PROVIDENCE Health Plan

# Healthcare Services Medical & Pharmacy Policy Alerts

Number 235

May 1, 2019

This is the May 1, 2019 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-and-provider-information/

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

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

# MEDICAL POLICY COMMITTEE

**New Policies or Major Changes**

*Effective May 1, 2019*

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| **Back: Stabilization Devices and Interspinous Spacers SUR126**<br><br>*Previously Titled: Back: Instrumentation and Stabilization Devices* | **Annual Update**<br>No change designating stabilization devices and interspinous spacers as investigational. The following changes have been made to the policy:<br>• Policy now solely addresses stabilization devices and interspinous spacers.<br>• Interbody fusion techniques (e.g. AxiaLIF and STALIF) will now be addressed on the "Back: Lumbar Spine Surgery" policy.<br>• Magnetically Controlled Growing Rods (MAGEC) now addressed on policy per consideration.<br>• Policy re-named to reflect these changes. |
| **Cardiac: External Ambulatory Electrocardiography (All Lines of Business Except Medicare) MED176** | **Annual Update**<br>No change to medical necessity criteria for external cardiac loop recorders (ELR), external cardiac patch recorders, and mobile cardiac outpatient telemetry (MCOT). PA will be removed for 0295T-0298T (i.e. external patch monitors) effective 5/1/19. |
| **Cardiac: External Ambulatory Electrocardiography (Medicare Only) MED433** | **New Policy**<br>**Recommendation:** New policy created based on relevant LCD by which patients are eligible for long-term electrocardiographic monitoring. Effective 5/1/19 PA will no longer be required for external patch recorders (0295T-0298T).<br>**CMS**:<br>National Coverage Determination (NCD) for Electrocardiographic Services (20.15)<br>Local Coverage Determination (LCD): Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring) (L34636). |
| **Hearing: Cochlear Implants and Auditory Brainstem Implants (All Lines** | **Annual Update**<br>• Hybrid cochlear implants now considered medically necessary. The medical necessity criteria are based on the FDA-approved indication for use.<br>• No change to criteria designating cochlear implants and auditory brainstem implants as medically necessary.<br>○ **Criteria V. B.**: Language added specifying that device component replacement will be covered only if the component |

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| **of Business Except Medicare)**<br>**SUR241** | is no longer under warranty and cannot be repaired. |
| **Hearing: Cochlear Implants and Auditory Brainstem Implants (Medicare Only)**<br>**SUR391** | **Annual Update**<br>No change to Medicare guidance. Auditory Brainstem Implants and Hybrid Cochlear Implants are not addressed by Medicare; therefore, commercial criteria will be followed per hierarchy. |

*Effective July 1, 2019*

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| **Urinary Incontinence Treatments (All Lines of Business Except Medicare)**<br><br>**SUR359**<br><br>*Previously: Urinary Dysfunction: Incontinence* | **Annual Update**<br>The following changes to the policy have been made:<br>• Policy now addresses and considers the following treatments for urinary incontinence to be medically necessary.<br>○ Artificial urinary sphincters<br>○ Injectable bulking agents<br>○ Percutaneous tibial nerve stimulation (PTNS)<br>○ Sacral nerve stimulation (SNS)<br>• Policy now addresses and considers the following treatments for urinary incontinence to be not medically necessary.<br>○ Pelvic floor electrical stimulation (PFES)<br>○ Transurethral radiofrequency therapy (i.e. Renessa procedure)<br>○ Vaginal Cones<br>○ Implanted Adjustable Continence Therapy (e.g. ProAct Therapy System)<br>**Codes:** Based on expanded criteria, 34 codes have been added to the policy. Among these, 7 codes will be considered not covered.<br>**PA:** 22 of the 34 new codes require PA. 12 out of 34 codes were already PA'ed. |
| **Urinary Incontinence Treatments (Medicare Only)**<br><br>**SUR440** | **New Policy**<br>• New policy created due to the following differences with commercial policy:<br>○ Pelvic Floor Electrical Stimulation covered by NCD, whereas commercial policy denies investigational.<br>○ NCD only addresses collagen injectable bulking agents; whereas commercial policy allows for FDA-approved bulking agents of any material. The Medicare policy will follow commercial criteria for all non-collagen bulking agents.<br>○ PTNS commercial criteria is less restrictive than LCD.<br>• Medicare no longer addresses radiofrequency tissue remodeling (Renessa procedure); therefore, we will follow commercial criteria and consider this procedure to be not medically necessary.<br>**Codes:** 34 codes have been added to the policy. Among these, 7 codes will be considered not covered.<br>**PA:** 22 of the 34 new codes require PA. 12 out of 34 codes were already PA'ed.<br>**CMS**: |

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| | • National Coverage Determination (NCD) for Incontinence Control Devices (230.10)<br>• National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18)<br>• National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)<br>• Local Coverage Determination (LCD): Posterior Tibial Nerve Stimulation (PTNS) (L34436)<br>• Local Coverage Article (LCA): Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017) |

**No Major Changes**

*Effective May 1, 2019*

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| **Pelvic Congestion Syndrome Treatment SUR340** | **Annual Update**<br>• No change to the current investigational criteria. Clarified that this policy only applies to the treatment of pelvic congestion syndrome (PCS) in females. There are similar conditions in males that are not addressed in this policy.<br>• Language added to the Billing Guidelines sections for providers and reviewers to provide instruction for codes 75894 and/or 36012 when billed with 37241 for pelvic congestion syndrome. |

*Effective June 1, 2019*

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| **Genetic Studies and Counseling GT234** | **Interim Update**<br>• Removed non-coverage criterion XII. D. "Whole exome sequencing for non-cancer indications".<br>• Updated coding tables and Cross References section.<br>**PA/Codes:** Added a code for whole exome sequencing (81417) to each of these policies, which had been inadvertently left off of a previous update. This code is already PAed for all lines of business and will continue to be PAed. |
| **Genetic Testing: Non-Covered Genetic Panel tests (All Lines of Business Except Medicare) GT235**<br><br>**Genetic Testing: Non-Covered Genetic Panel tests (Medicare Only)** | **Interim Update**<br>• No changes to criteria.<br>• Updated coding tables and Cross References sections.<br>**PA/Codes:** Added a code for whole exome sequencing (81417) to each of these policies, which had been inadvertently left off of a previous update. This code is already PAed for all lines of business and will continue to be PAed. |

