PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 231

January 1, 2019

This is the January 1, 2019 issue of the Providence Health Plans 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. Providence Health Plans has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink based on the Effective date noted below.

This Policy Alert, Prior Authorization Requirements, and Medical/Pharmacy policies are available through PHP ProvLink.

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

New Policies or Major Changes

Effective January 1, 2019

Dental Anesthesia Services **MED203** *Previously titled:* Dental Anesthesia for Children and Adults with Complicated Medical Conditions	**Annual Update** The policy has been clarified to indicate the following: • This policy does not address dental anesthesia performed in a dental office, which should be reviewed under the member's dental benefit. • This policy is intended to address the rare circumstances for which dental anesthesia may be covered as a medical benefit for select conditions or circumstances. • Dental anesthesia performed in a dental office for dental services is not covered for Medicare members. In addition, the coverage criteria were clarified to indicate that the policy only addresses dental anesthesia services at an ACS or hospital facility. Criterion II which indicated dental anesthesia was not covered in a dental office was removed from the policy.

No Major Changes

Effective January 1, 2019

Back: Epidural Steroid Injections (Medicare Only) **MED391**	**Annual Update** No change to criteria. This policy is based on the centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457) and Local Coverage Determination (LCD): Lumbar Epidural Injections (L34980).
Back: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (Medicare Only)	**Annual Update** Per the updated Medicare LCD, the following was added to the criteria: "It is inappropriate to bill for fluoroscopy (CPT® codes 77002 or 77003) with a 59 modifier when the procedure(s) billed on that date of service for the same patient by the same provider are included in the CPT® description of the procedure(s) performed." No other change to criteria.

SUR125	
Definition: Mobility Assistive Equipment **DME200**	**Annual Update** No change to criteria. This policy is based on the Centers for Medicare &Medicaid Services National Coverage Determination (NCD) 280.3: Mobility Assistive Equipment (MAE).
Definition: Urgent Care (Out of Area) **DME201**	**Annual Update** No change to criteria. This policy is based on clinical input.
Diabetes: Blood Glucose Monitors and Supplies **DME206**	**Annual Update** No change to criteria. This policy is based on Centers for Medicare and Medicaid Services Local Coverage Determination (LCD) L33822: Glucose Monitors.
General Prior-authorization Requirements Pages	**Annual Update** No change to prior-authorization requirements. Covenant Health was added to the Standard PA page.
Genetic Testing: Breast Cancer Prognostic Assays **(All Lines of Business Except Medicare)** **GT157** **And** **Genetic Testing: Breast Cancer Prognostic Assays** **(Medicare Only)** **GT158**	**Interim Update** Policies primarily updated to add new CPT codes effective 1/1/2019. All Lines of Business A diagram has been added to the Policy Guidelines section, which depicts the principles of HER2 testing and how to interpret HER2 testing scores. Medicare Only: • Links to all superseded LCDs and LCAs were updated. • Oncotype DX® Breast Cancer assay criteria: Per updated LCAs, policy criteria was added to indicate that patients with a diagnosis of breast carcinoma in situ are not to undergo this particular test (the is what the Oncotype DX® Breast Cancer for DCIS test is designed for). • Oncotype DX® Breast Cancer for DCIS test is now to be billed with specific code 0045U (as of 7/1/2018). • CMS database was searched in an attempt to identify new guidance on tests addressed in the policy. None were identified.
Genetic Testing: Non-Covered Genetic Panel Tests	**Interim Update** The following changes were made for this interim update: • Added new CPT codes effective 1/1/2019.

