PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

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

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

Number 256

March 1, 2021

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

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

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

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

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

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

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

Effective May 1, 2021

Back: Ablative Procedures to Treat Back and Neck Pain (All Lines of Business Except Medicare)
 	
MP21
	Annual Update
	• Add Policy Guidelines for pain and Documents Required for Review.
	• Moved all Billing Guidelines to separate section. Specified rolling calendar year to mean a 365-day window of time.
	• Updated frequency limits to the following:
	  ○ Facet joint denervation: For each covered spinal region no more than two (2) radiofrequency sessions will be reimbursed per rolling 12 months. If member meets criteria for repeat ablation, an additional two (2) radiofrequency sessions (for a total a four) per rolling 12 months will be allowed.
	  ○ Facet Joint Procedures (IA or MBB): For each covered spinal region no more than four (4) joint sessions will be reimbursed per rolling 12 months.
	Codes/PA: No changes to codes/PA

Back: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (Medicare Only) **MP13**	**Annual Update** Updated policy to new Medicare format; no recommended changes to criteria. • Continue to follow Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L34995) • Added Local Coverage Article: Billing and Coding: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (A57728) **Codes/PA:** No change to codes/PA
Back: Sacroiliac Joint Fusion or Stabilization (All Lines of Business Except Medicare) **MP24**	**Annual Update** • Add Policy Guidelines for pain and Documents Required for Review. • Criterion I.C. simplified open fusion request circumstances. **Codes/PA:** No changes to codes/PA
Back: Sacroiliac Joint Fusion or Stabilization (Medicare Only)	**Annual Update** No recommended changes to criteria. • Continue to follow Local Coverage Determination (LCD): Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain (L36000) and Local Coverage Article (LCA): Billing and Coding: Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain (A57596).

MP195	• Open sacroiliac joint fusion continues to follow Commercial policy, MP13. **Codes/PA:** No change to codes/PA
Radiofrequency Ablation or Cryoablation for Plantar Fasciitis **MP284**	**Annual Update** No recommended changes to criteria. No Medicare guidance identified. **Codes/PA:** For 0441T, configure code to deny as E/I when billed with dx codes listed in the Billing Guidelines for all lines of business. Currently Medicare is set to pay.

VENDOR UPDATES

eviCore

MSK Therapy (POSTCAM) Guideline Updates - Effective May 15, 2021

The annual review of eviCore's clinical guidelines for our MSK Therapy programs have been completed, these updates will become effective on 5-15-2021. We have created a unique link to support access to the change packages for each of the therapy solutions. You will find the link embedded in this email (see below). The links to each program include 5 files with varying components of information to support the review of the updates. Additionally, a link to the final documents are also available at the final document link provided below and have been posted to eviCore.com as of January 21, 2021- reminder that users will need to look under the future tab for the updated final guideline documents.

- Physical & Occupational Therapy Services Supporting Documents for V1.0 – Effective 05/10/2021
- Final Documents Available on eviCore.com Under the Future Tab

Table of Contents:

I. New Drugs or Combinations

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

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

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

PA PROGRAM NAME	Prophylactic Hereditary Angioedema Therapy
MEDICATION NAME	Orladeyo (berotralstat)
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	Combination prophylaxis therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®
REQUIRED MEDICAL INFORMATION	**Initial Authorization:** All of the following must be met: 1. Documentation of **one** of the following clinical criteria:

	a. Self-limiting, noninflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or c. Recurrent laryngeal edema **AND** 2. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (eg. estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary **AND** 3. One of the following: a. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show: i. C4 is less than 50 percent of the lower limit of normal **AND** ii. **one** of the following: a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or b. C1-INH function is less than 50 percent of the lower limit of normal b. For HAE with normal C1-INH or HAE Type III: i. Confirmed Factor 12 (FXII) , ANGPT1, PLG, KNG1 gene mutation **OR** ii. Positive family history for HAE **AND** attacks lack response with high dose antihistamines or corticosteroids. **For coverage of Cinryze®:** Documentation of trial and failure or contraindication to Haegarda®. **Reauthorization:** Documentation must be provided showing benefit of therapy with reduction of frequency and severity of HAE attack episodes by greater than or equal to 50% from baseline.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an immunologist or an allergist.
COVERAGE DURATION	Initial prior authorization will be approved for 3 months. Reauthorization may be approved for one year.

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

PA PROGRAM NAME	CINRYZE/HAEGARDA/TAKHZYRO
MEDICATION NAME	Orladeyo (berotralstat)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Combination prophylaxis therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®
REQUIRED MEDICAL INFORMATION	All of the following must be met: a. Diagnosis of Hereditary Angioedema (HAE) Type I, II or III. b. One of the following:

	A. For HAE Type I and Type II, documentation of a complement study that shows: i. C4 less than 50 percent of the lower limit of normal AND ii. One of the following: C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal or C1-INH function is less than 50 percent of the lower limit of normal. B. For HAE with normal C1-INH or HAE Type III, one of the following: i. Confirmed Factor 12 (FXII) mutation OR ii. Positive family history for HAE AND attacks that lack response with high dose antihistamines or corticosteroids. c. Dosing regimens are within FDA labeled dosing outlined in package insert or sufficient evidence-based rationale is provided for increased dosing and/or frequency. d. For coverage of Cinryze: Documentation of trial and failure or contraindication to Haegarda. Reauthorization requires documentation of benefit of therapy with reduction of frequency and severity of HAE attacks.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an immunologist or an allergist.
COVERAGE DURATION	Initial prior authorization will be approved for 3 months. Reauthorization may be approved for one year.

