PROVIDENCE
Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 245

March 1, 2020

This is the March 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.

Beginning May 1, 2020:

- ***Site of service criteria will be applied to select surgical procedures including, but not limited to, total knee arthroplasty. These criteria are based on the medical necessity of performing the procedures at an inpatient versus outpatient setting. If a provider would like a copy of the policy, or has any additional questions, please email: PHPMedicalPolicyInquiry@providence.org***
- ***Prior authorization for an insulin pump will only be required for Type 2 diabetes.***

Recall Alert:

Medtronic has issued a class I recall on MiniMed insulin pumps due to incorrect insulin dosing. Please see the FDA announcement (LINK) for more information.

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

Effective May 1, 2020

Cardiac: Ventricular Assist Device (VAD) and Artificial Heart (Biventricular Devices) SUR180	**Annual Update** Policy will continue to follow CMS guidance for all lines of business. Criteria for percutaneous VADs (i.e. Impella) updated to include all relevant FDA (contra)indications of use, per CMS guidance. Link to these indications is now also hyperlinked in policy. **Codes/PA:** 0451T-0463T will now deny NMN, per non-covered services LCD. **CMS:** • National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9) • National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1) • Local Coverage Determination (LCD): Non-Covered Services (L35008) • Local Coverage Article (LCA) for Percutaneous Endovascular Cardiac Assist Procedures and Devices (A52967)
Diabetes: Insulin Infusion Pumps (External and Implanted) (All LOB Except Medicare) DME208	**Annual Update** The following criteria changes have been made. *General:* • **Policy now solely addresses Type 2 diabetics. Beginning 5/1/2020, Prior Authorization for an insulin pump is only required for Type 2 diabetics.** Note added to top of policy clarifying that pumps (external and internal) may be considered medically necessary for Type 1 diabetics. • Implantable infusion pumps remain investigational (no FDA approved devices). • All Medicare-related language has been removed from criteria, as "CMS only" policy created. • Criteria now apply to all patient populations (previously separated by adults, pregnant women and children). *Specifics (eligibility for Insulin Pumps):* • Requirements for C-peptide testing and beta cell autoantibody testing have been removed. • Criterion I.C.: Patient must have either documented ability to self-adjust insulin dose **or** successfully use a CGM. • Criterion I.D.: Patient must have documented ability to glucose self-test at least 4x daily • Criterion I.E.5.: Documented need for more than 5 daily injections added to list of possible indications • *Removed* "Wide fluctuations in b.g. before mealtime" • *Removed* reference to "dawn phenomenon" • *Removed* criterion mandating visits to treating physician every 3 months • Criterion VII.: Replacement of a pump may be covered when patient either has documented need for a larger insulin reservoir

	Codes/PA: HCPCS codes A9274 (external ambulatory insulin delivery system, disposable) or E0784 (external ambulatory infusion pump, insulin) will be configured to require PA for T2D diagnosis codes only.
Diabetes: Insulin Infusion Pumps (External and Implanted) (Medicare Only) **DME414**	**New Policy** Medicare criteria now separated out due to differences in coverage criteria. **Codes/PA:** HCPCS E0784 (external ambulatory infusion pump, insulin) will be configured to require PA for T2D diagnosis codes only. Please see policy Billing Guidelines for complete list of diagnosis codes. A9274, which previously denied, will now be handled by pharmacy as disposable insulin pumps are only available through Part D Medicare benefits. **CMS:** • Local Coverage Determination (LCD): External Infusion Pumps (L33794) • National Coverage Determination (NCD) for Infusion Pumps (280.14)
Genetic Testing: Reproductive Planning and Prenatal Testing (All Lines of Business Except Medicare) **GT236**	**Annual Update** • Once per lifetime testing limit has been implemented for all reproductive and prenatal testing • Remove criterion II. from the policy. Direct-to-consumer testing is addressed by medical policy, Direct to Consumer Testing, med426. • Moved "Whole genome DNA screening (e.g., MaterniT® GENOME, Panorama® Prenatal Panel and Panorama® Prenatal Panel extended)" from investigational and not covered to not medically necessary and not covered. • Updated the last criterion regarding genetic panel testing to be not medically necessary and not covered if any component of a panel is either investigational or not medically necessary.
Genetic Testing: Reproductive Planning and Prenatal Testing (Medicare Only) **GT384**	**Annual Update** • Update the indication for gene testing for *MCOLN1*. The policy has historically read type 1 Mucolipidosis, however it is type IV that is associated with the *MCOLN1* gene. The name of the gene is mucolipin 1 (abbreviated *MCOLN1*) • Remove references to Wisconsin Physician Service Insurance Corporation articles or documents when a Noridian article or document covers the same topic. Noridian guidance takes precedent. • Add Local Coverage Article (LCA) A55286, MolDX: MECP2 Genetic Testing Billing and Coding Guidelines, which provides guidance for denying methyl CpG binding protein 2 (*MECP2*) are associated with Rett syndrome.

Effective March 1, 2020

Prostate: Protein Biomarkers and Genetic Testing (All Lines of Business Except Medicare) **LAB319**	**Annual Update** Molecular assays for the screening, detection, diagnosis and management of prostate cancer remain investigational and not covered. Two tests added to list of example assays (i.e. Oncotype DX AR-V7 Nucleus Detect Test and UroSeq).
Prostate: Protein Biomarkers and Genetic Testing (Medicare Only)	**Annual Update** No changes to criteria designating molecular assays as medically necessary for the screening, detection, diagnosis and management of prostate cancer.

LAB320	**CMS:** • Local Coverage Determination (LCD): MoIDX: 4Kscore Assay (L37122) • Local Coverage Determination (LCD): MoIDX: Decipher® Prostate Cancer Classifier Assay (L36345) • Local Coverage Determination (LCD): MoIDX: Decipher® Prostate Cancer Classifier Assay for Men with Very Low and Low Risk Disease (L37820) • Local Coverage Determination (LCD): MoIDX: ConfirmMDX® Epigenetic Molecular Assay (L36329) • Local Coverage Determination (LCD): MoIDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay (L36368) • Local Coverage Determination (LCD): MoIDX: Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer (MCRPC) (L37744) • Local Coverage Determination (LCD): MoIDX: Molecular Diagnostic Tests (MDT) (L36256) • Local Coverage Determination (LCD): MoIDX: Prolaris™ Prostate Cancer Genomic Assay (L36350) • Local Coverage Determination (LCD): MoIDX: Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease (L37082) • Local Coverage Determination (LCD): MoIDX: ProMark Risk Score (L36706)
Genetic Testing: *JAK2, CALR,* and *MPL* (All LOB except Medicare) GT400 Previously*: Genetic Testing: BCR-ABL1 Negative Myeloproliferative Neoplasms (All LOB except Medicare)*	**Annual Update** • Removed the requirement for BCR-ABL1 fusion chromosome status from criteria I, II and III. • Update the title of the policy to reflect the item, above.
Genetic Testing: *JAK2, CALR,* and *MPL* (Medicare Only) GT399 Previously*: Genetic Testing: BCR-ABL1 Negative Myeloproliferative Neoplasms (Medicare only)*	**Annual Update** Update the title of the policy to reflect commercial changes presented above. Update policy to new Medicare medical policy format, though no changes to medically necessary criteria per CMS. Updated Medicare guidelines. **CMS**: • Updated LCD L36186, MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease, to current effective version. • Added LCA A57422, Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease. • Updated LCA A55600, Billing and Coding: MolDX: BCR-ABL, to current effective version

