PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 251

September 1, 2020

This is the September 1, 2020 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

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

MEDICAL POLICY COMMITTEE

Effective 1/1/2021, Providence Health Assurance will be instituting the Centers for Medicare & Medicaid (CMS) National Coverage Determination (NCD) Coding Policy Manual for selected lab services for Medicare lines of business only.

Lab Management FAQ

Q: What is the CMS NCD coding policy manual?
A: The final rule, published in the Federal Register on November 23, 2001 (66 FR 58788), established the national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. It promoted Medicare program integrity and national uniformity, and simplified administrative requirements for clinical diagnostic services. A total of 23 lab NCDs for diagnostic lab testing services were established as part of this 2001 final rule.

For each of the 23 NCDs, the CMS NCD coding policy manual outlines ICD-10-CM codes that are "covered" by Medicare or codes that "do not support medical necessity". The coding policy manual also includes limitations to these lab testing services, such as frequency limits.

Q: What is a NCD for diagnostic laboratory testing?
A: A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the clinical circumstances in which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide.

Q: How is Providence Health Assurance implementing the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual?
A: Through medical policy, we are creating new medical policies based on the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual. The CPT/HCPCS codes for the various lab testing services will be configured to pay or deny (not medically necessary) based on the diagnosis codes outlined in the coding policy manual.

Q: What laboratory services will be affected by this change?
A: To begin, we will implement medical policies and coding configuration based on the CMS NCD coding policy manual for the following NCDs, for *Medicare lines of business only*:

- Blood Counts (NCD 190.15)
- Glycated Hemoglobin/Glycated Protein (NCD 190.21)
- Thyroid Testing (NCD 190.22)

- Lipids Testing (NCD 190.23)

In the future, we plan to implement all 23 diagnostic laboratory testing NCDs for all lines of business. Provider notice will be provided 60 days in advance of each implementation.

Q: When will the new policies and coding configuration take effect?
A: 1/1/2021 for *Medicare lines of business only*. On this date, the medical policies will be accessible here: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

Q: Where can I access the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual?
A: The NCDs are linked below. Within every NCD there is a section titled "**Covered Code Lists**". Under this section, you may download the most recent version of the CMS NCD coding policy manual.

- Blood Counts (NCD 190.15)
- Glycated Hemoglobin/Glycated Protein (NCD 190.21)
- Thyroid Testing (NCD 190.22)
- Lipids Testing (NCD 190.23)

Blood Counts (Medicare Only) LAB426	**New Policy** • Blood counts will be medically necessary and covered when criteria in National Coverage Determination (NCD) for Blood Counts (190.15) are met and codes are not billed with any diagnosis code taken from the Medicare NCD Coding Policy Manual and Change Report. **Codes/PA:** 11 codes added, none will require PA and will be configured to **deny** when billed with any dx code designated by Medicare. **CMS:** • National Coverage Determination (NCD) for Blood Counts (190.15) • Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM)
Thyroid Testing (Medicare Only) LAB428	**New Policy** • Thyroid testing will be medically necessary and covered when criteria in National Coverage Determination (NCD) for Thyroid Testing (190.22) are met and codes are billed with any diagnosis code taken from the Medicare NCD Coding Policy Manual and Change Report. • Also instituting a 4/rolling calendar year quantity limit, in accordance with the Medicare NCD linked above. **Codes/PA:** 4 codes added, none will require PA and will be configured to **pay** when billed with any diagnosis code designated by Medicare. **CMS:** • National Coverage Determination (NCD) for Thyroid Testing (190.22) • Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM)

Glycated Hemoglobin and Glycated Protein Testing (Medicare Only) **LAB431**	**New Policy** • Policy cites Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Glycated Hemoglobin/Glycated Protein (190.21). • Glycated hemoglobin and glycated protein testing billed with CPTs 82985 and 83036 will **pay** with any of the diagnostic codes listed in the Medicare NCD Coding Policy Manual, section for NCD 190.21, linked here. Other diagnosis codes paired with these CPTs will deny. **Codes/PA:** Add two codes from the NCD, neither of which will PA. Codes will pay for ICD-10 diagnosis codes listed in the Medicare Coding Policy manual, and will otherwise deny as not medically necessary. • 82985: Glycated protein • 83036: Hemoglobin; glycosylated (A1C)
Lipid Testing (Medicare Only) **LAB432**	**New Policy** • Lipid testing will be considered medically necessary and covered when criteria in Coverage Determination (NCD) for Lipid Testing (190.23) are met and codes are billed with dx codes listed in the Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM) **Codes/PA:** Eight codes added; none require PA. Codes will be configured to pay when billed with one of the diagnosis codes in the hyperlinked spreadsheet above.

Effective November 1, 2020

Cardiac Implantable Loop Recorder **SUR175**	**Annual Update** • Add replacement criteria to policy, considering replacement medically necessary only when criteria for initial implantation is met and the device is nonfunctioning, the electric replacement indicator signals replacement is necessary, or replacement is indicated in the manufacturer instructions. • No CMS guidance identified. **Codes/PA:** No change in codes or PA
Knee: Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects **SUR263**	**Annual Update** The following changes have been made: • Added language to criterion I.C– specifying that symptoms must interfere with age-appropriate activities of daily living. • Symptoms must have failed to improve after 3 months of conservative therapy (criterion I.D.); language added specifying that this is considered integral to pre-operative surgery planning. • All studies included in Hayes' systematic reviews include patients who had previously failed conservative treatment. • CMS section of policy has been updated due to retirement of non-covered services LCD **Codes/PA:** No coding or PA changes.
Knee: Meniscal Allograft Transplantation	**Annual Update** The following changes have been made: • Added language to criterion I.C– specifying that symptoms must interfere with age-appropriate activities of daily living.

and Other Meniscal Implants **SUR266**	• Symptoms must have failed to improve after 3 months of conservative therapy (criterion I.D.); language added specifying that this is considered integral to pre-operative surgery planning. **Codes/PA:** No coding or PA changes.
Knee: Osteochondral Allografts and Autografts for Cartilaginous Defects **SUR264**	**Annual Update** The following changes have been made: • Added language to criterion I.C– specifying that symptoms must interfere with age-appropriate activities of daily living. • Symptoms must have failed to improve after 3 months of conservative therapy (criterion I.D.); language added specifying that this is considered integral to pre-operative surgery planning. **Codes/PA:** No coding or PA changes.