(Medicare Only) GT420	• Links to all superseded LCDs and LCAs were updated. • Removed CDH1 and PIK3CA genes from the list of genes statutorily excluded when ordered in a panel, based on updates to LCDs and LCAs. **PA / Codes:** Added:. • 44 CPT codes to be PAed for all lines of business • 2 CPT codes to be denied as investigational for all lines of business • 1 CPT (81443) code to be deny as not medically necessary for Medicare and PAed for all other lines of business. Removed: 3 CPT codes that termed 12/31/2016
Genetic Testing: Pharmacogenetic Testing (Medicare Only) GT423	**Interim Update** The following changes were made for this interim update: • Added new CPT codes effective 1/1/2019 • Links to all superseded LCDs and LCAs were updated. • Removed all criteria, billing guidelines and references to the "Approved Gene Testing" LCA. This LCA has been retired. **PA / Codes:** Added • 11 CPT codes to be PAed for all lines of business • 1 CPT code to be denied as investigational for all lines of business
Genetic Testing: Reproductive Planning and Prenatal Testing (All Lines of Business Except Medicare) GT236 **AND** **Genetic Testing: Reproductive Planning and Prenatal Testing (Medicare Only) GT384**	**Interim Update** Policies primarily updated to add new CPT codes effective 1/1/2019. All Lines of Business PAs have been removed from three amniocentesis codes on the current policy. All Lines of Business Except Medicare Based on clinical input, a note has been added to the top of the criteria which states: "The tests addressed in this policy only apply to biological parents." Medicare Only: • Links to all superseded LCDs and LCAs were updated. • Removed all criteria, billing guidelines and references to the "Approved Gene Testing" LCA. This LCA has been retired. • Removed one general LCD that was retired. • Added 4 gene-specific LCAs (testing already addressed in the policy). No criteria changes required as a result of new LCAs. **PA / Codes:** Added • 38 CPT codes to be PAed for all lines of business • 1 CPT code to be denied as investigational for all lines of business

	• 1 CPT code to be deny as not medically necessary for Medicare and PAed for all other lines of business Removed PAs from: 3 CPT codes specific to amniocentesis (88235, 88267 and 88269)

Archived Policies

Effective January 1, 2019

Hernia Repair: Human Acellular Dermal Matrix **SUR244**	**Archive Policy** This policy will be archived as the use of skin substitutes for hernia repair, as well as the skin substitute product and HCPCS code, is already addressed in our skin substitutes policy.

Coding Updates Only

Effective January 1, 2019

The following are interim coding updates only. No other changes were made to the policies listed below. All of these policies will be brought back to the Medical Policy Committee (MPC) for full annual review over the coming months:

- Hearing Aids (All Lines of Business Except Medicare)
- Orthotic Foot Devices and Therapeutic Shoes
- Oxygen Therapy and Home Equipment
- Cardiac: Implantable Loop Recorder
- Cardiac: Disease Risk Screening (All Lines of Business Except Medicare)
- Cardiac: Disease Risk Screening (Medicare Only)
- Varicose Veins (All Lines of Business Except Medicare)
- Varicose Veins (Medicare Only)
- Chelation Therapy for Non-Overload Conditions
- Cardiac: Ventricular Assist and Artificial Heart Devices
- Skin Substitutes
- Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare)
- Investigational and Non-Covered Medical Technologies (Medicare Only)
- Deep Brain Stimulation (All Lines of Business Except Medicare)
- Depp Brain Stimulation (Medicare Only)
- Occipital Nerve Stimulation
- Vagus Nerve Stimulation
- Gastric Electrical Stimulation
- Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulator (All Lines of Business Except Medicare)
- Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulator (Medicare Only)

- Fecal Incontinence Treatments
- Urine Drug Testing for Therapeutic or Substance Abuse Monitoring (All Lines of Business Except Medicare)
- Urine Drug Testing for Therapeutic or Substance Abuse Monitoring (Medicare Only)
- Neuropsychological Testing (All Lines of Business Except Medicare)
- Neuropsychological Testing (Medicare Only)
- Genetic Studies and Counseling
- Genetic Testing: Hereditary Breast and Ovarian Cancer (All Lines of Business Except Medicare)
- Genetic Testing: Hereditary Breast and Ovarian Cancer (Medicare Only)
- Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business Except Medicare)
- Genetic Testing: Pharmacogenetic Testing (All Lines of Business Except Medicare)
- Eye: Corneal Collagen Cross Linking (All Lines of Business Except Medicare
- Eye: Corneal Collage Cross Linking (Medicare Only)

New Format Updates Only

Effective January 1, 2019

The following are interim updates only to place these policies in the new Medical Policy format. No other changes were made to the policies listed below. All of these policies will be brought back to the Medical Policy Committee (MPC) for full annual review over the coming months:

- Anesthesia Care with Diagnostic Endoscopy
- Back: Lysis of Epidural Adhesions
- Clinical Trials and Devices (All Lines of Business Except Medicare)
- Clinical Trials and Devices (Medicare Only)
- Chiropractic Care
- Defibrillators: Automatic External (AED)
- Salivary Hormone Testing (All Lines of Business Except Medicare)
- Salivary Hormone Testing (Medicare Only)
- Eye: Diabetic Retinopathy Telescreening
- Vestibular Autorotation Test
- Electrothermal Capsular Shrinkage
- Back: Intradiscal Injections
- Wounds: Non-Contact Ultrasound Treatment
- Hearing: Cochlear Implants and Auditory Brainstem Implants (All Lines of Business Except Medicare)
- Hearing: Cochlear Implants and Auditory Brainstem Implants (Medicare Only)
- Sensory Integration Therapy
- Hip: Total Joint Arthroplasty (All Lines of Business Except Medicare)
- Hip: Total Joint Arthroplasty (Medicare Only)
- Knee: Total Joint Arthroplasty (All Lines of Business Except Medicare)
- Knee: Total Joint Arthroplasty (Medicare Only)
- Liver Tumor Treatment
- Athletic Pubalgia Surgery
- Ganglion Impar Blocks

