tablets (e.g. norethindrone), depot medroxyprogesterone IM injection

- Commercial: Non-Formulary, Prior Authorization, Quantity Limit (1 unit per year)
- Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 unit per year)
- Medicare Part D: Non-Formulary, Prior Authorization, Quantity Limit (1 unit per year)

Prior Authorization Criteria:
For initial authorization:

1. Use must be for a FDA approved indication
2. Documented intolerance or contraindication to etonogestrel-EE vaginal ring (NuvaRing®)

Bremelanotide acetate (Vyleesi) Auto Injct

Indication:
Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition
- Problems within the relationship, or
- The effects of a medication or drug substance:

- Commercial: Non-Formulary, Prior Authorization, Quantity Limit (4 doses per 30 days)
- Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 doses per 30 days)
- Medicare Part D: Non-Formulary

Prior Authorization Criteria:
Age Restrictions: May be approved for patients aged 18 years and older
Prescriber Restrictions: Must be prescribed by or in consultation with an obstetrician, gynecologist, urologist, and/or women's health nurse practitioner
Exclusion Criteria: Uncontrolled hypertension and Known cardiovascular disease
Other Criteria: For initial authorization, must meet all of the following criteria:

1. Patient is female and premenopausal

AND

2. Diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
    a. A co-existing medical or psychiatric condition
    b. Problems within the relationship, or
    c. The effects of a medication or drug substance

Reauthorization requires documentation that the patient continues to be pre-menopausal and has had a positive response to the medication.

New Strengths and Formulations: See Other Formulary Changes

New Indications:

Emgality®

New Indication Update (Plus All Prior Indications):

- Treatment of episodic cluster headache.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update the Commercial/Medicaid policy as follows:

PA PROGRAM NAME	CALCITONIN GENE-RELATED PEPTIDE RECEPTOR (CGRP) ANTAGONISTS
MEDICATION NAME	**Emgality®**
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A

PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication
OTHER CRITERIA	Initial authorization for migraine prophylaxis: 1. Diagnosis of migraine headaches with at least four (4) headache days per month AND 2. Documentation of trial and failure$^{\Delta}$, intolerance, or contraindication to at least one prophylactic medication from **three (3)** of the following categories: a. Anticonvulsants (e.g., divalproex, valproate, topiramate) b. Beta-blockers (e.g., metoprolol, propranolol, timolol) c. Antidepressants (e.g., amitriptyline, venlafaxine) AND 3. Documentation that if the patient is currently receiving botulinum toxin, treatment with botulinum toxin will be discontinued. $^{\Delta}$An adequate trial and failure is defined as minimal to no improvement after at least six (6) weeks of therapy. Initial authorization for cluster headaches: 1. Diagnosis of episodic cluster headaches with all of the following: a. A history of at least five (5) cluster headache attacks with at least two of the cluster periods lasting at least 7 days b. Cluster periods are separated by at least three (3) months of pain-free remission 2. Documentation of trial and failure$^{\Delta}$, intolerance, or contraindication to all of the following prophylactic medications: a. Verapamil b. Melatonin c. Lithium AND 3. Documentation that if the patient is currently receiving botulinum toxin, treatment with botulinum toxin will be discontinued. $^{\Delta}$An adequate trial and failure is defined as minimal to no improvement after at least six (6) weeks of therapy.

	Reauthorization for all indications: Documented reduction in the severity or frequency of headaches.

Emflaza®
Expanded Patient Population Update: • Treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Emflaza® prior authorization policy age restriction to align with new indication.

Keytruda®

New Indication Update (Plus Prior Indications):

- Non-Small Cell Lung Cancer (NSCLC)
  - in combination with pemetrexed and platinum chemotherapy, as first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
  - in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, as first-line treatment of patients with metastatic squamous NSCLC.
  - as a single agent for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and is:
    - stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
    - metastatic.
  - as a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA.
- Small Cell Lung Cancer (SCLC)
  - for the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.[1]
- Head and Neck Squamous Cell Cancer (HNSCC)
  - in combination with platinum and FU for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC.
  - as a single agent for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test.

- as a single agent for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

- Esophageal Cancer
- for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy 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.