Effective September 1, 2020

Cosmetic and Reconstructive Procedures (All Lines of Business except Medicare) **SUR193**	**Annual Update** No recommended criteria changes **Codes/PA:** CPT codes 15840-15846 were removed.
Cosmetic and Reconstructive Procedures (Medicare Only) **SUR441**	**Annual Update** • The LCD/LCA guidelines and CPT codes for 'Benign Skin Lesion Removal (Excludes Actinic Keratosis, and Mohs)' have been added to the Medicare Only policy. • CPT codes for Dermabrasion procedures were moved to No PA from Cosmetic to be configured to pay with diagnosis codes listed in the Plastic Surgery LCA. These Dx codes can be found in the Group 1 ICD-10 Codes section of the LCA (A57222). • Current CMS guidance: ○ National Coverage Determination (NCD) for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5) ○ National Coverage Determination (NCD) for Plastic Surgery to Correct "Moon Face" (140.4) ○ National Coverage Determination (NCD) for Treatment of Actinic Keratosis (250.4) ○ Local Coverage Determination (LCD): Plastic Surgery (L37020) ○ Local Coverage Article (LCA): Billing and Coding: Plastic Surgery (A57222) ○ Local Coverage Determination (LCD): Benign Skin Lesion Removal (Excludes ACTINIC Keratosis, and Mohs) (L33979) ○ Local Coverage Article (LCA): Billing and Coding: Benign Skin Lesion Removal (Excludes Actinic Keratosis, and Mohs) (A57162) **Codes/PA:**

	• 33 CPT codes for Benign Skin Lesions were added to the No PA list. • CPT codes 15780-15783 were moved from Cosmetic/Noncovered to the No PA list to be configured to pay with the dx codes noted in the LCA.
Fecal Incontinence Treatments (All Lines of Business Except Medicare) **SUR224**	**Annual Update** No change to criteria. **Codes/PA:** • Removing A4653 and removing E/I denial: code was mistakenly added to this policy at last update; not applicable. No claims have been reported with this code. • Adding A4563 (vaginal insert rectal control system) as code should already be on policy. Currently configured to deny E/I per Investigational Medical Technologies (All LOB Except CMS) policy.

Fecal Incontinence Treatments (Medicare Only)
 	
SUR437
	Annual Update
	• Continue following: Local Coverage Article: Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017)
	• Two additional relevant CMS guidance documents identified addressing manual pump enema systems and vaginal inserts:
	  • Local Coverage Determination (LCD): Bowel Management Devices (L36267)
	  • Local Coverage Article: Bowel Management Devices - Policy Article (A54516)
	Codes/PA:
	• Adding A4459 (manual pump enema system) which will deny E/I.
	• Removing A4653 and removing E/I denial: code was mistakenly added to this policy at last update; not applicable. No claims have been reported with this code.
	• Adding A4563 (vaginal insert rectal control system) as code should already be on policy. Currently configured to deny E/I per IMT (Medicare Only) policy. Code will be removed from IMT (Medicare Only).

Automatic External Defibrillators (AED)
 	
DME196
	Annual Update
	• Remove PA for remaining two codes that are currently being prior authorized.
	• Continue to base policy off the following CMS guidelines:
	  ○ Local Coverage Determination (LCD) L33690: Automatic External Defibrillators
	  ○ Local Coverage Article (LCA) A52458: Automatic External Defibrillators
	Codes/PA: Removed PA for codes E0617 and K0606

Back: Percutaneous Vertebral Augmentation
 	
SUR418
	Annual Update
	Recommendations:
	• Continue with no PA on any codes in this policy. Codes are configured to pay/deny based on the medically necessary diagnosis codes included in the LCD/LCA.
	• Continue to follow CMS guidelines:
	  ○ Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)(L34106)
	  ○ Local Coverage Article (LCA): Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)(A56573)
	• *Note: Guidance on sacroplasty was based on LCA A55681, which was retired in the beginning of July 2020. An evidence review was conducted to replace Medicare guidance and has been added to the policy draft.*

	Codes/PA: New diagnosis codes added to pay and many diagnosis codes removed.
Bone Growth Stimulation (All Lines of Business Except Medicare) **MED149**	**Annual Update** No recommended criteria changes **Codes/PA:** No changes in codes or PA
Bone Growth Stimulation (Medicare Only) **DME409**	**Annual Update** No changes to relevant Medicare criteria. • National Coverage Determination (NCD) for Osteogenic Stimulators (150.2) • Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796) • Local Coverage Article (LCA): Osteogenesis Stimulators- Policy Article (A52513) **Codes/PA:** no changes in coding or PA
Clinical Trials and Devices (All Lines of Business Except Medicare) **MED184**	**Annual Update** No recommendation for changes to criteria. Continue to follow Oregon Revised Statutes 743A.192; Washington Administrative Code 284-43-5420, Clinical Trials; and United States Code, 2006 Edition, Supplement 4, Title 42, Sec. 300gg-8 - Coverage for individuals participating in approved clinical trials. **Codes/PA:** Add new 07/01/2020 effective code to deny as investigational. • C9760: Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study
Clinical Trials and IDE Studies (Medicare Only) **MED185**	**Annual Update** Continue to implement the following Centers for Medicare & Medicaid guidance: • Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) • Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services • Medicare Benefit Policy Manual, Chapter 14 - Medical Devices • Medicare Benefit Policy Manual, Chapter 4 – Benefits and Beneficiary Protections **Codes/PA:** Add new 07/01/2020 code. Code will PA and deny if not billed with the appropriate Q0 modifier.
Diabetes: Blood Glucose Monitor and Supplies (All Lines of Business Except Medicare)	**Annual Update** Urine test reagent strips or tables (A4250) now called out by CMS guidance documents (A4250) as non-covered. This has been added to the criteria. Continue to follow Local Coverage Determination (LCD): Glucose Monitors (L33822), and Local Coverage Article: Glucose Monitor – Policy Article (A52464). **Codes/PA:** Changing denials from "not a covered benefit" to "not medically necessary" since non-coverage is specifically called out by CMS. A4250 has been added to the coding table, but was already correctly configured and associated with this policy.