- Genetic Testing: Inherited Thrombophilias (All Lines of Business Except Medicare)
- Genetic Testing: Inherited Thrombophilias (Medicare Only)
- Low-Level and High-Power Laser Therapy
- Multi-Spectral Digital Skin Lesion Analysis
- Back: Vertebroplasty and Kyphoplasty (All Lines of Business Except Medicare)
- Back: Vertebroplasty and Kyphoplasty (Medicare Only)
- Bone Growth Stimulators (All Lines of Business Except Medicare)
- Bone Growth Stimulators (Medicare Only)
- Breast Cancer: Focused Microwave Phased Array Thermotherapy
- Celiac Disease Serologic Testing
- Genetic Testing: CADASIL Disease (All Lines of Business Except Medicare)
- Genetic Testing: CADASIL Disease (Medicare Only)
- Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies
- Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring
- Outpatient Physical Therapy (All Lines of Business Except Medicare)
- Peroral Endoscopic Myotomy (POEM)
- Intraoperative Neuropsychological Testing and Monitoring

PHARMACY & THERAPEUTICS COMMITTEE

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

New Drugs and Combinations:

Mogamulizumab-KPKC (Poteligeo®) Vial
• Indication: Treatment of adults with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. • Formulary Alternatives: retinoids (bexarotene, isotretinoin, acitretin), methotrexate, interferons (INF alpha, INF gamma), histone deacetylase inhibitors (vorinostat, romidepsin [medical benefit, prior authorization]), brentuximab vedotin [medical benefit, prior authorization]
• Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria:

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

For reauthorization: documentation of adequate response to the medication must be provided

Doravirine (Pifeltro®) Tablet

- Indication: Indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in adult patients with no prior antiretroviral treatment history.
- Formulary Alternatives: efavirenz, Intelence®, nevirapine

- Commercial/Medicare Part D: Formulary, Non-Preferred Brand
- Medicaid: Formulary, Brand

Doravirine, lamivudine, and tenofovir disoproxil fumarate (Delstrigo®) Tablet

- Indication: Indicated as a complete regimen for the treatment of human immunodeficiency virus (HIV)-1 infection in adult patients with no prior antiretroviral treatment history.
- Formulary Alternatives: Atripla®, Odefsey®, Complera®, Symfi®, Biktarvy®, Genvoya®, Triumeq®

- Commercial/Medicare Part D: Formulary, Non-Preferred Brand
- Medicaid: Formulary, Brand

Iobenguane Iodine-131 (Azedra Dosimetric®) Vial

Indication: Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL) who require systemic anticancer therapy.

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

Prior Authorization Criteria:

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

For reauthorization: documentation of adequate response to the medication must be provided.

Plazomicin Sulfate (Zemdri®) Vial

- Indication: Treatment of complicated urinary tract infections (including pyelonephritis) in patients who are at least 18 years old and have limited to no alternative treatments.
- Formulary Alternatives: IV medical antibiotic drugs

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

Sodium Zirconium Cyclosilicate (Lokelma®) Powd Pack

- Indication: Treatment of hyperkalemia in adults.
- Formulary Alternatives: sodium polystyrene sulfonate for oral suspension (Kayexalate®)

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

Prior Authorization Criteria:

Initial authorization criteria:

1. Documentation of confirmed diagnosis of hyperkalemia (greater than or equal to 5.1 mEq/L)

AND

2. Documented trial and failure, or contraindication to sodium polystyrene sulfonate oral suspension (Kayexalate®, Kionex®)

AND

3. If patient is receiving concurrent angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) therapy: documentation of an attempt to optimize the dose of all current renin-angiotensin –aldosterone (RAAS) inhibitors (e.g. ACE-I, ARB, aldosterone antagonists) to minimize hyperkalemia

Reauthorization Criteria:

1. Documentation that patient achieved normal potassium levels (3.5-5.0 mEq/L) within the last three months

AND

Patient is continuing on RAAS inhibitor therapy or medical rationale is provided for continuing therapy (e.g., patient remains at high risk for recurrence of hyperkalemia)