Victoza®

New Expanded Patient Population Update (Plus Prior Indications and Limitations of Use):

- as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update policy with new indication. Victoza® clinical policy does not have age restrictions; therefore, no changes to criteria coverage are warranted.

Inflectra®

New Indication Update (Plus Previous Indications):

- Pediatric Ulcerative Colitis:
  - reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update policy with new indication. Inflectra® clinical policy does not have age restrictions; therefore, no changes to criteria coverage are warranted.

Bictarvy®

New Expanded Weight Updated Indication:

- treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have 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 BIKTARVY.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Botox®
Updated Indication and Limitations (Plus Previous Indications): • Treatment of upper and lower limb spasticity in adult patients • Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age Important Limitations: Safety and effectiveness of BOTOX have not been established for: • Prophylaxis of episodic migraine (14 headache days or fewer per month) • Treatment of hyperhidrosis in body areas other than axillary
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. The botulinum toxin policies will be updated with new indications. The Commercial/Medicaid policy coverage criteria will be updated to include “upper limb spasticity in pediatric patients at least 2 years of age.” The Medicare Part B coverage criteria is based on the Centers for Medicare and Medicaid (CMS) local coverage determination (LCD) and cannot be updated.

Dextenza®
New Indication Update: • Treatment of ocular inflammation and pain following ophthalmic surgery
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Symdeko®
New Expanded Age Indication Update: • Treatment of patients with cystic fibrosis (CF) age 6 years and older who are homozygous for the *F508del* mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence. If the patient’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

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Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update policy with new indication. Symdeko® clinical policy does not have age restrictions; therefore, no changes to criteria coverage are warranted.

Doptelet®

New Indication (Plus Previous Indication):

- Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Doptelet® Commercial/Medicaid policy criteria with new indication as follows:

PA PROGRAM NAME	Doptelet
MEDICATION NAME	**Doptelet®** (Avatrombopag)
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Recent platelet counts For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	Approved for 18 years of age and older.
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an oncologist hematologist, gastroenterologist or liver specialist
COVERAGE DURATION	For Treatment of thrombocytopenia in patients with Chronic Liver Disease (CLD): authorization will be approved for 1 month for 1 course of treatment (15 tablets of Doptelet® or 7 tablets of Mulpleta®) For treatment of Thrombocytopenia in patients with Chronic Immune Thrombocytopenia (ITP): initial authorization for 3 months and reauthorization for 1 year
QUANTITY LIMIT	For Mulpleta®: 7 tablets per month
OTHER CRITERIA	No changes to criteri for thrombocytopenia in patients with chronic liver disease (CLD): For treatment of thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP) (Doptelet® only) Initial authorization: 1. Diagnosis of chronic immune thrombocytopenia (ITP)

	2. Platelet count of less than 30,000/uL (30 x 10^9 /L) 3. Inadequate response to at least TWO of the following therapies: a. Corticosteroids b. Immunoglobulins c. Splenectomy d. Rituximab Reauthorization: 1. Documentation of an improvement in platelet count to at least 50,000 /uL (50 x 10^9 /L) or greater

Add to formulary for Medicare Part D with Prior Authorization:

PA PROGRAM NAME	Doptelet
MEDICATION NAME	**Doptelet® (avatrombopag)**
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from Part D.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an oncologist hematologist, gastroenterologist or liver specialist
COVERAGE DURATION	For CLD for 1 month (15 tabs); For ITP initial auth for 3 months, reauth for 1 year
OTHER CRITERIA	For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD): 1. Diagnosis of chronic liver disease 2. Platelet count of less than 50,000 platelets/µL 3. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started 10-13 days prior to the procedure For chronic immune thrombocytopenia (ITP): 1. Platelet count of less than 30,000 platelets/uL 2. Inadequate response to at least TWO of the following therapies: a. Corticosteroids b. Immunoglobulins c. Splenectomy

	d. Rituximab Reauthorization: Documentation of a positive response to therapy, such as an increase in platelet count

Renflexis®
New Indication (Plus All Previous Indications): • Pediatric Ulcerative Colitis: ○ reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update policy with new indication. Inflectra® clinical policy does not have age restrictions; therefore, no changes to criteria coverage are warranted