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| **GT420** | |
| **Genetic Testing: Reproductive Planning and Prenatal Testing (All Lines of Business Except Medicare) GT236**<br><br>**Genetic Testing: Reproductive Planning and Prenatal Testing (Medicare Only) GT384** | **Interim Update**<br>• No changes to criteria.<br>• Updated coding tables.<br>• Added a Cross References section to each policy. |
| **Cardiac Disease Risk Screening (All Lines of Business Except Medicare) LAB173** | **Interim Update**<br>Moved the 82542 code from the "Not Covered" header on the coding table to "No PA Required" header. This code is currently denying u31 (not medically necessary), but it is a general lab code that can be used for various medically necessary services. Code will be reconfigured to pay. |

*Effective July 1, 2019*

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| **Allergy Testing (All Lines of Business except Medicare) LAB105** | **Annual Update**<br>No change to the current criteria.<br>**Codes/PA:** The PAs have been removed from the following codes: 86003 and 86008. |
| **Allergy Testing (Medicare Only) LAB394** | **Annual Update**<br>Based on a 4/18 update to the LCD, for clarification of criterion II.A.2, "d. Vaccines" was added as a covered intracutaneous/intradermal test. The CPT codes for vaccines are already listed in the LCD as a "Group 1 – Covered" CPT code.<br>**PA / Codes:** The PAs have been removed from the following codes: 86003 and 86008. |

**Vendor Updates**

*AIM Speciality Health*
*Effective June 29, 2019*: Cardiac Imaging Guidelines update

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Note: Please see AIM for full guideline.

## Guideline Change Summary

| Legend | Text color | Indicates… |
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| **Proposed Change** (column) | **Blue** | Change to guideline wording |
| | **Black** | Preservation of existing guideline wording |
| | | **Changes expected to be…** |
| **Change Rationale** (row) | **Green** | More expansive on appropriateness |
| | **Red** | More restrictive on appropriateness |
| | **Black** | Have minimal if any impact on appropriateness review and exists primarily to clarify intent |

## Advanced Imaging of the Heart

| Imaging study | Current Guideline | Proposed Change |
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| **Resting Transthoracic Echocardiography (TTE)** | • Baseline and serial reevaluation in patients undergoing, planning to undergo or who have undergone therapy with cardiotoxic agents (examples including but not limited to some chemotherapeutic agents for cancer, Novantrone® (mitoxantrone) for multiple sclerosis | • Evaluation of ventricular function prompted by treatment with cardiotoxic agents (examples including but not limited to some chemotherapeutic agents for cancer, Novantrone [mitoxantrone] for multiple sclerosis etc.)<br>○ Baseline evaluation prior to starting treatment<br>○ Serial evaluation during or within 6 months of completion of treatment<br>○ Surveillance annually thereafter |
| **Change Rationale**<br>Current guideline written in 2008. Over the past 10 years the field of cardio-oncology has developed and new literature has become available which addresses frequency of surveillance of LV function in this cohort. The language is a liberal position based on review of that literature. | | |
| **TTE** | Not addressed | • Following transcatheter mitral valve repair, TTE is appropriate on one occasion within the first three months, at one year and annually thereafter for patients with moderate or severe residual mitral regurgitation. |
| **Change Rationale**<br>Frequency of surveillance echocardiography following transcatheter mitral valve repair was not addressed in the original guideline. These recommendations follow CMS guidelines. | | |

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## References


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4. Lipshultz SE, Adams MJ, Colan SD, et al. Long-term cardiovascular toxicity in children, adolescents, and young adults who receive cancer therapy: pathophysiology, course, monitoring, management, prevention, and research directions: a scientific statement from the American Heart Association. Circulation. 2013 Oct 22;128(17):1927-95.
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6. Scottish Intercollegiate Guidelines Network (SIGN). Long term follow up of survivors of childhood cancer. Edinburgh: SIGN; 2013. (SIGN publication no. 132). [March 2013]. Available from URL: http://www.sign.ac.uk
7. Spallarossa P, Maurea N, Cadeddu C, et al. A recommended practical approach to the management of anthracycline-based chemotherapy cardiotoxicity: an opinion paper of the working group on drug cardiotoxicity and cardioprotection, Italian Society of Cardiology. J Cardiovasc Med (Hagerstown). 2016 May;17 Suppl 1 Special issue on Cardiotoxicity from Antiblastic Drugs and Cardioprotection:e84-e92.
8. Virani SA, Dent S, Brezden-Masley C, et al. Canadian Cardiovascular Society Guidelines for Evaluation and Management of Cardiovascular Complications of Cancer Therapy. Can J Cardiol. 2016 Jul;32(7):831-41.

| **Ravulizumab-CWVZ (Ultomiris™) Vial** |
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| **Indication:** Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)<br><br>**Formulary Alternatives:** Pharmacy benefit: None; Medical benefit: Soliris® |
| • Commercial: Medical Benefit, Prior Authorization<br>• Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization<br><br>**Prior Authorization Criteria:**<br>For Paroxysmal Nocturnal Hemoglobinuria (PNH), all of the following must be met:<br>1. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using least two independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)<br>2. Documentation of severe disease as indicated by at least one of the following (a or b):<br>a. Documented history of thrombosis,<br>b. Documentation of at least 10% PNH type III red cells AND at least one of the following: i. Transfusion dependence (eg. hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL) ii. Disabling fatigue iii. End-organ complications iv. Frequent pain paroxysms (eg. dysphagia or abdominal pain) v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal<br>For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris ™): Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1) and severe disease (criteria 2). However, this can be based on patient's history prior to starting eculizumab.<br><br>Reauthorization for PNH: documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms |

| **Epoetin alfa-epbx (Retacrit®) Vial** |
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| **Indication:** |

- Treatment of anemia due to:
  - Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis
  - Zidovudine in patients with HIV-infection
  - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery

**Formulary Alternatives:** Epogen, Procrit

All Lines of Business:

- Pharmacy benefit: Specialty tier, Prior Authorization
- Medical Benefit: Prior Authorization

**Prior Authorization Criteria:**

1. All diagnoses with the exception of 2f, preoperative use in anemic patients scheduled for elective hip or knee surgery, must have **documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior** to initiation of therapy,

