PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 233

March 1, 2019

This is the March 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.

Effective 5/1/2019 proton beam radiation therapy for the treatment of prostate cancer will be considered not medically necessary and not covered.

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

New Policies or Major Changes

Effective March 1, 2019

Genetic Testing: Breast Cancer Prognostic Assays **(All Lines of Business Except Medicare)** **GT157**	**Interim Update** MammaPrint Assay: Based on new NCCN guidelines, we have liberalized our stance on the MammaPrint assay for both node-positive (up to 3 positive nodes) and node-negative women. Currently, NCCN provides a category 1 recommendation for the use of MammaPrint to guide decisions regarding adjuvant chemotherapy in both these subsets of patients. This recommendation is based on 5-year outcomes from the MINDACT trial. The criteria are primarily based on the patient inclusion criteria and analyses from the MINDACT trial, FDA labelling indications for the MammaPrint test, and NCCN and/or ASCO guidelines. Exception: Of note, the MammaPrint assay is the only assay with 5-year follow-up that we will be liberalizing at this time. Other assays currently considered investigational for node-negative and node-positive women will remain so until longer-term studies are published. Note: Medicare already considered MammaPrint medically necessary; therefore, the Genetic Testing: Breast Cancer Prognostic Assays (Medicare only) policy did not require updating. Oncotype DX Breast and Prosigna: Added criterion I.G. "Adjuvant chemotherapy is not precluded due to any other factor…". This same requirement was added to the criteria for MammaPrint. **PA/Codes:** The specific CPT code for the MammaPrint assay (81521) will change from investigational to PA required for all lines of business except Medicare.
Genetic Testing: Hereditary Breast and Ovarian Cancer **(All Lines of Business Except Medicare)** **GT155**	**Interim Update** The policy criteria were updated to be in-line with NCCN's current guidelines (version 2.2019). Therefore the following changes to each section of the criteria were made: In all sections, we have clarified that when there are mutations known in the family, that those mutations must have been classified as pathogenic or likely pathogenic. *Personal History of Cancer* (III.B.1.a.): Reduced the age at which a patient diagnosed with breast cancer may be eligible for testing from 50 years to 45 years. (III.B.1.b.) *NEW*: Added criteria specific to patients between 46-50 years old. (III.B.1.d): Additional indications allowed for testing of patients diagnosed with breast cancer at any age. (III.B.) Additional indications allowed for patients with a personal history of breast cancer:

	• pancreatic cancer (III.B.4.) • high-grade prostate cancer (III.B.6.) • when a known pathogenic/likely pathogenic variant in a hereditary breast and/or ovarian cancer gene* has been detected by tumor profiling (III.B.8.) (III.B.7.) Added diagnoses which may be present in patient or family members which warrant testing: • Dermatological manifestations of Cowden syndrome (link to NCCN guidelines for complete list) • Gastrointestinal cancer • Ovarian sex chord tumors • Testicular Sertoli cell tumors • Childhood skin pigmentation indicative of Peutz-Jeghers syndrome (link to NCCN guidelines for complete list) *No Personal History of Cancer (IV.)* Removed criterion for third-degree relatives and added a note indicating that criteria for first- and second- degree relatives "may apply to an affected third-degree relative if related through two male relatives (e.g., paternal grandfather's mother or sister)". *Non-Covered Testing* (VI.) Revised the language in the non-coverage criteria for patients who have undergone bone-marrow transplants to indicate that only blood and buccal samples are non-covered. Cultured fibroblasts may be used. **PA / Codes:** No changes.
Genetic Testing: Hereditary Breast and Ovarian Cancer **(Medicare Only)** **GT380**	**Interim Update** The medical necessity criteria were updated based on updated criteria in the LCD. Significant liberalizations have been made by Medicare regarding criteria for BRCA1/2 testing. Some of these changes include, but are not limited to: • Allowing for testing of an individual with breast, ovarian, pancreatic, or prostate cancer from a family with a known deleterious BRCA1 or BRCA2 gene mutation. • Reducing the age at which a patient diagnosed with breast cancer may be eligible for BRCA1/2 testing (reduced from 50 to 45 years old). • Expanded the coverage criteria for patients diagnosed at 50 years or older. • Allow for testing in patients with a personal history of prostate or pancreatic cancer when criteria are met. • Allowing for BRCA1/2 testing when a pathogenic mutation has been detected by tumor profiling. • Removed criteria for adopted individuals, and added it down into the "Notes" section, per the current LCD. The intent remains the same. For clarification purposes, we have also added language surrounding the appropriate use of BART testing and billing guidelines (similar to language in the commercial policy). Removed LCA from the Medicare policy, since it only addresses the use of Myriad's BRACAnalysis CDx™ test to inform treatment with Lynparza. This is now addressed in the Genetic Testing: Pharmacogenetic Testing policy. **PA / Codes:** No changes.

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Effective May 1, 2019

Fecal Incontinence Treatments (All Lines of Business Except Medicare) **SUR224**	**Annual Update** • No change to status of sacral nerve stimulation (SNS) as medically necessary and covered for trial period and permanent implantation. • This policy now also addresses five additional investigational treatments (biofeedback, bulking agents, transanal radiofrequency therapy, anal sphincter replacement, posterior tibial nerve stimulation, and Eclipse™ Vaginal Insert System). • Added language requiring that SNS is first conducted in a 14-day trial period • Added criterion specifying that trial period must generate 50 percent or greater improvement in reported symptoms to render patient eligible for permanent implantation • Added criterion stating that replacement of SNS device is not medically necessary if the initial device remains functional. **Codes:** Several codes were added to address the treatments which we consider investigational: • 0377T and L8605: injectable bulking agents will continue to deny investigational • 90911: Biofeedback training for anorectal sphincter will deny as investigational when billed with a fecal incontinence diagnosis codes • A4653: transvaginal insert for fecal incontinence will deny investigational • 64566: PTNS will deny as investigational when billed with a fecal incontinence diagnosis codes
Fecal Incontinence Treatments (Medicare Only) **SUR437**	**New Policy** A new policy was created for Medicare only that addresses sacral nerve stimulation (SNS) for fecal incontinence. A few minor differences were noted between the commercial and CMS policies: • SNS trial period timeline (one week for Medicare vs. two weeks for commercial); and • Medicare does not include the sacral nerve stimulation contraindication of recent rectal surgery (criterion I.C.4. in commercial policy). Besides SNS, Medicare does not address any other fecal incontinence treatments; therefore, commercial criteria will apply to other treatment modalities in accordance with our CMS hierarchy. **Codes:** Codes and configuration are the same as the commercial policy. **NCD/LCD/LCA**: Local Coverage Article (LCA): Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017).