DME206	
Diabetes: Blood Glucose Monitor and Supplies (Medicare Only) **DME421**	**New Policy** No recommended changes to criteria**.** Home blood glucose monitors and related supplies will be covered when criteria from the follow CMS guidance documents are met: • Local Coverage Determination (LCD): Glucose Monitors (L33822) • Local Coverage Article: Glucose Monitor – Policy Article (A52464). **Codes/PA:** See entry for Commercial policy above
Genetic Testing: CADASIL Disease **GT405**	**Annual Update** No recommended criteria changes and no CMS coverage guidance identified. **Codes/PA:** No change in codes or PA
Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing **GT389**	**Annual Update** No recommended criteria changes and no CMS coverage guidance identified. **Codes/PA:** No change in codes or PA

Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies
 	
LAB403
	Annual Update
	Add measurement of antibodies to ustekinumab (Stelara) to the investigational criteria, i.e., Anser UST Assay (Prometheus Laboratories, Inc.). No CMS guidance identified.
	Codes/PA:
	• Add three codes to the policy for measurement of specific drug antibodies, denying each as investigational.
	  ◦ 80145, Adalimumab (see nThrive entry which specifies this is a therapeutic drug *assay*, not the drug itself as the description implies)
	  ◦ 80230, Infliximab (see nThrive entry which specifies this is a therapeutic drug *assay*, not the drug itself as the description implies)
	  ◦ 80280, Vedolizumab (see nThrive entry which specifies this is a therapeutic drug *assay*, not the drug itself as the description implies)
	• Removed CPT 0164U from policy, as this code is not for a test that measures antibodies to immunosuppressive therapies. The code has been placed in the Investigational and Non-covered Medical Technologies policies and remains investigational.

Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring	**Annual Update**
	• Continues to include the following CMS guidance:
	  ◦ Local Coverage Determination (LCD): MolDX: Prometheus IBD sgi Diagnostic Policy (L37313)
	  ◦ Local Coverage Article: Billing and Coding: MolDX: Prometheus IBD sgi Diagnostic Policy (A57517)
	• Panel testing is changing from investigational to not medically necessary because:

LAB312	(1) This assay has been on the market and available to patients for 5+ years; (2) Medicare policy for Prometheus IBD sgi Diagnostic tests is reported as not medically necessary. **Codes/PA:** No changes to codes or PA
Knee: Ablative Procedures of Peripheral Nerves to Treat Knee Pain **SUR436**	**Annual Update** No change to coverage criteria- ablative procedures of peripheral nerves to treat knee pain remain investigational and not covered. CMS section of policy has been updated due to retirement of non-covered services LCD **Codes/PA:** • 0441T: CRF needed to apply dx configuration, currently in place for commercial, to CMS lines of business as well. • 64624: CRF needed to change CMS denial to E/I (currently denies "not medically necessary")
Platelet-Rich Plasma (PRP) for Orthopedic Indications and Wound Healing (Medicare Only) **MED430**	**Annual Update** Updated to new Medicare policy format. • No changes to criteria. • Removed reference to retired local coverage determination, Non-Covered Services (L35008) • Continue to reference National Coverage Determination (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3) **Codes/PA:** No change to coding/PA.

Archive September 1, 2020

Heating Pads and Heat Lamps **DME242**	**Archive** Archive; confirmed with Home Services that this policy is rarely used. **Codes/PA:** Codes currently deny u21; medical policy configuration will be removed and allowed to pay for all codes except E0236 which will continue to deny per "Cold Therapy and Cooling Devices in the Home Setting" policy.

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting August 7, 2020

Go-Live Date: Thursday, October 01, 2020, unless otherwise noted

Special Announcement for Pneumococcal Vaccinations: Effective November 1st 2020 adults 19 years of age and older will be limited to one dose of PCV13 (Prevnar-13®)

- In November 2019, the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) outlined new recommendations for the use of pneumococcal vaccines.
- They are no longer recommending routine vaccination with 13-valent pneumococcal conjugate vaccine (PCV13 or Prevnar-13®) for patients aged 65 years and older, unless there is an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant.
- All patients aged 65 years and older should continue to receive a single dose of 23-valent polysaccharide vaccine (PPSV23).

Table of Contents:

New Drugs and Combinations:

1. **Peanut allergen Powder-DNFP (Palforzia) Cap Sprink and Powd Pack**
   a. **Indication:** An oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients was confirmed diagnosis of peanut allergy.
      - Initiation of therapy may be administered to patients aged 4 through 17 years
      - Up-dosing and maintenance therapy may be continued in patients aged 4 years and older
      - Patients must continue to maintain a peanut-avoidant diet