Dupixent®
New Indication (Plus All Previous Indications): • as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Dupixent® Commercial/Medicaid policy criteria with new indication as follows:

PA PROGRAM NAME	Topical Products
MEDICATION NAME	**Dupixent®** (dupilumab injection)
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.
EXCLUSION CRITERIA	Moderate-to-severe atopic dermatitis: Use in combination with other therapeutic immunomodulators used for the treatment of skin disorders (e.g., Xolair®, Taltz®). Eosinophilic and corticosteroid dependent asthma: Use in combination with other anti-asthma monoclonal antibodies, such as mepolizumab (Nucala®), benralizumab (Fasenra®), reslizumab (Cinqair®), and omalizumab (Xolair®) for any indication.

REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. Eosinophilic and corticosteroid dependent asthma: Absolute Eosinophil Count, and Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ) score
AGE RESTRICTIONS	Moderate-to-severe atopic dermatitis: Must be 12 years of age or older. Eosinophilic and corticosteroid dependent asthma: Must be 12 years of age or older.
PRESCRIBER RESTRICTIONS	• Moderate-to-severe atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist • Eosinophilic and corticosteroid dependent asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist) • Chronic rhinosinusitis with nasal polyposis: otolaryngologist, allergist, pulmonologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
QUANTITY LIMIT	Two (2) 200 mg injections per 28 days Two (2) 300 mg injections per 28 days. Note: • The recommended dose of Dupixent® for adults with atopic dermatitis is an initial loading dose of 600 mg (two 300 mg injections) subcutaneously, followed by 300 mg given every other week for maintenance. • The recommended dose of Dupixent® for adolescents (12 year of age and older) for eosinophilic and oral corticosteroid dependent asthma is an initial loading dose of 400 mg (two 200 mg injections) or 600 mg (two 300 mg injections) subcutaneously, followed by 200 mg or 300 mg given every other week for maintenance • The recommended dose of Dupixent® for adults with CRSwNP is 300 mg every other week
OTHER CRITERIA	No changes to coverage criteria for moderate-severe atopic dermatitis, eosinophilic asthma, or corticosteroid-dependent asthma For Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP): 1. Diagnosis of chronic rhinosinusitis with nasal polyp as defined by: a. Objective confirmation by anterior rhinoscopy, nasal endoscopy, or computed tomography of sinuses b. Confirmed presence of nasal polyp(s)

	c. Symptoms of nasal congestion/blockage/ obstruction, nasal discharge, facial pain or pressure, and/or decreased or lost sense of smell 2. Documentation of one of the following: a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery b. Trial and failed at least one course of oral systemic corticosteroid in the past 90 days c. Intolerant to, or have contraindication for, oral systemic corticosteroids 3. Trial and failed an intranasal corticosteroid of at least 3 months' duration 4. Documentation that patient is currently on standard maintenance treatment of intranasal corticosteroid and will continue therapy in combination with dupilumab Reauthorization for CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement

Soliris®

New Indication (Plus Previous Indications and Limitation):

- The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Soliris® policy criteria with new indication as follows:

PA PROGRAM NAME	Soliris
MEDICATION NAME	**Soliris® (eculizumab)**
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), NCCN, or Drugdex and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	PNH or aHUS: Prescribed by a Hematologist/Oncologist MG or NMOSD: Prescribed by a Neurologist
COVERAGE DURATION	Initial authorization for up to 3 months and reauthorization will be approved for up to one year.
OTHER CRITERIA	No changes to criteria for Paroxysmal Nocturnal Hemoglobinuria (PNH), Compliment-Mediated Hemolytic Uremic Syndrome (HUS), or myasthenia gravis For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met: 1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following: a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions) AND b. Anti-AQP4 antibody positive 2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis) 3. Trial and failure, intolerance or contraindication to rituximab Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD): Documentation of positive clinical response to therapy

Darzalex®
New FDA-Approved Indication: • in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant • in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy • in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor • as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

Inform prescribers via Healthcare Services Medical & Pharmacy Policy 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.

Lynparza®

New Ovarian Cancer Indication Update (Plus Previous Breast Cancer Indication):
• Ovarian cancer
  ○ For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
  ○ for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.
  ○ for the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza

Inform prescribers via Healthcare Services Medical & Pharmacy Policy 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.