Proton Beam Radiation Therapy
MED324
 	
Previously known as: Proton Beam Therapy
	Annual Update
	<u>Changes to Existing Criteria</u>
	• Proton beam radiation therapy for prostate cancer will now be considered not medically necessary for all LOBs.
	• Maintain our medical necessity criteria for intraocular (uveal) melanomas, but have removed the metastases requirement.
	• Maintain our medical necessity criteria for chordomas and chondrosarcomas, but have removed “axial skeleton” and replaced with “spine”.
	<u>New Criteria</u>
	• The following indications are now considered medically necessary (when criteria are met):
	  ○ Intracranial arteriovenous malformation (AVMs)
	  ○ Central nervous system (CNS) tumors

	○ Primary head and neck cancers ○ Reirradiation • Added criteria that outline clinical situations where proton beam therapy is considered not medically necessary. These are based on the 2017 ASTRO guidelines. • Added a note to the top of the criteria stating that the policy does not address patients under 21 years of age. <u>No major changes</u> • The following oncologic indications remain investigational and not covered: breast, esophageal, gastric, gynecologic, hepatobiliary, lung, lymphomas, pancreatic, skin, soft tissue sarcomas, and thymomas/thymic cancers. • The non-oncologic indications of age related macular degeneration and cavernous hemangioma remain investigational. **PA/Codes:** No major changes. PA will be added to one S code which may be billed with PBT for intraocular melanomas.

<u>No Major Changes</u>

Effective April 1, 2019

Athletic Pubalgia Surgery **SURG326**	**Annual Update** No change to criteria designating surgery for the treatment of athletic pubalgia as investigational. **Codes/PA:** No changes.
Bronchial Thermoplasty **SUR113**	**Annual Update** No change to criteria designating bronchial thermoplasty (BT) as not medically necessary for all indications, including asthma. **Codes/PA:** No changes
Clinical Trials and Devices **(All Lines of Business Except Medicare)** **MED184**	**Annual Update** No major changes to the policy criteria at this time. However, we have made a few small changes, as follows: • Added a note to the top of the criteria indicating that member benefits regarding coverage of out of network (OON) clinical trial benefit may vary by line of business and that benefit contract language takes precedence over medical policy. • Added language from the affordable care act (ACA) regarding the use of in-network and out-of-network providers. A note in criterion I. in the policy directs reviewers down to the policy guidelines section for in-network versus out-of-network guidelines.
Clinical Trials and IDE Studies **(Medicare only)** **MED185**	**Annual Update** There are no major changes to the criteria. Criterion V.H. was clarified to reflect the current Medicare terminology. Additions have been made to the policy: 1. Added a Policy Guidelines section which included language from the Medicare Benefit Policy Manual (Chapter 4) regarding CMS's coverage of healthy volunteers in clinical trials. 2. The Billing Guidelines section of the policy had additional general language from the Medicare Claims Processing Manual (Chapter 32) added regarding the use of in-network and out-of-network providers and cost-sharing.

Eye: Retinopathy Telescreening **MED217** *Previously: Diabetic Retinopathy Telescreening*	**Annual Update** No change to the current criteria. Title of policy modified slightly to account to the fact that we address telescreening for more than diabetic retinopathies. **Codes/PA:** No changes.
Ganglion Impar Blocks **SUR226**	**Annual Update** No change to criteria designating ganglion impar blocks as investigational for all indications. Eighteen example indications added to criteria. **Codes/PA:** No changes.
Joint Resurfacing **SUR258**	**Annual Update** No change to criteria designating joint resurfacing as investigational for all non-hip indications. **Codes/PA:** No changes.
Knee: Ablative Procedures of Peripheral Nerves to Treat Knee Pain **SUR 436**	**Interim Update** This new policy was recently approved at MPC, with an effective date of 4/1/2019. The changes described below will not impact the effective date. • Criteria were clarified slightly to change the denial for radiofrequency ablation from NMN to investigational for Medicare only. Medicare only has non-coverage guidance on cryoablation, and not radiofrequency ablation. Therefore, per PHP hierarchy, RFA will be denied as investigational for Medicare. ○ *This criteria change does NOT require any coding set-up changes, and is NOT considered a restriction for the purposes of provider notification*.
Low-level and High-power Laser Therapy **MED272**	**Annual Update** No change to low-level laser therapy (LLLT) and high-power laser therapy (HPLT) as investigational for all indications. Based on evidence review, two example indications have been added ("chronic pain" and "oral mucositis") for which LLLT and HPLT would be denied. **Codes/PA:** No changes.
Multi-spectral Digital Skin Lesion Analysis **MED279**	**Annual Update** Multi-spectral digital skin lesion analysis systems, including but not limited to MelaFind®, are considered investigational for all indications. **Codes/PA:** No changes.
Peroral Endoscopy Myotomy **SUR407**	**Annual Update** No change to criteria designating peroral endoscopic myotomy (POEM) as investigational for all indications, including achalasia, dysphagia, gastroesophageal reflux, diffuse esophageal spasm, distal esophageal spasm, jackhammer (hypercontractile) esophagus, gastroparesis, and other esophageal disorders. **Codes/PA:** No changes.