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Non-formulary
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: N/A			

   b. **Prior Authorization Criteria for Commercial/Medicaid**

PA PROGRAM NAME	Palforzia
MEDICATION NAME	Peanut Allergen Powder-dnfp
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit
EXCLUSION CRITERIA	• Uncontrolled asthma • History of eosinophilic esophagitis and other eosinophilic gastrointestinal disease • Severe or life-threatening anaphylaxis in the last 60 days
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	For Initiation of therapy: Aged 4 to 17 years For Continuation (up-dosing or maintenance): Aged 4 years or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an allergist and/or immunologist.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year
OTHER CRITERIA	Initial Authorization requires all of the following criteria to be met: 1. Documented history of an anaphylactic allergic reaction to peanuts or peanut-containing foods that required epinephrine injection that occurred between 60 days and one year prior to treatment 2. Confirmed peanut allergy by at least one (1) of the following: a. Positive skin prick test (SPT) response to peanut with a wheal diameter of 3mm or greater when compared to the negative control b. Serum immunoglobulin E (IgE) to peanut of 0.35 kU_A/L or greater (kU_A/L = kilos of allergen specific units per liter) 3. Documentation that patient will continue to maintain a peanut-avoidant diet 4. Documentation that patient has an active prescription for auto-injectable epinephrine 5. Provider attestation that the patient is a good candidate for therapy (e.g., will be able to maintain daily dosing requirements after initiation and dose titration) Reauthorization (all of the following criteria must be met): 1. Documentation that patient is tolerating peanut allergen immunotherapy at doses greater than 3 mg and is not exceeding 300 mg daily 2. Documentation that the patient is not experiencing adverse events on Palforzia® (e.g., recurrent asthma exacerbations, persistent loss of asthma control, persistent heartburn, dysphagia, persistent abdominal pain) 3. Provider attestation that the patient continues to be to comply with daily dosing requirements 4. Documentation that patient has an active prescription for auto-injectable epinephrine

4. **Tucatinib (Tukysa) Tablet**
    a. **Indication**: Tucatinib is FDA approved in combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received ≥1 prior anti-HER2-based regimens in the metastatic setting.

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: Nerlynx®, Tykerb®			

    b. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications policy
    c. **Prior Authorization Criteria for Medicare:** Added to Anti-cancer Agents policy

5. **Pemigatinib (Pemazyre) Tablet**
    a. **Indication**: The treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: None			

b. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications policy
c. **Prior Authorization Criteria for Medicare:** Added to Anti-cancer Agents policy

6. **Daratumumab-hyaluronidase-fihj (Darzalex Faspro) Vial**
   a. **Indication**: Daratumumab/hyaluronidase injection is indicated for the treatment of adult patients with multiple myeloma:
      - In combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant.
      - 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, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.
      - In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy.
      - 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

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Medicare Pare D: Non-Formulary Medicare Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: N/A			

   b. **Prior Authorization Criteria**: Added to Injectable Anti-Cancer Medications Policy

7. **Cefiderocol sulfate tosylate (Fetroja) Vial**
   a. **Indication**: For the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by a susceptible Gram-negative microorganism in adult patients who have limited or no alternative treatment options.

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Medicare Pare D: Non-Formulary Medicare Part B: Medical

Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
Audit			
Formulary Alternatives: N/A			

8. **Osilodrostat phosphate (Isturisa) Tablet**
    a. **Indication**: For the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-formulary	Non-formulary	Formulary
Tier**	N/A	N/A	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: Signifor (Commercial, Medicaid, Medicare); Korlym (Medicare)			

    b. **Prior Authorization Criteria**: Added to Signifor Policy

9. **Lemborexant (Dayvigo) Tablet**
    a. **Indication:** Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-formulary	Non-formulary	Non-formulary
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	N/A	0.5/1	N/A
Audit			

Formulary Alternatives: zolpidem, zaleplon, eszopiclone (Commercial, Medicare); flurazepam, triazolam, temazepam (Medicaid)

b. **Prior Authorization Criteria for Commercial**: Added to Insomnia Agents Policy
c. **Prior Authorization Criteria for Medicaid:** Added to Insomnia Agents Policy – Medicaid

10. Ozanimod hydrochloride (Zeposia) Capsule and Cap DS PK

a. **Indication**: For the treatment of relapsing forms of MS, including CIS, relapsing-remitting disease, and active secondary progressive disease, in adult patients.

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	N/A	N/A	N/A
Audit			
Formulary Alternatives: Mayzent®, Gilenya®			

New Drug Strengths and Formulations: See Other Formulary Changes

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Apomorphine hcl (Kynmobi®) Film	New route (sublingual) and dosage form (film); • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 films per day) • Medicaid: Commercial: Formulary, Specialty, Prior Authorization, Quantity Limit (5 films per day) • Medicare Part D: Commercial: Formulary, Tier 5, Prior Authorization, FDA Max (5 films per day)	Apokyn

Drug Name	Recommendation	Policy Name
Buprenorphine hcl (Belbuca) Film	Medicare Part D: add to Formulary, Tier 4, Prior Authorization	Long Acting Opioids
Cetrorelix acetate (Cetrotide®) Kit	• Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary Effective 11/01/2020	Infertility and Related Medications
Clobetasol propionate Oint	Add to Medicaid formulary	N/A
Dexmethylphenidate hcl (Focalin XR®) CPBP 50-50	Add to Medicaid Formulary to align with Oregon Health Authority	Adult Long-Acting Stimulant Medications - Medicaid
Lisdexamfetamine dimesylate (Vyvanse®) Capsule	Add to Medicaid Formulary to align with Oregon Health Authority	Adult Long-Acting Stimulant Medications - Medicaid
Dextroamphetamine/amphetamine (Adderall XR®) Cap ER 24 H	Commercial (WA): Change from Tier 4 to Tier 3	N/A
Diazepam (Valtoco) Spray	Add to Medicaid formulary	Rescue Medications for Epilepsy
Diclofenac epolamine (Licart®) Patch TD24	New dosage form (24h patch); • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Formulations and Medications without Established Benefit • Medicare Part D: N/A
Dolutegravir sodium/lamivudine (Dovato®) Tablet	• Commercial: change from Tier 5 to Tier 3 • Medicaid: Formulary, remove Specialty	N/A
Fentanyl patches (Duragesic®)	**All strengths:** • Commercial: Increase quantity limit to 15 patches per 30 days • Medicaid: Add quantity limit of 15 patches per 30 days	N/A
Erythromycin base in ethanol (Erygel® 2%) Gel	Medicaid: Formulary, add Prior Authorization	Acne Medications in Medicaid
Evolocumab (Repatha®) Syringe	Commercial: change from Tier 5 to Tier 3	PCSK9 Inhibitors - Commercial
Glucagon (Baqsimi®) Spray	• Commercial: add to Formulary, Tier 3 • Medicaid: add to Formulary • Medicare Part D: Formulary, Tier 3, **remove** Quantity Limit Effective 9/1/2020	N/A