Continuous Passive Motion (CPM) Device in the Home Setting (All LOB Except Medicare) DME192	**Annual Update** No change in criteria. Continuous Passive Motion (CPM) in the home setting remains not medically necessary and not covered for all indications.
Continuous Passive Motion (CPM) Device in the Home Setting (Medicare Only) DME414	**New Policy** Criteria separated into new policy due to clearer formatting and difference in coverage. No change in CMS guidance – continuous passive motion (CPM) in the home setting remains medically necessary for patients who have recently undergone total knee arthroplasty. The commercial medical policy should be used for any other requested indication.
Premature Rupture of Membranes (PROM) Testing DME280	**Annual Update** Tests for the evaluation of premature rupture of fetal membranes (PROM) will change from investigational to not medically necessary.
Direct-to-Consumer Testing MED426	**Annual Update** No change to criteria.
Radiofrequency Lesioning or Cryoablation for Plantar Fasciitis (All LOB Except Medicare) SUR328 Previously: *Radiofrequency Lesioning or Cryoablation as an Alternative to Surgical Treatment for Plantar Fasciitis*	**Annual Update** Medicare criteria split out and made into new policy. No change to criteria denying cryoablation and radiofrequency ablation as investigational and not covered for the treatment of plantar fasciitis. **Codes/PA:** No coding changes. Clarifying note added to coding table that 64640 and 0441T are investigational when billed with the diagnosis of plantar fasciitis (M72.2) or related ICD codes (G57.60 – G57.63).
Radiofrequency Lesioning or Cryoablation for Plantar Fasciitis (Medicare Only) SUR447	**New Policy** New Medicare Only policy for clarity and formatting purposes. No criteria changes. **Codes/PA:** No coding changes. Clarifying note added to coding table that 64640 is investigational when billed with the diagnosis of plantar fasciitis (M72.2) or related ICD codes (G57.60 – G57.63).

Autologous Fat Transfer **SUR117**	**Annual Update** No change to policy criteria. Autologous fat transfer (AFT) for breast reconstruction remains medically necessary and covered.
Back: Fusion and Decompression Procedures **SUR120**	**Interim Update** Per National Coverage Determination (NCD) for Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13), minimally invasive lumbar decompression (MILD procedure) may be covered for Medicare patients when performed in an approved clinical trial. Note added to criteria, billing guidelines and coding table. **Codes/PA:** The following changes have been made: • PA removed from 0275T to allow for new coding configuration: ○ Per relevant NCD Billing Guidelines, MILD may be covered for Medicare LOB only when billed with ICD-9 V70.7 (or ICD-10 Z00.6), Condition Code 30, Modifier Q0 and an 8-digit clinical trial identifier number. • G0276 added to policy. PA removed to allow for same coding configuration as above.

Back: Epidural Steroid Injections (All LOB Except CMS)
MED123
	Interim Update
	Criterion I.B.1 has been edited as follows to clarify that we do not require the imaging report to state that the stenosis is directly causing nerve root impingement:
	1. Advanced imaging (MRI or CT) identifying **either** of the following (1.-2.):
	  a. Foraminal or lateral recess stenosis which may be causing nerve root impingement and/or demonstrated nerve contact; **or**
	  b. Disc protrusion which may be causing nerve root impingement and/or demonstrated nerve contact; **or**

Breast Reconstruction **SUR162**	**Annual Update** No changes to criteria covering reconstructive breast surgery as medically necessary when criteria are met. No evidence review was conducted as criteria are based primarily on past MD input and the Women's Health and Cancer Rights Act (WHCRA) of 1998. "Note" designating skin substitutes as medically necessary has been relocated as criterion III. References to relevant policies (i.e. Autologous Fat Transfer, Skin Substitutes) have been relocated to the top of criteria as "notes".
Home Oxygen Therapy and Equipment for Cluster Headaches **DME301** *Previously:* *Home Oxygen Therapy for Cluster Headaches*	**Annual Update** No change to policy criteria. Home oxygen therapy remains medically necessary and covered for all lines of business, albeit under different criteria (Medicare only allows under context of a clinical trial). **Codes/PA:** No codes require PA. One code removed E0446 – code not specific to cluster headaches, currently auto-denying not medically necessary per "Hyperbaric Oxygen" policy. **CMS:** Covered when performed as part of a clinical trial. • National Coverage Determination (NCD) for Home Oxygen Use to Treat Cluster Headache (CH) (240.2.2) • Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797)

Home Oxygen Therapy and Equipment for Lung Disease and Hypoxia DME300 *Previously: Oxygen Therapy and Home Equipment*	**Annual Update** No change in coverage criteria. Home oxygen therapy remains medically necessary for treatment of lung disease and hypoxia. Title of policy changed to better reflect the scope of CMS guidances. **CMS:** • National Coverage Determination (NCD) 240.2: Home Use of Oxygen • Local Coverage Determination (LCD) L33797: Oxygen and Oxygen Equipment • Local Coverage Article (LCA) A52514: Oxygen and Oxygen Equipment
MRI-guided High Frequency Ultrasound for Palliative Treatment of Bone Metastases MED281	**Annual Update** No change to investigational criteria.
Orthotic Foot Devices and Orthopedic Shoes DME297	**Annual Update** No change in relevant CMS guidance or coverage criteria **CMS:** • Local Coverage Determination (LCD) L33641: Orthopedic Footwear • Local Coverage Determination (LCD) L33369: Therapeutic Shoes for Persons with Diabetes • Local Coverage Article (LCA) A52481: Orthopedic Footwear • Local Coverage Article (LCA) A52501:Therapeutic Shoes for Persons with Diabetes
Prostate: MRI-Transrectal Ultrasound (MRI-TRUS) Fusion Biopsy RAD424	**Annual Update** No change to criteria. MRI-TRUS fusion remains medically necessary and covered for diagnosis of prostate cancer among patients who have previous negative TRUS biopsies, or in the setting of active surveillance. MRI-TRUS remains investigational when performed as the initial biopsy.

Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies DME354	**Annual Update**
	Criteria based on relevant CMS guidances (see below). No changes in guidance content since last update. TENS remains medically necessary and covered.
	CMS:
	• National Coverage Determination (NCDs):
	  ○ 160.7.1. Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy
	  ○ 10.2: Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain.
	  ○ 160.27: Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP).
	  ○ 160.13: Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES).
	• Local Coverage Determination (LCD) LCD L33802: Transcutaneous Electrical Nerve Stimulators (TENS).

	• A52520: Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article
Vitamin D Assay Testing **LAB372**	**Annual Update** No change to Medicare guidance on which all criteria are based. Per MD input, we have updated the "Billing Guidelines" to specify that testing should be limited to no more than 4 per year. No coding changes, codes will remain configured to only pay with specific diagnosis codes. **CMS:** • Local Coverage Determination (LCD) L34051: Vitamin D Assay Testing
Wireless Capsule for Gastrointestinal Motility Monitoring **MED427**	**Annual Update** No change to investigational criteria.
Speech Generating Devices **DME344**	**Annual Update** Criteria continue to be based on Medicare for all LOBs. Links to relevant guidances updated with no change to criteria. **CMS:** • Centers for Medicare and Medicaid Services LCD L33739. LCD Title: Speech Generating Devices • Centers for Medicare and Medicaid Services LCA A52469. LCA Title: Speech Generating Devices • National Coverage Decision NCD 50.1. Manual Section Title: Speech Generating Devices; and • Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Section 90 - Payment for Additional Expenses for Deluxe Features (Rev. 1, 10-01-03) B3-5107, PM AB-02-114.
Knee Braces (Functional) **DME260**	**Annual Update** Criteria continue to be based on Medicare for all LOBs. Links to relevant guidances updated with no change to criteria. **CMS:** Local Coverage Determination (LCD): Knee Orthoses (L33318) and Local Coverage Article (LCA): Knee Orthoses – Policy Article (A52465)
Chelation Therapy for Non-Overload Conditions **MED182**	**Annual Update** No change to criteria. Chelation therapy remains not medically necessary for non-overload conditions. **CMS:** Two NCDs address chelation therapy for atherosclerosis and both consider it to be non covered.
Back: Lysis of Epidural Adhesions **SUR122**	**Annual Update** No major changes to criteria. Changing denial from investigational to not medically necessary based on no new evidence or trials evaluating this technique. **CMS:** CMS Local Coverage Article (LCA) for Non-Covered Services (A57642) includes both CPTs 62263 and 62264 as not medically necessary and not covered.
Electrothermal Capsular Shrinkage **SUR111**	**Annual Update** No changes to criteria. Electrothermal capsular shrinkage remains not medically necessary and not covered.