Rebif®
New Indication Update: • Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Plegridy®
New Indication Update: • Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

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Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Avonex®
New FDA-Approved Indication: • Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Gadavist®
New Indication (Plus All Previous Indications): • To assess myocardial perfusion (stress, rest) and late gadolinium enhancement in adult patients with known or suspected coronary artery disease (CAD).
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Ocrevus®
New FDA-Approved Indication: • Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults • Primary progressive MS, in adults
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Otezla®	
New Indication Update (Plus Previous Indications): • Adult patients with oral ulcers associated with Behçet's Disease	
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Commercial/Medicaid policy will be updated as follows:	
PA PROGRAM NAME	Otezla

MEDICATION NAME	**Otezla® (apremilast)**
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	When used in combination with other therapeutic immunomodulators (TIMs)
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a rheumatologist or dermatologist
COVERAGE DURATION	Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication
QUANTITY LIMIT	60 tablets per 30 days
OTHER CRITERIA	No changes to criteria for other FDA approved indications For active oral ulcers associated with Behcet's Disease: 1. Patient has had at least three occurrences of active oral ulcers within the previous 12 months 2. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g. topical corticosteroids, colchicine, azathioprine)

Bydureon Bcise®
Updated Limitation (Plus Previous Indications and Limitations): • Limitations of Use: Use with prandial insulin has not been studied.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. No changes to policies or coverage criteria are warranted.

Taclonex®
New Indication Update: • Topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update policy with new indication; no changes to coverage criteria are warranted.

Jadenu®
Updated Indication (Removed Previous Limitation): Limitations of Use: • The safety and efficacy of JADENU when administered with other iron chelation therapy have not been established.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Enstilar®
New FDA-Approved Indication: • Topical treatment of plaque psoriasis in patients 12 years and older**.**
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Enstilar® policy age restriction to align with new indication.

Arranon®
Expanded Age Indication: • Treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma in adult and pediatric patients age 1 year and older whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy 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.

Imfinzi®
New Indication (Plus Previous Indications):

• Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
Inform prescribers via Healthcare Services Medical & Pharmacy Policy 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.

Drug Safety Monitoring:

Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Due to an Increased Risk of Blood Clots and Death with Higher Dose

ISSUE:

FDA has approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of Xeljanz, Xeljanz XR (tofacitinib), which is used in patients with ulcerative colitis. In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. We approved these changes, including adding our most prominent Boxed Warning, after reviewing interim data from an ongoing safety clinical trial of tofacitinib in patients with rheumatoid arthritis (RA) that examined a lower and this higher dose of the medicine.

RECOMMENDATION:

Patients should tell your health care professionals if you have a history of blood clots or heart problems, and talk to them about any questions or concerns. Stop taking tofacitinib and seek emergency medical attention right away if you experience any unusual symptoms, including those that may signal a blood clot such as:

- Sudden shortness of breath
- Chest pain that worsens with breathing
- Swelling of a leg or arm
- Leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm

Do not stop taking tofacitinib without first talking to your health care professional, as doing so can worsen your condition.

Healthcare professionals should discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. Counsel patients about the risks and advise them to seek medical attention immediately if they experience any unusual symptoms, including those of thrombosis listed above. Reserve tofacitinib to treat ulcerative colitis for patients who have failed or do not

tolerate tumor necrosis factor (TNF) blockers. Avoid tofacitinib in patients who may have a higher risk of thrombosis. When treating ulcerative colitis, use tofacitinib at the lowest effective dose and limit the use of the 10 mg twice daily dosage to the shortest duration needed.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Commercial and Medicare therapeutic immunomodulators (TIMS) policy is being updated to remove tofacitinib as a preferred agent for rheumatoid arthritis; however, due to limited treatment options in ulcerative colitis, this agent will continue to be a secondary preferred agent after trial of TNF inhibitors.