Migalastat HCl (Galafold®) Capsule

- Indication: Fabry disease with an amenable galactosidase alpha gene
- Formulary Alternatives: Fabrazyme® (medical benefit)

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (14 capsules per 28 days)
- Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (14 capsules per 28 days)
- Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (14 capsules per 28 days)

Prior Authorization Criteria:

1. Diagnosis of Fabry Disease
2. Documentation that patient has an amenable galactosidase alpha gene (GLA) variant based on an in vitro assay

Lusutrombopag (Mulpleta®) Tablet

- Indication: Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (7 tablets per month)
- Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (7 tablets per month)

Prior Authorization Criteria:

For Mulpleta®:

1. Diagnosis of chronic liver disease
2. Platelet count of less than 50,000 platelets/µL
3. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started 8-14 days prior to the procedure

Lanadelumab-FLYO (Takhzyro®) Vial

- Indication: Prophylaxis to prevent attacks of hereditary angioedema (HAE).
- Formulary Alternatives: C1-Esterase inhibitor [human] (Cinryze®), C1-Esterase inhibitor [human] (Haegarda®), danazol

(Danocrine®), tranexamic acid (Lysteda®)

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

Prior Authorization Criteria for Commercial/Medicaid:

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 (e.g., estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary

AND

3) Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone unless not indicated (e.g., pregnancy, lactation, pre-pubescent children, hepatitis)

AND

4) 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:
         (1) C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
         (2) 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) 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®.

Dosing regimens that exceed the manufacturer recommended dose will only be approved if evidence-based rationale is provided.

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.

Prior Authorization Criteria for Medicare:

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 (e.g., estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary;

AND

3) Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone unless not indicated (e.g,. pregnancy, lactation, pre-pubescent children, hepatitis);

AND

4) 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:
         (1) C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
         (2) 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) mutation, or
      ii) Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

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.

Glycopyrronium Tosylate (Qbrexza®) Towelette

- Indication: Primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older.

- Commercial/Medicare Part D: Formulary, Non-Preferred Brand, Prior Authorization, Quantity Limit (30 towelettes per 30 days)
- Medicaid: Non-Formulary, Quantity Limit (30 towelettes per 30 days)

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Prior Authorization Criteria for Commercial:

Initial authorization:

1. Diagnosis of severe primary axillary hyperhidrosis
2. Documentation that patient has had axillary hyperhidrosis for at least 6 months
3. Documentation that member's hyperhidrosis is causing social anxiety, depression, or other issues that are impacting quality of life
4. Documented trial and failure of Drysol® for a least 1 month, unless contraindicated or clinically significant adverse effects were experienced

For Age ≥ 18 years only: Documented trial and failure of botulinum toxin for at least 6 months, unless contraindicated or clinically significant adverse effects were experienced

Prior Authorization Criteria for Medicare Part D:

Initial authorization:

1. Diagnosis of severe primary axillary hyperhidrosis
2. Documentation that patient has had axillary hyperhidrosis for at least 6 months

Documentation that member's hyperhidrosis is causing social anxiety, depression, or other issues that are impacting quality of life

FVIII rec,B-dom delet peg-aucl (Jivi®) Vial

- Indication: On-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis in patients 12 years of age and older with previously treated hemophilia A (congenital Factor VII deficiency).
- Formulary Alternatives: (medical without PA): Kogenate®, Advate®, Eloctate®, Adynovate®, NovoEight®, Xyntha®, Nuwiq®, Helixate FS®, Kovaltry®; medical with PA: Hemlibra®

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

Fremanezumab-VFRM (Ajovy®) Syringe

- Indication: Preventive treatment of migraine in adults.
- Formulary Alternatives: amitriptyline, divalproex, metoprolol, timolol, topiramate, venlafaxine, botulinum toxin

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

Prior Authorization Criteria:

Initial authorization:

- Diagnosis of migraine headaches
  AND
- Documentation of trial and failure[Δ], intolerance, or contraindication to at least one prophylactic medication from three (3) of the following categories:
  - Anticonvulsants (e.g., divalproex, valproate, topiramate)
  - Beta-blockers (e.g., metoprolol, propranolol, timolol)
  - Antidepressants (e.g., amitriptyline, venlafaxine)
  - Botulinum toxin

  AND
- Documentation that member has not received a botulinum toxin injection in the past three months, or if the patient is currently receiving botulinum toxin, the provider indicates that treatment with botulinum toxin will be discontinued.