   **AND**

2. Must meet all of the listed criteria below for each specific diagnosis:
   a. **Treatment of Anemia in Chronic Renal Failure (CRF)**
      i. Aranesp®/Epogen®/Procrit® may be covered
   b. **Treatment of anemia secondary to myelosuppressive chemotherapy in cancer and related neoplastic conditions**
      i. There is at least two months of chemotherapy planned post-initiation
      ii. Chemotherapy is not curative in nature (e.g., treatment is for palliative correction of anemia)
      iii. May only be used up to 8 weeks following the final dose of myelosuppressive chemotherapy (subject to audit)
   c. **Treatment of Anemia in Myelodysplastic Syndrome (MDS)**
      i. Must have documented endogenous serum erythropoietin levels less than 500 mIU/ml
   d. **Anemia associated with zidovudine-treated HIV-infection patients:**
      i. Coverage is for epoetin only (Procrit®, Epogen®)

ii. Documented endogenous serum erythropoietin level is less than or equal to 500 mIU/ml

iii. Zidovudine dose is less than or equal to 4200mg/week

e. **Anemia associated with the treatment of specific chronic diseases with agents known to cause anemia (rheumatoid arthritis, regional enteritis (or Crohn's Disease), and ulcerative colitis):**

i. Coverage is for epoetin only (Procrit®, Epogen®)

ii. Treatment may not be continued beyond 8 weeks after therapy with agent known to cause anemia is complete

f. **Preoperative use in anemic patients scheduled for elective noncardiac and nonvascular surgery (e.g., hip/knee surgery)**

i. Coverage is for epoeitin only (Procrit®, Epogen®)

ii. All of the following must be met:

1. Member has preoperative anemia with pretreatment HGB between 10 and 13 g/dL
2. The surgery has a high-risk for perioperative blood loss (e.g., expected to lose more than 2 units of blood)
3. Patient is unwilling to donate autologous blood pre-operatively.

Covered range during treatment: HGB 10-12g/dL or HCT 30-36%. Dosing should be adjusted for patients to achieve and maintain target HGB not to exceed 12g/dL. HGB and HCT levels must be drawn and documented within 30 days of the requested date of service

**Pegfilgrastim-jmdb (Fulphila®) and Pegfilgrastim-cbqv (Udenyca®)**

**Indication:**

Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

**Formulary Alternatives:** pegfilgrastim (Neulasta®)

- All Lines of Business:
  - Pharmacy benefit: Specialty tier
  - Medical Benefit: Covered

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| **Filgrastim-aafi (Nivestym®) Syringe** |
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| **Indication:**<br>• To reduce the incidence of infection and/or neutropenia/neutropenia-related clinical sequelae in patients receiving myelosuppressive chemotherapy or with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia<br>• For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis |
| • All Lines of Business:<br>  ○ Pharmacy benefit: Specialty tier<br>  ○ Medical Benefit: Covered |

| **Larotrectinib Sulfate (Vitrakvi®) Capsule and Solution** |
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| **Indication:**<br>Treatment of adult and pediatric patients with solid tumors that:<br>• Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation<br>• Are metastatic or where surgical resection is likely to result in severe morbidity, and<br>• Have no satisfactory alternative treatments or that have progressed following treatment<br><br>**Formulary Alternatives:** Formulary options vary according to primary tissue type but no other drug is currently available that is for patients with solid tumors harboring NTRK fusion that is tissue agnostic |
| • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization<br>• Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization<br><br>**Prior Authorization Criteria:**<br>For initial authorization: 1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher 2. For Erleada®, high risk for progression as evidenced by documentation of Prostate Specific Antigen Doubling time of less than or equal to 10 months<br>**For reauthorization**: documentation of adequate response to the medication must be provided. |

| **Amifampridine Phosphate (Firdapse®) Tablet** |
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| **Indication:** Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults |

**Formulary Alternatives:** pyridostigmine, guanidine

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

**Prior Authorization Criteria for Commercial/Medicaid:**
All of the following must be met:
1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) with one of the following confirmatory tests:
    a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent in two (2) or more muscles compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise OR
    b. Positive anti-P/Q type voltage-gated calcium channel antibody test
2. Documentation that clinical symptoms of LEMS, including dyspnea or functionally significant muscle weakness, interfere with activities of daily living
3. Member has been evaluated for malignancy and treated for malignancy if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy.

Documented trial and failure of at least one month, intolerance, or contraindication to pyridostigmine

**Prior Authorization Criteria for Medicare Part D:**
All of the following must be met:
1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
2. Clinical symptoms of LEMS, including dyspnea or functionally significant muscle weakness interfere with daily activities.
3. Member has been evaluated for malignancy and treated for malignancy if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy.

Documented trial and failure of at least one month, intolerance, or contraindication to pyridostigmine

**Cenegermin-BKBJ (Oxervate®) Drops**

**Indication:** Treatment of neurotrophic keratitis

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

**Prior Authorization Criteria for Commercial/Medicaid:**
1. Patient has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in

the affected eye(s) with diagnosis supported by chart notes
2. Patient is refractory to at least two conventional treatments for neurotrophic keratitis (e.g. preservative-free artificial tears, topical antibiotic eye drops, therapeutic contact lenses, amniotic membrane transplant, tarsorrhaphy)
3. The request specifies the affected eye(s) intended for treatment

**Prior Authorization Criteria for Medicare Part D:**
Initial and reauthorization will be approved for 8 weeks
1. Patient has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in the affected eye(s) with diagnosis supported by chart notes
2. The request specifies the affected eye(s) intended for treatment

**Elapegademase-LVLR (Revcovi®) Vial**

**Indication:** Treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients

**Formulary Alternatives:** Adagen® (pegademase bovine)

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

**Prior Authorization Criteria for Commercial/Medicaid:**
1. Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following:
   a. Documentation of a mutation in the ADA gene by molecular genetic testing
   b. Deficient ADA catalytic activity (<1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); AND
2. A marked increase in the metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides (the sum of dAMP, dADP, and dATP) in erythrocytes; AND
3. Documentation showing that patient is not a candidate for or has failed a HSCT (hematopoietic stem cell transplantation); AND
4. Documentation that patient does not have severe thrombocytopenia (platelet count < 50 x $10^9$/L); AND
5. If patient is transitioning from Adaden® (pegademase bovine) to Revcovi®: Documentation of patient's current Adaden® (pegademase bovine) weekly dose in units/kilogram