Sensory Integration Therapy **MED396**	**Annual Update** No change to criteria designating sensory integration therapy (SIT) as investigational for the treatment of any condition in non-autistic patients. The Optum® Coverage Determination Guideline for Neurodevelopmental Disorders (BH727ND_012017) addresses sensory integration therapy in patients with autism spectrum disorder. **Codes/PA:** No changes.
Vestibular Function Testing **MED368** *Previously Titled: Vestibular Autorotation Testing*	**Annual Update** No change to criteria designating VAT as not medically necessary. Investigational criteria added to address the use of vestibular evoked myogenic potential (VEMP) for the diagnosis of any indication, including but not limited to, Meniere disease (MD). Policy name changed from "Vestibular Autorotation Test (VAT)" to "Vestibular Function Testing" per addition of VEMP to criteria. **Codes/PA:** No changes.

Effective May 1, 2019

Radiofrequency Ablation or Cryoablation as an Alternative to Surgical Treatment for Plantar Fasciitis
SUR328
 	
Previously:
Radiofrequency Lesioning or Cryosurgery/Cryotherapy as an Alternative to Surgical Treatment for Plantar Fasciitis
	Interim Update
	• Title and language throughout the policy modified slightly to be more consistent with our other medical policies addressing ablative techniques.
	  ○ The term "radiofrequency lesioning" has been changed to radiofrequency ablation.
	  ○ The term "cryosurgery" has been changed to "cryoablation".
	• Criteria were clarified slightly to change the denial for radiofrequency ablation from NMN to investigational for Medicare only. Medicare only has non-coverage guidance on cryoablation, and not radiofrequency ablation. Therefore, per PHP hierarchy, RFA will be denied as investigational for Medicare.
	  ○ *This criteria change does NOT require any coding set-up changes, and is NOT considered a restriction for the purposes of provider notification*.
	• Additional coding edits are being put in place to pair the CPT codes already in the policy with an additional range of ICD codes to deny as non-covered per this policy.
	PA / Codes: The following coding edit changes will be made:
	0441T will be paired the following 4 codes to deny as investigational for all LOB except Medicare.
	• G57.60 Lesion of plantar nerve, unspecified lower limb
	• G57.61 Lesion of plantar nerve, right lower limb
	• G57.62 Lesion of plantar nerve, left lower limb
	• G57.63 Lesion of plantar nerve, bilateral lower limbs
	64640 will be paired with the same four ICD codes above to deny as investigational for all LOB.

Vendor Updates

AIM Specialty Health

***Effective May 18, 2019**, the AIM Specialty Health® (AIM) Clinical Appropriateness Guidelines for Oncologic Imaging will address use of PET radiotracers.*

Currently, non-FDG radiotracers are outside the scope of the AIM Oncologic Imaging Program and are sent to the health plan for review. With this content, clients who use AIM guidelines for PET-CT will soon have the option for AIM to complete a prior authorization review of both the non-FDG radiotracer and the PET-CT.

Please note:

- These changes will be effective on May 18, 2019.
- The final guidelines, including the updates, will be available on our website in early February.
- Our initial solution will pass CPTs for PET CT only in the extract, so claims systems will need to be configured to pay the radiotracer A code if the CPT for PET /PET CT is authorized.
- We are working on a long-term solution that will accept A codes for direct entry into the prior authorization process, and we will keep you informed of progress in this area.
- Medical policy and NCD/LCD's takes precedence for applicable lines of business (i.e., FEP, Government programs).

PHARMACY & THERAPEUTICS COMMITTEE

Oregon Region P&T Committee Meeting February 8, 2019
Go-Live Date: Monday, April 01, 2019, unless otherwise noted

New Drugs and Combinations:

Aripiprazole (Abilify Mycite®) Tab Senspt

• Indication:
  ○ Treatment of adults with schizophrenia
  ○ Treatment of bipolar I disorder
  ▪ Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
  ▪ Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
  ○ Adjunctive treatment of adults with Major Depressive Disorder

- **Limitations of use:**
  - The ability of the Abilify Mycite® to improve patient compliance or modify aripiprazole dosage has not been established
  - The use of Abilify Mycite® to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur

- Formulary Alternatives: generic aripiprazole tablets, long acting injectable anti-psychotics (medical benefit)

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

Prior Authorization Criteria for Commercial:
Added to the New Drugs Without Established Benefit Policy

Prior Authorization Criteria for Medicare Part D:

1. Documentation of low medication adherence to generic aripiprazole tablets (less than 80%)
Trial, failure, intolerance or contraindication to at least two injectable depot antipsychotic (e.g. Risperdal Consta, Abilify Maintena, Aristada, Aristada Initio, Invega Sustenna etc.)

Cannabidiol (CBD) Extract (Epidiolex®) Solution

- Indication: Treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years of age and older.