2. **Naxitamab-gqgk (Danyelza®) Vial**
   a. **Indication**: In combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.
   b. **Decision**:

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

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

3. **Nifurtimox (Lampit®) Tablet**
   a. **Indication**: For the treatment of Chagas disease (American Trypanosomiasis) caused by *Trypanosoma cruzi*.

- This indication is approved under accelerated approval based on the number of treated patients who became immunoglobulin G (IgG) antibody negative or who showed an at least 20% decrease in optical density on two different IgG antibody tests against antigens of *T. cruzi*.
- Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
Formulary Alternatives: benznidazole			

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

4. **Opicapone (Ongentys®) Capsule**
   a. **Indication**: Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.
   b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	Brand	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Step Therapy	Step Therapy	Step Therapy
Quantity Limit	1 tablet per day	1 tablet per day	1 tablet per day
Formulary Alternatives: tolcapone, entacapone			

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

ST PROGRAM NAME	ONGENTYS (OPICAPONE)
MEDICATION NAME	Ongentys (opicapone)

COVERED USES	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Documented trial, intolerance, or contraindication to generic entacapone
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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

ST PROGRAM NAME	ONGENTYS (OPICAPONE)
MEDICATION NAME	Ongentys (opicapone)
ST INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A.
REQUIRED MEDICAL INFORMATION	Documented trial, intolerance, or contraindication to generic entacapone
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

5. **Levamlodipine maleate (Conjupri®) Tablet**
   a. **Indication**: For the treatment of hypertension in adults and children 6 years and older.
   b. **Decision**:

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

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to New medications and formulations without established benefit policy

6. **Remdesivir (Veklury®) Vial**
   a. **Indication**: Treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization.
   b. **Decision**:

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

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

7. **Lumasiran sodium (Oxlumo®) Vial**
   a. **Indication**: For the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients.
   b. **Decision**:

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

   c. **Prior Authorization Criteria**:

PA PROGRAM NAME	Oxlumo
MEDICATION NAME	Oxlumo®
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	1. Patients with a history of liver transplant

	2. Patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Patient has a diagnosis of primary hyperoxaluria type 1 (PH1) 2. Diagnosis of PH1 has been confirmed by one of the following : a. Genetic testing demonstrating mutation in the alanine:glyoxylate aminotransferase (AGXT) gene b. Liver biopsy demonstrating significantly decreased or absent alanine:glyoxylate aminotransferase (AGT) enzyme activity 3. Documentation of one of the following: a. Elevated urine oxalate (UOx) excretion as measured by body surface area-normalized daily UOx output greater than upper limit of normal (ULN) b. Elevated UOx excretion as measured by UOx:creatinine ratio above age-specific upper limit of normal (ULN) OR c. Elevated plasma oxalate (POx) concentration (POx concentration greater than ULN) 4. Documentation of a trial of high fluid intake of at least 3 liters per meter-squared of Body Surface Area (BSA) per day and that high fluid intake will continue with therapy 5. Concurrent use of pyridoxine or previous trial of at least 3 months with no significant improvement in urine oxalate concentration Reauthorization: 1. Documentation of a clinically significant reduction in urine or plasma oxalate levels relative to pre-treatment baseline 2. Patient continues with concurrent high fluid intake (at least 3 liters per meter-squared BSA per day) and pyridoxine (unless individual is a pyridoxine non-responder)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist or urologist
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization for 12 months

II. New Strengths or Formulations

1. **Oxybates salts (calcium, magnesium, potassium, and sodium) oral solution (Xywav)** reviewed by Jane Hoh, PharmD.
   a. **Indication**: For the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
   b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	540 mL per 30 days	540 mL per 30 days	540 mL per 30 days

Formulary Alternatives: Xyrem®, Wakix®, armodafinil, modafinil, Sunosi®, methylphenidate, and amphetamine

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

PA PROGRAM NAME	Xyrem and Xywav
MEDICATION NAME	Xywav
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. For treatment of narcolepsy with cataplexy the following criteria must be met: a. Diagnosis of narcolepsy as confirmed by sleep study or 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) b. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months c. Documentation of presence of cataplexy 2. For treatment of excessive daytime sleepiness in narcolepsy without cataplexy the following criteria must be met: a. Diagnosis of narcolepsy as confirmed by sleep study or 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) b. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months c. Other causes of sleepiness have been ruled out or treated (i.e. obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders) d. Documentation of a three (3)-month trial and failure, incomplete response, intolerance, or contraindication to both of the following: i. Stimulant (e.g., amphetamine, methylphenidate) ii. Modafinil or armodafinil Reauthorization: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks. QUANTITY LIMIT: Xyrem® is limited to 9 grams per day, which is 540 mL/30 days. There is no evidence of additional benefit achieved with Xyrem® doses over 9 grams per day.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a sleep specialist or neurologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