Reauthorization criteria:
1. Documentation of plasma target trough ADA activity of at least 30 mmol/hr/L in the past two (2) months; AND

2. Documentation of a trough erythrocyte dAXP level maintained below 0.02 mmol/L in the past six (6) months; AND
3. Documentation of immune function improvement (e.g. decrease in number of infections)

**Prior Authorization Criteria for Medicare Part D:**
1. Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following:
   a. Documentation of a mutation in the *ADA* gene by molecular genetic testing
   b. Deficient ADA catalytic activity (less than 1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); AND
2. A marked increase in the metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides (the sum of dAMP, dADP, and dATP) in erythrocytes; AND
3. If patient is transitioning from Adaden® (pegademase bovine) to Revcovi®: Documentation of patient's current Adaden® (pegademase bovine) weekly dose in units/kilogram

Reauthorization criteria:
1. Documentation of plasma target trough ADA activity of at least 30 mmol/hr/L in the past two (2) months; AND
2. Documentation of a trough erythrocyte dAXP level maintained below 0.02 mmol/L in the past six (6) months; AND
3. Documentation of immune function improvement (e.g. decrease in number of infections)

**Emapalumab-LZSG (Gamifant®) Vial**

**Indication:** Treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy

**Formulary Alternatives:** dexamethasone, cyclosporine A, etoposide, anti-thymocyte globulin

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

**Prior Authorization Criteria:**
Initiation Criteria:
1. Diagnosis of primary HLH based on a molecular diagnosis OR family history consistent with primary HLH OR 5 out of the following 8 criteria fulfilled:
   a. Fever
   b. Splenomegaly
   c. Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100 x

$10^9$/L, neutrophils less than 1 x $10^9$/L
   d. Hypertriglyceridemia (fasting triglycerides greater than 3 mmol/L or equal or greater than 265 mg/dL) and/or hypofibrinogenemia (equal or less than 1.5 g/L)
   e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
   f. Low or absent NK-cell activity
   g. Ferritin equal or greater than 500 mcg/L
   h. Soluble CD 25 equal or greater than 2400 U/mL
2. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin) based on one of the following criteria:
   a. Having not responded or not achieved a satisfactory response
   b. Having not maintained a satisfactory response to conventional HLH therapy
   c. Intolerance to conventional HLH treatments
3. Patient is a candidate for stem cell transplant and emapalumab is being used as part of the induction or maintenance phase for stem cell transplant and will discontinued at the initiation of conditioning for stem cell transplant
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling
5. Documentation that patient currently has no active infection (e.g. mycobacteria and Histoplasma Capsulatum)

Reauthorization Criteria:
1. Patient continues to be a candidate for stem cell transplant
2. Documentation of disease improvement such as:
   - Complete response defined as normalization of all HLH abnormalities (i.e. no fever, no splenomegaly, neutrophils > 1x$10^9$/L, platelets > 100x$10^9$/L, ferritin <2,000 µg/L, fibrinogen >1.50g/L, D-dimer < 500 µg/L, normal CNS symptoms, no worsening of sCD25 > 2-fold baseline)
   - Partial response was defined as normalization of ≥3 HLH abnormalities
   - HLH improvement was defined as ≥3 HLH abnormalities improved by at least 50% from baseline
3. Documentation that patient is being monitored for serious infections (such as tuberculosis, adenovirus, EBV, and CMV)

Documentation that dose does not exceed max FDA approved dosing of 10 mg/kg per dose for two doses per week

**Omadacycline Tosylate (Nuzyra®) Tablet**

**Indication:**

Adult patients with:
Community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae*

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| Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp*. (includes *S. anginosus, S. intermedius*, and *S. constellatus*), *Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae*<br><br>**Formulary Alternatives:** linezolid, doxycycline, vancomycin, TMP/SMX, moxifloxacin |
| • Commercial: Non-Formulary<br>• Medicaid: Non-Formulary<br>• Medicare Part D: Non-Formulary |

| **Revefenacin (Yupelri®) Vial-Neb** |
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| **Indication:** Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)<br><br>**Formulary Alternatives:** Spiriva® Handihaler® (tiotropium), Spiriva® Respimat (tiotropium), Incruse® Ellipta (umeclidinium), Ipratropium 0.2 mg/mL solution |
| • Commercial: Non-Formulary, Quantity Limit (3 ml per day)<br>• Medicaid: Non-Formulary, Quantity Limit (3 ml per day)<br>• Medicare Part D: Non-Formulary |

| **Rifamycin Sodium (Aemcolo®) Tablet DR** |
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| **Indication:** Travelers' diarrhea caused by noninvasive strains of Escherichia coli in adults. Limitations: not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of Escherichia coli<br><br>**Formulary Alternatives:** xifaxan, ciprofloxacin, azithromycin, levofloxacin |
| • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (12 tablets per 28 days)<br>• Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization, Quantity Limit (12 tablets per 28 days<br><br>**Prior Authorization Criteria:**<br>Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. Rifamycin is not covered if documentation shows diarrhea that is complicated by fever or blood in stool. |

PROVIDENCE Health Plan

**New Strengths and Formulations:** See Other Formulary Changes

**New Indications:**

| **Atezolizumab (Tecentriq®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br><br>Non-Small Cell Lung Cancer (NSCLC)<br>• In combination with bevacizumab, paclitaxel, and carboplatin, for the first line treatment, of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.<br>• For the treatment of patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted |

| **Palonosetron** |
|---|
| **Expanded FDA-approved or New Indication:**<br>PALONOSETRON EXPANDED PATIENT POPULATION UPDATE:<br>• Prevention of nausea and vomiting associated with cancer chemotherapy in patients ages 1 month of age to less than 17 years. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |

| **Tenofovir disoproxil fumarate (Viread®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>VIREAD EXPANDED PATIENT POPULATION UPDATE:<br>• Chronic hepatitis B in adults and pediatric patients 2 years and older weighing at least 10 kg. |

