PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 239

September 1, 2019

This is the September 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.

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

New Policies and/or Major Criteria Changes

Effective September 1, 2019

Tumor Treatment Field Therapy for Glioblastoma (Medicare Only) DME413	A new LCD allowing coverage of tumor treatment field therapy for glioblastoma in Medicare members (currently considered not medically necessary) goes into effect 9/1/2019. A new Medicare only policy has been created with links to the new LCD. The current policy has been updated to remove Medicare. **Codes/PA:** The NMN denial will be removed from the TTFT codes (A4555, E0766) and a PA will be added for Medicare **Medicare Guidance:** • Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823) • Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (A52711)

Effective November 1, 2019

Back: Epidural Steroid Injections (All Lines of Business Except Medicare) MED123	The following changes to medical necessity criteria have been made:
	• **Criterion I. (*new, restriction*):** ESI with imaging guidance.
	• **Criterion I.A. *(new, restriction)*:** Detailed neurological exam within the last 3 months' documents radiculopathy.
	• **Criterion I.B. (*modified, liberalization)***: Radiculopathy may now also be documented by electrodiagnostic studies. As with the previous policy, advanced imaging may also be used.
	• **Criterion I.B.1.:**
	  ○ ***(liberalization)*** "Foraminal or lateral recess stenosis" replacing "severe foraminal stenosis"
	  ○ ***(restriction)*** "causing nerve root impingement and/or contact". Because the stenosis must be causing nerve root impingement/contact, this is a restriction from our current policy.
	• **Criterion III. (*new, restriction*)**: repeat injections. Covered if:
	  ○ Symptoms of radiculopathy return; and
	  ○ Documentation that the initial injection: reduced pain, decreased medication use, and improved patient's functional abilities; and
	  ○ Documentation that patient is concurrently participating in an active rehabilitation program/home exercise program/functional restoration program.
	• **Criterion V. (no change):** Frequency limitations will remain the same (3 per region per 12 months). Clarified that this is "3 sessions" per region.

	• **Criterion VI.** ***(new, liberalization)***: ESI may be considered medically necessary for the treatment of post-herpetic neuralgia
	• **Criterion VII.** ***(new, restriction)*** ESI without imaging guidance (62320, 62322) is not medically necessary.
	• **Criterion VIII.** ***(new, restriction)*** ESI with ultrasound guidance (0228T-0231T) is not covered.
	• **Criterion IX. (*new*)**: List of investigational indications expanded to also include:
	  ○ Back or neck pain without radiculopathy
	  ○ Isolated central spinal stenosis
	  ○ Chemical radiculitis caused by annular tears
	  ○ Post-operative pain relief from spinal fusions or discectomy/laminectomy
	• ***(Liberalization)*** Removed caudal ESI as not-covered.
	Codes:
	• 2 codes for injection without imaging guidance (62320, 62322) now considered "not medically necessary".
	• 4 codes added to coding table as "Not Covered" for ESI with ultrasound guidance (0228T-0231T)

Back: Epidural Steroid Injections (Medicare Only) **MED391**	No changes to relevant guidance documents. Added criterion addressing ESI with ultrasound guidance as investigational. Medicare does not address; therefore, we are following commercial criteria in accordance with our hierarchy. **Codes:** • No change to current frequency limits • 4 codes added to coding table as "Not Covered" for ESI with ultrasound guidance (0228T-0231T). **CMS:** • LCD: Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457) • LCD: Lumbar Epidural Injections (L34980)

Back: Percutaneous Vertebral Augmentation SUR418
 	
Previously Titled: Back: Vertebroplasty and Kyphoplasty for Vertebral Fractures (All Lines of Business Except Medicare)
	• For all lines of business, the policy criteria are based on the LCD for percutaneous vertebral augmentation.
	• From 1/1/17-6/30/18, we've had 167 PAs and only 4 of them were denied. Over 70% of these were for Medicare members.
	Major differences: *in general, the Medicare LCD criteria are more restrictive than our current commercial policy.*
	  ○ Medicare LCD does not allow for treatment of more than 3 vertebral levels.
	  ○ Treatment must be within the range of T1-L5
	  ▪ Exceptions to the above two bullets: steroid-induced osteoporosis and multiple myeloma
	  ○ Requires the fracture be acute, less than 4 months' old—established by history, MRI, or bone scan
	  ○ Medicare only allows for vertebral augmentation when billed with select diagnosis codes—one for the vertebral fracture and one for the pain.
	PA: PA is being removed from the 6 CPT codes for vertebroplasty and kyphoplasty.
	Codes: No codes added or removed. The 6 CPT codes for vertebroplasty and kyphoplasty will pay when billed with *both* a group 1 (vertebral fracture) and group 2 (pain) diagnosis code (please see the policy Billing Guidelines for a complete list of diagnosis codes). The 2 CPT codes for sacroplasty will continue to deny as investigational.
	NCD/LCD/LCA: Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (L34106)