Reauthorization:

- Documented reduction in the severity or frequency of headaches.

[Δ]An adequate trial and failure is defined as minimal to no improvement after at least three (3) months of therapy

Galcanezumab-GNLM (Emgality®) Pen Injctr

- Indication: Preventive treatment of migraine in adults.
- Formulary Alternatives: amitriptyline, divalproex, metoprolol, timolol, topiramate, venlafaxine, botulinum toxin

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

Prior Authorization Criteria:

Initial authorization:

- Diagnosis of migraine headaches
  AND
- Documentation of trial and failure[Δ], intolerance, or contraindication to at least one prophylactic medication from three (3)

of the following categories:
  - Anticonvulsants (e.g., divalproex, valproate, topiramate)
  - Beta-blockers (e.g., metoprolol, propranolol, timolol)
  - Antidepressants (e.g., amitriptyline, venlafaxine)
  - Botulinum toxin

AND

- Documentation that member has not received a botulinum toxin injection in the past three months, or if the patient is currently receiving botulinum toxin, the provider indicates that treatment with botulinum toxin will be discontinued.

Reauthorization:

- Documented reduction in the severity or frequency of headaches.

[Δ]An adequate trial and failure is defined as minimal to no improvement after at least three (3) months of therapy

Baloxavir Marboxil (Xofluza®) Tablet
• Indication: Treatment of acute uncomplicated influenza in patients 12 years of age or older who have been symptomatic for no more than 48 hours. • Formulary Alternatives: oseltamivir (Tamiflu®), zanamivir (Relenza®), amantadine (Symmetrel®)
• Commercial/Medicaid: Non-Formulary, Quantity Limit (2 tablets per 30 days) • Medicare Part D: Formulary, Non-Preferred Drug

Pegfilgrastim-JMDB injection (Fulphila®)

New Strengths and Formulations: See Other Formulary Changes

New Indications:

Metronidazole (Nuvessa®)
Expanded FDA-approved or New Indication: • Treatment of bacterial vaginosis in **females 12 years of age and older**

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Nivolumab (Opdivo®)
Expanded FDA-approved or New Indication: • Patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy.[2] [2]This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
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.

Citric acid; magnesium oxide; sodium picosulfate (Prepopik ®)
Expanded FDA-approved or New Indication: • For cleansing of the colon as a preparation for colonoscopy in adults **and pediatric patients ages 9 years and older**
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Ivacaftor (Kalydeco®)
Expanded FDA-approved or New Indication: • Treatment of cystic fibrosis (CF) in patients **age 12 months and older** who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and update clinical policy.

Lenvatinib (Lenvima®)
Expanded FDA-approved or New Indication: • For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are

warranted.

Pembrolizumab (Keytruda®)
Expanded FDA-approved or New Indication: • In combination with pemetrexed and platinum chemotherapy, as first-line treatment of patients with metastatic nonsquamous Non-Small Cell Lung Cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
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.

Perampanel (Fycompa®)
Expanded FDA-approved or New Indication: • Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy **4 years of age and older**
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.and update policy.

Adalimumab (Humira®)
Expanded FDA-approved or New Indication: • Uveitis (UV)   ○ The treatment of non-infectious intermediate, posterior, and panuveitis in adults **and pediatric patients 2 years of age and older**
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Drug Safety Monitoring:

Zithromax, Zmax (azithromycin): FDA Warning - Increased Risk of Cancer Relapse With Long-Term Use After Donor Stem Cell Transplant
ISSUE: The serious lung condition for which long-term azithromycin was being studied called bronchiolitis obliterans syndrome is caused by inflammation and scarring in the airways of the lungs, resulting in severe shortness of breath and dry cough. Cancer patients

who undergo stem cell transplants from donors are at risk for bronchiolitis obliterans syndrome. The manufacturer of brand name azithromycin is providing a Dear Healthcare Provider letter on this safety issue to health care professionals who care for patients undergoing donor stem cell transplants.

Azithromycin is not approved for preventing bronchiolitis obliterans syndrome.

RECOMMENDATION:

Health care professionals should not prescribe long-term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for cancer relapse and death.