PROVIDENCE Health Plan

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

| **Romiplostim (Nplate®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>NPLATE EXPANDED PATIENT POPULATION UPDATE:<br>• 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. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |

| **Pembrolizumabab (Keytruda®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>• For the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma<br>[1]This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted. |

| **Tacrolimus (Envarus® XR)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>• Prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |

| **Olaparib (Lynparza®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>• Ovarian cancer |

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|---|
| ○ for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer for therapy based on an FDA-approved companion diagnostic for Lynparza. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted. |

| **Dasatinib (Sprycel®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>• Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted. |

| **Reslizumab (Cinqair®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>• U.S. prescribing information allows for infusion of Cinqair IV in the home healthcare setting, by a healthcare provider who is prepared to manage the signs and symptoms of anaphylaxis. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |

| **Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Adacel®)** |
|---|
| **Expanded FDA-approved or New Indication:**<br>• A second dose of Adacel may be administered 8 years or more after the first dose of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap). |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |

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| **Cabozantinib (Cabometyx®)** |
| **Expanded FDA-approved or New Indication:**<br>Patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted. |

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|---|
| **Influenza vaccine 0.5 mL (Fluzone Quadrivalent®)** |
| **Expanded FDA-approved or New Indication:**<br>Approved for use in patients 6 months of age and older |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |
| **Ospemifene (Osphena®)** |
| **Expanded FDA-approved or New Indication:**<br>• Treatment of moderate to severe vaginal dryness, a symptom of vulva and vaginal atrophy, due to menopause. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |
| **Voriconazole (Vfend®)** |
| **Expanded FDA-approved or New Indication:**<br>• Pediatric patients 2 years of age and older for the indications stated above. |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |
| **Epinephrine (Adrenalin®)** |
| **Expanded FDA-approved or New Indication:**<br>• To increase mean arterial blood pressure in adult patients with hypotension associated with septic shock |
| **Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. |
| **Pemetrexed (Alimta®)** |
| **Expanded FDA-approved or New Indication:**<br>• In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations. |

- As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
- As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy.
- Initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

**Decision:** Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

## Drug Safety Monitoring:

**Update On Expanded Angiotensin Receptor Blocker Recall**

**ISSUE:** Irbesartan, valsartan, and losartan are used to treat high blood pressure and heart failure. Not all products containing irbesartan, valsartan, and losartan are being recalled. This update will clarify which irbesartan, valsartan, and losartan-containing products are being recalled.

The recalled products contain an impurity, N-nitrosodimethylamine (NDMA), in the API manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China. The presence of the potentially cancer-causing NDMA was unexpected, and the agency believes the NDMA is related to changes in the way the active substance was manufactured.

**RECOMMENDATION:**

**Health professionals should:**

- FDA has determined the recalled irbesartan, valsartan, and losartan products pose an unnecessary risk to patients. Therefore, FDA recommends patients use irbesartan, valsartan, and losartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition.
- If you have medication samples from these companies, quarantine the products and do not provide them to patients.

**Patients should:**

- Compare the information on your prescription bottle with the information in this list (company, National Drug Code, lot number) to determine if your current medicine has been recalled.
- Continue taking your current medicine until your health care provider or pharmacist gives you a replacement or a different treatment option.

**DECISION:** Letters were sent to all commercial, Medicaid, and Medicare members who filled a prescription within the last 12-months for a recalled losartan-containing product. In addition, providers were also notified if they had prescribed a irbesartan-containing product that was on the recalled product list. For the expanded recall of valsartan-containing products and the one lot recall of losartan-hydrochlorothiazide product, the updated list of recalled valsartan-containing products, the updated list of non-recalled valsartan-containing products, and information on the expanded recall of losartan and losartan-hydrochlorothiazide tablets were communicated via Providence Medical Group Clinical Pharmacy Alerts and health plan announcements.
**FDA updated list of valsartan products under recall:** https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf

**FDA updated list of vasartan prodcuts not under recall:**
https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615704.pdf

**FDA updated list of irbesartan products under recall:**
https://www.fda.gov/downloads/Drugs/DrugSafety/UCM624627.pdf

**Modifications To The Approved Clozapine Risk Evaluation And Mitigation Strategy (REMS)**

**Effective February 28, 2019,** the Clozapine REMS Program has new requirements for all clozapine prescribers and pharmacies that dispense clozapine.

***Highlights of the modified Clozapine REMS Program requirements are as follows:***

**Outpatient clozapine prescribers:**

- Prescribers must certify in the Clozapine REMS program.
- Ensure that all patients receiving clozapine are enrolled in Clozapine REMS prior to clozapine being dispensed. If patients are not enrolled in the Clozapine REMS program, clozapine will not be dispensed.
- Obtain and submit an ANC in accordance with clozapine prescribing guidelines; a current ANC must be documented in the REMS Program database prior to clozapine dispensing. If a current ANC is not on file, clozapine will not be dispensed.
- If the last ANC indicates moderate or severe neutropenia, clozapine will not be dispensed unless the prescriber documents that benefits outweigh the risks of neutropenia.

**Inpatient clozapine prescribers:**

- Inpatient clozapine prescribers are not required to be certified if prescribing clozapine to patients already enrolled in the Clozapine REMS program.
- If clozapine is started on the inpatient unit, providers must enroll patients in Clozapine REMS Program prior the patient receiving their first dose of clozapine.

**Pharmacies that dispense clozapine:**

- Pharmacies must be certified in the Clozapine REMS Program prior to dispensing clozapine.

- Outpatient pharmacies must obtain a “Pre-Dispense Authorization” (PDA) prior to dispensing clozapine. Outpatient pharmacies will not receive a PDA if an ANC is not on file, or if a patient has an ANC that indicates moderate or severe neutropenia without a prescriber treatment rationale on file.
- Inpatient pharmacies are required to complete an “Eligibility Check” prior to dispensing clozapine. If the patient is not enrolled in the Clozapine REMS Program, a PDA will not be issued and the Eligibility Check will be unsuccessful.
- Pharmacies will no longer be able to enroll patients in the Clozapine REMS Program. Patients must be enrolled by prescribers or the prescriber designee.
- Pharmacies are encouraged to submit ANCs to the Clozapine REMS program when a pharmacist is aware of a more current ANC.