Organic Acid Testing	• Removing TIN denial for Genova Labs from several codes.

LAB295 *Previously Titled: Organic Acid Testing and Nutritional Panels*	• Made no changes to the medical necessity criteria (newborn screening) or list of not medically necessary conditions. • Added a list of non-covered organic acid testing panels. **Codes:** • The Genova TIN denial will be removed from several codes. • The following codes were added to the policy: 82570, 83919 • The following codes were removed from the policy: 82542, 82656, 82784, 82978, 83789, 83986, 84311, 84378, 87798
Peripheral Nerve Stimulation for Chronic Pain (Medicare Only) MED434	**New Policy** **Recommendation:** A new Medicare only policy has been created for peripheral neurostimulators (we plan on creating a commercial policy within the next several months). **PA/Codes:** Codes included in the LCD were added to the policy. All codes are already PA'ed per other stim policies; therefore, no PAs have been added. **NCD/LCD:** **Local Coverage Determination (LCD): Peripheral Nerve Stimulation (L37360)**

No Major Criteria Changes

Effective September 1, 2019

Cardiac: Ventricular Assist (VAD/pVAD/LVAD) and Artificial Heart (Biventricular) Devices SUR180	**Interim Update** • This policy is based on CMS guidance for all lines of business. • CMS now requires that destination VAD therapy be performed at a Medicare approved facility. • A note has been added to the top of the policy criteria with a hyperlink to the list of Medicare approved facilities.
Wheelchairs and Power Vehicles DME375	**Interim Coding Update** • Code E2359 is listed on the policy as no PA required; however, this code is denying for PA. • This code is for a power wheel chair battery. None of the other battery codes require PA, and neither should this one. • A CRF will be submitted to remove PA from this code. • No policy updates were needed.

Effective October 1, 2019

Skin and Tissue Substitutes MED378	**Interim Coding Update** • Two codes denying per the policy (Q4112 and Q4114) for injectable collagen products (Cymetra and Integra flowable) may be used for vocal cord paralysis treatment.

Previously Titled: *Skin Substitutes*	○ The E/I denial will be removed from these two codes and they will pay ○ These should only pay when billed with a vocal cord paralysis diagnosis code ▪ J38.02 Paralysis of vocal cords and larynx, bilateral ▪ J38.00 Paralysis of vocal cords and larynx, unspecified ▪ J38.01 Paralysis of vocal cords and larynx, unilateral ○ A note has been added to the billing guidelines that these codes should only pay with the diagnosis codes above. • Policy title was also updated to reflect that some of the products included on the policy are injectable tissue substitutes

Vendor Updates

Updates to AIM Advanced Imaging Clinical Appropriateness Guidelines

Effective for dates of service on and after November 10, 2019, the following updates will apply to the AIM Advanced Imaging Clinical Appropriateness Guidelines.

Oncologic Imaging Guideline contains updates to the following:

- Colorectal cancer, germ cell tumors, kidney cancer, multiple myeloma, prostate cancer and cancers of unknown primary / cancers not otherwise specified,
- Added new sections on hepatobiliary cancer and suspected metastases
- Added allowance for MRI and/or MRCP for diagnostic workup of hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma
- Added allowance for PET "When standard imaging prior to planned curative surgery for cholangiocarcinoma has been performed and has not demonstrated metastatic disease"

Vascular Imaging Guideline contains updates to the following:

- Brain, Head and Neck: Aneurysm - intracranial, Aneurysm - extracranial, Arteriovenous malformation (AVM) and fistula (AVF), Fibromuscular dysplasia, Hemorrhage - intracranial, Stenosis or occlusion - extracranial, Stenosis or occlusion - intracranial, stroke and Venous thrombosis or compression - intracranial
- Chest: Acute aortic syndrome, Aortic aneurysm, Pulmonary artery hypertension
- Abdomen and Pelvis: Acute aortic syndrome, Aneurysm of the abdominal aorta or iliac arteries, Hematoma/hemorrhage within the abdomen or unexplained hypotension, Renal artery stenosis (RAS)/Renovascular hypertension, Venous thrombosis or compression – intracranial, Stenosis or occlusion of the abdominal aorta or branch vessels, not otherwise specified
- Upper Extremity: Peripheral arterial disease, Venous thrombosis or occlusion
- Lower Extremity: Added physiologic testing for peripheral arterial disease and further defined indications for classic presenting symptoms of lower extremity peripheral arterial disease

Imaging of the Heart Guideline contains updates to the following:

- Blood Pool Imaging: Changes address appropriate evaluation and surveillance of LV function in patients following cardiac transplantation. Additional language is more restrictive based on the literature and aligns with the resting transthoracic echocardiography guideline.

- Cardiac CT: Quantitative evaluation of coronary artery calcification has been revised with new more expansive language based on review of the 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 guidelines here.

PHARMACY & THERAPEUTICS COMMITTEE

Oregon Region P&T Committee Meeting August 10, 2018
Go-Live Date: Tuesday, October 01, 2019, unless otherwise noted

New Drugs and Combinations:

Tafamidis (Vyndaqel®) – Capsule
Indication: Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. **Formulary Alternatives:** None
• Commercial: Formulary, Non-preferred Specialty, Prior Authorization, Quantity Limit (4 capsules per day) • Medicaid: Formulary Specialty, Prior Authorization, Quantity Limit (4 capsules per day) • Medicare Part D: Formulary Specialty, Prior Authorization, Quantity Limit (4 capsules per day)

Tafamidis (Vindamax®) – Capsule (Not on market. Launch plans pending. Likely to be available in the second half of 2019.)
Indication: Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. **Formulary Alternatives:** None
• Commercial: Formulary, Non-preferred Specialty, Prior Authorization, Quantity Limit (4 capsules per day) • Medicaid: Formulary Specialty, Prior Authorization, Quantity Limit (4 capsules per day)

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

Alpelisib (Piqray®) – Tablet

Indication:
In combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

Formulary Alternatives:
abemaciclib (Verzenio®), palbociclib (Ibrance®), ribociclib (Kisqali®)

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

Erdafitinib (Balversa®) - Tablet

Indication:
Treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has: susceptible FGFR3 or FGFR2 genetic alterations, and progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Formulary Alternatives:
atezolizumab, nivolumab, durvalumab, avelumab, pembrolizumab

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

Polatuzumab vedotin-piiq (Polivy®) – Vial

Indication:
Treatment of diffuse large B-cell lymphoma, relapsed or refractory, in combination with bendamustine and a rituximab product, after at least 2 prior therapies

Formulary Alternatives:
rituximab, bendamustine

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

Stiripentol (Diacomit®) – Capsule and Powd Pack

Indication:
For the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam.

Formulary Alternatives: valproic acid, clobazam, Epidiolex®

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (**250 mg**: 360 capsules per 30 days; **500 mg**: 180 capsules per 30 days; **250 mg powder for suspension**: 360 packets per 30 days; **500 mg power for suspension**: 180 packets per 30 days)

- Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (**250 mg**: 360 capsules per 30 days; **500 mg**: 180 capsules per 30 days; **250 mg powder for suspension**: 360 packets per 30 days; **500 mg power for suspension**: 180 packets per 30 days)

Benzhydrocodone HCL Acetaminophen (Apadaz®) – Tablet

Indication:
Approved for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Formulary Alternatives:
Immediate-release generic hydrocodone/APAP products, hydrocodone/ibuprofen, tramadol/APAP

- Commercial/Medicaid: Non-Formulary, Quantity Limit (12 tablets per day)
- Medicare Part D: Non-Formulary

Risankizumab-rzaa (Skyrizi) - Syringe Kit
Indication: Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy **Formulary Alternatives:** Stelara®, Humira®, Enbrel®, Cosentyx®
• Commercial: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1.66 mL/84 days) • Medicaid: Non-Formulary, Specialty, Quantity Limit (1.66 mL/84 days) • Medicare Part D: 2019: Non-Formulary; 2020: Formulary, Specialty, Prior Authorization