Patients who have had a stem cell transplant should not stop taking azithromycin without first consulting with your health care professional. Doing so could be harmful without your health care professional's direct supervision. Talk with them if you have any questions or concerns about taking this medicine.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

SGLT2(sodium-glucose cotransporter-2) Inhibitors for Diabetes: Drug Safety Communication - Regarding Rare Occurrences of a Serious Infection of the Genital Area

ISSUE:

SGLT2 inhibitors are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine. First approved in 2013, medicines in the SGLT2 inhibitor class include canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin (see FDA-Approved SGLT2 Inhibitors). In addition, empagliflozin is approved to lower the risk of death from heart attack and stroke in adults with type 2 diabetes and heart disease. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

RECOMMENDATION:

Patients should:

- Seek medical attention immediately if you experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.

- Read the patient Medication Guide every time you receive a prescription for an SGLT2 inhibitor because there may be new or important additional information about your drug. The Medication Guide explains the benefits and risks associated with the medicine.

Health care professionals should:

- Assess patients for Fournier's gangrene if they present with the symptoms described above. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary.

Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Opioid Analgesics REMS

ISSUE:

To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers.

RECOMMENDATION:

Healthcare providers are strongly encouraged to do all of the following:

- Complete a REMS-compliant education program offered by an accredited provider of continuing education (CE) or another education program that includes all the elements of the FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain.

- Discuss the safe use, serious risks, and proper storage and disposal of opioid analgesics with patients and/or their caregivers every time these medicines are prescribed. The Patient Counseling Guide (PCG) can be obtained at this link: www.fda.gov/OpioidAnalgesicREMSPCG.

- Emphasize to patients and their caregivers the importance of reading the Medication Guide that they will receive from their pharmacist every time an opioid analgesic is dispensed to them.

Consider using other tools to improve patient, household, and community safety, such as patient-prescriber agreements that reinforce patient-prescriber responsibilities.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

PROVIDENCE Health Plan

Valsartan-Containing Products: Update Health Professional and Consumer on Recent Recalled Products

ISSUE:

Valsartan is used to treat high blood pressure and heart failure. Not all products containing valsartan are being recalled. This update will clarify which valsartan-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. Some levels of the impurity may have been in the valsartan-containing products for as long as four years.

RECOMMENDATION:

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.

Health professionals should:

- FDA has determined the recalled valsartan products pose an unnecessary risk to patients. Therefore, FDA recommends patients use valsartan-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.

Health Plan Action taken: Due to the large member impact of the initial recall of valsartan-containing products (7/13/2018), letters were sent to all commercial, Medicaid, and Medicare members who filled a prescription within the last 12-months for a valsartan-containing product. In addition, providers were also notified if they had prescribed a valsartan-containing product that was on the initial recalled product list.
For the expanded recall of valsartan-containing products effective (8/8/2018 & 8/23/18), updated lists of recalled valsartan-containing products, and updated lists of non-recalled valsartan-containing products were communicated via PMG Clinical Pharmacy Alerts and PHP announcements.
FDA updated list of valsartain 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
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Other Formulary Changes:

Drug/Policy Name	Recommendation
Ketoprofen Cap 24H Pel	Remove from Commercial and Medicaid formulary.
Budesonide (Uceris®) Foam	Add Prior Authorization to Commercial and Medicaid. • Add to Uceris policy
Lidocaine (Ztlido®) Adh. Patch	New combination. Add Prior Authorization to Commercial and Medicaid. • Add to New Medications and Formulations without Established Benefit policy
Cresemba® Vial	Add Prior Authorization to Medicare Part B (Antifungal Policy).
Mavyret®, Vosevi®	• Commercial: Change from Non-Preferred Specialty to Preferred Specialty
Sovaldi®, Technivie®	• Commercial: Change from Preferred Specialty to Non-Preferred Specialty
Trulicity®	• Commercial: Change from Non-Preferred Brand to Preferred Brand (effective 1/1/2019)
Itraconazole 100 mg tablet	• Commercial: Move from Non-Preferred Brand to Non-Preferred Generic • Medicare Part D: Add to Formulary, Non-preferred Drug
Aptiom	Commercial and Medicaid: • Formulary, Non-Preferred Brand, Step Therapy
Banzel	Commercial and Medicaid: • Formulary, Non-Preferred Brand, Step Therapy
Briviact	Commercial and Medicaid: • Formulary, Non-Preferred Brand, Step Therapy, Quantity Limit (60 tablets per 30 days)
Fycompa	Commercial and Medicaid: • Formulary, Non-Preferred Brand, Step Therapy, Quantity Limit (1 tablet per day)