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

## Other Formulary Changes:

| Drug/Policy Name | Recommendation |
|---|---|
| **Loteprednol etabonate (Inveltys®) Drops Susp** | New strength.<br>• Commercial: Add to Formulary, Non-Preferred Brand<br>• Medicare Part D: Add to Formulary, Non-Preferred Drug<br>Effective 3/1/2019 |
| **Gardasil Vaccine** | Remove Quantity Limit from Medicare Part D. |
| **Alprazolam Tablet** | • Medicare Part D: Add to Formulary, Non-Preferred Drug<br>Effective 5/1/2019 |
| **Generic testosterone 1% gel** | Add to formulary<br>• Commercial: Formulary, Non preferred Generic<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Non-preferred Drug |
| **Imiglucerase (Cerezyme®) Vial / Enzyme Replacement Therapy Policy** | Add Prior Authorization:<br>• Commercial/Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Formulary, Specialty<br>• Medicare Part B: Medical Benefit, Prior Authorization<br>Effective 7/1/2019 |
| **Taliglucerase alfa (Elelyso®) Vial / Enzyme Replacement Therapy Policy** | Add Prior Authorization:<br>• Commercial/Medicaid: Medical Benefit, Prior Authorization |

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|---|---|
| | • Medicare Part D: Formulary, Specialty<br>• Medicare Part B: Medical Benefit, Prior Authorization<br>Effective 7/1/2019 |
| **Velaglucerase Alfa (Vpriv®) Vial / Enzyme Replacement Therapy Policy** | Add Prior Authorization:<br>• Commercial/Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization |
| **Eliglustat tartrate (Cerdelga®) Capsule** | Add Prior Authorization to Commercial and Medicaid<br>• Added to Medications for Rare Indications (Orphan Drugs) policy |
| **Guanfacine HCL ER Tab ER 24H** | Remove Quantity Limit from Commercial and Medicaid |
| **Hydroxyzine HCL Tablet** | • Medicare Part D: Add to Formulary, Non-Preferred Drug<br>Effective 5/1/2019 |
| **Hydroxyzine pamoate Capsule** | • Medicare Part D: Add to Formulary, Non-Preferred Drug<br>Effective 5/1/2019 |
| **Sodium chloride for inhalation (Hyper-Sal®) 3.5% Vial-Neb** | Change formulary status as follows:<br>• Commercial: Formulary, change from Non-Preferred Brand to Non-Preferred Generic<br>• Medicare Part B: Medical Benefit |
| **Sodium chloride for inhalation 10% Vial-Neb** | Change formulary status as follows:<br>• Commercial: Formulary, Non-Preferred Generic<br>• Medicaid: Formulary<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit |
| **Midazolam hcl Vial** | Change formulary status as follows:<br>• Commercial: Change from Medical Benefit to Formulary, Non-Preferred Generic<br>• Medicaid: Add to Formulary<br>• Medicare Part D: Add to Formulary, Non-Preferred Drug |
| **Tacrolimus (Protopic®) Oint** | Change formulary status as follows:<br>• Commercial: Remain on Formulary, change from Non-Preferred Brand to Non-Preferred Generic |

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| **Cyclosporine 0.09% (Cequa®) droperette** | New formulation. Non-formulary for all lines of business |
| **Medroxyprogesterone 150 mg/mL syringe/vial** | Medicaid: Add to formulary |
| **Itraconazole (Tolsura®) 65 mg capsule** | New to market brand. New strength, new dosage form<br>• Commercial/Medicaid: Non-formulary, Prior Authorization<br>  ○ Add to New Medications and Formulations without established benefit policy<br>• Medicare Part D: Non-formulary |
| **Simeprevir (Olysio®) capsule** | Commercial/Medicaid: Remove from formulary (obsolete product) |

**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 | |
|---|---|
| **Galcanezumab-GNLM (Emgality®) Syringe** | New dosage form (syringe). Line extend with Emgality pen.<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>  ○ Added to Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists policy<br>• Medicare Part D: Non-Formulary |
| **Penicillamine (D-Penamine®) Tablet** | New strength. Line extend with Depen during shortage.<br>• Commercial: Formulary, Preferred Specialty<br>• Medicaid: Non-Formulary<br>• Medicare Part D: Formulary, Specialty |
| **Coagulation Factor XA, inactivated-ZHZO (Andexxa®) Vial** | New strength. Line extend with Andexxa 100mg vial.<br>• Commercial/Medicaid: Medical Benefit<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit |
| **Estradiol (Divigel®) Gel Packet** | New strength. Line extend with Divigel.<br>• Non-Formulary for all lines of business |
| **Tafenopuine succinate (Krintafel®) Tablets** | New strength. Line extend with Arakoda.<br>• Non-Formulary for all lines of business<br>Effective 04/01/2019 |
| **Sufentanil citrate (Dsuvia®) Tab in app** | New dosage form (sublingual tablet). Line extend with sufentanil |

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| | products.<br>• Commercial/Medicaid: Medical Benefit<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit |
| **Tocilizumab (Actemra® actpen) Pen Injuctr** | New dosage form (autoinjector). Line extend with Actemra.<br>• Commercial: Non-Formulary, Prior Authorization, Quantity Limit (3.6ml per 28 days)<br>  ○ Added to Therapeutic Immunomodulators (TIMs) policy – Commercial<br>• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (3.6ml per 28 days)<br>  ○ Therapeutic Immunomodulators (TIMs) policy – Medicaid<br>• Medicare Part D: Non-Formulary<br>Effective: 4/1/2019 |
| **Levothyroxine sodium (Tirosint®) Capsule** | New Strengths 175 mcg & 200 mcg. Line extend to existing Tirosint. Non-formulary for all lines of business.<br>Effective: 4/1/2019 |
| **Insulin Degludec (Tresiba®) Vial** | New Dosage Form (vial). Line extend with Tresiba pen.<br>• Commercial/Medicare Part D: Formulary, Preferred Brand<br>• Medicaid: Non-Formulary<br>Effective: 4/1/2019 |
| **Rivaroxaban (Xarelto®) Tablet** | New Strength. Line extend with Xarelto.<br>• Commercial/Medicare Part D: Formulary Preferred Brand<br>• Medicaid: Formulary<br>Effective 4/1/2019 |
| **Fluocinolone acetonide (Yutiq®) Implant** | New Strength. Line extend with Iluvien.<br>• Commercial/Medicaid: Medical Benefit<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit |
| **Eltrombopag Olamine (Promacta®) Powd Pack** | New dosage form (packet). Line extend with Promacta.<br>• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization<br>• Medicaid: Formulary, Prior Authorization<br>• Medicare Part D: Formulary, Specialty, Prior Authorization<br>Added to Promacta policy |
| **Guselkumab (Tremfya®) Auto Injct** | New Dosage Form (injector). Line extend with Tremfya syringe. |