Athletic Pubalgia Surgery SUR326	**Annual Update** No changes to criteria. Athletic pubalgia surgery remains investigational and not covered.
Multi-Spectral Digital Skin Lesion Analysis MED279	**Annual Update** No changes to criteria. Multi-spectral digital skin lesion analysis remains investigational and not covered.
Sensory Integration Therapy MED396	**Annual Update** No changes to criteria. Sensory integration therapy remains not medically necessary and not covered. Optum policy should continue to be used for requests in patients with autism spectrum disorder. Optum policy is linked in our policy criteria.
Vestibular Function Testing MED368	**Annual Update** No changes to criteria. Vestibular autorotation testing (VAT) remains not medically necessary and Vestibular Evoked Myogenic Potential (VEMP) remains investigational.
Ganglion Impar Blocks SUR226	**Annual Update** No changes to criteria. Ganglion impar blocks remain investigational for all indications (extensive indication list included in policy criteria).
Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) & Investigational and Non-Covered Medical Technologies (Medicare Only)	**Interim Update** Removing denials for new 1/1/2020 islet cell transplant codes. Denial was added in error as islet cell transplant is standard with pancreas transplant. New codes were created only for the addition of imaging guidance. We will reprocess any denied claims. **LOB:** All LOB **Codes:** • 0584T Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous • 0585T Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic • 0586T Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open
Eye: Blepharoplasty, Blepharoptosis Repair, and Brow Lift (Medicare Only) SUR435	**Interim Update** **Recommendation:** Medicare no longer requires visual fields testing for upper bleph, bleph repair, and brow ptosis repair. Medicare has updated the LCD to state that published literature indicates an MRD of 2.0 mm or less correlates to a visual field restriction of 30 degrees or less.

Archived Effective March 1, 2020

Hip Arthroscopy SUR 246	**Archive** *Policy archived as of effective date above; codes will pay without review.*

VENDOR UPDATES

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Effective for dates of service on and after May 17, 2020, the following updates will apply to the AIM Advanced Imaging: Vascular Imaging Clinical Appropriateness Guidelines.

Updates by section:

Aneurysm of the abdominal aorta or iliac arteries

- Added new indication for asymptomatic enlargement by imaging
- Clarified surveillance intervals for stable aneurysms as follows:
- Treated with endografts, annually
- Treated with open surgical repair, every 5 years

Stenosis or occlusion of the abdominal aorta or branch vessels, not otherwise specified

- Added surveillance indication and interval for surgical bypass grafts

Code changes

- None

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

PHARMACY & THERAPEUTICS COMMITTEE

New Site of Care Prior authorization for Infusion Services

Beginning on March 2, 2020, Providence Health Plan (PHP) will require a prior authorization for site of care for certain infusion medications provided in an outpatient hospital infusion center setting. This site of care prior authorization is in addition to the prior authorization for the medication, if required. Refer to individual drug specific policies for clinical criteria.

PHP will require a prior authorization for infusion medications administered in an outpatient hospital infusion setting per criteria defined in the Infusion Therapy Site of Care policy. Infusion medications included in this Infusion Therapy Site of Care policy are as follows:

HCPCS	Brand Name	Generic Name
J3262	**Actemra**	**Tocilizumab**
J0490	Benlysta	Belimumab
J3380	Entyvio	Vedolizumab
Q5103	Inflectra	Infliximab-dyyb
J0129	Orencia	Abatacept
J1745	Remicade	Infliximab
Q5104	Renflexis	Infliximab-abda
J1602	Simponi Aria	Golimumab
J2350	Ocrevus	Ocrelizumab
J1300	Soliris	Eculizumab
J1303	Ultomiris	Ravulizumab-cwvz

A prior authorization for site of care will not be required when these medications are administered in an approved site of care. Approved Sites of Care include:

- Home Infusion (POS 12)
- Ambulatory Infusion Centers (POS 49)
- Physician Offices and Clinics (POS 11)
- Certain approved outpatient hospital facilities

Transition Period:

- For Members with existing prior-authorizations for one of the drugs above at an unapproved outpatient hospital facility, providers 60 days to coordinate transition of patient infusions at an approved site of care location or request a prior authorization for site of care.

- For all new starts at an unapproved outpatient hospital facility, a 60-day transition period will be allowed to coordinate patient transfers to an approved Site of Care request a prior authorization for site of care, or administer an initial dose of an infusion medication in a hospital infusion setting. Infusion medications will be covered at the unapproved outpatient hospital facility during the transition period.

Who is excluded from the Infusion Therapy Site of Care policy?

- Providence Medicare and Medicaid members
- Certain Commercial Plan members (ALL Providence St. Joseph Healthcare employer group)
- Members 12 years of age and under

A Site of Care prior authorization is required for the use of an unapproved hospital-based outpatient infusion center. An unapproved hospital-based outpatient infusion center may be considered medically necessary if the patient has concomitant conditions or clinical history that may increase the risk of infusion reactions or drug specific adverse events. Please see the Infusion Therapy Site of Care policy for a complete list of criteria.

- Submit PA requests through ProvLink https://phpprovider.providence.org/portal/
- The full policy can be found in ProvLink. Search the Literature Rack for 'Infusion Therapy Site of Care'.

New Drugs and Combinations:

Luspatercept-aamt (Reblozyl) Vial
• Indication: Treatment of anemia in adults with β-thalassemia requiring regular RBC transfusions. • Formulary Alternatives: N/A
• Commercial: Medical Benefit, Prior Authorization • Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria:

PA PROGRAM NAME	Reblozyl
MEDICATION NAME	Luspatercept-aamt
COVERED USES	Treatment of anemia in adults with β-thalassemia requiring regular red blood cell (RBC) transfusions
EXCLUSION CRITERIA	Evidence of active pregnancy and history of thrombosis
REQUIRED MEDICAL INFORMATION	Hemoglobin (Hgb) levels. 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	At least 18 years of age
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a hematologist
COVERAGE DURATION	Initial authorization will be for 9 weeks. Reauthorization will be for 1 year.
OTHER CRITERIA	For initial authorization, all of the following must be met: 1. Diagnosis of β-thalassemia, which can be confirmed by one of the following: a. Hemoglobin analysis or genetic testing b. Complete blood count that showed reduced Hgb level (<7 g/dL), MCV between >50 and <70 fL and MCH between >12 and <20 pg c. Peripheral blood smear results that show RBC morphologic changes including microcytosis, hypochromia, anisocytosis, poikilocytosis and nucleated RBC 2. Documentation that patient is transfusion-dependent, defined as receiving at least 6-20 units RBC transfusions every 24 weeks 3. Documented baseline Hgb level of at least 9 g/dL, drawn within the previous 30 days For continuation of therapy beyond 9 weeks, ongoing documentation of patient response to therapy must include: • Maintenance of reduced transfusion levels

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Elexacaftor-tezacaftor-ivacaftor (Trikafta) Tablet

- Indication: Cystic fibrosis with evidence of at least one *F508del* mutation in the CFTR gene, in patients who are aged 12 years and older.
- Formulary Alternatives: lumacaftor-ivacaftor (Orkambi®) and tezacaftor-ivacaftor (Symdeko®)

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

Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	CFTR Modulators
MEDICATION NAME	Trikafta™ (elexacaftor, tezacaftor, and ivacaftor)
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	FDA-cleared CF mutation test results 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	Patients aged 12 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a Pulmonologist or provider at a Cystic Fibrosis Center
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization for 1 year
OTHER CRITERIA	Diagnosis of cystic fibrosis with at least one *F508del* mutation in the *CFTR* gene Reauthorization requires documented response to therapy as defined by one (1) of the following: 1. A lack of decline in lung function as measured by percentage of predicted FEV1 when the patient is clinically stable 2. A reduction in the incidence of pulmonary exacerbation 3. An improvement in BMI from baseline

Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	CFTR Modulators
MEDICATION NAME	Trikafta™ (elexacaftor, tezacaftor, and ivacaftor)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	FDA-cleared CF mutation test results For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a Pulmonologist or provider at a Cystic Fibrosis Center
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization for 1 year
OTHER CRITERIA	Diagnosis of cystic fibrosis (CF) with documentation of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to the requested drug (as indicated in FDA package labeling) through an FDA-cleared CF mutation test. Reauthorization requires documented response to therapy as defined by one (1) of the following: 1. A lack of decline in lung function as measured by percentage of predicted FEV1 when the patient is clinically stable 2. A reduction in the incidence of pulmonary exacerbations, or 3. An improvement in BMI from baseline

Pitolisant hcl (Wakix) Ta

- Indication: Pitolisant is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy
- Formulary Alternatives: modafinil, armodafinil, methylphenidate, dextroamphetamine/amphetamine

- Commercial: Non-Formulary, Prior Authorization, Quantity Limit (2 tablets per day)

- Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 tablets per day)
- Medicare: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day)

Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Wakix
MEDICATION NAME	Pitolisant Tablet
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit
EXCLUSION CRITERIA	Idiopathic central nervous system hypersomnia
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. Full nocturnal polysomnogram and a multiple sleep latency test.
AGE RESTRICTIONS	May be covered for patients 18 years or older
PRESCRIBER RESTRICTIONS	Must be prescribed by a sleep specialist, neurologist, pulmonologist, or psychiatrist
COVERAGE DURATION	Initial authorization approved for 6 months. Reauthorization approved for 12 months.
OTHER CRITERIA	**Initial Authorization**: All of the following criteria must be met: For Narcolepsy: 1. Diagnosis of narcolepsy as confirmed by one of the following: a. The patient has a Multiple Sleep Latency Test (MSLT) showing both of the following: i. Mean sleep latency of 8 minutes or less; AND ii. Two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs) b. The patient has a Multiple Sleep Latency Test (MSLT) showing all of the following: i. Mean sleep latency of 8 minutes or less; AND ii. One (1) SOREMP; AND iii. Additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the

	polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS) c. The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay) 2. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months 3. Documentation of a three (3)-month trial and failure, incomplete response, intolerance, or contraindication to both of the following: a) Stimulant (e.g., amphetamine, methylphenidate) b) Modafinil or armodafinil **Reauthorization**: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness

Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Wakix
MEDICATION NAME	Pitolisant Tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Idiopathic central nervous system hypersomnia
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. Full nocturnal polysomnogram and a multiple sleep latency test.
AGE RESTRICTIONS	May be covered for patients 18 years or older
PRESCRIBER RESTRICTIONS	Must be prescribed by a sleep specialist, neurologist, pulmonologist, or psychiatrist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA	**Initial Authorization**: For Narcolepsy: 1. Diagnosis of narcolepsy as confirmed by one of the following: a. The patient has a Multiple Sleep Latency Test (MSLT) showing both of the following: i. Mean sleep latency of 8 minutes or less; AND ii. Two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs) b. The patient has a Multiple Sleep Latency Test (MSLT) showing all of the following: i. Mean sleep latency of 8 minutes or less; AND ii. One (1) SOREMP; AND iii. Additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS) c. The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay) 2. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months 3. Documentation of a three (3)-month trial and failure, incomplete response, intolerance, or contraindication to both of the following: a) Stimulant (e.g., amphetamine, methylphenidate) b) Modafinil or armodafinil **Reauthorization:** Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness

Rituximab-abbs (Truxima) Vial
Indication: A biosimilar for rituxumab (Rituxan®) approved for use in:

▪ Non–Hodgkin's Lymphoma (NHL) ▪ Chronic Lymphocytic Leukemia (CLL) • Formulary Alternatives: rituximab (Rituxan®)
• Commercial: Medical, Prior Authorization • Medicaid: Medical, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical, Prior Authorization **Prior Authorization Criteria:** For Commercial/Medicaid/Medicare Part B: Added to Rituxan Policy

Trastuzumab-dkst (Ogivri) Vial
• Indication: A biosimilar for trastuzumab (Herceptin®) approved for use in: ▪ Adjuvant Breast Cancer ▪ Metastatic Breast Cancer ▪ Metastatic Gastric Cancer • Formulary Alternatives: trastuzumab (Herceptin®)
• Commercial: Medical, Prior Authorization • Medicaid: Medical, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical, Prior Authorization **Prior Authorization Criteria:** For Commercial/Medicaid/Medicare Part B: Added to Injectable Anti-Cancer policy

Zanubrutinib (Brukinsa) Capsule
• Indication: Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. • Formulary Alternatives: Imbruvica®, Calquence®, Venclexta®

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

Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Oral Anti-Cancer Medications
MEDICATION NAME	Zanubrutinib capsule (Brukinsa®)
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation, with an oncologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for 3 months up to 1 year.
OTHER CRITERIA	For initial authorization: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher For reauthorization: Documentation of adequate response to the medication must be provided.

Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Anti-Cancer Agents
MEDICATION NAME	Zanubrutinib capsule (Brukinsa®)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
PA TYPE	New Starts Only

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an oncologist, transplant specialist, or neurologist.
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.
OTHER CRITERIA	Indications supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

Pretomanid Tablet

- Indication: Orphan drug approval as part of a 3-drug combination regimen with bedaquiline (Sirturo®) and linezolid for adults with extensively drug-resistant tuberculosis (XDR-TB) or treatment-intolerant/non-responsive multi-drug resistant tuberculosis (MDR-TB).
- Formulary Alternatives: N/A

- Commercial: Non-Formulary
- Medicaid: Non-Formulary
- Medicare Part D: Non-Formulary

Trifarotene (Aklief) Cream

- Indication: A retinoid for the treatment of acne vulgaris in patients aged 9 years or older.
- Formulary Alternatives:
  tretinoin 0.01% gel, tretinoin (Avita®, Retin-A®) 0.025% cream/gel, tretinoin (Atralin®, Refissa®, Retin-A®) 0.05% cream/emollient cream/gel, tretinoin (Retin-A®) 0.1% cream, Altreno® 0.05% lotion, tazarotene (Tazorac®) 0.1% cream, Tazorac® 0.05% cream/gel

- Commercial: Non-Formulary
- Medicaid: Non-Formulary

- Medicare Part D: Non-Formulary

Upadacitinib (Rinvoq ER) Tab ER 24H

- Indication: Moderately to severely active rheumatoid arthritis.
- Formulary Alternatives: adalimumab (Humira®), etanercept (Enbrel®), tofacitinib (Xeljanz®)

- Commercial: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1 tablet per day)
- Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (1 tablet per day)
- Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (1 tablet per day)

Prior Authorization Criteria for Commercial: Effective 01/01/2020

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Rinvoq
COVERED USES	All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit. Drug Compendia supported indications may be covered.
EXCLUSION CRITERIA	Combination therapy with another therapeutic immunomodulator (TIM) agent or Otezla®
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis: must be prescribed by, or in consultation with, a rheumatologist
COVERAGE DURATION	Prior Authorization: Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication
OTHER CRITERIA	1. For all requests, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.) **AND** 2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®)

	AND 3. One of the following: a. For patients already established on the requested therapeutic immunomodulator (starting on samples will not be considered as established on therapy): Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency) b. Patients not established on the requested therapeutic immunomodulator must meet ALL of the following indication-specific criteria: i. For Rheumatoid Arthritis: 1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) 2. For non-preferred TIMs therapies: a. Documentation of trial and failure, intolerance, or contraindication to two of the following agents: i. etanercept (Enbrel®) ii. adalimumab (Humira®) iii. upadacitinib (Rinvoq®) **AND** b. If patient has satisfied criteria above (i.2.a.), documentation of trial and failure, intolerance, or contraindication to tocilizumab (Actemra®) or certolizumab (Cimzia®) Remainder of criteria in policy to remain the same

PRIOR AUTHORIZATION CRITERIA FOR MEDICAID: Effective 01/01/2020

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Rinvoq
COVERED USES	All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit. Drug Compendia supported indications may be covered.

	Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.
EXCLUSION CRITERIA	Below the line diagnosis Combination therapy with another therapeutic immunomodulator (TIM) agent or Otezla®
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis: must be prescribed by, or in consultation with, a rheumatologist
COVERAGE DURATION	Prior Authorization: Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication
OTHER CRITERIA	1. For all requests, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.) **AND** 2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®) **AND** 3. One of the following: a. For patients already established on the requested therapeutic immunomodulator (starting on samples will not be considered as established on therapy): Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency) b. Patients not established on the requested therapeutic immunomodulator must meet ALL of the following indication-specific criteria: i. For Rheumatoid Arthritis: 1. Use of disease-modifying anti-rheumatic drugs (DMARDs): a. Documented inadequate response to at least one DMARD after at least 6 months of therapy: methotrexate, leflunomide, sulfasalazine or hydroxychloroquine

	OR b. Documented intolerance or contraindication to DMARDs 2. For non-preferred TIMs therapies: a. Documented adequate trial and failure, intolerance or contraindication to at least one of the following preferred TIMs agents: adalimumab (Humira®), etanercept (Enbrel®), or infliximab biosimilar (Inflectra® or Renflexis®) **AND** b. If patient has satisfied criteria above (i.2.a.), documented trial, failure, intolerance or contraindication to tofacitinib (Xeljanz®/Xeljanz XR®) Remainder of criteria in policy to remain the same

PRIOR AUTHORIZATION CRITERIA FOR MEDICARE PART D: Effective 01/01/2020

PA PROGRAM NAME	THERAPEUTIC IMMUNOMODULATORS
MEDICATION NAME	Rinvoq
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Patient is currently being treated with another therapeutic immunomodulator
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan
OTHER CRITERIA	For patients already established on the requested therapy: 1. Documentation of response to therapy (i.e. slowing of disease progression or decrease in symptom severity and/or frequency), AND 2. One

		of the following: a. Patient is not currently being treated with another biologic immunomodulator, OR b. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator. For patients being initiated on therapy, all of the following criteria must be met: 1. Patient must have an FDA labeled indication for the requested agent, AND 2. Documentation of trial and failure, intolerance, or contraindication to one conventional therapy prerequisite for the requested indication (see notes below), AND 3. One of the following: a. Patient is not currently being treated with another biologic immunomodulator, OR b. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent. Notes: Use of ONE conventional agent prerequisite is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, or juvenile idiopathic arthritis. No prerequisites are required for diagnoses of ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, or uveitis. Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include methotrexate, hydroxychloroquine, sulfasalazine, minocycline, or leflunomide. Formulary conventional topical or systemic agents for plaque psoriasis include topical corticosteroids, tazarotene, cyclosporine, calcipotriene, methotrexate, tacrolimus, pimecrolimus, or acitretin.

New Strengths and Formulations: See Other Formulary Changes

New Indications:

1. **Entresto®**
   Sacubitril And Valsartan
   New indication approved 10/01/2019:
   ENTRESTO® NEW INDICATION UPDATE
   - Reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.
   - **For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.**

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

2. **Tybost®**
   Cobicistat
   New indication approved 10/03/2019:
   TYBOST® NEW EXPANDED PATIENT POPULATION UPDATE
   - **Increase systemic exposure of atazanavir or darunavir (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection in adults and in pediatric patients:**
     - **weighing at least 35 kg coadministered with atazanavir or**
     - **weighing at least 40 kg coadministered with darunavir.**

   Limitations of Use:
   - TYBOST is not interchangeable with ritonavir to increase systemic exposure of darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranavir due to lack of exposure data. The use of TYBOST is not recommended with darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranavir. (1.2, 5.4)
   - Complex or unknown mechanisms of drug interactions preclude extrapolation of ritonavir drug interactions to certain TYBOST interactions. TYBOST and ritonavir when administered with either atazanavir or darunavir may result in different drug interactions when used with concomitant medications.

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

3. **Descovy®**
   Emtricitabine; Tenofovir Alafenamide Fumarate
   New indication approved 10/03/2019:
   DESCOVY® NEW INDICATION UPDATE
   - In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg.
   - In combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.
   - **HIV-1 PrEP: DESCOVY is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating DESCOVY for HIV-1 PrEP.**

   Limitations of Use:

- **The indication does not include use of DESCOVY in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.**

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

4. **Xarelto®**
   Rivaroxaban
   New indication approved 10/11/2019:
   XARELTO® NEW INDICATION UPDATE
   - to reduce the risk of stroke and systemic embolism in patients with
   - nonvalvular atrial fibrillation
   - for the treatment of deep vein thrombosis (DVT)
   - for the treatment of pulmonary embolism (PE)
   - for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months
   - for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
   - **for the prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding**
   - in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD)

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

5. **Xofluza®**
   Baloxavir Marboxil
   New indication approved 10/16/2019:
   XOFLUZA® NEW EXPANDED PATIENT POPULATION UPDATE
   - **Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are:**

- **Otherwise healthy, or**
- **At high risk of developing influenza-related complications.**

Limitations of Use:

- Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use XOFLUZA.

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

6. Nplate®

Romiplostim

New indication approved 10/17/2019:

NPLATE® NEW EXPANDED PATIENT POPULATION UPDATE

- thrombocytopenia in:
  - **Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.**
  - Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy

Limitations of Use:

- **Nplate is not indicated for the treatment of thrombocytopenia due myelodysplastic syndrome (MDS) or any cause of thrombocytopenia placebo other than ITP.**
- Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding.
- Nplate should not be used in an attempt to normalize platelet counts

RECOMMENDATION: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Commercial/Medicare Part B/Medicaid policy as follows:

PA PROGRAM NAME	HEMATOLOGY
MEDICATION NAME	**Nplate® (romiplostim subcutaneous injection)**
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Prescribed by or in consultation with an oncologist, hematologist, or hepatologist.
COVERAGE DURATION	Initial authorization will be approved for up to 3 months. Reauthorization will be approved for up to 6 months.
OTHER CRITERIA	Must meet all of the following: 1. A diagnosis of ~~chronic~~ immune thrombocytopenia (ITP) AND 2. Patient is at risk for bleeding with a platelet count of less than 30 x 109/L AND 3. Treatment by at least one of the following was ineffective or not tolerated: a. Systemic corticosteroids, OR b. Immune globulin, OR c. Splenectomy Reauthorization will require submission of platelet values demonstrating a response to therapy and a dose below 10 mcg/kg. QUANTITY LIMITS: Nplate is available as 250mcg and 500mcg vials of lyophilized powder. Quantity approved may be rounded down to nearest available vial size within 10% of calculated dose.