New Strengths and Formulations:

Levodopa (Inbrija®) - Cap with Dev
Indication: Treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa **Formulary Alternatives:** Apokyn®
• Commercial: Formulary, Preferred Brand • Medicaid: Formulary, Brand • Medicare Part D: Formulary, Specialty

New Indications:

Palbociclib (Ibrance®)
Patient Population Update:

- Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
  - An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or
  - Fulvestrant in patients with disease progression following endocrine therapy.

Decision: 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.

Pembrolizumab (Keytruda®)

New FDA-approved Indication:

- As a single agent for the first-line treatment of patients with stage III NSCLC, who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
- Renal Cell Carcinoma (RCC)
  - In combination with axitinib, for the first-line treatment of patients with advanced RCC.

Decision: 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.

Belimumab (Benlysta®)

New FDA-Approved Indication (Plus All Limitations of Use):

- Treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Benlysta clinical policy does not have age restrictions; therefore, no updates are necessary to policy.

Alirocumab (Praluent®)

New FDA-approved Indication:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.

- As adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C.

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

Ivacaftor (Kalydeco®)

New FDA-approved Indication:

- Treatment of cystic fibrosis (CF) in patients age 6 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.

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

Glecaprevir and Pibrentasvir (Mavyret®)

Expanded Patient Population and Indication Update:

- Treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- Treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Mavyret clinical policy does not have age or weight restrictions; therefore, no updates are necessary to policy.

Dapagliflozin and Saxagliptin (Qtern®)

FDA-Approved Indication Update:

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Limitations of Use: QTERN is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Qtern clinical policy not affected by new indication update; therefore, no updates are necessary to policy.

PROVIDENCE Health Plan

Ivosidenib (Tibsovo®)

FDA-Approved Indication Update:
• Treatment of acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test in:
  ○ Adult patients with newly-diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.
  ○ Adult patients with relapsed or refractory AML

Decision: 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.

Ado-trastuzumab emtansine (Kadcvla®)
New FDA-approved Indication: • The adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
Decision: 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.

Calcipotriene (Sorilux®)
Expanded Patient Population: • Patients 12 years and older for the indication listed above.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Sorilux policy has no age restrictions; therefore, no updates to the policy are warranted.

IncobotulinumtoxinA (Xeomin®)
FDA-Approved Indication Update: • Treatment or improvement of adult patients with: ○ chronic sialorrhea

- upper limb spasticity
- cervical dystonia
- blepharospasm
- temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Botulinum toxin Commercial/Medicaid clinical policy not affected by new indication update; therefore, no updates are warranted. For Medicare Part B, coverage criteria is based on the Local Coverage Determination LCD35172 and cannot be altered.

Aflibercept (Eylea®)

FDA-Approved Indication Update:

- Treatment of patients with:
  - Neovascular (Wet) Age-Related Macular Degeneration (AMD)
  - Macular Edema Following Retinal Vein Occlusion (RVO)
  - Diabetic Macular Edema (DME)
  - Diabetic Retinopathy (DR)

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Eylea Commercial/Marketplace/Medicaid/Medicare Part B policy with new indication; no changes to coverage criteria are warranted.

Avelumab (Bavencio®)

New FDA-Approved Indication:

- First-line treatment, in combination with axitinib of patients with advanced renal cell carcinoma (RCC).

Decision: 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.

Venetoclax (Venclexta®)

FDA-Approved Indication Update:

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

- In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
  This indication is approved under accelerated approval based on response rates. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Decision: 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.

Dalteparin sodium (Fragmin®)

New FDA-Approved Indication:

- Treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence in pediatric patients 1 month of age and older
- Limitations of Use FRAGMIN is not indicated for the acute treatment of VTE

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Teduglutide Recombinant (Gattex® Kit)

Expanded Patient Population:

- Treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Gattex policy criteria to 1 year and older and remove “adult” from criteria.

Trastuzumab-pkrb (Herzuma®)

New FDA-Approved Indication:

- Treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Decision: 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.