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| | • Commercial: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1 dose every 56 days)<br>  ○ Added to Therapeutic Immunomodulators (TIMs) policy – Commercial<br>• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 dose every 56 days)<br>  ○ Added to Therapeutic Immunomodulators (TIMs) policy – Medicaid<br>• Medicare Part D: Non-Formulary |
| **Levothyroxine Sodium (Tirosint-Sol®) Solution** | New dosage form (solution). Line extend with Tirosint capsule. Non-Formulary for all lines of business |
| **Sodium Polystyrene Sulfonate Susp** | Add to Medicaid Formulary |
| **Insulin Regular, Human (Afrezza) Cart Inhal** | New combination package. Line extend with Afrezza.<br>• Non-formulary for all lines of business |

## Health Plan Clinical Policy Changes:

| Policy Name | Change Summary |
|---|---|
| **Aczone** | The policy will be changed to a step therapy policy, requiring trial or contraindication to a topical antibiotic. |
| **Adult Long-Acting Stimulant Medications - Medicaid** | Updated the quantity limit section to include the following exceptions: Adderall XR® (dextroamphetamine-amphetamine ER) 20mg capsules and Concerta® 36mg (methylphenidate ER) are covered at 2 tablets/capsules per day. Table 1 in the policy was also updated to reflect these changes. The coverage duration section was changed to "authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication." |
| **CAR-T** | Criteria was added to ensure the patient was stable enough to tolerate therapy. |
| **Compounded Drugs** | Removed criteria that referenced Medicare Part D as policy does not apply to Medicare Part D. |
| **Corlanor** | Added inappropriate sinus tachycardia as a covered indication and created criteria for approval. While drug is not FDA approved for inappropriate sinus tachycardia it is the only treatment recommended in the 2015 Heart Rhythm Society consensus statement. Updated |

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| | positions statement with information about inappropriate sinus tachycardia. |
| **Diabetic Durable Medical Equipment (DME)** | Due to recent recommendations regarding self-monitoring of blood glucose in the American Diabetes Association (ADA) 2019 Standards of Care, this policy has been updated to allow coverage up to 10 test strips per day for those patients with clinical need (e.g., type 1 diabetes, intensive insulin regimens). Use of more than 10 test strips per day is considered not medically necessary and will not be covered. |
| **DPP4 Inhibitors** | Increased initial authorization length from 6 months to 1 year. Updated position statement to reflect ADA 2019 Standards of Care update. |
| **Dupixent** | Updated FDA indication and age restriction for atopic dermatitis as now FDA approved for patients 12 and older. Removed trial of phototherapy for all lines of business. Removed trial of systemic immunomodulatory agents for non-Medicaid lines of business. |
| **Elidel, Protopic – Medicaid** | Criteria has been updated to require trial and failure of TWO topical steroids unless not indicated. Current criteria requires trial and failure of topical steroids but does not quantify how many. Trial and failure of TWO has been selected to align with Oregon Health Authority criteria. |
| **Enzyme Replacement Therapy** | Added Imiglucerase (Cerezyme®), Taliglucerase alfa (Elelyso™) and Velaglucerase Alfa (VPRIV®) to the policy. |
| **Epinephrine auto-injector QL** | Versions of epinephrine injectors were added to this policy and criteria was reworded to improve clarity. |
| **Forteo** | Breaking out the "Osteoanabolic Medications: Forteo® & Tymlos®" clinical policies into two separate polices for each individual medication for commercial and Medicaid lines of business. Updated the coverage duration to: "May be approved for up to 2 years, ensuring the total duration of Forteo® and Tymlos® does not exceed 2 years of total therapy duration for any combination of osteoanabolic therapies." Updated Forteo® clinical policy to include a for female patients only section for trial/failure of Tymlos® since Tymlos® is not FDA approved for males. |
| **GnRH Agonists** | Added statement around use in in vitro fertilization (IVF) for members with IVF benefits. Re-worded criteria for central precocious puberty to clarify that age cut off is for diagnosis and not patient's current |

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| | age. |
| **GnRH Antagonists** | Updated how the exclusion criteria was written as it stated "subject to criteria below" but in the policy the criteria is above so it was confusing to the clinical reviewers. |
| **Hepatitis C Direct Acting Antivirals** | Olysio® has been removed from commercial and Medicaid formularies as well as this policy since it is an obsolete drug. |
| **Hepatitis C Direct Acting Antivirals – Medicaid** | Olysio® has been removed from commercial and Medicaid formularies as well as this policy since it is an obsolete drug. |
| **Human Growth Hormones for Adults** | Added treatment of isolated growth hormone deficiency as an exclusion. Added new criteria for patients with a diagnosis of multiple (≥ 3) pituitary hormone deficiencies |
| **Human Growth Hormones for Pediatrics** | Removal of criteria that "other causes of growth failure have been ruled out (hypothyroidism, chronic systemic disease, skeletal disorders, and psychosocial deprivation), “as these request are coming from specialist that should be doing this as part of a normal evaluation for Growth Hormone Deficiency. |
| **Infertility Medications** | Updated infertility definition to include both sexual intercourse and intrauterine insemination (IUI). |
| **Kuvan** | Initial criteria has been modified to include pre-treatment phenylalanine levels to be >360 micromol/L for under 12 years of age and >900 micromol/L for 12 years and older to qualify for therapy. Criteria requiring documentation that the provider will monitor phenylalanine levels has been removed for initial and reauthorization since a documentation of at least a 30% reduction in levels and maintenance of at least 30% reduction is already required. |
| **Lamotrigine ER** | Medicaid was removed from this policy, as this medication is covered under DMAP and not through Providence Health Assurance. |
| **Long-acting Stimulants** | Table 1 in this policy was updated to reflect the increased quantity limit of 2 tablets/capsules per day for Adderall XR® (dextroamphetamine-amphetamine ER) 20mg and Concerta® 36mg. The coverage duration was also changed to "authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication." |
| **Medications for Rare Indications - Orphan Drugs** | Added Cerdelga® to this policy |
| **Otezla** | Removed age restriction and updated coverage duration section |
| **Palynziq** | Updated criteria to require trial and failure of both Kuvan® and diet. |