Other Formulary Changes:

Drug Name	Change Summary	Policy Name
Carglumic acid (Carbaglu) Tab disper	Add prior authorization to Commercial and Medicaid only. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization	• Commercial/Medicaid: Medications for Rare Indications (Orphan Drugs) policy • Medicare Part D: N/A

Amlodipine/valsartan/HCTZ (Exforge HCT)	Commercial/Medicaid: Remove Prior Authorization and add to formulary:
	• Commercial:
	  ○ 2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Tier 3
	Medicaid: Formulary
		N/A

Daclatasvir dihydrochloride (Daklinza) Tablet	Remove from Commercial OR formulary due to state review/request. • Commercial 2020 OR: Non-Formulary, Specialty, Prior Authorization	• Commercial: Hepatitis C – Direct Acting Antivirals • Medicaid/Medicare Part D: N/A

Estradiol cypionate (Depo-Estradiol) Vial	Add to Commercial/Medicaid formulary.
	• Commercial:
	  ○ 2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Tier 4
	• Medicaid: Formulary
		N/A

Drug Name	Change Summary	Policy Name
Erythromycin Tablet DR	• Remove from Medicaid formulary • Medicare Part D: Add generic to formulary ○ Formulary, Non-Preferred Drug	N/A

Estradiol Valerat Vial	Add to Commercial/Medicaid formulary.
	• Commercial:
	  ○ 2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Tier 4
	• Medicaid: Formulary
		N/A

Pregabalin Capsule/Solution	• 2020 WA: Change from Tier 3 to Tier 2 • Medicare: Change from Non-preferred Drug to Non-preferred generic tier	N/A
Pyridostigmine bromide Tablet	New strength. Non-Formulary for all lines of business	N/A
Fluticasone/salmeterol inhaler (generic Advair®)	Move to non-preferred generic tier for Medicare	N/A
Golimumab (Simponi) pen injector and syringe	Remove from formulary for Commercial	Therapeutic Immunomodulators
Amifampridine (Ruzurgi) Tablet	New entity. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization	• Commercial/Medicaid: Firdapse (policy name changing to Amifampridine) • Medicare Part D: Ruzurgi
PA PROGRAM NAME	Ruzurgi	
MEDICATION NAME	Amifampridine (Ruzurgi®)	
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit	
EXCLUSION CRITERIA	N/A	
REQUIRED MEDICAL INFORMATION	Repetitive Nerve Stimulation (RNS) or anti-P/Q type voltage-gated calcium channel antibody test. For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.	

Drug Name	Change Summary	Policy Name
AGE RESTRICTIONS	N/A	
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a neurologist	
COVERAGE DURATION	Initial approval will be approved for 3 months. Reauthorization will be approved for 12 months.	
OTHER CRITERIA	Initial authorization (all of the following must be met): 1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) AND 2. Clinical symptoms of LEMS, including dyspnea or functionally significant muscle weakness interfere with daily activities. AND 3. Patient has been evaluated for malignancy and treated for malignancy if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy. AND 4. Documented trial and failure of at least one month, intolerance, or contraindication to pyridostigmine Reauthorization: Documentation of a positive response to therapy such as improvement or stabilization of muscle weakness from baseline	
Tiopronin (Thiola EC) Tablet DR	New dosage form. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization	Thiola
Nitrofurantoin 25 mg/5 mL oral suspension	Commercial/Medicaid: Remove from formulary	N/A
Ombita /paritap/riton/dasabuvir (Viekira XR) Tab BP 24H	Remove from 2020 OR Commercial formulary due to state review/ request	Hepatitis C - Direct Acting Antivirals

Tadalafil (Adcirca) Tablet	Change tier from specialty as follows:
	• Commercial:
	  ○ 2020 OR: Formulary, Non-Preferred Generic, Prior Authorization
	  ○ 2020 WA: Formulary, Tier 3, Prior Authorization
	• Medicaid: Formulary, Prior Authorization
	• Medicare Part D: Formulary, Non-Preferred Generic, Prior Authorization
		Pulmonary Arterial Hypertension