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

PA PROGRAM NAME	Xyrem
MEDICATION NAME	Xywav

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Narcolepsy: 1. Full nocturnal polysomnogram and a multiple sleep latency test showing mean onset to sleep less than 10 minutes, AND 2. No other polysomnographic reasons to explain sleepiness, AND 3. Documentation of trial and failure, contraindication, or intolerance to modafinil AND armodafinil, unless the patient is diagnosed with cataplexy. Reauthorization requires documentation that treatment has been effective.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a sleep specialist or neurologist.
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

III. Other Formulary Changes

Drug Name	Recommendation	Policy Name
Alkeran® (melphalan) Tablets	Retire Prior Authorization for Medicare Part B • Covered under medical benefit	Oral Anti-Cancer Medications
Alkindi Sprinkle® (hydrocortisone) Capsules	New Dosage Form and Strength: • All lines of business: Non-Formulary	N/A
Atorvastatin 10, 20, and 40 mg Tablets	Remove Quantity Limit for Commercial and Medicaid • Commercial: Formulary, Tier 1 • Medicaid: Formulary	N/A
Citalopram Tablets **Escitalopram Tablets** **Fluoxetine Capsules** **Fluvoxamine Tablets** **Paroxetine Tablets** **Sertraline Tablets**	Add to Safe Harbor and Custom Safe Harbor Lists for Commercial, Effective 1/1/2022	N/A

Clinolipid® (fat Emulsion/olive/soy/ phospho) 20% Emulsion	Add to Medicare Part D formulary: Formulary, Tier 4, Prior Authorization for Part B vs Part D coverage	N/A
Cosentyx® (secukinumab)	Add to Medicaid Formulary: Formulary, Specialty, Prior Authorization, Quantity Limit (2 injections per 28 days)	Therapeutic Immunomodulators - Medicaid
Dificid® (fidaxomicin) 40 mg/mL suspension	New Dosage Form • Commercial: Formulary, Tier 6, Step Therapy • Medicaid: Formulary, Step Therapy • Medicare Part D: Formulary, Tier 5	• Commercial/Medicaid: Dificid • Medicare: N/A
Epclusa® (sofosbuvir/velpatasvir)	New Strength • Medicare Part D: Non-Formulary	N/A
Icatibant (Firazyr)	Commercial: Move generic formulation to Tier 5, brand remains on Tier 6	Acute Hereditary Angioedema Therapy
Impeklo® (clobetasol) 0.05% lotion pump	New Dosage Form • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare: N/A
Indomethacin Capsule	Add to Medicare formulary: Formulary, Tier 2	N/A
Indomethacin ER Capsule	Add to Medicare formulary: Formulary, Tier 2	N/A
Moxifloxacin (Vigamox®) Eye Drops	Down-tier the generic and add to Medicaid formulary: • Commercial (Cost-Based): Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Omegaven® (fatty acid6/fish oil/gly/p-lip) 10% Emulsion	Add to Medicare Part D formulary: Formulary, Tier 4, Prior Authorization for Part B vs Part D coverage	N/A
Otezla® (apremilast)	Remove from Medicaid Formulary: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day)	Therapeutic Immunomodulators - Medicaid
Pregabalin (Lyrica®) Capsules	Remove Quantity Limits for Commercial and Medicaid • Commercial: Formulary, Tier 2 • Medicaid: Formulary	N/A
Qdolo® (tramadol) 5 mg/mL Oral Solution	New Dosage Form:	• Commercial/Medicaid: Pediatric Analgesics • Medicare: N/A

	• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit 80 mL/day • Medicare Part D: Non-Formulary, FDA Max 80 mL/day	
Silodosin (Rapaflo®) Capsule	Down-tier the generic: • Commercial (Cost-Based): Formulary, Tier 3	BPH Treatment- Rapaflo, Cialis
Simvastatin 40 and 80 mg Tablets	Remove Quantity Limits for Commercial and Medicaid • Commercial: Formulary, Tier 1 • Medicaid: Formulary	N/A
Smoflipid® (fat emul/ soy/mct/oliv/fish oil) 20% Emulsion	Add to Medicare Part D formulary: Formulary, Tier 4, Prior Authorization for Part B vs Part D coverage	N/A
Solifenacin (Vesicare®) Tablet	Down-tier the generic: • Commercial (Cost-Based): Formulary, Tier 2	N/A
Sutab® (sodium sulfate/potassium chloride/magnesium sulfate) Tablet	New Combination: • Commercial: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Temozolomide (Temodar®) Capsule	Retire Prior Authorization for Medicare Part B • Covered under Part B	Oral Anti-Cancer Medications
Trelstar® (triptorelin pamoate) Vial	Add Prior Authorization for Commercial and Medicaid: • Commercial/Medicaid: Medical Benefit, Prior Authorization Effective 5/1/2021	Gonadotropin Releasing Hormone Agonists
Zejula® (niraparib tosylate) Capsule	Down-tier for Commercial: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Tresiba® (insulin degludec) Vial and pen	Add to Custom Safe Harbor List	N/A
Relion® 70/30, N, and R Flexpens and Vial	Clarify formulary status • Commercial: Non-Formulary, Prior Authorization	Non-Preferred Insulins