Pregabalin (Lyrica®)
Expanded Patient Population: • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia (PHN) • Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older • Fibromyalgia • Neuropathic pain associated with spinal cord injury
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Lyrica Medicaid policy with expanded patient population; no changes to coverage criteria are warranted.

Rituximab-abbs (Truxima®)

New FDA-Approved Indication:
• Non-Hodgkin's Lymphoma (NHL)
  ○ Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.
• Chronic Lymphocytic Leukemia (CLL).
  ○ Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)

Decision: 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.

Ruxolitinib Phosphate (Jakafi®)
New FDA-Approved Indication: • Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.
Decision: 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.

Cariprazine Hydrochloride (Vraylar®)
New FDA-Approved Indication: • Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Commercial/Medicaid policy with new indication; no changes to coverage criteria are warranted.

Lenalidomide (Revlimid®)
New FDA-Approved Indication: • Previously treated follicular lymphoma (FL), in combination with a rituximab product. • Previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.
Decision: 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.

Ramucirumab (Cyramza®)
New FDA-Approved Indication: • As a single agent, for the treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of ≥400 ng/mL and have been treated with sorafenib.
Decision: 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:

Certain Prescription Insomnia Medicines: New Boxed Warning - Due to Risk of Serious Injuries Caused by Sleepwalking, Sleep Driving and Engaging in Other Activities While Not Fully Awake
ISSUE:

FDA is advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with • Lunesta (eszopiclone) • Sonata (zaleplon) • Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist (zolpidem) than other prescription medicines used for sleep. **RECOMMENDATION:** If patients experience a complex sleep behavior where you engage in activities while you are not fully awake or if you do not remember activities, you have done while taking the medicine you should: • Stop taking your insomnia medicine. • Contact your health care professional right away Healthcare professionals should not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medicines. Healthcare Professionals should advise all patients that: • Although rare, the behaviors caused by these medicines have led to serious injuries or death. To discontinue taking these medicines if they experience an episode of complex sleep behavior.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Other Formulary Changes:

Drug Name	Policy Name	Change Summary
Mepolizumab (Nucala®) Auto Injc/Syringe	Commercial/Medicaid: Add to Il-5 Inhibitors policy Medicare: Nucala (see below for criteria)	New dosage form. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (1 vial/syringe per 28 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (1 vial/syringe per 28 days) • Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (3 vials/syringes per 28 days) Effective: 09/01/2019
For eosinophilic asthma:		

1) Documentation of one of the following: a. A blood eosinophil count of at least 150 cells/microliter in the past 3 months b. A blood eosinophil count of at least 300 cells/microliter in the past 12 months c. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids 2) Documentation of a trial/failure of a combination of a high-dose inhaled corticosteroid and a long-acting inhaled beta2-agonist unless there is intolerance or contraindication to the medications 3) Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or poor asthma control scores Reauthorization: Documentation of response to therapy such as an improvement in baseline asthma control scores, reduction in exacerbations/hospitalizations or oral corticosteroids For Eosinophilic Granulomatosis with Polyangiitis (EGPA): 1) History or presence of asthma 2) Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter 3) At least two of the following clinical findings: biopsy evidence of eosinophilic vasculitis, motor deficit or nerve conduction abnormality, pulmonary infiltrates, sinonasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura or positive test for ANCA 4) Documentation of inadequate control of EGPA while on oral corticosteroids and immunosuppressive therapy (such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil) or a contradiction/intolerance to these therapies Reauthorization: Documentation of a positive response to therapy, such as no active vasculitis, a reduction in relapses or reduction of daily oral corticosteroids		
Perampanel (Fycompa®) Tablet/Suspension	• Commercial/Medicaid: Antiepileptic Medications • Medicare Part D: Fycompa	Remove quantity limits for all lines of business
Brivaracetam (Briviact®) tablet	• Commercial/Medicaid: Briviact • Medicare Part D: Antiepileptic Agents	Remove quantity limits for all lines of business
Clobazam tablets/oral suspenstion	• Commercial/Medicaid: Antiepileptic Medications • Medicare Part D: Onfi/Banzel	Remove quantity limits for all lines of business Retire Prior authorization and/or step therapy for all lines of business
Clobazam film (Symapzan®)	• Commercial/Medicaid: Sympazan	Remove quantity limits for all lines of business