Drug Name	Recommendation	Policy Name
Insulin lispro-aabc (Lyumjev®) Vial and U-100 (Lyumjev Kwikpen®) insulin pen	New Formulation; • Commercial: Non-Formulary, Prior Authorization • Medicaid/Medicare Part D: Non-Formulary	Commercial: Non-preferred Insulins
Ledipasvir/sofosbuvir (Harvoni®) Tablet	Remove from Medicaid formulary to align with OHA	Hepatitis C - Direct Acting Antivirals - Medicaid
Leuprolide acetate (Fensolvi®) Syringe	New Strength (45/mg); • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Gonadotropin Releasing Hormone Agonists
Methylphenidate hcl (Ritalin LA®) CPBP 50-50	Remove from Medicaid Formulary to align with Oregon Health Authority	Adult Long-Acting Stimulant Medications - Medicaid
Morphine sulfate ER (MS Contin®) Tablet	Commercial **all strengths:** Increase quantity limit to 3 tablets per day	N/A
Promethazine hcl 12.5 mg Supp Rect	Add to Medicare Part D formulary, Tier 4	N/A
Rotigotine (Neupro®) Patch TD24	Medicaid: keep Non-Formulary, add Step Therapy	Neupro - Step Therapy
Sucralfate (Carafate®) Susp	Add to Commercial (OR) formulary, Tier 2	N/A
Tolvaptan 30 mg Tablet	First Generic (Jynarque/Samsca); Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Add to Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Tolvaptan - Jynarque, Samsca
Topiramate ER (Qudexy XR® 25mg/50mg) Cap spr 24h	Medicare Part D: Formulary, add to Tier 4, Prior Authorization	Qudexy XR, Trokendi XR
Tivicay PD® (Dolutegravir Sodium) 5 Mg Tab Susp	Add to formulary: • Commercial: Formulary, Tier 4, Quantity Limit (6 tablets per day) • Medicaid: Formulary, Quantity Limit (6 tablets per day) • Medicare Part D: Formulary, Tier 4	N/A

Drug Name	Recommendation	Policy Name

Ursodiol Capsule	Add to Commercial/Medicaid formulary;
	• Commercial:
	  ○ OR (Standard): Formulary, Tier 2
	  ○ WA (Cost-Based): Formulary, Tier 3
	• Medicaid: Formulary
		N/A

Vyepti®	**Correction**: Medicare Part B Vyepti formulary status: • Medical, Prior Authorization	Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis
Xembify® (immune globulin subcutaneous, human – klhw)	Commercial: This formulation will be included in the site of care program. It was not included in June policy review due to being a new drug Effective 9/1/2020	Infusion therapy site of care
Narcan® nasal spray	Remove quantity limitations for all lines of business Move to Tier 2 from Tier 3 for Commercial	N/A
Naloxone auto-injector (authorized generic of Evzio®)	Add to formulary: • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	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**
Allergenic extract-botrytis cinerea (Botrytis Cinerea) Vial	New Strength (43,000PNU/ml). Line extend with other Botrytis Cinerea strengths; • Medical Benefit for all lines of business	N/A
Amantadine hcl (Osmolex ER) Tab BP 24h	New Dose Pack Combination (332mg). Line extend with Osmolex ER;	Osmolex ER

	• Commercial: Formulary, Tier 4, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day) • Medicare Part D: Formulary, Tier 4, Prior Authorization, FDA Max (2 tablets per day)	
Dextranomer/hyaluronate/nacl (Deflux) Gel Implnt	Line extend as medical; • Medical Benefit for all lines of business	N/A
Ephedrine sulfate (Emerphed) Vial	New Strength (50mg/10ml). Line extend with ephedrine vials; • Non-Formulary for all lines of business	N/A
Hydromorphone hcl/pf (Dilaudid) Syringe	New Strength (0.2mg/ml). Line extend with other Dilaudid syringe; • Medical Benefit for all lines of business	N/A
Infliximab-axxq (Avsola) Vial	Biosimilar to Remicade. Line extend to Remicade biosimilars (e.g., Inflectra®); • Commercial: Medical Benefit, Prior Authorization • Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicare Part B: Medically Infused Therapeutic Immunomodulators (TIMs) Policy • Medicaid: Therapeutic Immunomodulators (TIMs) Policy – Medicaid
Mitomycin (Jelmyto) Kit	New Strength (40mg/kit). Line extend with mitomycin vial; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Nimodipine (Nymalize) Syringe	New Strength (30mg/5ml & 60mg/10ml). Line extend with Nymalize; • Non-Formulary for all lines of business	N/A
Palbociclib (Ibrance)	**Update from June 2020 P&T:** • Commercial: Formulary, **change** from Tier 6 to Tier 5, Prior Authorization	Oral Anti-Cancer Medications

Selinexor (Xpovio) Tablet	New weekly dose pack. Line extend with Xpovio; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Sofosbuvir (Sovaldi) Pelet Pack	New Dosage Form (pellet packet) and strengths (150mg; 200mg). Line extend with Sovaldi; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Hepatitis C-Direct Acting Antivirals • Medicare Part D: N/A
Ledipasvir/sofosbuvir (Harvoni) Pelet Pack	New Dosage Form (Pellet packet) and Strengths (33.75mg-150mg; 45mg-200mg). Line extend with Harvoni brand; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Hepatitis C-Direct Acting Antivirals • Medicare Part D: N/A
Tolvaptan (Jynarque) Tablet SEQ	New Dose Pack Combination (30mg-15mg; 15mg-15mg). Line extend with other Jynarque combinations; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Tolvaptan - Jynarque, Samsca