Lamotrigine ER	Commercial and Medicaid: • Formulary, Non-Preferred Generic, Step Therapy
Onfi (clobazam)	Commercial and Medicaid: • Formulary, Non-Preferred Brand, Step Therapy, Quantity Limit (2 tablets per day)
Oxtellar XR (oxcarbazepine)	Commercial and Medicaid: • Formulary, Non-Preferred Brand, Step Therapy
Sabril (vigabatrin)	Commercial and Medicaid: • Formulary, Non-Preferred Specialty, Prior Authorization
Vimpat (lacosamide)	Commercial and Medicaid: • Formulary, Preferred Brand, Step Therapy

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	
Zortress	New strength. Line extend to Zortress®. • Commercial/Medicaid: Formulary, Specialty • Medicare Part D: Formulary Specialty, FDA Max (2 tablets per day)
NEW GENERICS	
Dalfampridine ER Tab ER 12H	First generic. Line extend to brand. Add to Ampyra® policy. • Commercial/Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day) • 2019 Commercial: Change from Specialty to Non-Preferred Specialty

Itraconazole Solution	First generic. Line extend as generic.
	• Commercial: Formulary, Non-Preferred Generic, Prior Authorization
	  ○ Add to Antifungal Agents policy
	• Medicaid: Formulary, Prior Authorization
	  ○ Add to Antifungal Agents policy
	• Medicare Part D: Non-Formulary

Albendazole Tablet	First generic. Line extend as generic.

	• Commercial: Formulary, Non-Preferred Generic, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization Add to Albenza, Emverm policy
Bupropion HCL XL Tablet	First generic. Line extend as generic. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Add to New Medications and Formulations without Established Benefit policy • Medicare Part D: Non-Formulary
Morphine Sulfate ER Cap ER Pel	First generic. Line-extend as Generic, Non-Formulary, Quantity Limit (2 capsules per day) across all lines of business.

Tadalafil Tablet	First generic. Line-extend as generic.
	• Commercial: Formulary, Non-Preferred Generic, Prior Authorization, Quantity Limit (30 tablets per 30 days)
	  ○ Add to BPH Treatment – Cialis, Rapaflo policy
	• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (30 tablets per 30 days)
	  ○ Add to BPH Treatment – Cialis, Rapaflo policy
	• Medicare Part D: Non-Formulary

Norethindrone Acetate-Ethinyl Estradiol/Ferrous Fumara (Tarina FE®) Tablet	New generic. Line extend as generic. • Commercial/Medicaid: Formulary, Non-Preferred Generic, ACA eligible • Medicare Part D: Formulary, Non-Preferred Generic
Desogestrel-Ethinyl Estradio (Cyred® EQ) Tablet	New generic. Line extend as generic. • Commercial/Medicaid: Formulary, Non-Preferred Generic, ACA eligible • Medicare Part D: Formulary, Non-Preferred Generic
Testosterone Gel Pump	First generic. Line-extend as generic. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Add to Testosterone Replacement Therapy policy • Medicare Part D: Formulary, Non-Preferred Drug
Guaifenesin/Hydrocodone Bitartrate (Hydrocodone-Guaifenesin) Solution	First generic for Obredon®. Line extend to brand. • Non-Formulary for all lines of business
Clobazam Oral Susp	New generic. Line extend to Onfi®.

	• Commercial: Formulary, Non-Preferred Generic, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day) • Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization, Quantity Limit (2 tablets per day) • 2019 Medicare Part D: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (2 tablets per day) Add to Banzel, Onfi policy

Health Plan Clinical Policy Changes:

Policy Name	Change Summary
IL-5 Inhibitors - Cinqair, Fasenra, Nucala	Added dupilumab as a product to not be used in combination with reslizumab, benralizumab, and mepolizumab.
Xolair	Added dupilumab as a product to not be used in combination with omalizumab.
Aciphex Sprinkles, Dexilant, Esomeprazole, Nexium	Removed quantity limit (one per day) for all lines of business for esomeprazole (Nexium) 20mg capsules due to high volume of requests and low cost of product.
Dupixent	Policy criteria updated for new indication of eosinophilic and corticosteroid dependent asthma. Adding Dupixent 200mg injection prior authorization for eosinophilic and corticosteroid dependent asthma. Quantity limit of 2/28 days added to both 200mg and 300mg syringe strengths (FDA max dosing) for all lines of business.
Hepatitis C - Direct Acting Antivirals	Exclusion criteria has been added to exclude the use of protease inhibitors in patients with moderate to severe hepatic impairment to coincide with package labeling. In addition, preferred medications have been changed to Epclusa, Vosevi, Mavyret, and Harvoni while other Hepatitis C antivirals have been moved to non-preferred specialty tiers.
Amitiza, Linzess, Movantik, Trulance, Symproic	Quantity limits have been removed from this policy for improving operational efficiency and low risk of overutilization.