- Formulary Alternatives: valproic acid, topiramate, clobazam, lamotrigine, leviteracetam, zonisamide, rufinamide (Banzel®)

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

Prior Authorization Criteria for Commercial/Medicaid:
Initial Authorization:
1. Documentation that patient has one of the following:
   a. Seizures associated with Lennox-Gastaut syndrome (LGS)

   b. Seizures associated with Dravet syndrome (DS)
2. Documented trial, failure, intolerance or contraindication to clobazam
3. Documented trial, failure, intolerance or contraindication to one additional of the following:
   a. Valproate / Valproic acid
   b. Lamotrigine
   c. Levetiracetam
   d. Topiramate
   e. Felbamate
   f. Zonisamide
4. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
5. Baseline liver function tests must be documented
6. Dose will not exceed 20 mg/kg/day

Reauthorization:
1. Documentation of recent liver function test
2. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy

Dose continues to not exceed 20 mg/kg/day

Prior Authorization Criteria for Medicare Part D:
Initial Authorization:
1. Documentation that patient has one of the following:
   a. Seizures associated with Lennox-Gastaut syndrome (LGS)
   b. Seizures associated with Dravet syndrome (DS)
2. Documented trial, failure, intolerance or contraindication to two of the following medications:
   a. Onfi (clobazam)
   b. Valproate / Valproic acid (i.e. Depakote, Depacon)
   c. Lamotrigine
   d. Levetiracetam
   e. Banzal (rufinamide)
   f. Topiramate
   g. Felbamate
3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs

Dose will not exceed 20 mg/kg/day

PROVIDENCE Health Plan

Cemiplimab-RWLC (Libtayo®) Vial
• Indication: Patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced cutaneous squamous cell carcinoma (laCSCC) who are not candidates for curative surgery or curative radiation.
• Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization **Prior Authorization Criteria:** Added to Injectable ANTI-Cancer Medications policy

Dacomitinib (Vizimpro®) Tablet
• Indication: First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations. • Formulary Alternatives: afatinib, erlotinib, gefitinib, osimertinib
• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization **Prior Authorization Criteria:** Added to Oral Anti-Cancer Medications Policy

Duvelisib (Copiktra®) Capsule

• Indication:
  ○ Relapsed or refractory (RR) chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL) after at least two prior therapies
  ○ Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies
 	
• Formulary Alternatives: acalabrutinib, alemtuzumab, ibrutinib, idelalisib

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

Added to Oral Anti-Cancer Medications policy (see dacomitinib for specific criteria)

Gilteritinib Fumarate (Xospata®) Tablet

- Indication: Acute myeloid leukemia, Relapsed or refractory, with FLT3 mutation

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

Prior Authorization Criteria:
Added to Oral Anti-Cancer Medications policy (see dacomitinib for specific criteria)

Glasdegib Maleate (Daurismo®) Tablet

- Indication: In combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

- Formulary Alternatives: Venclexta®, Idhifa®

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

Prior Authorization Criteria:
Added to Oral Anti-Cancer Medications policy (see dacomitinib for specific criteria)

Lorlatinib (Lorbrena®) Tablet

- Indication: Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease

- Formulary Alternatives: crizotinib (Xalkori®), alectinib (Alecensa®), ceritinib (Zykadia®), brigatinib (Alunbrig®)

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

Prior Authorization Criteria:
Added to Oral Anti-Cancer Medications policy (see dacomitinib for specific criteria)

Moxetumomab pasudotox-tdfk (Lumoxiti®) Vial

- Indication: Treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).
  - Limitations of Use: not recommended in patients with severe renal impairment (CrCl ≤29 mL/min
- Formulary Alternatives: vemurafenib, ibrutinib, rituximab

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

Prior Authorization Criteria:
Added to Injectable ANTI-Cancer Medications policy (see cemiplimab for specific criteria)

Talazoparib Tosylate (Talzenna®) Capsule

- Indication: Treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.
- Formulary Alternatives: olaparib (Lynparza®)

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

Prior Authorization Criteria:
Added to Oral Anti-Cancer Medications policy (see dacomitinib for specific criteria)

Inotersen sodium (Tegsedi®) Syringe

- Indication: Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults.

- Formulary Alternatives: diflunisal (off-label use)

- Commercial: Formulary, Non-Preferred Specialty, Prior Authorization, Quantity Limit (4 pens per 28 days)
- Medicaid/Medicare Part D: Formulary, Specialty, Prior Authorization, Quantity Limit (4 pens per 28 days)

Prior Authorization Criteria for Commercial/Medicaid:
1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
AND
2. Documentation of a pathogenic TTR mutation
AND
3. Patient has a baseline polyneuropathy disability (PND) score of ≤ IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II
AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130
AND
5. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score
AND
6. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
   - Peripheral sensorimotor polyneuropathy (e.g., tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
   - Autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])
AND
7. Not taking in combination with patisiran (Onpattro®) or tafamidis

Reauthorization Criteria:
1. Documentation that patient is tolerating inotersen
AND
2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) and at least one of the following measures:
(a) baseline polyneuropathy disability (PND) score OR familial amyloid polyneuropathy (FAP) stage
OR
(b) Familial amyloid polyneuropathy (FAP) stage
OR
(c) Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

Prior Authorization Criteria for Medicare Part D:
1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
AND
2. Documentation of a pathogenic TTR mutation
AND
3. Patient has a baseline polyneuropathy disability (PND) score of less than or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II
AND
4. Baseline neuropathy impairment score (NIS) between 10 and 130
AND
5. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score
AND
6. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
AND
7. Not taking in combination with patisiran (Onpattro®) or tafamidis

Reauthorization Criteria:
1. Documentation that patient is tolerating inotersen
2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) and at least one of the following measures:
(a) baseline polyneuropathy disability (PND) score familial amyloid polyneuropathy (FAP) stage
OR
(b) Familial amyloid polyneuropathy (FAP) stage
OR
(c) Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

Ozenoxacin (Xepi®) Cream

- Indication: Topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older.[1]

- Formulary Alternatives: FDA approved topical therapies: mupirocin 2% ointment and gentamicin sulfate 0.1% cream and 0.1% ointment; FDA-approved oral therapies for impetigo and uncomplicated skin and skin structure infections (includes impetigo) include antistaphylococcal penicillins, cephalosporins, clindamycin, and fluoroquinolones.

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

Patisiran Sodium, Lipid Complex (Onpattro®) Vial

- Indication: Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults.