PROVIDENCE Health Plan

7. Botox®

Onabotulinumtoxin A

New indication approved 10/18/2019:

BOTOX® NEW INDICATION UPDATE

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of upper and lower limb spasticity in adult patients
- Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age
- **Treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy**
- Treatment of cervical dystonia in adult patients, to reduce the severity of
- abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Treatment of blepharospasm associated with dystonia in patients 12 years of age and older
- Treatment of strabismus in patients 12 years of age and older

Important Limitations:

- Safety and effectiveness of BOTOX have not been established for:
  - Prophylaxis of episodic migraine (14 headache days or fewer per month)
  - Treatment of hyperhidrosis in body areas other than axillary

RECOMMENDATION: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update Commercial/Medicaid and Medicare Part B BOTOX® policies with new indication. The Medicare Part B coverage criteria is based on the Centers for Medicare and Medicaid (CMS) local coverage determination (LCD) and cannot be updated. Update Commercial/Medicaid BOTOX® policies as follows:

PA PROGRAM NAME	NEUROMUSCULAR DRUGS BOTULINUM TOXIN

MEDICATION NAME	**Botox® (onabotulinumtoxinA)** **Dysport® (abobotulinumtoxinA)** **Jeuveau® (prabotulinumtoxinA-xvfs)** **Myobloc® (rimabotulinumtoxinB)** **Xeomin® (incobotulinumtoxinA)**
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.
EXCLUSION CRITERIA	When the above criteria are not met, botulinum toxin is considered investigational and not covered. Botulinum toxin is considered cosmetic and is not covered for the treatment of glabellar lines and/or fine wrinkles on the face. • PrabotulinumtoxinA (Jeuveau®) will not be covered as it is only FDA approved for the treatment of glabellar lines and/or fine wrinkles on the face.
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.
OTHER CRITERIA	OnabotulinumtoxinA (Botox®) may be covered for the following indications when criteria are met: 1. Chronic migraine headaches in adults when all of the following is met: a. Documentation of at least 15 headache days per month with headaches lasting 4 hours or longer

		b. Documentation of trial and failure, intolerance, or contraindication to at least TWO of the following classes used for migraine prevention. Trial and failure is defined as inadequate response following a minimum three (3) months of consistent use. i. Antidepressants (e.g., amitriptyline, venlafaxine) ii. Beta-blockers (e.g., metoprolol, propranolol, timolol) iii. Antiepileptics (e.g., divalproex, valproate, topiramate) c. Documentation that onabotulinumtoxinA will not be used in combination with Calcitonin Gene-Related Peptide (CGRP) Inhibitors (e.g., Aimovig®) 2. Upper and lower limb spasticity in adults 3. Upper limb spasticity in pediatric patients at least 2 years of age 4. Treatment of lower limb spasticity in pediatric patients at least 2 years of age, excluding spasticity caused by cerebral palsy 5. Cervical dystonia in adults 6. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age 7. Severe axillary hyperhidrosis in adults after documented trial and failure, intolerance or contraindication to topical agents 8. Overactive bladder in adults with: a. Symptoms of urge urinary incontinence, urgency, and frequency b. Documented trial and failure, intolerance, or contraindication to at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine) 9. Urinary incontinence in adults: a. Due to detrusor over activity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis) b. Documented trial and failure, intolerance, or contraindication at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine) 10. Excessive salivation due to advanced Parkinson's disease 11. Hemifacial spasm	

	AbobotulinumtoxinA (Dysport®) may covered for the following indications: 12. Spasticity in adults 13. Cervical dystonia in adults 14. Lower-limb spasticity in patients at least 2 years of age 15. Blepharospasm in adults IncobotulinumtoxinA (Xeomin®) may covered for the following indications: 16. Chronic sialorrhea in adult patients 17. Upper limb spasticity in adult patients 18. Cervical dystonia in adults 19. Blepharospasm in adults RimabotulinumtoxinB (Myobloc®) may covered for the following indications: 20. Cervical dystonia in adults

8. Farxiga®

Dapagliflozin

New indication approved 10/18/2019:

FARXIGA® NEW INDICATION UPDATE

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- **to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.**

Limitations of use:

- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

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

9. Orenitram®
Treprostinil Diolamine
New indication approved 10/18/2019:
ORENITRAM® NEW INDICATION UPDATE
- **Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1)**
  - **To delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).**

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

10. Xigduo Xr®
Dapagliflozin; Metformin Hydrochloride
New indication approved 10/18/2019:
XIGDUO XR® NEW INDICATION UPDATE
- **Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapagliflozin is indicated in adults with type 2 diabetes mellitus to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.**

Limitations of use:
- **•Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.**

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

11. Erelzi®
Etanercept-Szzs
New indication approved 10/18/2019:
CLENPIC® NEW INDICATION UPDATE
- Rheumatoid Arthritis (RA)
- Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older
- **Psoriatic Arthritis (PsA)**
- Ankylosing Spondylitis (AS)

- Plaque Psoriasis (PsO) in adults

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

12. Stelara®
Ustekinumab
New indication approved 10/18/2019:
STELARA® NEW INDICATION UPDATE

- Adult patients with:
  - Moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy.
  - Active psoriatic arthritis (PsA), alone or in combination with methotrexate.
  - Moderately to severely active Crohn's disease (CD).
  - **Moderately to severely active ulcerative colitis.**
- Adolescent patients (12 years or older) with:
  - Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.

RECOMMENDATION: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. The Commercial Therapeutic Immunomodulators (TIMs) policy has been update in December 2019 to include the new indication; therefore, no changes to Commercial criteria coverage are warranted. Update Medicaid Therapeutic Immunomodulators (TIMs) policy with new indication. No changes to Medicaid criteria coverage are warranted.

13. Ultomiris®
Ravulizumab-CWVZ
New indication approved 10/18/2019:
ULTOMIRIS® NEW INDICATION UPDATE

- Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
- **the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)**
- **Limitations of Use: ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).**

RECOMMENDATION: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. The Commercial/Medicare Part B/Medicaid Ultomiris® policy has been updated in November 2019 to include the new indication; therefore, no changes to criteria coverage are warranted.

14. Cinvanti®

Aprepitant

New indication approved 10/21/2019:

CINVANTI® NEW EXPANDED PATIENT POPULATION UPDATE

- **Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen.**
- **Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen.**
- **Nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen.**

Limitations of Use: CINVANTI has not been studied for treatment of established nausea and vomiting.

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

15. KEPPRA®

LEVETIRACETAM

New indication approved 10/23/2019:

KEPPRA® NEW INDICATION UPDATE

- **treatment of partial-onset seizures in patients 1 month of age and older**
- adjunctive therapy for the treatment of:
  - Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy
  - Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy

KEPPRA® injection label only:

- KEPPRA® injection is for intravenous use only as an alternative for patients when oral administration is temporarily not feasible

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

16. Keppra Xr®

Levetiracetam

New indication approved 10/23/2019:

KEPPRA XR® NEW INDICATION UPDATE

- **Treatment of partial-onset seizures in patients 12 years of age and older**

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

17. Zejula®

Niraparib Tosylate

New indication approved 10/23/2019:

ZEJULA® NEW INDICATION UPDATE

- 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.
- **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 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.

18. Baxdela®

Delafloxacin Meglumine

New indication approved 10/24/2019:

BAXDELA® NEW INDICATION UPDATE

- Treatment of adults with the following infections caused by
- Designated susceptible bacteria:
    - Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
    - **Community-Acquired Bacterial Pneumonia (CABP)**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BAXDELA and other antibacterial drugs, BAXDELA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

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

19. Liletta®
Levonorgestrel
New indication approved 10/25/2019:
LILETTA® NEW EXPANDED PATIENT POPULATION UPDATE
- **Prevention of pregnancy for up to 6 years.**

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

20. Campath®/Lemtrada®
Alemtuzumab
New indication approved 08/08/2019:
CAMPATH®/LEMTRADA® NEW EXPANDED PATIENT POPULATION UPDATE
- Treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS
- **Limitations of Use: LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile**

RECOMMENDATION: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Update LEMTRADA® policy with new indication. No changes to criteria coverage are warranted.

21. Sorilux®
Calcipotriene
New indication approved 11/05/2019:
SORILUX® NEW EXPANDED PATIENT POPULATION UPDATE
- Topical treatment of plaque psoriasis of the scalp and body in adults and pediatric patients **4 years of age and older.**

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

22. Lumason®
Sulfur Hexafluoride Lipid-Type A Microspheres

New indication approved 11/13/2019:
LUMASON® NEW EXPANDED PATIENT POPULATION UPDATE

- In echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult **and pediatric patients** with suboptimal echocardiograms
- In ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients
- In ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients

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

23. Calquence®
Acalabrutinib

New indication approved 11/21/2019:
CLENPIC® NEW INDICATION UPDATE

- Treatment of adult patients with
  - Mantle cell lymphoma (MCL) who have received at least one prior therapy
    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 confirmatory trials.
  - **Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)**

RECOMMENDATION: 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.