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

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Ravulizumab-cwvz (Ultomiris) Vial	New Strength (300mg/3ml). Line extend with Ultomiris 300mg/30ml; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization Effective 2/1/2021	Ultomiris
Sofosbuvir/velpatasvir (Epclusa) Tablet	New Strength (200mg/50mg). Line extend with Epclusa (400mg/100mg); • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization Effective 2/1/2021	• Commercial: Hepatitis C - Direct Acting Antivirals – Commercial • Medicaid: Hepatitis C - Direct Acting Antivirals - Medicaid
Clinimix IV Soln	New Strengths. Line extend with Clinimix; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization Effective 2/1/2020	• Commercial/Medicaid: Total Parenteral Nutrition (TPN) • Medicare Part B: Total Parenteral Nutrition (TPN) – Medicare Part B
Epoetin alfa-epbx (Retacrit) Vial	New Strength (20000/2ml). Line extend with Retacrit; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Prior Authorization • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid/Medicare Part D: Erythropoiesis Stimulating Agents (ESAs) • Medicare Part B: Erythropoiesis Stimulating Agents (ESAs) – Medicare Part B
Pegfilgrastim-apgf (Nyvepria) Syringe	Biosimilar to Neulasta. Line extend with Neulasta; • Commercial/Medicare Part D: Formulary, Tier 5 • Medicaid: Formulary	N/A

Diphtheria,pertus(acell), tetanus/hepb/polio/hib conj-meng/pf (Vaxelis) Syringe / Vial	New Combination; Line extend with TDAP vaccines; • Commercial; Formulary, Preventive, Quantity Limit (1.5 mL per lifetime) • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Fluoroestradiol f-18 (Cerianna) Vial	New Entity; Medical; Line extend as Medical; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	N/A
Rituximab-arrx (Riabni) Vial	Biosimilar to Rituxan. Line extend with Rituxan; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Rituximab

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Rufinamide Oral Susp	First generic (Banzel). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost Based: Formulary, Tier 4, Step Therapy • Medicaid: Formulary, Step Therapy • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Antiepileptic Medications • Medicare Part D: Antiepileptic Agents
Icosapent ethyl 1 gram Capsule	First Generic (Vascepa). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Cost Based: Formulary, Tier 3, Prior Authorization • Medicaid: Formulary, Prior Authorization	Vascepa

	• Medicare Part D: Formulary, Tier 3, Prior Authorization	
Timolol maleate Droperette	First Generic (Timoptic). Line extend as generic; • Non-formulary for all lines of business	N/A
Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Gemmily) Capsule	Line extend with noreth-estradiol-FE; • Commercial: Formulary, Preventive • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Levothyroxine sodium (Levothyroxine) Capsule	First Generic (Tirosint). Line extend as generic; • Non-formulary for all lines of business	N/A
Estradiol (Lyllana) Patch TDSW	Line extend with generic Minivelle; • Commercial Standard: Formulary, Tier 2 • Commercial Cost Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Ethynodiol diacetate-ethinyl estradiol (Zovia) Tablet	Line extend with other generic Zovia; • Commercial: Formulary, Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Alvimopan Capsule	First Generic (Entereg). Line extend as generic; • Non-Formulary for all lines of business	N/A
Ivermectin Lotion	First Generic (Sklice). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost Based: Formulary, Tier 4 • Medicaid/Medicare Part D: Non-Formulary	N/A
Nitazoxanide Tablet	First Generic (Alinia). Line extend as generic; Generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (2 Tablets per day)	• Commercial/Medicaid: Alinia • Medicare Part D: N/A

	• Commercial Cost Based: Formulary, Tier 3, Prior Authorization, Quantity Limit (2 Tablets per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 Tablets per day) • Medicare Part D: Formulary, Tier 5, Quantity Limit (6 Tablets per 30 days)	
Norgestimate-ethinyl estradiol (Nymyo) Tablet	Line extend with Ortho-Cyclen generics; • Commercial: Formulary, Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Meloxicam, submicronized (Meloxicam) Capsule	First Generic (Vivlodex). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Abiraterone acetate Tablet	First Generic (Zytiga). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents
Asenapine maleate Tab Subl	First Generic (Saphris). Line extend as generic; Brand: • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost Based: Formulary, Tier 4, Step Therapy • Medicaid: Non-Formulary (covered by DMAP) • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Commercial: Antipsychotics Step Therapy • Medicare Part D: Antipsychotics
Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Merzee) Capsule	Line extend with noreth-estradiol-FE; • Commercial: Formulary, Preventive • Medicaid: Non-Formulary	N/A