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| | Previous criteria was Kuvan® or diet. Kuvan® must be given with diet restrictions to be most effective. |
| **Rituxan** | The policy criteria for vasculitis was updated to allow rituximab as first-line for patients with severe disease (e.g., critical organ system involvement) instead of requiring cyclophosphamide or methotrexate first. |
| **SGLT-2 Inhibitors/SGLT-2 Inhibitors – Medicaid** | Increased initial authorization length from 6 months to 1 year. Updated position statement to reflect 2019 ADA update. |
| **Testosterone Replacement Therapy** | Testosterone level requirements have been updated with 2018 guidelines as well as input from expert opinion. Guidelines recommend using the local laboratory's lower limit of normal if available due to variability and lack of standardization. Numerical values for free testosterone levels have been updated to reflect Providence local levels for ease of administration when local laboratory limits are not available. |
| **Therapeutic Immunomodulators Medicaid** | The requirement for conventional therapy prior to biologic therapy was removed for the indication of ankylosing spondylitis. |
| **Tolvaptan** | Added criteria that patient must have rapidly progressing autosomal dominant polycystic kidney disease. Updated the criteria to exclude patients with an eGFR of less than 25 mL/min as the safety and efficacy in this patient population has not been established. |
| **The following policies were retired effective 6/1/2019.**<br>• Natroba<br>• Stimulants – Medicare Part D<br>• Butalbital – Medicare Part D<br>• Musculoskeletal – Medicare Part D | |

## New Generic Medications:

| **First time generics to market** | |
|---|---|
| **Cinacalcet HCLTablet** | First generic (Sensipar). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Specialty, Quantity Limit (30 mg and 60 mg tablets: 2 tablets per day. 90 mg tablets: 4 tablets per day)<br>• Medicaid: Formulary, Quantity Limit (30 mg and 60 mg tablets: 2 |

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| | tablets per day. 90 mg tablets: 4 tablets per day)<br>• Medicare Part D: Formulary, Specialty, Prior Authorization (Part B vs Part D),<br>Quantity Limit (30 mg and 60 mg tablets: 2 tablets per day. 90 mg tablets: 4 tablets per day) |
| **Norgestimate-Ethinyl Estradiol (Tri-Vylibra Lo) Tablet** | New MedID. Line extend with existing Ortho Tri-Cyclen Lo generics.<br>• Commercial: Formulary<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Non-Preferred Generic |
| **Albuterol Sulfate HFA** | First generic (Ventolin & Proair). Line extend as Non-Formulary for all lines of business |
| **Halobetasol Propionate Foam** | New MedID. Line extend with Lexette.<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>○ Added to New Medications and Formulations without Established Benefit policy<br>• Medicare Part D: Non-Formulary<br>Effective 04/01/2019 |
| **Vigabatrin Tablet** | First generic (Sabril). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization<br>• Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization<br>Added to Sabril Policy. |
| **Sirolimus Solution** | First generic (Rapamune). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Generic<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization (Part B vs Part D) |
| **Toremifene citrate Tablet** | First generic (Fareston). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Specialty<br>• Medicaid: Formulary, Specialty<br>• Medicare Part D: Formulary, Specialty |
| **Minocycline HCL ER (Minocycline HCL) Tab ER 24h** | First generic (Solodyn). Line extend as generic.<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>○ Added to New Medications and Formulations without Established Benefit policy |

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| | • Medicare Part D: Non-Formulary |
| **Buprenorphine-Naloxone (Buprenorphine hcl/Naloxone hcl) Film** | First generic (Suboxone film). Line extend as generic.<br>• Commercial/Medicare Part D: Formulary, Non-Preferred Generic, Quantity Limit (3 films per day)<br>• Medicaid: Formulary, Quantity Limit (3 films per day) |
| **Naproxen (Ec-Naproxen) Tablet DR** | Line extend with naproxen DR.<br>• Commercial: Formulary<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Non-Preferred Generic |
| **Mesalamine Supp. Rect** | First generic (Canasa). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Generic<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Non-Preferred Drug<br>Effective: 04/01/19 |
| **Pimecrolimus 1% Cream** | First generic (Elidel). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Generic, Step Therapy<br>• Medicaid: Non-Formulary, Prior Authorization<br>• Medicare Part D: Formulary, Non-Preferred Drug, Step Therapy<br>Effective: 04/01/19 |
| **Sevelamer HCL Tablet** | First generic (Renagel). Line extend as generic.<br>• Commercial: Formulary, Non-Preferred Generic, Step Therapy<br>• Medicaid: Formulary<br>• Medicare Part D: Non-Formulary |
| **Acyclovir (Zovirax®) Cream** | First generic (Zovirax cream). Line extend as generic.<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>  ○ Added to Denavir, Sitavig, Xerese, Zovirax policy<br>• Medicare Part D: Non-Formulary |
| **Ganirelix acetate Syringe** | First generic (Ganirelix). Line extend as generic.<br>• Commercial: Non-Formulary, Prior Authorization<br>  ○ Added to Infertility Medications policy<br>• Medicaid: Non-Formulary<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization |
| **Ethinyl Estradiol/Drospirenon (Jasmeil®) Tablet** | New MedID. Line extend to other MedIDs in GCN.<br>• Commercial: Formulary |

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| | • Medicaid: Formulary<br>• Medicare Part D: Formulary, Non-Preferred Generic |
| **Amphetamine Sulfate Tablet** | First generic. Line extend to Evekeo.<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>  ○ Added to New Medications and Formulations Without Established Benefit policy<br>Effective 4/1/2019<br>• Medicare Part D: Non-Formulary |
| **Tadalafil (Alyq®) Tablet** | New MedID. Line extend with tadalafil (Adcirca) generics.<br>• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (2 tablets per day)<br>• Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day)<br>  ○ Added to Pulmonary Arterial Hypertension policy-Commercial/Medicaid<br>• Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day)<br>  ○ Added to Adcirca/Revatio policy |