Drug Name	Change Summary	Policy Name
	All lines of business: Continue to have Quantity Limit (2 tablets per day)	
• **Bupropion HBR (Aplenzin) Tablet ER 24** • **Bupropion HCL (Forfivo) Tablet ER 24**	The prior authorization for Medicaid was removed, as these medications are covered under DMAP and not through Providence Health Assurance. • Medicaid: Non-Formulary	New Medications and Formulations without Established Benefit
Secukinumab (Cosentyx) Pen Injctr/Syringe	Remove from Medicaid formulary	Therapeutic Immunomodulators - Medicaid
Etanercept (Enbrel) 50 mg/ml Cartridge/Pen Injctr/Syringe	• Commercial/Medicaid: Change quantity limit from 3.92 ml per 28 days to 4 ml per 28 days Effective 9/1/2019	Therapeutic Immunomodulators
Infliximab (Remicade®)	Medicare Part D: Remove from formulary (medical drug) Medicare Part B: Add prior authorization	Medically Infused Therapeutic Immunomodulators – Medicare Part B
Treprostinil diolamine (Orenitram ER) Tablet ER	Remove from Commercial and Medicaid formulary. • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization	Pulmonary Arterial Hypertension
Treprostinil (Tyvaso) Ampul-Neb	Add to Commercial and Medicaid formulary. • Commercial: Formulary, Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization	Pulmonary Arterial Hypertension

Fluocinonide (Vanos) Cream	Add to formulary for all lines of business. Remove prior authorization for Commercial and Medicaid
	• Commercial:
	  ○ OR: Formulary, Non-Preferred Generic
	  ○ WA: Formulary, T3
	• Medicaid: Formulary
	• Medicare Part D: Formulary, Non-Preferred Generic
		N/A

Drug Name	Change Summary	Policy Name
Icosapent ethyl (Vascepa) Capsule	• Commercial: change to Preferred Brand ○ Formulary, Preferred Brand, Prior Authorization • Medicare Part D: Change to Formulary, Preferred Brand, Prior Authorization	N/A
Iloprost tromethamine (Ventavis) Ampul-Neb	Remove from Commercial and Medicaid formularies. • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization	Pulmonary Arterial Hypertension
Avatrombopag maleate (Doptelet) Tablet	Remove quantity limit for Commercial/Medicaid and add to formulary for all lines of business. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization	Doptelet, Mulpleta
Somatropin (Norditropin Nordiflex) Pen Injctr	Add to formulary for Commercial/Medicaid: • Commercial: Formulary, Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization	Human Growth Hormones for Adults Human Growth Hormones for Pediatrics
Somatropin (Omnitrope) Cartridge/Vial	Remove from Commercial formulary •	Human Growth Hormones for Adults Human Growth Hormones for Pediatrics
Zaleplon 5 mg Capsule	• Commercial/Medicaid: Increase quantity limit from 1 capsule per day to 2 capsules per day.	N/A

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

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Ivabradine hcl (Corlanor) Solution	New Dosage Form. Line extend with Corlanor; • Commercial: Formulary, Non-Preferred Brand, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization	Corlanor
Amphetamine sulfate (Evekeo® ODT) Tab Rapdis	New dosage form (ODT). Line extend with Evekeo tablet; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit policy • Medicare Part D: N/A
Epinephrine (Symjepi) Syringe	New strength (0.15mg/0.3ml). Line extend with Symjepi 0.3mg/0.3ml; • Commercial: Formulary, Preferred Brand, Quantity Limit (age 0-17: 6 doses per year; age 18+: 4 doses per year) • Medicaid: Formulary, Quantity Limit (age 0-17: 6 doses per year; age 18+: 4 doses per year) Medicare Part D: Formulary	• Commercial/Medicaid: Quantity Limits of: Epinephrine Auto-Injector • Medicare Part D: N/A
Deferiprone (Ferriprox) Tablet	New Strength. Line extend with Ferriprox 500mg; • Commercial: Formulary, Non-Preferred Specialty • Medicaid: Non-Formulary • Medicare Part D: Non-Formulary	N/A
Immune globulin, gamm/glycine/iga greater than 50 mcg/ml (Cuvitru) Vial	New Strength; Line extend with Cuvitru; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid/Medicare Part B: Immune Gamma Globulin (IgG) • Medicare Part D: N/A

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Health Plan Clinical Policy Changes:

Policy Name	Change Summary
Bystolic, Byvalson	The policy was updated to align with current HTN guidelines.
Compounded Drugs	Criteria updated to allow ingredients that are listed on the FDA's 503A Bulk List or 503B Bulk List.
Continuous Glucose Monitors for Personal Use (Non-professional)	Minor updates were made to language to satisfy requirements of cost-positioning contract. Additionally, the criteria was updated to reflect differences in traditional test strip requirements for different models of continuous glucose monitors for personal use. Effective 11/1/2019
Corlanor	Policy was updated to align with current treatment guidelines.
Diabetic Durable Medical Equipment (DME)	Criteria was updated to reflect differences in traditional test strip requirements for different models of continuous glucose monitors for personal use. Effective 11/1/2019
Juxtapid, Kynamro	Added the following provider restrictions to the policy, "Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist".
Medically Infused Therapeutic Immunomodulators (TIMs) - Medicare Part B	Prior authorization will be added to preferred agents, requiring trial of conventional therapies, similar to the commercial policy. Current established members will not be held to these criteria.
Medications for Rare Indications - Orphan Drugs	Added the therapy Carbaglu (carglumic acid) for patients with NAGS Deficiency to this policy. Added clarification that diagnosis must be confirmed by appropriate lab values and/or genetic testing.
New Medications and Formulations without Established Benefit	• REMOVE: Luvox CR 100MG, 150 MG SR capsules, Vanos (fluocinonide), Zmax (azithromycin 2gm), Sumavel DosePro 6 mg/0.5mL, and Ultravate X (halobetasole/lactic acid. • ADD: Ximino (minocycline ER), Evekeo 5MG, and 10MG ODT tablets.
Northera	Added prescriber restrictions requiring a cardiologist or neurologist to prescribe or be consulted. Also added criteria requiring confirmation that patient has been diagnosed with orthostatic hypotension.
Potassium Lowering Agents	The policy exclusion criteria of "Patients on Dialysis" was removed based on data supporting use in hyperkalemic hemodialysis (HD)

	patients whom were prescribed Veltassa. In addition, patients on dialysis are not a labeled contraindication per the PI for both Lokelma and Veltassa.
Pulmonary Arterial Hypertension – Commercial/Medicaid	Policy was updated to align with current treatment guidelines.
Pulmonary Arterial Hypertension - Medicare Part B	Policy was updated to align with current treatment guidelines.
Therapeutic Immunomodulators	Policy was updated to reflect changes in preferred products for 1/1/2020. No changes to criteria were made.
Vascepa	Criteria has been modified to align with the REDUCE-IT trial to include an indication for secondary atherosclerotic cardiovascular disease (ASCVD) risk prevention. Criteria will include established ASCVD, current use or intolerance of a statin therapy, and documentation of a triglyceride level and a low-density lipoprotein cholesterol within the past 6 months.
Welchol	The policy exclusion criteria of "Monotherapy for Type 2 diabetes" was removed as this is no longer listed as a limitation to use in the package insert.
Doptelet, Mulpleta	Commercial/Medicaid: Updated to require trial and failure of Doptelet before Mulpleta. In addition, criteria added for new indication, Chronic Immune Thrombocytopenia (ITP) for Doptelet.
GnRH Antagonists	Removed requirement that elagolix must be given with add-back therapy based on provider feedback, removed criteria that other causes of gynecologic pain have been ruled out and in placed added a prescriber restriction. Added that there must be documentation that patient has moderate to severe pain associated with endometriosis and documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives. Effective 11/1/2019
Firdapse	Renamed policy to amifampridine and added new drug Ruzurgi to policy, removed age requirements and change policy to require trial and failure of Ruzurgi prior to approval of Firdapse. Added specific reauthorization criteria. Position statement also updated with information about Ruzurgi.
Rituxan	Added diagnosis of Neuromyelitis Optica as a coverable diagnosis to policy based on compendial support for off-label use. Criteria will