	• Medicare Part D: Onfi/Banzel	
Estradiol/progesterone (Bijuva®) Capsule	N/A	New combination. • Commercial: Formulary, Non-Preferred Brand Medicaid/Medicare Part D: Non-Formulary
Methylphenidate hcl (Adhansia® XR) CPBP	• Commercial/Medicaid: Add to New Medications and Formulations without Established Benefit • Medicare: N/A	New strength. • Commercial/Medicaid: Non-Formulary, Prior Authorization Medicare Part D: Non-Formulary
Halobetasol propion/tazarotene (Duobrii®) Lotion	• Commercial/Medicaid: Add to New Medications and Formulations without Established Benefit • Medicare: N/A	New combination. • Commercial/Medicaid: Non-Formulary, Prior Authorization Medicare Part D: Non-Formulary
Methylphenidate hcl (Jornay® PM) CPDR ER SP	• Commercial/Medicaid: Add to New Medications and Formulations without Established Benefit • Medicare: N/A	New dosage form. • Commercial/Medicaid: Non-Formulary, Prior Authorization Medicare Part D: Non-Formulary
Orphenadrine/aspirin/caffeine (Norgesic®)	N/A	New dosage form. Non-formulary for all lines of business
Eluxadoline (Viberzi®) 100 mg and 75 mg Tablets	Viberzi	Remove quantity limit on all lines of business.
Isavuconazonium (Cresemba®) Capsule	• Commercial/Medicaid: Antifungal Agents • Medicare: Cresemba	Remove quantity limit on all lines of business.
Oxycodone hcl 5 mg Tablet	N/A	Commercial/Medicaid: Increase quantity limit from 10 tablets per day to 12 tablets per day.
Valbenazine Tosylate (Ingrezza® Initiation Pack) CAP DS PK	• Commercial/Medicaid: VMAT2 Inhibitors • Medicare: Ingrezza	• Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization Medicare Part D: Formulary, Specialty, Prior Authorization

Guselkumab (Tremfya®)	Therapeutic Immunomodulators_ Commercial	Commercial: Make preferred agent for FDA indications: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1 dose every 56 days)
Apomorphine hcl (Apokyn®) Cartridge	Apokyn	Remove from Medicaid formulary
Rosuvastatin calcium (Ezallor sprinkle®) Cap Sprink	• Commercial/Medicaid: Add to New Medications and Formulations without Established Benefit • Medicare: N/A	New dosage form. • Commercial/Medicaid: Non-Formulary, Prior Authorization Medicare Part D: Non-Formulary
Immune globulin, gamma(igg)-hipp human/maltose (Cutaquig®) Vial	Immune Gamma Globulin (IGG)	New formulation. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization Medicare: Prior Authorization B vs D
Halobetasol propion/tazarotene (Duobrii®) Lotion	• Commercial/Medicaid: Add to New Medications and Formulations without Established Benefit • Medicare: N/A	New combination. Commercial/Medicaid: Non-Formulary, Prior Authorization Medicare Part D: Non-Formulary
Prabotulinumtoxina-xvfs (Jeuveau®) Vial	Botulinum Toxin	New entity. Excluded from coverage due to cosmetic use. • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary Medicare Part B: Medical Benefit, Prior Authorization
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		
Ivacaftor (Kalydeco®) Gran Pack	New strength. Line extend with Kalydeco. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (56 granule packages for 28 days)	

	• Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (56 granule packages for 28 days) • Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (56 granule packages for 28 days) Added to CFTR Modulators policy
Dapagliflozin/saxagliptin HCL (Qtern®) Tablet	New strength. Line extend with Qtern. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Added to SGLT-2 Inhibitors policy Medicare Part D: Non-Formulary
Galcanezumab-gnlm (Emgality®) Syringe	New Strength. Line extend with Emgality. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Added to Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists policy Medicare Part D: Non-Formulary
Tolvaptan (Jynarque) Tablet	Line extend with Jynarque. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization Added to Tolvaptan policy
Ceritinib (Zykadia®) Tablet	New dosage form (tablet). Line extend with Zykadia capsule. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization Added to Oral ANTI-cancer Medications policy
Tezacaftor/ivacaftor (Symdeko®) Tablet SEQ	New strength. Line extend with Symdeko 100/150mg-150mg tablets. • Commercial: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day) • Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day)