- Formulary Alternatives: diflunisal (off-label use)

- Commercial: Medical Benefit, Prior Authorization, Quantity Limit (see dosing table below)
- Medicaid: Medical Benefit, Prior Authorization, Quantity Limit (see dosing table below)
- Medicare Part D: Non-Formulary
- Medicare Part B: Medical Benefit, Prior Authorization, Quantity Limit (see dosing table below)

Patisiran (Onpattro®) dosing, which may be subject to audit:

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults	
Body Weight	**# Vials (10mg/5mL)**
<33.4kg	1
33.4-66.6kg	2
66.7-100kg	3
>100kg (maximum dose)	3

Prior Authorization Criteria:
1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
AND
2. Documentation of a pathogenic TTR mutation
AND
3. Patient has a baseline polyneuropathy disability (PND) score of ≤ IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II
AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130
AND
5. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

AND
6. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
- Peripheral sensorimotor polyneuropathy (e.g., tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
- Autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])

AND
7. Not taking in combination with inotersen (Tegsedi®) or tafamidis

AND
2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) and at least one of the following measures:
(a) baseline polyneuropathy disability (PND) score
OR
(b) Familial amyloid polyneuropathy (FAP) stage
OR
(c) Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

Appendix 1:
Patisiran (Onpattro®) dosing, which may be subject to audit:

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults	
Body Weight	**# Vials (10mg/5mL)**
<33.4kg	1
33.4-66.6kg	2
66.7-100kg	3
>100kg (maximum dose)	3

* Dose rounding to the nearest vial will be required within 10% of calculated dose based on a dosing of 0.3mg/kg per dose

Reauthorization Criteria:
1. Documentation that patient is tolerating patisiran

Tafenoquine succinate (Arakoda®) Tablet

- Indication: Prophylaxis of malaria (*Plasmodium vivax* and *Plasmodium falciparum*) in patients aged 18 years and older.

Formulary Alternatives: atovaquone/proguanil, chloroquine, primaquine, hydroxychloroquine, mefloquine, doxycycline
• Commercial: Non-Formulary • Medicaid: Non-Formulary • Medicare Part D: Non-Formulary

Tildrakizumab-ASMN (Ilumya®) Syringe
• Indication: Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. • Formulary Alternatives: ustekinumab, adalimumab, secukinumab
• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1mL per 84 days) • Medicare Part D: Non-Formulary **Prior Authorization Criteria for Commercial:** 1. For **all requests**, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.) **AND** 2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®) **AND** 3. One of the following: a. For patients already established on the requested therapeutic immunomodulator (starting on samples will not be considered as established on therapy): i. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency) b. Patients not established on the requested therapeutic immunomodulator must meet ALL of the following indication-specific criteria: v. For moderate to severe **Plaque Psoriasis:** 1. Documentation of trial and failure$^{\Delta}$, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol) 2. For non-preferred TIMs therapies: documentation of trial and failure$^{\Delta}$, intolerance, or contraindication to **three** of the following preferred agents: a. etanercept (Enbrel®)

b. adalimumab (Humira®)
c. secukinumab (Cosentyx®)
d. ustekinumab (Stelara®)

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

Prior Authorization Criteria for Medicaid:

1. For **all requests**, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.) and is a covered indication according to the Prioritized List of Health Care Services.

AND

2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®)

AND

3. One of the following:
   b. For patients <u>already established</u> on the requested therapeutic immunomodulator (starting on samples will not be considered as established on therapy):
      v. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
   c. Patients <u>not established</u> on the requested therapeutic immunomodulator must meet ALL of the following indication-specific criteria:
      iii. For **psoriasis**:
         1. Member must have severe disease, as defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND at least one of the following:
            a. At least 10% of body surface area involved
            b. Hand, foot or mucous membrane involvement
         2. Documented adequate trial and failure[Δ], intolerance or contraindication to each of the following first-line agents:
            a. Topical high-potency corticosteroids (e.g., betamethasone 0.05%, clobetasol 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%, triamcinolone 0.5%)
            b. Another topical agent (e.g., calcipotriene, tazarotene)
            c. Phototherapy
            d. Systemic therapy (e.g., methotrexate, cyclosporine)
         3. For non-preferred TIMs agent: Documented adequate trial and failure[Δ], intolerance or contraindication to the following preferred agents:
            a. One of the following agents: adalimumab (Humira®), etanercept (Enbrel®) or infliximab biosimilar (Inflectra® or Renflexis®)

AND

b. If patient has satisfied criteria above (iii.3.a.), documented trial, failure, intolerance or contraindication to apremilast (Otezla®)

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

New Strengths and Formulations:

Amikacin sulfate liposomal with nebulizer accessories (Arikayce®) Vial-Neb
• Indication: Treatment of pulmonary *Mycobacterium avium* complex (MAC) infection, as part of a combination antibacterial drug regimen in patients with limited or no alternative treatment options.[1] • Formulary Alternatives: Generic amikacin sulfate 250mg/ml solution for injection, generic streptomycin sulfate 1-gram vial
• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (8.4ml per day) • Medicare Part D: Non-Formulary **Prior Authorization Criteria:** 1. Documentation of a confirmed diagnosis *of Mycobacterium avium* complex (MAC) infection confirmed by MAC-positive sputum or bronchoscopy cultures, **AND** 2. Documentation that the patient is unable to achieve negative sputum cultures after a minimum of 6 consecutive months of a standard guideline-based therapy (GBT). Guideline-based therapy is a three-drug oral antibiotic regimen composed of a macrolide (clarithromycin or azithromycin), ethambutol and rifamycin (rifabutin), **AND** 3. Documented trial, failure, intolerance or contraindication to intravenous aminoglycoside (streptomycin or amikacin) and inhaled amikacin sulfate, AND 4. Documentation that organism is susceptible to amikacin. Reauthorization requires documentation of negative sputum cultures.

New Indications:

Emicizumab (Hemlibra®)
Expanded FDA-approved or New Indication:

• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Updates to clinical prior authorization policy will be deferred to April 2019 ORPTC meeting to complete a full review of clinical evidence for this updated indication.