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Micafungin Vial	First generic (Mycamine). Line extend as generic; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Formulary, Tier 5	N/A
Methyphenidate ER CSBP	Authorized generic (Aptensio). Line extend as generic; • Commercial: Non-Formulary, Quantity Limit (1 capsule per day) • Medicaid: Non-Formulary, Prior Authorization (18+), Quantity Limit (1 capsule per day); • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Long-Acting Stimulant Medications Quantity Limit Policy • Medicaid: Adult Long-Acting Stimulant Medications Policy – Medicaid • Medicare Part D: N/A
Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Hailey FE) Tablet	Line extend with other Loestrin FE generics; • Commercial: Formulary, ACA; • Medicaid: Formulary, • Medicare Part D: Formulary, T2	N/A
Fluoride (sodium) (Sodium fluoride) Paste	First Generic (Prevident). Line extend as generic: Non-Formulary for all lines of business	N/A
Sodium fluoride/potassium nitrate (Sodium fluoride sensitive) Paste	First Generic (Prevident). Line extend as generic: Non-Formulary for all lines of business	N/A
Desonide Gel	First generic (Desonate). Line extend as generic; • 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

Clinical Policy Changes:

- **Addyi -** Criteria related to abstaining from alcohol was removed, as the package labeling was recently updated to down-grade possible side effects. Alcohol use is no longer contraindicated.
- **Adult Long-Acting Stimulant Medications – Medicaid -** Policy criteria were updated to align with OHA. Prescriber restrictions only are required when use is outside of FDA labeling or OHA recommendations.
- **Apokyn -** Updated policy name to "Apomorphine"; changed criteria to clarify that off episodes should be averaging 2 hours daily instead of per episode. Additionally, a new formulation called Kynmobi® was added to this policy and will be required before approval of Apokyn®.
- **Botulinum Toxin -** This policy was updated to expand coverage for spasticity to all types of spasticity in the upper and lower limbs.
- **Extavia -** Criteria were updated to reflect recently approved preferred multiple sclerosis agents. Also updated coverage duration to lifetime approval.
- **Evzio –** The criteria were updated to now only require medical rationale for not being able to use more cost-effective naloxone products (injection, Narcan® nasal spray, or generic auto-injector)
- **Hetlioz -** Criterion related to non-pharmacologic was removed as the American Academy of Sleep Medicine updated 2015 guidelines does not provide recommendations around planned sleep schedules, light therapy (other non-pharms) due to lack of evidence.
- **Horizant -** The policy criterion for post-herpetic neuralgia was updated to remove tricyclic antidepressants and add pregabalin.
- **Lemtrada -** Due to significant safety concerns with the use of Lemtrada®, the criterion related to prerequisite therapy was updated to require use of Ocrevus® and one additional disease-modifying therapy.
- **Mavenclad -** Updated coverage duration so that coverage can be initially approved for two years, not to exceed two years total in a lifetime.
- **Medical Nutrition – Medicaid -** Coverage duration was updated to allow for lifetime authorization for permanent conditions. Also clarified some requirements.
- **Nuplazid -** The criterion, related to required prerequisite therapy, was updated and quetiapine was removed. The International Parkinson and Movement Disorder Society commissioned review, “Update on Treatments for Nonmotor Symptoms of Parkinson’s Disease – An Evidence-Based Medicine Review” recommend clozapine or pimavanserin (Nuplazid®) as efficacious and clinically useful for treatment of psychosis in Parkinson’s Disease. Quetiapine is recommended as ‘possibly useful’ due to insufficient efficacy evidence. In addition, the 17 mg strength is obsolete and has been removed from this policy.
- **Savella -** Criteria was update to allow gabapentin OR pregabalin as the initial prerequisite requirement.
- **Spinraza -** Policy criterion for diagnosis was updated to align with Zolgensma and clinical evidence supporting its use.
- **Spravato -** The prescriber restrictions were updated to require prescribing by only a psychiatrist and additional criteria were added to ensure patients are being appropriately followed by psychiatry. Additional depression scores used more commonly in practice were added to allow for different ways to show severe depression. The coverage duration was reduced from six to three months for initial authorization
- **Tysabri -** The requirement for relapsing remitting form of multiple sclerosis was removed due to broadened indication. Updated coverage duration to "lifetime".

- **VMAT2 Inhibitors -** Due to the availability of a relatively low-cost generic for Xenazine® (tetrabenazine), requests for Austedo® will not require trial of tetrabenazine, or rationale for not using this therapy. Indirect comparisons suggest tetrabenazine may have larger magnitude of effect but Austedo® may be better tolerated.
- **Zolgensma -** The requirement for symptoms for patients with 3 copies of SNM2 was removed, as evidence is suggesting treating patients as early as possible has better outcomes.
- **Antiepileptic Medications -** Recommend adding Briviact® to anti-epileptic medication policy.
- **Antipsychotics -** Split out trial and failure criteria for schizophrenia and bipolar disorder and added lithium, lamotrigine and divalproex to step therapy for bipolar disorder.
- **Diacomit -** Updated duration of approval for reauthorization to lifetime.
- **Epidiolex -** Updated trial and failure list to include clobazam and changed Medicaid to only require one previous trial to align with OHA criteria.
- **Insomnia Agents -** Removing references to Medicaid, as it will have its own policy.
- **Lamictal ODT -** Exclusion criteria for use for neuropathic pain was removed.
- **Neupro - Step Therapy -** Added step therapy criteria to Medicaid. Removed quantity limit from policy, as this is not currently set up to process that way.
- **Osmolex ER -** Updated duration of approval to be "lifetime."
- **Qudexy XR, Trokendi XR -** Updated criteria for commercial policy to allow for continuity of care if patient is established on drug and has a diagnosis of seizure disorder. Medicaid policy was split out to align with OHA criteria.
- **Radicava -** Reauthorization criteria was updated to allow continuation of coverage with "slowing of disease or progression or stabilization" of function and removed specific scoring requirements.
- **Sympazan -** Added criteria to allow medication if patient is established on therapy. If this is a new start to therapy, criteria was added to require CI/intolerance to both clobazam tablets and solution if no documentation of a previous trial and failure is provided.
- **Wakix -** Updated initial criteria to rule out other causes of sleepiness, modified diagnostic criteria question.
- **Xyrem -** Updated diagnostic criteria for patients with and without cataplexy. Also updated trial and failure requirements for patients being treated for excessive daytime sleepiness without cataplexy.
- **Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis -** This policy was included to clarify recommendations for Vyepti®. This medication was added as non-preferred agent to this policy at June 2020 ORPTC, so clarifying that this policy also applies to Medicare Part B.
- **Qudexy XR, Trokendi XR – Medicaid –** New policy
- **Long-Acting Stimulant Medications QL -** The criteria for new starts was updated to clarify that doses above maximum doses in FDA labeling will not be approved.
- **PCSK9 Inhibitors -** The criteria was updated to clarify prior use of stating therapy. The duration of therapy with a high-intensity statin was defined as eight (8) weeks and statin intolerance is defined as one of the following: rhabdomyolysis, skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation, elevated liver enzymes. Additional minor updates to definition of familial hypercholesterolemia.