	require diagnosis of NMO and medication to be prescribed by, or in consultation, with a neurologist.
Maximum Allowable Opioid Dose – Commercial	Separated into two policies. One for Medicaid and one for Commercial lines of business.
Human Growth Hormones for Adults	Policy was updated to reflect the change in preferred growth hormone product for 1/1/2020. This changed was approved with annual formulary documentation, but policy has now been updated to reflect change.
Human Growth Hormones for Pediatrics	Policy was updated to reflect the change in preferred growth hormone product for 1/1/2020. This changed was approved with annual formulary documentation, but policy has now been updated to reflect change.
Continuous Glucose Monitors for Personal Use – Medicaid	The policy criteria were updated for the Medicaid line of business. To promote affordability for this patient population, the criteria was updated to ensure there is a true medical need for these systems and that they are not being requested for convenience or lack of desire to use finger sticks. Criteria was updated to reflect differences in traditional test strip requirements for different models of continuous glucose monitors for personal use.
Amitiza, Linzess, Motegrity, Movantik, Symproic, Trulance, Zelnorm	Zelnorm recently returned to the market and was added to this policy. Criteria was added to ensure safe and effective use of this medication given significant safety concerns.
Maximum Allowable Opioid Dose – Medicaid	Separated into two policies. One for Medicaid and one for Commercial lines of business. PA Update to Medicaid policy only, changing wording on MME from 120 to 90 Medicaid policy changes from individual quantity limits to a cumulative MME 90 dose. However, no changes to the policy criteria. The position statement was updated. Effective 12/1/2019
The following policy was retired effective 11/1/2019. ○ Lyrica for Medicaid	

PROVIDENCE Health Plan

New Generic Medications:

First time generics to market		
Drug Name	**Action Taken**	**Policy Name**
Hyaluronate sodium (Sodium hyaluronate) Syringe	Line extend with other hyaluronate sodium products. • Commercial: Non-Formulary, Medical Benefit • Medicaid: Non-Formulary, Medical Benefit • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
Erythromycin base (Ery-tab) Tablet DR	Return of generic. Line extend as generic; • Commercial/Medicare Part D: Non-Formulary	N/A
Febuxostat Tablet	First generic (Uloric). Line extend as generic; • Commercial: Formulary, Non-Preferred • Medicaid: Non-Formulary • Medicare Part D: Formulary, Non-Preferred Drug	N/A
Desogestrel-ethinyl estradiol (Kalliga) Tablet	Line extend with other generics; • Commercial: Formulary, Preventative • Medicaid: Formulary • Medicare Part D: Formulary, Non-Preferred Generic	N/A
Rabeprazole sodium Cap DR SPR	First generic (Aciphex sprinkles). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Proton Pump Inhibitors policy • Medicare Part D: N/A

Icatibant acetate Syringe	First generic (Firazyr). Line extend as generic;
	• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (9 ml per 30 days)
	• Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (9 ml per 30 days)
	• Medicare Part D:
	  ○ 2019: Formulary, Specialty, Prior Authorization
	  ○ 2020: Formulary, Specialty, Prior Authorization, Quantity Limit (18 ml per 30 days)
		Hereditary Angioedema policy

Ramelteon Tablet	First generic (Rozerem). Line extend as generic;
	• Commercial:
	  ○ 2019/2020 OR: Formulary, Non-Preferred Generic, Prior Authorization
	  ○ 2020 WA: Tier 4, Prior Authorization
	• Medicaid: Non-Formulary
	• Medicare Part D: Non-Formulary
		• Commercial: Insomnia Agents policy
		• Medicaid/Medicare Part D: N/A

Posaconazole Tablet DR	First generic (Noxafil). Line extend as generic; • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization	Antifungal Agents policy
Norethindrone acetate-ethinyl estradiol (Hailey) Tablet	Line extend with generic Loestrin 21;	N/A

	• Commercial: Formulary, Preventative
	• Medicaid: Formulary
	• Medicare Part D:
	  ○ 2019: Formulary, Non-Preferred Generic (V1) / Formulary, Non-Preferred Drug (V2)
	  ○ 2020: Formulary, Non-Preferred Drug	

Triamterene Capsule	First generic (Dyrenium). Line extend as generic; • Commercial: Formulary, Non-Preferred Generic ○ 2020 WA: Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Non-Preferred Drug	N/A
Halcinonide Cream	First generic (Halog). Line extend as generic; • Commercial: Formulary, Non-Preferred Generic ○ 2020 WA: Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Non-Formulary	N/A