Rivaroxaban (Xarelto®)
Expanded FDA-approved or New Indication: • in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD)
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and add to formulary.

Levonorgestrel-releasing intrauterine system (Liletta®)
Expanded FDA-approved or New Indication: • Prevention of pregnancy for up to 5 years
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Adalimumab (Humira ®)
Expanded FDA-approved or New Indication: • Hidradenitis Suppurativa (HS)   ○ The treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Amphetamine (Dyanavel® XR)
Expanded FDA-approved or New Indication: • treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

dupilumab (Dupixent®)
Expanded FDA-approved or New Indication: • As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Updates to prior authorization policy were completed for December 2018 ORPTC meeting).

Sodium oxybate (XyrEm®)
Expanded FDA-approved or New Indication: • Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and update clinical policy with new patient population.

Canagliflozin (Invokana®), canagliflozin/metformin (Invokamet®/Invokamet XR®)
Expanded FDA-approved or New Indication: • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Pembrolizumab (Keytruda®)

Expanded FDA-approved or New Indication:
• Non-Small Cell Lung Cancer (NSCLC)
  ○ in combination with carboplatin and either paclitaxel or nabpaclitaxel, as first-line treatment of patients with metastatic squamous NSCLC.
• Hepatocellular Carcinoma (HCC)
  ○ for the treatment of patients with HCC who have been previously treated with sorafenib[1]
 	
• [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.

Emtricitabine/rilpivirine/tenofovir disoproxil fumarate (Complera®)
Expanded FDA-approved or New Indication: • a complete regimen for the treatment of HIV-1 infection in patients weighing at least 35 kg as initial therapy in those with no antiretroviral treatment history and with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy, or to replace a stable antiretroviral regiment in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least 6 months with no treatment failure and no known substitutions associated with resistance to the individual components of Complera.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Elotuzumab (Empliciti®)
Expanded FDA-approved or New Indication: • Combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Etravirine (Intelence®)
Expanded FDA-approved or New Indication: • Treatment of HIV-1 infection in treatment-experienced patients 2 years of age and older.
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.

Eltrombopag olamine (Promacta®)

Expanded FDA-approved or New Indication: • In combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and update policy criteria.

Venetoclx (Venclexta®)
Expanded FDA-approved or New Indication: • In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy[1]
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 (Astagraf® XL)
Expanded FDA-approved or New Indication: • Prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants in adult and pediatric patients.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Drug Safety Monitoring:

Worsening of disease with discontinuation of Gilenya®
ISSUE: Gilenya is one of several medicines approved to treat a form of MS called relapsing MS, which are periods of time when MS symptoms get worse. The medicine was approved in the United States in 2010.

RECOMMENDATION: Health professionals should:

- Inform patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya.
- Patients should be carefully observed for evidence of an exacerbation of their MS and treated appropriately when Gilenya is stopped.
- Patients should be advised to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped.
- Test for new or enhancing lesions by magnetic resonance imaging (MRI) if an increase in disability occurs and begin appropriate treatment as needed.
- Encourage patients to read the patient Medication Guide they receive with their Gilenya prescriptions, which explains the benefits and risks of the medicine.
- Patients who have been instructed to stop Gilenya, should contact your health professional immediately if you experience new or worsened symptoms such as:
- Weakness, trouble using arms or legs, and changes in thinking, eyesight, or balance

Patients should:

Not stop taking the medicine on their own and should speak to their health professional first, as stopping treatment can lead to worsening MS symptoms.

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Update on angiotensin receptor blocker recall

ISSUE:

Based on the FDA analyses of the manufacturing processes, the FDA is now testing all products in the ARB class to determine if they contain NDMA. In some cases, the steps in the synthesis of other ARBs can have similarities to the synthesis of valsartan. These tests will continue until the FDA identifies all products that may contain NDMA in the ARB class, and they are no longer available in the U.S.

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.

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 one lot recall of losartan-hydrochlorothiazide (Lot- JB8912) were communicated via PMG Clinical Pharmacy Alerts and PHP announcements.

Other Formulary Changes:

Drug/Policy Name	Change Summary
Aciphex® (rabeprazole) sprinkle	Remove quantity limit for all lines of business and all strengths of medication
Altreno® (tretinoin) 0.5% lotion	New Dosage Form • Commercial: Formulary, Non-preferred Brand tier • Medicaid: Non-formulary • Medicare : Formulary, Non-preferred Drug tier
Colchicine capsule	Add to formulary and remove quantity limits

	• Commercial: Formulary, Non-preferred Generic tier • Medicaid: Formulary • Medicare : Formulary, Non-preferred Generic tier
Colchicine tablets	Remove quantity limit for all lines of business and all strengths of medication
Daklinza® (daclatasvir) tablets	Medicaid: Remove from formulary All lines of business: Remove quantity limit for all strengths of medication
dronabinol (Marinol®) capsules	Remove quantity limit for all lines of business and all strengths of medication
Durezol® (difluprednate) 0.05% drops	Medicare: Add to Formulary, Non-Preferred Drug tier
Epclusa® (sofosbuvir/velpatasvir) tablets	Remove quantity limit for all lines of business and all strengths of medication
Epinephrine auto-injector (EpiPen®) 0.15 and 0.3 mg	EpiPen® brand and generic products will be on formulary in non-preferred generic tier (No changes to quantity limits)
Auvi-Q® (epinephrine) 0.15 and 0.3 mg auto-injector	Non-formulary for all lines of business (No changes to quantity limits)

Auvi-Q® (epinephrine) 0.1 mg auto-injector	Add to formulary
	• Commercial: Formulary, Non-Preferred Brand, Quantity limit:
	  ○ Age 0-17: 6 doses per year
	  ○ Age 18+: 4 doses per year
	• Medicaid: Formulary, Brand, Quantity limit:
	  ○ Age 0-17: 6 doses per year
	  ○ Age 18+: 4 doses per year
	• Medicare Part D: Formulary, Non-Preferred Drug tier