- **Long Acting Opioids -** The quantity limits for individual products were updated to reflect appropriate dosing recommendations rather than a maximum of 120 MME. A cumulative opioid edit of 90 MME was previously approved by ORPTC and will be implemented on 9/1/20. These quantity limits will allow for better and more applicable utilization management of long-acting opioids.
- **Long Acting Opioids – Medicaid -** Quantity limits similar to the Commercial policy will be implemented on high risk and high-cost, non-formulary agents to allow for better and more applicable
- **Acne Medications – Medicaid -** Additional preferred agents were added to this policy to align with the Oregon Health Authority (OHA) Preferred Drug List (PDL). Over-the-counter (OTC) benzoyl peroxide gel and wash were added along with prescription clindamycin 1% lotion and clindamycin/benzoyl peroxide 1%-5% pump.

New Indications:

1. **REBLOZYL®**
   LUSPATERCEPT-AAMT
   New indication approved 04/03/2020:
   - Anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

   Limitations of Use:
   - Not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

   RECOMMENDATION: Inform prescribers via MD alert. The Reblozyl Commercial/Medicaid/Medicare B policy was updated at June 2020 ORPTC to include the new indication; therefore, no changes to the policy are currently warranted.

2. **BRAFTOVI®**
   ENCORAFENIB
   New indication approved 04/08/2020:
   - In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy

   Limitations of Use:
   - BRAFTOVI is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC.

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

3. **CYMBALTA®**
   DULOXETINE

New indication approved 04/20/2020:
- Major depressive disorder (MDD) in adults
- Generalized anxiety disorder (GAD) in adults and pediatric patients 7 years of age and older
- Diabetic peripheral neuropathic pain (DPNP) in adults
- Fibromyalgia (FM) in adults and pediatric patients 13 years of age and older
- Chronic musculoskeletal pain in adults

RECOMMENDATION: Inform prescribers via MD alert.

4. **ZEJULA®**
NIRAPARIB
New indication approved 04/29/2020:
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
    - a deleterious or suspected deleterious BRCA mutation, or
    - genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA
RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

5. **MANNITOL IN PLASTIC CONATINER®**
MANNITOL 5%, 10%, 15%, 20% IN PLASTIC CONATINER
INDICATION REMOVAL approved 04/29/2020:
- for diagnostic use (measurement of glomerular filtration rate).

RECOMMENDATION: Inform prescribers via MD alert.

6. **YERVOY®**
IPILIMUMAB
New indication approved 05/15/2020:
- Treatment of adult patients with metastatic non-small cell lung cancer expressing PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with nivolumab.

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

7. **OPDIVO®**
NIVOLUMAB
New indication approved 05/15/2020 and 05/26/2020:
Non-Small Cell Lung Cancer (NSCLC)
- adult patients with metastatic non-small cell lung cancer expressing PD-L1(≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with ipilimumab.
- adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy.

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

8. **TECENTRIQ®**
ATEZOLIZUMAB
New indication approved 05/18/2020 and 5/29/2020:
Non-Small Cell Lung Cancer (NSCLC)
- for the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

Heptatocellular Carcinoma (HCC)
- in combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy

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

9. **DUPIXENT®**
DUPILUMAB
New indication approved 05/26/2020:
- for the treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

Limitation of Use
Not for the relief of acute bronchospasm or status asthmaticus
RECOMMENDATION: Inform prescribers via MD alert. The Commercial/Medicaid policy age restriction will be updated to age 6 and older for moderate-to-severe atopic dermatitis.

10. **AVASTIN®**
BEVACIZUMAB

New indication approved 05/29/2020:
Hepatocellular Carcinoma (HCC)

- in combination with atezolizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy

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

11. CYRAMZA®
RAMUCIRUMAB
New indication approved 05/29/2020:

- in combination with erlotinib, for first-line treatment of metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.

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

12. TALTZ®
LXEKIZUMAB
New indication approved 05/29/2020:

- adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

RECOMMENDATION: Inform prescribers via MD alert. Update the Therapeutic Immunomodulators (TIMs) Commercial to include criteria for use of a non-preferred agent (Taltz®) in adults with active non-radiographic axial spondyloarthritis. Criteria will require documentation of trial and failure, intolerance, or contraindication to certolizumab (Cimzia), the preferred TIMs agent for this indication. For the Medicaid policy, Taltz® will be added as an option for this indication. No changes are warranted for Medicare.

13. TECENTRIQ®
ATEZOLIZUMAB
New indication approved 05/18/2020 AND 5/29/2020:
Heptatocellular Carcinoma (HCC)

- in combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy

Non-Small Cell Lung Cancer (NSCLC)

- for the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

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

14. TREXALL®
METHOTREXATE
New indication approved 05/04/2020:
- Treatment of adults and pediatric patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen
- Treatment of adults with mycosis fungoides
- Treatment of adults with relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen
- Treatment of adults with rheumatoid arthritis
- Treatment of pediatric patients with polyarticular juvenile idiopathic arthritis (pJIA)
- Treatment of adults with severe psoriasis

RECOMMENDATION: Inform prescribers via MD alert.