	Added to CFTR Modulators policy

Health Plan Clinical Policy Changes:

Policy Name	Change Summary
Adult Long-Acting Stimulant Medications - Medicaid	Removed "prior to 18 years old" for continuity of care criteria. Patient established on long-acting therapy will be able to continue therapy regardless of age.
Antiepileptic Medications	Retired the prior authorization on clobazam (Onfi) tablet and suspension due to low cost and low risk of overutilization. Changed trial and failure wording to say preferred rather than just formulary agent as this is more accurate of how the step therapy edit is set up.
Bepreve, Lastacaft, Pataday, Patanase, Pazeo	Due to availability of inexpensive generic formulations, the prior authorization for olopatadine 0.2% eye drops (Pataday®) and olopatadine nasally spray (Patanase®) will be retired. The criteria were updated to require trial of olopatadine 0.2% (instead of 0.1%) for the other non-preferred ophthalmic agents. The coverage duration was updated to approve for lifetime.
Calcitonin gene-related peptide (CGRP) antagonists	The commercial criteria were updated to require documentation of at least four (4) headache days per month. The Medicaid criteria was updated to match the Oregon Health Authority current criteria: 1) require documentation of at least four (4) headache days per month and 2) documentation that member has not received a botulinum toxin injection in the past two months
Continuous Glucose Monitors for Personal Use (Non-professional)	Policy was updated define quantity limitation criteria and make criteria less restrictive for the Libre. In addition, the Dexcom system was added to this policy and will require different criteria depending on diagnosis.
Injectable Anti-Cancer Medications	Herceptin Hylecta® is a new formulation for trastuzumab that was added to this policy with criteria requiring trial and failure of Herceptin®

Lamotrigine ER	Added bipolar I disorder to covered uses section as the immediate release is approved for this indication.
Lemtrada	Ocrelizumab (Ocrevus®) was added as one of the options for disease modifying therapies for the treatment of multiple sclerosis.
Medical Nutrition - Commercial **Medical Nutrition - Medicaid**	Removed "within last 3 months" for criterion #1 addressing feeding tube placement, as coverage would be allowed for anyone with a feeding tube already in place
Mircera	The coverage duration was updated to one year for both initial and reauthorization to align with Aranesp/Epogen/Procrit/Retacrit policy.
Qudexy XR, Trokendi XR	Updated criteria for migraine prophylaxis use. Previous criteria stated “Requests are generally not approved because the requested drug is effective and available in the standard formulation. In unique circumstances, approval will be considered on a case-by-case basis given the medical rationale and the clinical evidence provided.” However, it was determined that defined criteria with trial and failure would allow more consistent reviews. The new criteria will now require that medication is written by or in consultation with a neurologist as well as trial of immediate release topiramate and prophylactic medications from at least three different classes.
Revcovi	The policy criteria was updated to require documentation of current weight to ensure appropriate dosing.
Savella	The criteria were updated to require six weeks of trial and failure of medication. In addition, if patient experiences intolerance to gabapentin, pregabalin (Lyrica®) will be required.
Spinraza	Added exclusion for use in combination, or following, Zolgensma therapy
Spravato	The prescriber restrictions were further restricted to a psychiatrist or psychiatric nurse practitioner. The following additions were made to the criteria: 1) require evaluation by prescriber within previous 3 months, 2) documentation of a Montgomery Asberg Depression Rating Scale (MADRS)

	total score of at least 28 on initial authorization and a significant decrease in MADRS score for reauthorization, and 3) prerequisite therapy was updated to require trial and failure of at least three different antidepressants (from two classes) and trial and failure of augmentation therapy.
Sympazan	The quantity limits were removed on this drug due to low risk of overutilization.
Zolgensma	Removed exclusion for use of this gene therapy after use of Spinraza. The exclusion for concomitant use will remain in place.
The following policies were retired effective 6/1/2019. ○ Cyanocobalamin injection Quantity Limit	

New Generic Medications:

NEW GENERICS	
Levonorgestrel-ethinyl estradiol (Afirmelle) Tablet	Line extend with other generics. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Formulary, Non-Preferred Generic
Norethindrone-ethinyl estradiol-iron (Aurovela FE) Tablet	Line extend as generic. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Formulary, Non-Preferred Generic
Levonorgestrel-ethinyl estradiol and ethinyl estradiol (Simpesse) Tablet	Line extend with other generics for Seasonique. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Non-Formulary
Levonorgestrel-ethinyl estradiol (Ayuna) Tablet	Line extend with other generics. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Formulary, Non-Preferred Generic
Cefixime Capsule	First generic (Suprax). Line extend as generic.