Symjepi® (epinephrine) 0.3 mg syringe	New Dosage Form. Add to formulary
	• Commercial: Formulary, Preferred Brand, Quantity limit:
	  ○ Age 0-17: 6 doses per year
	  ○ Age 18+: 4 doses per year
	• Medicaid: Formulary, Brand, Quantity limit:
	  ○ Age 0-17: 6 doses per year
	  ○ Age 18+: 4 doses per year
	• Medicare: Formulary, Preferred Brand

Esomeprazole (Nexium®)	Remove quantity limit for all lines of business and all strengths of medication
Gardasil® vaccine	• Commercial/Medicaid: Remove age restrictions

	• Medicare Part D: Retire Prior Authorization
Harvoni® (ledipasvir/sofosbuvir)	Medicaid: Remove from formulary All lines of business: Remove quantity limit for all strengths of medication
Lonsurf® (trifluride/tipiracil)	Remove quantity limit for all lines of business and all strengths of medication
Lyrica CR® (pregabalin) tablets	Commercial/Medicaid: Remove from formulary and add to New Formulations and Medications without established benefit policy
Lyrica® (pregabalin) capsules	Commercial: Retire prior authorization and move to Preferred Brand tier
Minolira ER® (minocycline extended-release) 105 mg and 135 mg tablets	New Dosage Form • Commercial/Medicaid: Non-Formulary, Prior Authorization (add to New Formulations and Medications without established benefit policy) • Medicare: Non-Formulary
Nocdurna® (desmopressin acetate) 27.7 and 55.3 mg rapid dissolving tablets	New Dosage Form and Strength • Commercial: Non-formulary, Prior Authorization (Add to Noctiva policy) • Medicaid/Medicare: Non-formulary
Novolin 70/30 FlexPen® (insulin NPH/insulin regular)	New Dosage Form • Commercial: Non-formulary, prior authorization (Add to short-acting insulin policy) • Medicaid: Non-formulary, but Relion manufacturer to be added to formulary • Medicare: Non-Formulary
Olysio® (simeprevir) capsule	Medicaid: Remove from formulary All lines of business: Remove quantity limit for all strengths of medication
palonosetron 0.25 mg vial	New Dosage Form • Medical benefit for all lines of business
Panzyga® (immune globulin-IFAS human/glycine) 10% vial	New entity. Line extend to other medically infused immune globulin products • Commercial/Medicaid: Medical benefit, Prior Authorization (add to Immune Gamma Globulin policy) • Medicare Part D: Non-formulary • Medicare Part B: Prior Authorization (add to Immune Gamma

	Globulin policy)
Prolensa® (bromfenac sodium) 0.07% drops	Add to formulary: • Commercial: Formulary, Non-Preferred Brand tier • Medicare: Formulary, Non-Preferred Drug tier
Ryclora® (dexchlorpheniramine) 2 mg/5mL syrup	Return of Drug to Market • Commercial: Formulary, Non-preferred generic tier • Medicaid/Medicare: Non-formulary
Siklos® (hydroxyurea) 1000 mg tablet	New Strength • Non-formulary for all lines of business
Sovaldi® (sofosbuvir)	Medicaid: Remove from formulary
Sympazan® (clobazam) 5, 10, and 20 mg film	New Dosage Form • Commercial: Formulary, Non-Preferred Specialty tier, Prior Authorization, Quantity Limit (2 films per day) • Medicaid: Formulary, Specialty tier, Prior Authorization, Quantity Limit (2 films per day) Prior Authorization criteria for Commercial/Medicaid: ○ Prescriber restrictions: Must be prescriber by or in consultation with a neurologist ○ Other Criteria: Documentation of trial and failure, contraindication, or intolerance to generic clobazam and two (2) additional alternative generic formulary antiepileptic agents (e.g., valproic acid, lamotrigine, topiramate, felbamate) • Medicare: Formulary, Specialty, Prior Authorization (Add to Banzel/Onfi policy)
Technivie® (ombitasvir/paritaprevir/ritonavir) tablets	Medicaid: Remove from formulary All lines of business: Remove quantity limit for all strengths of medication
Tiglutik® (riluzole) 50 mg/10mL oral suspension	New Dosage Form • Commercial: Formulary, Non-Preferred Specialty tier • Medicaid/Medicare: Non-Formulary
Viekira®/Viekira XR® (ombitasvir/paritaprevir/ritonavir/dasabuvir)	Medicaid: Remove from formulary All lines of business: Remove quantity limit for all strengths of medication

Vosevi® (sofosbuvir/grazoprevir) tablets	Remove quantity limit for all lines of business and all strengths of medication
Xelpros® (latanoprost) 0.005% emulsion drops	New Dosage Form • Commercial: Formulary, Non-Preferred Brand tier • Medicaid: Non-Formulary • Medicare: Formulary, Non-Preferred Drug tier
Xyosted® (testosterone enanthate) auto-injector	New Dosage Form and Strength • Commercial/Medicaid: Non-formulary, prior authorization (Add to Testosterone Replacement Policy) • Medicare: Non-Formulary
Zepatier® (elbasvir/velpatasvir/ voxilaprevir) tablets	Remove quantity limit for all lines of business and all strengths of medication

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	
Omalizumab (Xolair®) Syringe	New dosage form. Line extend to Xolair. • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Formulary, Preferred Specialty, Prior Authorization
TBO-Filgrastim (Granix®)	New Dosage Form. Line extend to Granix syringe. • Commercial: Formulary, Non-Preferred Specialty • Medicaid: Formulary • Medicare Part D: Formulary, Preferred Specialty
Fatty Acid6/Fish Oil/Gly/P-Lip (Omegaven®) Emulsion	New entity. Line extend to other TPN products. • Non-formulary for all lines of business
Halobetasol Propionate (Bryhali) Lotion	New strength; Line extend to Ultravate 0.05% lotion. • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary
Levothyroxine Sodium (Euthyrox®)	Line extend with Levoxyl, Levo-T, Unithroid. • Commercial/Medicaid: Formulary • Medicare Part D: Formulary, Non-Preferred Generic
Levoleucovorin (Khapzory®) Vial	New combination. Line extend with Fusilev.