Aimovig	Emgality and Ajovy are new medications that are being added to this policy. Policy name will be changed to "Calcitonin Gene-Related Peptide."
Injectable Anti-Cancer Medications	Azedra will be added to this policy.
Immune Gamma Globulin (IGG)	The reauthorization criteria for primary and secondary immunodeficiency disorders was updated. Whether or not patients that have been treated for two years or more should attempt discontinuation of treatment should be left to the discretion of the treating provider.
Mepron	The quantity limit was removed from the policy document, as no quantity limit is currently in place for this medication and there is low risk of overutilization.
Xifaxan	Increased quantity limit of the 550 mg tablet to 3 a day.
Doptelet	Renamed policy to Doptelet/Mulpleta. Added Mulpleta to the policy. Made Mulpleta the preferred agent and added requirement that authorization for Doptelet will require trial, failure, or contraindication to Mulpleta.
Xermelo	Policy and position statement update to reflect most current National Comprehensive Cancer Network (NCCN) guidelines. The required long-acting octreotide therapy examples were changed to list octreotide LAR (Sandostatin LAR®) or lanreotide (Somatuline®) and ortreotide infusion pump was removed from this list.
Enzyme Replacement Therapy	Added Fabrazyme to the policy.

New Generic Medications:

First time generics to market

• **Dalfampridine ER Tab ER 12H -** First generic. Line extend to brand. Add to Ampyra® policy.
  ○ Commercial/Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (2 tablets per day)
  ○ 2019 Commercial: Change from Specialty to Non-Preferred Specialty
• **Itraconazole Solution -** First generic. Line extend as generic.
• Commercial: Formulary, Non-Preferred Generic, Prior Authorization
  ○ Add to Antifungal Agents policy
• Medicaid: Formulary, Prior Authorization

- Add to Antifungal Agents policy
- Medicare Part D: Non-Formulary

- **Albendazole Tablet -** First generic. Line extend as generic.
- Commercial: Formulary, Non-Preferred Generic, Prior Authorization
- Medicaid: Formulary, Prior Authorization
- Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization
  - Add to Albenza, Emverm policy
- **Bupropion HCL XL Tablet -** First generic. Line extend as generic.
- Commercial/Medicaid: Non-Formulary, Prior Authorization
  - Add to New Medications and Formulations without Established Benefit policy
- Medicare Part D: Non-Formulary
- **Morphine Sulfate ER Cap ER Pel -** First generic. Line-extend as Generic, Non-Formulary, Quantity Limit (2 capsules per day) across all lines of business.
- **Tadalafil Tablet -** First generic. Line-extend as generic.
- Commercial: Formulary, Non-Preferred Generic, Prior Authorization, Quantity Limit (30 tablets per 30 days)
  - Add to BPH Treatment – Cialis, Rapaflo policy
- Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (30 tablets per 30 days)
  - Add to BPH Treatment – Cialis, Rapaflo policy
- Medicare Part D: Non-Formulary

Norethindrone Acetate-Ethinyl Estradiol/Ferrous Fumara (Tarina FE®) Tablet - New generic. Line extend as generic.

- Commercial/Medicaid: Formulary, Non-Preferred Generic, ACA eligible
- Medicare Part D: Formulary, Non-Preferred Generic

- **Desogestrel-Ethinyl Estradio (Cyred® EQ) Tablet -** New generic. Line extend as generic.
- Commercial/Medicaid: Formulary, Non-Preferred Generic, ACA eligible
- Medicare Part D: Formulary, Non-Preferred Generic

Testosterone Gel Pump - First generic. Line-extend as generic.

- Commercial/Medicaid: Non-Formulary, Prior Authorization
  - Add to Testosterone Replacement Therapy policy
- Medicare Part D: Formulary, Non-Preferred Drug

- **Guaifenesin/Hydrocodone Bitartrate (Hydrocodone-Guaifenesin) Solution -** First generic for Obredon®. Line extend to brand.
- Non-Formulary for all lines of business
- **Clobazam Oral Susp -** New generic. Line extend to Onfi.
- Commercial: Formulary, Non-Preferred Generic, Prior Authorization, Quantity Limit (2 tablets per day)
- Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day)
- Medicare Part D: Formulary, Non-Preferred Drug, Prior Authorization, Quantity Limit (2 tablets per day)

- 2019 Medicare Part D: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (2 tablets per day)
  - Add to Banzel, Onfi policy