	• Medicare Part D: Formulary, Tier 4	

IV. Clinical Policy Changes

Policy Name	Summary of Change
CAR-T	Updated exclusion and indication-specific criteria to align with clinical trial inclusion/exclusion criteria, FDA label and National Comprehensive Cancer Network (NCCN) recommendations.
Hepatitis C - Direct Acting Antivirals - Medicaid	Add Epclusa® 200-50 MG Tablet to Medicaid Formulary, Specialty, Prior Authorization to align with OHA
Injectable Anti-Cancer Medications	Updated authorization duration to until no longer eligible with the plan. Removed requirement for use of intravenous trastuzumab and pertuzumab prior to approval of Phesgo® and/or Herceptin Hylecta®. Minimal cost differences and possible future availability of home administration for these products.
Insomnia Agents - Medicaid	Updated policy criteria to require a trial and failure of preferred agents for all requests, added a trial of cognitive behavior therapy for new starts as recommended per the American Academy of Sleep Medicine guidelines, updated criteria to restrict use of sedatives to Medicaid funded conditions.
Lidocaine Patch	Based on drug utilization review, criteria were updated to allow coverage if the patient has a diagnosis of post-herpetic neuralgia, diabetic peripheral neuropathy, or neuropathic Pain
Non-Preferred Fumarate Products	Added Medicaid to policy as well as Commercial, requiring Vumerity® and Bafiertam® to step through generic dimethyl fumarate (Tecfidera®).
Oral Anti-Cancer Medications	Removed Zejula® indication-specific criteria to align with cost-positioning contracts. In addition, removed prior authorization for Medicare Part B temozolomide and Alkeran® given low risk for over utilization.
Provenge	Removed comment about “no complaints of bone pain as an example of minimally symptomatic metastatic disease” to better reflect population in clinical trials. Updated definition of castrate resistant prostate cancer to include clinical or biochemical progression (as well as radiographic) to align with NCCN Prostate Cancer guideline definition. Added other visceral metastases in addition to hepatic to align with NCCN guidelines. Clarified exclusion statement regarding immunosuppressive agents.
Rituximab	Changed criteria for Rheumatoid Arthritis to trial/failure of one tumor necrosis factor (TNF) antagonist to align with FDA labeling. Criteria

	change for Relapsing and Remitting Multiple Sclerosis to trial/failure of two disease modifying agents (removed requirement for specific agents) OR patient has severe disease (without trial/failure of two agents) to align with current practice patterns. For warm autoimmune hemolytic anemia, removed requirement for splenectomy as it is moving to third line therapy after corticosteroids and rituximab. Increased reauthorization duration from 6 months to one year for all indications.
Therapeutic Immunomodulators - Commercial	Updated to include criteria for Behcet's disease, as this was supposed to be transferred from the Otezla policy to this policy at December 2020 ORPTC.
Therapeutic Immunomodulators - Medicaid	Based on a drug utilization review of psoriasis treatments in this population, Cosentyx® was added as a preferred agent for the indication. Otezla® and Enbrel® were removed as preferred agents due to their poor efficacy in this disease state.

V. New Indications Monitoring

1. **YERVOY®**
   IPILIMUMAB
   New indication approved 10/02/2020:
   - **In combination with nivolumab, for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma**

   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.

2. **KEYTRUDA®**
   PEMBROLIZUMAB
   New indication approved 10/14/2020:
   - **For the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL)**
   - **For the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy**
   - **For the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy.**

   Limitations of use:
   Keytruda is not recommended for treatment of patients with PMBCL who require urgent cytoreductive 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.

3. **OPDIVO®**
NIVOLUMAB
New indication approved 10/02/2020:
- **In combination with ipilimumab, for the treatment of adult patients with unresectable malignant pleural mesothelioma**

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.

4. **RUBRACA®**
RUCAPARIB
New indication approved 10/08/2020:
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. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.

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.

5. **WAKIX®**
PITOLISANT HYDROCHLORIDE
New indication approved 10/13/2020:
- **Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial, Medicaid, and Medicare policies will be updated as followed:

Applies to: Commercial and Medicaid

PA PROGRAM NAME	**WAKIX®** (pitolisant tablet)
MEDICATION NAME	Wakix (pitolisant tablet)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Idiopathic central nervous system hypersomnia
REQUIRED MEDICAL INFORMATION	Initial Authorization: For excessive daytime sleepiness with narcolepsy, the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or 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. Other causes of sleepiness have been ruled out or treated (i.e. obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders) 4. 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 For cataplexy in adult patients with narcolepsy, the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or 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 excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score ≥12 or documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months 3. Documentation of at least 3 weekly cataplexy attacks Reauthorization: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks.
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.

Applies to: Medicare Part D

PA PROGRAM NAME	WAKIX
MEDICATION NAME	Wakix
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Idiopathic central nervous system hypersomnia
REQUIRED MEDICAL INFORMATION	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. For cataplexy in adult patients with narcolepsy, the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or 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 excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score ≥12 or documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months 3. Documentation of at least 3 weekly cataplexy attacks Reauthorization: Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks.
AGE RESTRICTIONS	Approved for patients 18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a sleep specialist, neurologist, pulmonologist, or psychiatrist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

6. **VENCLEXTA®**
VENETOCLAX
New indication approved 10/16/2020:
- **For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).**
- **In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction 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.