24. Toujeo Solostar®/Toujeo Max Solostar®
Insulin Glargine Recombinant

New indication approved 11/26/2019:
TOUJEO SOLOSTAR®/TOUJEO MAX SOLOSTAR® NEW EXPANDED PATIENT POPULATION UPDATE

- **Improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus**

Limitations of Use: not recommended for treating diabetic ketoacidosis

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

DECISION: Recommendations were approved as outlined above.

PROVIDENCE Health Plan

Drug Safety Monitoring: N/A

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Abemaciclib (Verzenio) tablet	Commercial: Move to Preferred Specialty Tier	Oral Anti-Cancer Agents
Abiraterone acetate 250 mg tablet	Commercial: Move to Preferred Specialty Tier	Oral Anti-Cancer Agents
Albuterol sulfate (Proair Digihaler) AER PW BAS	New dosage form. • Commercial/Medicaid: Non-Formulary, Quantity Limit (2 inhalers per 30 days)	N/A
Albuterol sulfate (Proair Respiclick) HFA AER AD	• Commercial (Oregon): Change from Non-Preferred Generic to Non-Preferred Brand ○ Formulary, Non-Preferred Brand, Quantity Limit (2 inhalers per 30 days) • Medicaid: Remove from formulary ○ Non-Formulary, Quantity Limit (2 inhalers per 30 days)	N/A
Amlodipine besylate/ celecoxib (Consensi) Tablet	New formulation. • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	Commercial/Medicaid: • New Medications and Formulations Without Established Benefit Medicare: N/A
Asenapine (Secuado) Patch TD24	New Route (Transdermal), Dosage Form (patch): • Commercial: Non-Formulary, Prior Authorization • Medicaid: Non-Formulary • Medicare Part D: Formulary, Specialty, Prior Authorization	• Commercial: New Medications and Formulations Without Established Benefit • Medicaid: N/A • Medicare: Antipsychotics

Azelaic acid (Azelex) Cream	Commercial: Add Step Therapy ○ Formulary, Non-Preferred Brand, Step Therapy	Azelaic Acid
Baricitinib (Olumiant) Tablet	New strength: • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1 tablet per day) • Medicare Part D: Non-Formulary	• Commercial: Therapeutic Immunomodulators • Medicaid: Therapeutic Immunomodulators – Medicaid • Medicare Part D: N/A
Benralizumab (Fasenra Pen) Auto Injct	New dosage form. • Commercial: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1 auto injector per 56 days) • Medicaid: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1 auto injector per 56 days) • Medicare: Formulary, Specialty, Prior Authorization, Quantity Limit (1 auto injector per 56 days)	Commercial/Medicaid: Add to IL-5 Inhibitors policy (see policy review section for criteria) Medicare: Fasenra (new policy – see below for criteria)

PA Criteria for Medicare Part D:

PA PROGRAM NAME	Fasenra
MEDICATION NAME	Fasenra
PA INDICATION INDICATOR	All FDA-approved indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	Approved for patients 12 years of age and older
PRESCRIBER RESTRICTIONS	For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a Pulmonologist, Immunologist, or Allergist)
COVERAGE DURATION	Initial authorization will be approved for 6 months, reauthorization will be approved for 1 year
OTHER CRITERIA	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 a poor asthma control scores (An ACT score less than 20 or an ACQ greater than 15) Reauthorization: Documentation of response to therapy such as an improvement in baseline asthma control scores, reduction in exacerbations/hospitalizations or oral corticosteroids	
Colchicine (Gloperba) Solution	New dosage form. • Non-Formulary for all lines of business	N/A
Darolutamide (Nubeqa) tablet	Commercial: Move to Preferred Specialty Tier	Oral Anti-Cancer Agents
Diclofenac sodium/lidocaine (Lidovix) Combo. pkg	New Co-packaged Combination: • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations Without Established Benefit • Medicare: N/A
Drospirenone (Slynd)	Add to formulary: • Commercial (Oregon): Formulary, Non-Preferred Brand • Commercial (Washington): Formulary, Tier 4 • Medicaid: Formulary • Medicare: Non-Formulary	N/A
Dupilumab (Dupixent) Syringe 200 mg/1.14 ml	Commercial: Move to Preferred Specialty tier ○ Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (2.28 ml per 28 days)	Dupixent
Dupilumab (Dupixent) Syringe 300 mg/2ml	• Commercial: Move to Preferred Specialty ○ Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (4 ml per 28 days)	Dupixent
Elbasvir/grazoprevir (Zepatier) Tablet	Medicaid: Remove from formulary	Hepatitis C - Direct Acting Antivirals - Medicaid

Fenofibrate 67, 134, and 500 mg Capsules	Commercial (Washington): Formulary, Tier 2	N/A
Gallium citrate GA-67	New entity. • Commercial/Medicaid: Medical Benefit • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
Glucagon (Baqsimi) Spray	Commercial/Medicaid: Remove from formularies	N/A
Glucagon, human recombinant (Glucagen) diagnostic Vial	Remove from Commercial and Medicaid formularies • Non-Formulary, Medical Benefit	N/A
Hydrocortisone Cream	Commercial (Washington): Change from Tier 4 to Tier 2	N/A
Ibuprofen 800 & 600 mg tablets	Commercial (Washington): Change from Tier 4 to Tier 2	N/A
Immune globulin,gamma (igg)-slra human (Asceniv) Vial	New Formulation (slra human). • Commercial: Medical Benefit, Prior Authorization • Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Immune Gamma Globulin (IgG)
Insulin pump cartridge (Omnipod Dash Pack Pod) Hi-Cartridge	• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (10 pods per 30 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: ○ Disposable Insulin Pumps (new policy – see policy section for details) • Medicare Part D: N/A
Ketorolac tromethamine (Sprix) Spray	Medicare Part D: add to Formulary, Specialty tier, Prior Authorization, Quantity Limit (630 mg per 30 days)	Sprix (see criteria below)

PA Criteria for Medicare Part D:

PA PROGRAM NAME	Sprix
MEDICATION NAME	Ketorolac tromethamine spray
PA INDICATION INDICATOR	1 – All FDA approved indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization and reauthorization will be approved for 6 months
OTHER CRITERIA	**Initial authorization:** For short-term pain: 1. The patient is being treated for acute pain 2. Documented trial and failure, intolerance or contraindication to two formulary generic nonsteroidal anti-inflammatory drugs

Lidocaine hcl Jel/PF App	Commercial (Washington): Change from Tier 4 to Tier 2	N/A
Mepolizumab (Nucala) Syringe/Auto Injct 100 mg/ml	Commercial: Change from Non-Preferred Specialty to Preferred Specialty ○ Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1 ml per 28 days)	IL-5 Inhibitors
Metronidazole 0.75% Lotion	Add to formulary. • Commercial (Oregon): Formulary, Non-Preferred Generic • Commercial (Washington): Formulary, Tier 3 • Medicare Part D: Formulary, Preferred Brand	N/A
Minocycline hcl (Amzeeq) Foam	New route (foam), and new strength (4%); • Non-Formulary for all lines of business	N/A
Morphine sulfate (Kadian) Cap ER Pel	Medicaid: add prior authorization ○ Non-Formulary, Prior Authorization, Quantity Limit (90 MME per day)	Long-Acting Opioids
Olaparib (Lynparza) capsule	Commercial: Move to Preferred Specialty Tier	Oral Anti-Cancer Agents
Palbociclib (Ibrance)	Commercial: Move to Preferred Specialty Tier	Oral Anti-Cancer Agents

Rucaparib (Rubraca)	Commercial: Move to Preferred Specialty Tier	Oral Anti-Cancer Agents
Siponimod (Mayzent) Tablet	Commercial/Medicaid: add quantity limit • Formulary, Preferred Specialty, Quantity Limit (4 tablets per day)	N/A
Terconazole Cream/APPL	Commercial (Washington): Change from Tier 4 to Tier 3	N/A