	• Commercial:
	  ○ 2019/2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Formulary, Tier 4
	• Medicaid: Non-Formulary
	• Medicare Part D:
	  ○ 2019: Non-Formulary
	2020: Formulary, Non-preferred Drug

Dicyclomine hcl Ampule	Return of generic (Bentyl). Line extend as generic Medical benefit for all lines of business

Estradiol (Dotti) Patch	Line extend as generic (Vivelle-DOT).
	• Commercial:
	  ○ 2019/2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Formulary, Tier 3
	• Medicaid: Formulary
	• Medicare Part D:
	  ○ 2019: Formulary, Non-Preferred Generic
	2020: Formulary, Non-Preferred Drug

Fluticasone propionate (Beser®) Lotion	Line extend with fluticasone propionate lotion.
	• Commercial:
	  ○ 2019/2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Formulary, Tier 4
	• Medicaid: Non-Formulary
	Medicare Part D: Formulary, Non-Preferred Drug

Fulvestrant Syringe	First generic (Faslodex). Line extend as generic. • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization Added to Injectable Anti-Cancer Medications policy

Loteprednol etabonate Drops Susp	Line extend as generic (Lotemax).
	• Commercial:
	  ○ 2019 OR: Formulary, Non-Preferred Generic
	  ○ 2020 OR/WA: Formulary, Tier 4
	• Medicaid: Formulary

	• Medicare Part D: ○ 2019: Formulary, Non-Preferred Generic 2020: Formulary, Non-Preferred Drug
Ethinyl estradiol/drospirenone (Lo-Zumandimine/Zumandimine) Tablet	Line extend as generic. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Formulary, Non-Preferred Generic

Mesalamine DR Cap(DRTAB)	First generic (Delzicol DR). Line extend as generic.
	• Commercial:
	  ○ 2019/2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Formulary, Tier 4
	• Medicaid: Formulary
	Medicare Part D: Formulary, Non-Preferred Generic

Mifepristone Tablet	First generic (Mifeprex). Line extend as generic. Non-Formulary for all lines of business

Naftifine HCL Topical	First generic (Naftin). Line extend as generic.
	• Commercial:
	  ○ 2019/2020 OR: Formulary, Non-Preferred Generic
	  ○ 2020 WA: Formulary, Tier 4
	• Medicaid/Medicare: Non-Formulary

Desog-e.estradiol/e.estradiol (Simliya) Tablet	Line extend as generic. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Formulary, Non-Preferred Generic
Norgestimate-ethinyl estradiol (Tri-Lo-Mili) Tablet	Line extend as generic. • Commercial: Formulary, Preventive • Medicaid: Formulary Medicare Part D: Formulary, Non-Preferred Generic
Bosentan Tablet	First generic (Tracleer). Line extend as generic. • Commercial: Formulary, Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization

	Added to Pulmonary Arterial Hypertension Policy
Erlotinib hcl Tablet	First generic (Tarceva). Line extend as generic. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization Added to Oral ANTI-cancer Medications policy
Penicillamine Capsule	First generic (Cuprimine). Line extend as generic. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Added to New Medications and Formulations without Established Benefit Policy Medicare Part D: Non-Formulary

Sildenafil citrate Susp Recon	First generic (Revatio suspension). Line extend as generic.
	• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization
	  ○ Added to Pulmonary Arterial Hypertension policy
	• Medicaid: Formulary, Specialty, Prior Authorization
	  ○ Added to Pulmonary Arterial Hypertension policy
	Medicare Part D: Non-Formulary

Doxylamine succ-pyridoxine hcl Tablet DR	First generic (Diclegis). Line extend as generic. • Commercial: Formulary, Non-Preferred Generic, Quantity Limit (4 tablets per day) 1. Medicaid: Formulary, Quantity Limit (4 tablets per day) Medicare Part D: Non-Formulary