7. **SELZENTRY®**
MARAVIROC
New indication approved 10/30/2020:
- **in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in adults and pediatric patients weighing at least 2 kg.**
- **Limitations of Use:**
  - **Not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1**

RECOMMENDATION: Inform prescribers via MD alert.

8. **TOTECT®**
DEXRAZOXANE
New indication approved 11/02/2020:
- **Reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m2 and who will continue to receive doxorubicin therapy to maintain tumor control. Do not use Totect with doxorubicin initiation**

RECOMMENDATION: Inform prescribers via MD alert.

9. **BRILINTA®**
TICAGRELOR
New indication approved 11/05/2020:
- **To reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA)**

RECOMMENDATION: Inform prescribers via MD alert.

10. **VIMPAT®**
LANCOSAMIDE
New indication approved 11/16/2020:
- **Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older**

RECOMMENDATION: Inform prescribers via MD alert. The FDA approved indications section for the Commercial/Medicaid antiepileptic medication step therapy policy will be updated with the current February P&T cycle.

11. **CEFAZOLIN AND DEXTROSE®**
CEFAZOLIN SODIUM
New indication approved 11/23/2020:
- **Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients for whom appropriate dosing with this formulation can be achieved:**
  - **Respiratory tract infections**
  - **Urinary tract infections**
  - **Skin and skin structure infections**
  - **Biliary tract infections**
  - **Bone and joint infections**
  - **Genital infections**
  - **Septicemia**
  - **Endocarditis**
- **Perioperative prophylaxis in adults and pediatric patients aged 10 to 17 years old for whom appropriate dosing with this formulation can be achieved.**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefazolin for Injection and Dextrose Injection and other antibacterial drugs, Cefazolin for Injection and Dextrose Injection 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.

12. **XOFLUZA®**

BALOXAVIR MARBOXIL

New indication approved 11/23/2020:

- **Post-exposure prophylaxis of influenza in patients 12 years of age and older following contact with an individual who has influenza**

RECOMMENDATION: Inform prescribers via MD alert.

13. BENLYSTA®

BELIMUMAB

New indication approved 12/16/2020:

- **Adult patients with active lupus nephritis who are receiving standard therapy**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial, Medicaid, and Medicare policies will be updated as followed:

Applies to: Commercial, Medicare Part B, Medicaid

PA PROGRAM NAME	BENLYSTA®
MEDICATION NAME	BENLYSTA 200 MG/ML AUTOINJECT BENLYSTA 200 MG/ML SYRINGE
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. Severe active central nervous system lupus 2. Current use of other biologic immunomodulator 3. Previous use of dialysis in the past 12 months or currently using dialysis
REQUIRED MEDICAL INFORMATION	**For Systemic Lupus Erythematous (SLE) and active lupus nephritis:** All of the following must be met: 1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist **AND** 2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one (1) of the following: a. Positive Antinuclear antibody (ANA) b. Positive anti-double-stranded DNA (anti-dsDNA) on two (2) or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies **AND** 3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one (1) of the following: a. For SLE without Active Lupus Nephritis: i. Oral corticosteroid(s) ii. Azathioprine

	iii. Methotrexate iv. Mycophenolate mofetil v. Hydroxychloroquine vi. Chloroquine vii. Cyclophosphamide b. For SLE with Active Lupus Nephritis: i. Mycophenolate for induction followed by mycophenolate for maintenance, OR ii. Cyclophosphamide for induction followed by azathioprine for maintenance. 4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate) Reauthorization: 1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction of renal related events) 2. Patient currently receiving standard therapy
AGE RESTRICTIONS	**For SLE without active lupus nephritis**: Age 5 years and older for IV infusion Age 18 years and older for subcutaneous injection **For SLE with Active Lupus Nephritis:** Age 18 years and older for IV infusion or subcutaneous injection
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a rheumatologist or nephrologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months

Applies to: Medicare Part D

PA PROGRAM NAME	BENLYSTA
MEDICATION NAME	BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	1.Severe active Central Nervous System Lupus, 2. Current use of other biologic immunomodulator,
REQUIRED MEDICAL INFORMATION	For Systemic Lupus Erythematosus (SLE) or active lupus nephritis: All of the following must be met: 1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist AND 2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one (1) of the following: a. Positive Antinuclear antibody (ANA) b. Positive antidouble-stranded DNA (anti-dsDNA) on two (2) or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies AND 3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or

	frequent flares), contraindication, or intolerance to at least one (1) of the following: a. For SLE without active lupus nephritis: oral corticosteroid(s), azathioprine, methotrexate, mycophenolate mofetil, hydroxychloroquine, chloroquine, or cyclophosphamide, b. For SLE with active lupus nephritis: mycophenolate for induction followed by mycophenolate for maintenance, OR cyclophosphamide for induction followed by azathioprine for maintenance. AND 4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate). Reauthorization: 1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction in renal related events) AND 2. Patient currently receiving standard therapy for SLE or active lupus nephritis.
AGE RESTRICTIONS	**For SLE without active lupus nephritis**: Age 5 years and older for IV infusion Age 18 years and older for subcutaneous injection **For SLE with Active Lupus Nephritis:** Age 18 years and older for IV infusion or subcutaneous injection
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a rheumatologist or nephrologist.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for 6 months.