Vancomycin hcl (Firvanq) Solution Recon	New strength.
	• Commercial:
	  ○ OR: Formulary, Preferred Brand
	  ○ WA: Formulary, Tier 4
	• Medicaid: Non-Formulary
	• Medicare Part D: Formulary, Non-Preferred Drug
		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-venom-mixed vespid protein (Mixed Vespid Venom Protein) 3900 mcg vial	New strength. Line extend with Mixed Vespid Venom 300 mcg/ml; • Commercial: Medical Benefit • Medicaid: Medical Benefit • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
Phenylephrine hcl (Biorphen) Ampul	New Strength. Line extend with phenylephrine hcl vial; • Commercial: Medical Benefit • Medicaid: Medical Benefit • Medicare Part D: Non-Formulary • Medicare Part A: when administered inpatient during surgery	

Romiplostim (Nplate) Vial	New Strength (125mcg). Line extend with Nplate 250, 500mcg; • Commercial: Medical Benefit, Prior Authorization • Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Nplate
Tesamorelin acetate (Egrifta SV) Vial	New strength (2 mg). Line extend with Egrifta (1 mg); • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization	Egrifta

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Ciprofloxacin hcl-fluocinolone	First generic (Otovel). Line extend as generic; • Non-Formulary for all lines of business	N/A
Diltiazem hcl (Tiadylt ER)	Line extend with generic diltizem ER 360; • Commercial: Formulary, Non-Preferred Generic • Medicaid: Formulary • Medicare Part D: Formulary, Non-Preferred Generic Effective 01/06/2020	N/A
Deferasirox Tablet	First generic (Jadenu). Line extend as generic; • Commercial: Formulary, Non-Preferred Specialty • Medicaid: Formulary, Specialty	N/A

	• Medicare Part D: Formulary, Specialty	

Mesalamine ER Cap ER24H	First Generic (Apriso). Line extend as generic;
	• Commercial:
	  ○ OR: Formulary, Non-Preferred Generic
	  ○ WA: Formulary, Tier 3
	• Medicaid: Formulary
	• Medicare Part D: Non-Formulary
		N/A

Aflibercept (Eylea) Syringe	New Dosage Form (syringe). Line extend with Eylea vial; • Commercial: Medical Benefit, Prior Authorization • Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid/Medicare Part B: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors • Medicare Part D: ○ N/A

Insulin Aspart Vial, FlexPen, Penfill	Authorized Generic for Novolog. Line extend as generic;
	• Commercial:
	  ○ OR: Formulary, Non-Preferred Generic, Prior Authorization
	  ○ WA: Formulary, Tier 4, Prior Authorization
	• Medicaid: Non-Formulary
	• Medicare Part D: Non-Formulary
		• Commercial:
		  ○ Non-Preferred Insulins
		• Medicaid: N/A
		• Medicare: N/A

Insulin Aspart Prot-Insulin ASP	Authorized Generic for Novolog Mix 70/30. Line extend as generic;
	• Commercial:
	  ○ OR: Formulary, Non-Preferred Generic, Prior Authorization
	  ○ WA: Formulary, Tier 4, Prior Authorization
	• Medicaid: Non-Formulary
	• Medicare Part D: Non-Formulary
		• Commercial:
		  ○ Non-Preferred Insulins
		• Medicaid: N/A
		• Medicare: N/A

Everolimus Tablet	First generic (Afinitor). Line extend as generic; • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization	Oral Anti-Cancer

Norethindrone acetate-ethinyl estradiol/ferrous fumarate Tablet	Line extend as Loestrin FE generic;
	• Commercial:
	  ○ OR: Formulary, Non-Preferred Generic
	  ○ WA: Formulary, Tier 4
	• Medicaid: Formulary,
	• Medicare Part D: Non-Formulary
		N/A

Isosorbide dinitrate Tablet	Return of generic (Isordil); Line extend as generic; • Non-Formulary for all lines of business	N/A
Hydrocodone bitartrate ER Cap ER 12H	Marketed Under NDA (Zohydro ER). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 capsules per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: ○ Long Acting Opioids • Medicare Part D: N/A
Dapsone Gel w/ Pump	Line extend as generic; • Commercial: Non-Formulary, Step Therapy • OHP: Non-Formulary • MAPD: Non-Formulary	Commercial: Aczone
Eluryng Vag Ring	First Generic (Nuvaring); • Commercial: Non-Formulary • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Etonogestrel-Ethinyl Estradiol	First Generic (Nuvaring); • Commercial: Non-Formulary • Medicaid: Formulary	N/A

	• Medicare Part D: Non-Formulary	

Sulconazole Nitrate Solution	Marketed under NDA. Line extend as generic;
	• Commercial:
	  ○ OR: Formulary, Non-Preferred Generic
	  ○ WA: Formulary, Tier 4
	• Medicaid: Non-Formulary
	• Medicare Part: Non-Formulary
		N/A

Amphetamine Sus BP 24H	Authorized Generic (Adzenys ER). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: ○ New Formulation Without Established Benefit • Medicare Part D: N/A

Health Plan Clinical Policy Changes:

Policy Name	Summary of Change
BPH Treatment- Rapaflo, Cialis	Prior authorization was retired for tadalafil (Cialis) 5 mg for the Commercial line of business. No changes were made to Medicaid criteria.
CAR-T	Policy was revised criteria to align with current guidelines.
Disposable Insulin Pumps	New Policy
Human Growth Hormones for Pediatrics	Policy was updated to reflect changes to preferred products for Medicaid based on aligning with Oregon Health Authority (OHA) Preferred Drug List (PDL).
IL-5 Inhibitors	Policy change: Faserna for self-injection added to the policy. Minor changes to align policy with other asthma monoclonal antibodies.
Long-Acting Opioids	The criteria were made consistent for all opioid products on the policy. Documentation of a pain agreement will be required for chronic non-malignant pain. For all types of pain, documentation of a trial of scheduled short-acting opioid medication will be required for initiating long-acting therapy. Criteria for OxyContin was updated to reflect formulary replacement with Xtampza ER (abuse-deterrent formulation of long-acting oxycodone). For certain, high-cost formulations of other products, documentation of medical necessity for the requested formulation will be required.
Long-Acting Opioids – Medicaid	Medicaid was broken out from the Commercial policy and will be reviewed in more depth at a later date.

Medically Infused Therapeutic Immunomodulators (Tims) – Comm	Policy was updated to reflect new indication for ustekinumab (Stelara®) of ulcerative colitis
Medically Infused Therapeutic Immunomodulators (TIMs) - Medicare Part B	Policy was updated to reflect new indication for ustekinumab (Stelara®) of ulcerative colitis
Oral Anti-Cancer Medications	Added specific trial and failure criteria for Kisqali, Talzenna and Zejula. Removed criteria for Inrebic and Turalio. Changed coverage duration to "Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication". Removed the following from the required medical information section: “For Erleada®, Prostate Specific Antigen Doubling time will be required."
Pulmonary Arterial Hypertension - Part B	Revised policy criteria to align with most current treatment guidelines.
Rituxan, Rituxan Hycela	Revised policy criteria for Rheumatoid Arthritis and vasculitis.
Sunosi	Added reauthorization criteria for Obstructive Sleep Apnea (OSA) to ensure modalities to treat underlying airway obstruction will be continued. Updated wording of initial criteria regarding modalities to treat OSA and changed “continuous positive airway pressure” (CPAP) to "positive airway pressure."
Therapeutic Immunomodulators – Comm	Policy was updated to reflect changes in preferred products with cost-positioning contracts.
Thiola	Criterion for prerequisite penicillamine (Depen) was removed to reflect Thiola's updated indication.
Vascepa	Policy was updated to reflect new indication for Vascepa.
The following policies were retired effective 4/1/2020. ○ Slynd ○ Annovera	