15. FARXIGA®
DAPAGLIFLOZIN
New indication approved 05/05/2020:
Heart Failure:
- to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV).

RECOMMENDATION: Inform prescribers via MD alert. The SGLT-2 Inhibitors Commercial/Medicaid/Medicare Part D policies will be updated to include the new indication, as follows:

For heart failure (with or without diabetes), Farxiga® (dapagliflozin) may be covered if the following criteria are met:
1. Documented diagnosis of heart failure with reduced ejection fraction (HFrEF) with New York Heart Association (NYHA) functional class II-IV
2. Documented left ventricular ejection fraction of less than or equal to 40% that has been present for at least 2 months
3. Patients are currently on maximally tolerated background standard of care for HFrEF, including:
    a. One of the following:
        i. Angiotensin-converting enzyme (ACE) inhibitors
        ii. Angiotensin II receptor blockers (ARBs)
        iii. Entresto® (sacubitril/valsartan)
    b. Beta-blocker (e.g., metoprolol succinate)

16. LYNPARZA®
OLAPARIB
New indication approved 05/08/2020 and 05/19/2020:
Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza
  Ovarian cancer
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability.

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

17. **POMALYST®**
POMALIDOMIDE
New indication approved 05/14/2020:
- with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)

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

18. **RUBRACA®**
RUCAPARIB
New indication approved 05/15/2020:
Prostate cancer
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
  This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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

19. **ALUNBRIG®**
BRIGATINIB
New indication approved 05/22/2020:
- for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

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

20. **ZOSYN® AND ZOSYN IN PLASTIC CONTAINER®**
PIPERACILLIN/TAZOBACTAM
New indication approved 05/26/2020:
- Intra-abdominal infections in adult and pediatric patients 2 months of age and older
- Nosocomial pneumonia in adult and pediatric patients 2 months of age and older
- Skin and skin structure infections in adults
- Female pelvic infections in adults
- Community-acquired pneumonia in adults

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZOSYN and other antibacterial drugs, ZOSYN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria
RECOMMENDATION: Inform prescribers via MD alert.

21. **SIRTURO®**
BEDAQUILINE
New indication approved 05/27/2020:
- as part of combination therapy in adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve SIRTURO for use when an effective treatment regimen cannot otherwise be provided.

This indication is approved under accelerated approval based on time to sputum culture conversion. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
Limitations of Use: Do not use SIRTURO for the treatment of latent, extra pulmonary or drug-sensitive tuberculosis or for the treatment of infections caused by non-tuberculous mycobacteria. Safety and efficacy of SIRTURO in HIV-infected patients with MDR-TB have not been established, as clinical data are limited.
RECOMMENDATION: Inform prescribers via MD alert.

Drug Safety Monitoring:

1. **Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication - FDA Cautions Against Use Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems**
[Posted 6/24/2020]
ISSUE:
FDA is concerned that hydroxychloroquine and chloroquine are being used inappropriately to treat non-hospitalized patients for coronavirus disease (COVID-19) or to prevent that disease. We authorized their temporary use only in hospitalized patients with

COVID-19 when clinical trials are not available, or participation is not feasible, through an Emergency Use Authorization (EUA). These medicines have a number of side effects, including serious heart rhythm problems that can be life-threatening.

We have reviewed case reports in the FDA Adverse Event Reporting System database, the published medical literature, and the American Association of Poison Control Centers National Poison Data System concerning serious heart-related adverse events and death in patients with COVID-19 receiving hydroxychloroquine and chloroquine, either alone or combined with azithromycin or other QT prolonging medicines. These adverse events included QT interval prolongation, ventricular tachycardia and ventricular fibrillation, and in some cases, death. We are continuing to investigate these safety risks in patients with COVID-19 and will communicate publicly when more information is available.

FDA RECOMMENDATION:

- Patients taking hydroxychloroquine or chloroquine for FDA-approved indications to treat malaria or autoimmune conditions should continue taking their medicine as prescribed.
- The benefits of these medicines outweigh the risks at the recommended doses for these conditions.
- Do not stop taking your medicine without first talking to your health care professional and talk to them if you have any questions or concerns.

Be aware that there are no proven treatments for COVID-19 and no vaccine. If you are receiving hydroxychloroquine or chloroquine for COVID-19 and experience irregular heartbeats, dizziness, or fainting, seek medical attention right away by calling 911.

Health Professionals:

- FDA recommends initial evaluation and monitoring when using hydroxychloroquine or chloroquine under the EUA or in clinical trials to treat or prevent COVID-19. Monitoring may include baseline ECG, electrolytes, renal function and hepatic tests.
- Be aware that hydroxychloroquine or chloroquine can:
    - cause QT prolongation
    - increase the risk of QT prolongation in patients with renal insufficiency or failure
    - increase insulin levels and insulin action causing increased risk of severe hypoglycemia
    - cause hemolysis in patients with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
    - interact with other medicines that cause QT prolongation even after discontinuing the medicines due to their long half-lives of approximately 30-60 days

Health Plan Recommendation: Notify via MD alert.

2. Ivermectin Intended for Animals: Letter to Stakeholders - Do Not Use in Humans as a Treatment for COVID-19
[Posted 4/10/2020]

ISSUE:
FDA is concerned about the health of consumers who may self-medicate by taking ivermectin products intended for animals, thinking they can be a substitute for ivermectin intended for humans.

FDA RECOMMENDATION:
Ivermectin is FDA-approved for use in animals for prevention of heartworm disease in some small animal species, and for treatment of certain internal and external parasites in various animal species.

The Antiviral Research pre-publication paper, “The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro” documents how SARS-CoV-2 (the virus that causes COVID-19) responded to ivermectin when exposed in a petri dish.

People should never take animal drugs, as the FDA has only evaluated their safety and effectiveness in the particular animal species for which they are labeled. These animal drugs can cause serious harm in people. People should not take any form of ivermectin unless it has been prescribed by a licensed health care provider and is obtained through a legitimate source.

Health Plan Recommendation: Notify via MD alert.