14. KINERET®
ANAKINRA

New indication approved 12/18/2020:

- **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**
  - **Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**

RECOMMENDATION: Inform prescribers via MD alert. The new indication will be added to the Commercial, Medicaid and Medicare part D policies with the current February P&T cycle.

15. ARCALYST®
RILONACEPT

New indication approved 12/18/2020:

- **Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg.**

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

Applies to the Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	INTERLEUKIN – 1 INHIBITORS
MEDICATION NAME	**Arcalyst®** (rilonacept injection), **Ilaris®** (canakinumab injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) confirmed by: 1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3) or CIAS1 (Cold-Induced Auto-inflammatory Syndrome-1), **AND** 2. Classic symptoms associated with Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) – recurrent intermittent fever and rash typically associated with natural or artificial cold **For Arcalyst® only:** 1. Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist) 2. Current inflammatory remission of DIRA 3. Weight of at least 10 kg **For Ilaris® only:** For Familial Mediterranean Fever (FMF), and all the following: 1. Documented trial and failure, contraindication or intolerance to colchicine, **AND** 2. Classic symptoms associated with FMF (febrile episodes, pain in the abdomen, chest, or arthritis of large joints). Diagnosis of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) confirmed by: 1. Laboratory evidence of genetic mutation MVK (mevalonate kinase), **AND** 2. Classic symptoms associated with HIDs (abdominal pain; lymphadenopathy, aphthous ulcers). Diagnosis of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) confirmed by: 1. Laboratory evidence of genetic mutation TNFRSF1A (tumor necrosis factor receptor super family), **AND** 2. Classic symptoms associated with TRAPs (abdominal pain, skin rash, musculoskeletal pain, eye manifestations). Diagnosis of Active Still's Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease: 1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND** 2. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)

	Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)
AGE RESTRICTIONS	Arcalyst®: may be covered for patients aged 12 years and older with CAPS (which includes FCAS, MWS). Ilaris® may be covered for patients aged 4 years of age and older in patients with CAPS (which includes FCAS, MWS); Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF Ilaris® may be covered for patients aged 2 years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis and Adult Onset Still's Disease (AOSD)
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

Applies to Medicare Part D:

PA PROGRAM NAME	INTERLEUKIN – 1 INHIBITORS
MEDICATION NAME	**Arcalyst®** (rilonacept injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): Diagnosis confirmed by: 1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family pyrin domain containing 3) or CIAS1 (Cold-induced auto-inflammatory syndrome-1), AND 2. Classic symptoms associated with FCAS or MWS (e.g., recurrent intermittent fever and rash typically associated with natural or artificial cold). Reauthorization: requires documentation of improvement of symptoms, such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis. For Deficiency of Interleukin-1 Receptor Antagonist (DIRA): 1. Confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist) 2. Current inflammatory remission of DIRA 3. Weight of at least 10 kg Reauthorization: Documentation submitted of improvement of symptoms
AGE RESTRICTIONS	For CAPS (which includes FCAS, MWS).may be covered for patients aged 12 years and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

16. XEOMIN®
INCOBOTULINUMTOXIN-A
New indication approved 12/18/2020:
- **treatment of chronic sialorrhea in patients 2 years of age and older**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial/Medicaid and Medicare Part B policies will be updated to reflect the new population without significant change to criteria.

17. OPDIVO®
NIVOLUMAB
New indication approved 12/29/2020:
- **Small Cell Lung Cancer (SCLC)**
  - **patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy**

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

18. HETLIOZ®
TASIMELTEON
New indication approved 12/01/2020:
- **HETLIOZ® Capsules: Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older**
- **HETLIOZ® LQ oral suspension: Nighttime sleep disturbances in SMS in pediatric patients 3 years to 15 years of age**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial, Medicaid, and Medicare policies will be updated as follows:

Applies to Commercial and Medicaid:

PA PROGRAM NAME	HETLIOZ®
MEDICATION NAME	**HETLIOZ®** (tasimelteon capsules) **HETLIOZ® LQ** (tasimelteon oral suspension)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Sleep disorders other than Non-24 and SMS.
REQUIRED MEDICAL INFORMATION	**For Non-24-Hour Sleep-Wake Disorder (Non-24):** All of the following criteria must be met: 1. Member is totally blind (i.e. no light perception) 2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by: a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic periods 3. Documented sleep study to exclude other sleep disorders