	New combination. Line extend to other albumin products. • Medical benefit for all lines of business
Albumin Human-KJDA (Albuminex®) Vial	New combination. Line extend to other albumin products. • Non-Formulary for all lines of business
NEW GENERICS	
Minocycline HCL ER Tab ER 24H	First generic (Solodyn). Line extend. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Listed on New Medications and Formulations with Established Benefit policy • Medicare Part D: Non-Formulary
Azelaic Acid Topical	First generic (Finacea). Line extend as generic. • Commercial: Formulary, Non-Preferred Generic, Step Therapy • Medicaid: Non-Formulary • Medicare Part D: Formulary, Non-Preferred Drug, Step Therapy
Saliva Substitute Combo No.3 (Xerostomia Relief) Spray/Pump	First generic (Aquoral). Line extend. • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary
Vardenafil HCL Tab Rapids	First generic (Staxyn). Line extend as generic. • Non-formulary for all lines of business
Ledipasvir-Sofosbuvir Tablet	First generic (Harvoni). Line extend as generic. • Commercial/Medicare Part D: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (1 tablet per day)
Silodosin Capsule	First generic (Rapaflo). Line extend as generic. • Commercial: Formulary, Non-Preferred Generic, Prior Authorization (BPH Treatment- Rapaflo, Cialis policy) • Medicaid: Formulary, Prior Authorization (BPH Treatment- Rapaflo, Cialis policy) • Medicare Part D: Non-Formulary
Abiraterone Acetate Tablet	First generic (Zytiga). Line extend as specialty. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Preferred Specialty, Prior

	Authorization Added to Oral Anti-Cancer Medications policy

Sofosbuvir-Velpatasvir Tablet	First generic (Epclusa). Line extend as generic.
	• Commercial: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1tablet per day)
	  ○ Added to Hepatitis C - Direct Acting Antivirals policy - Commercial
	• Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (1tablet per day)
	  ○ Added to Hepatitis C - Direct Acting Antivirals - Medicaid
	• Medicare Part D: Formulary, Preferred Specialty, Prior Authorization, Quantity Limit (1tablet per day) - Effective 01/01/2019

Health Plan Clinical Policy Changes:

Policy Name	Change Summary
Enstilar, Taclonex, Taclonex Scalp	Removed quantity limit due to low risk of overutilization. Updated coverage duration to lifetime approval
Eucrisa	Removed quantity limit due to low risk of overutilization
Extavia	Removed quantity limit due to low risk of overutilization
Hepatitis C Direct-acting Antivirals_Medicaid	Policy criteria was updated to
Insomnia Agents	Due to large operational/administrative burden in reviewing prior authorization requests, the criteria related to comorbid diagnoses and failure of non-pharmacologic measures were removed.
Kapvay	Removed quantity limit due to low risk of overutilization
Lidocaine Patch	Removed quantity limit due to low risk of overutilization
Lyrica, Lyrica CR	Lyrica CR will be moved from this policy to the New Medications and Formulations without Established Benefits. Prior Authorization for Lyrica to be retired for Commercial, but will remain for Medicaid due to several uses for below the line indications.
Therapeutic Immunomodulators Policies: • Medically Infused Therapeutic Immunomodulators (TIMs) – Commercial • Medically Infused TIMs – Medicare Part B	Coverage duration was updated to lifetime coverage after initial response to therapy is documented.

• TIMs – Commercial • TIMs - Medicaid	
New Medications and Formulations Without Established Benefit	Lexette® (halobetasol propionate) 0.05% foam , Abilify Mycite®, and Lyrica CR® are being added to the policy
Noctiva	Nocdurna® added to this policy and name will be updated. Both drugs will have the same criteria except that Nocdurna® is approved for adults 18 older whereas Noctiva® is only approved for adults 50 and older.
PCSK9 Inhibitors	A preferred product strategy will be employed (Repatha® preferred). Expert opinion did not feel there were any clinical issues with choosing a preferred product. Criteria for approval were updated so that a patient with either form of familial hypercholesterolemia (FH) would be approved for coverage after failure of statin therapy. To meet cost-positioning contracts, criteria related to statin utilization would be based on provider attestation rather than clinical documentation. Utilization outside of FH will be limited to patients with atherosclerotic cardiovascular disease and will not be covered for primary prevention, consistent with latest guidelines.
Promacta	Removed criterion requiring immunosuppressive therapy for the severe aplastic anemia indication.
Provenge	Medicare Part B will be split out from this policy due to requirement from CMS on coverage. The commercial/Medicaid criteria was updated to reflect current National Comprehensive Cancer Network guidelines.
Provenge_Medicare Part B	Medicare Part B was split away from the Commercial/Medicaid policy as the Centers for Medicare & Medicaid Services (CMS) requires the health plan to follow their National Coverage Determination and not be more restrictive. Therefore, the policy follows the FDA indication only.
Rituxan	Criteria was added for oncologic indications, Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA), and autoimmune hemolytic anemia.
Xifaxan	The diagnostic criteria was removed for the irritable bowel syndrome with diarrhea (IBS-D) indication, as this was deemed unnecessary due to restricting prescribing to gastroenterologists. Total number of treatment courses approved was increased to three for IBS-D consistent with package labeling.

PROVIDENCE
Health Plan