	4. Documentation of clinically significant distress or impairment in social, occupational, and other important areas of functioning 5. Documented trial, failure, intolerance or contraindication to an adequate trial (at least 30 days) of melatonin Reauthorization criteria: 1. Documentation of improvement in social, occupational, and other important areas of functioning **AND** 2. Documentation of entrainment to the 24-hour circadian period. **For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS):** All of the following criteria must be met: 1. Documented diagnosis of SMS, as characterized by: a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene 2. Documented sleep study to exclude other sleep disorders 3. Documentation of at least one of the following: a. difficulties falling asleep b. shortened sleep cycles c. frequent and prolonged nocturnal awakenings d. excessive daytime sleepiness e. daytime napping 4. Documented trail and failure or contraindication of melatonin dosed in the morning or daytime administration of acebutolol combined with melatonin dosed at bedtime. **Reauthorization Criteria:** Documentation of improvement in sleep quality or total sleep time.
AGE RESTRICTIONS	Non-24: 18 years or older for capsules SMS: 3-15 years old for suspension and 16 years or older for capsules
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a sleep specialist.
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

Applies to Medicare Part D:

PA PROGRAM NAME	HETLIOZ
MEDICATION NAME	Hetlioz
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Sleep disorders other than Non-24 and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
REQUIRED MEDICAL INFORMATION	For Non-24-Hour Sleep-Wake Disorder (Non-24): All of the following criteria must be met: 1. Member is totally blind (i.e. no light perception), 2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by all of the following: a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night AND b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic

	periods, 3. Documented sleep study to exclude other sleep disorders. Reauthorization requires documentation of entrainment to the 24-hour circadian period. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): All of the following criteria must be met: 1. Documented diagnosis of SMS, as characterized by: a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene, 2. Documented sleep study to exclude other sleep disorders, 3. Documentation of at least one of the following: a. difficulties falling asleep, b.shortened sleep cycles, c. frequent and prolonged nocturnal awakenings, d. excessive daytime sleepiness or e. daytime napping. Reauthorization requires documentation of improvement in sleep quality or total sleep time.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a sleep specialist or neurologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year

19. **SAXENDA®**
LIRAGLUTIDE
New indication approved 12/04/2020:
- **Pediatric patients aged 12 years and older with:**
  - **body weight above 60 kg and**
  - **an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs**

RECOMMENDATION: Inform prescribers via MD alert.

20. **TAGRISSO®**
OSIMERTINIB
New indication approved 12/18/2020:
- **As adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, 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.

21. **ICLUSIG®**
PONATINIB
New indication approved 12/182020:
- **Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.**
- **Accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated.**
- **T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL**

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.

22. XPOVIO®
SELINEXOR
New indication approved 12/18/2020:
- **In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy**
- **In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four pri or therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulat ory agents, and an anti-CD38 monoclonal antibody**
- **For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical bene fit in 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.

23. PROHANCE®
GADOTERIDOL INJECTION
New indication approved 12/19/2020:
- **expansion of the central nervous system (CNS) indication to include pediatric patients younger than age 2 years, including term neonates, at a dose of 0.1 mmol/kg (0.2 mL/kg)**

RECOMMENDATION: Inform prescribers via MD alert.

24. KALYDECO®
IVACAFTOR
New indication approved 12/21/2020:
- **Expansion of the indicated Cystic Fibrosis patient population to include additional mutations in the CFTR gene that have been identified as responsive to ivacaftor based upon in vitro data**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial/Medicaid policy will be updated with the new indication with the current February P&T cycle.

25. SYMDECO®
IVACAFTOR/TEZACAFTOR
New indication approved 12/21/2020:

- **Expansion of the indicated Cystic Fibrosis patient population to include additional mutations in the CFTR gene that have been identified as responsive to tezacaftor/ivacaftor based upon in vitro data.**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial/Medicaid policy will be updated with the new indication with the current February P&T cycle.

26. TRIKAFTA®
IVACAFTOR/TEZACAFTOR/ELEXACAFTOR
New indication approved 12/21/2020:

- **Treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial/Medicaid policy will be updated with the new indication with the current February P&T cycle.

27. GAVRETO®
PRALSETINIB
New indication approved 12/01/2020:

- **Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy**
- **Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).**

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.

VI. Drug Safety and Recall Monitoring

1. Paroex Chlorhexidine Gluconate Oral Rinse, 4 oz and 16 oz, Recalled due to Potential Contamination with *Burkholderia lata*
[Posted 10/27/2020]
ISSUE:
Potential contamination with *Burkholderia lata*

FDA RECOMMENDATION:
Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% products bearing an expiration date from 6/30/22 – 9/30/22 (see specific lots below) to the consumer level. This product may be contaminated with the bacteria *Burkholderia lata*.

Use of the defective product in the immunocompetent host may result in oral and, potentially, systemic infections requiring antibacterial therapy. In the most at-risk populations, the use of the defective product may result in life-threatening infections, such as pneumonia and bacteremia. To date, no adverse events have been reported to SAI related to this recall.

SAI is notifying its direct distributors and customers by USPS Priority mail and is arranging for return of all recalled products. Patients, pharmacies, and healthcare facilities in possession of these products should stop using and dispensing immediately.

Recommendation: Notify via MD alert. PHP action was taken. This recall has been classified by majority decision as Class 2. Following policy, members effected by the recall will receive letters to inform them within 30 days from the date the recall was released.