PROVIDENCE Health Plan

# Healthcare Services Medical & Pharmacy Policy Alerts

This is the July 1, 2020 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

Number 249

July 1, 2020

***Effective July 1, 2020:***

**Colorectal Cancer Screening**

***In response to the 2019 US Multi-Society Task Force recommendations (LINK), medical policy criteria will now be applied to colonoscopy screening intervals for average risk patients. The USMSTF recommendations extend the surveillance interval for patients with 1-2 tubular adenomas less than 10 mm from 5-10 years to 7-10 years. In addition, the Task Force made a weak recommendation to extend the surveillance interval for patients with 3-4 tubular adenomas from 3 years to 3-5 years. If a provider would like a copy of the policy or has any additional questions, please email: PHPMedicalPolicyInquiry@providence.org***

**Surgical Site of Service for Total Knee Arthroplasties**

***Beginning 7/1/2020, prior authorization requests for total knee arthroplasties will only be required for inpatient locations (POS 21). Requests for outpatient or ASC locations (POS 22 and 24, respectively) will no longer require prior authorization.***

PROVIDENCE Health Plan

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

# MEDICAL POLICY COMMITTEE

*Effective October 1, 2020*

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| **Blood Counts (Medicare Only) LAB426** | **NEW Policy**<br>• Blood counts will be medically necessary and covered when criteria in National Coverage Determination (NCD) for Blood Counts (190.15) are met and codes are not billed with any diagnosis code taken from the Medicare NCD Coding Policy Manual and Change Report.<br>**Codes/PA:** 11 codes added, none will require PA and will be configured to **deny** when billed with any dx code designated by Medicare.<br>**CMS:**<br>• National Coverage Determination (NCD) for Blood Counts (190.15)<br>• Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM) |
| **Thyroid Testing (Medicare Only) LAB428** | **New Policy**<br>• Thyroid testing will be medically necessary and covered when criteria in National Coverage Determination (NCD) for Thyroid Testing (190.22) are met and codes are billed with any diagnosis code taken from the Medicare NCD Coding Policy Manual and Change Report.<br>• Also instituting a 4/rolling calendar year quantity limit, in accordance with the Medicare NCD linked above.<br>**Codes/PA:** 4 codes added, none will require PA and will be configured to **pay** when billed with any diagnosis code designated by Medicare.<br>**CMS:**<br>• National Coverage Determination (NCD) for Thyroid Testing (190.22)<br>• Medicare NCD Coding Policy Manual and Change Report (ICD-10-CM) |

*Effective July 1, 2020*

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| **Colorectal Cancer Screening MED187** | **Interim Update**<br>Criteria for "subsequent screening colonoscopies" for patients at average risk of colon cancer added to policy. Intent is to control utilization after first screening colonoscopy, which would already have been performed at the discretion of GI doctor based on patient history (no specific criteria). New criteria aim to ensure that subsequent screenings occur within recommendations provided by the U.S. Multi-Societal Task Force (MSTF). The following changes have been made:<br>• Note added – policy does not address diagnostic colonoscopies, initial screening colonoscopies, or screening colonoscopies for individuals at high-risk of colorectal cancer.<br>• Definitions for "average risk" and "family history" given via hyperlink in "Policy Guidelines," based on 2008 American College of Gastroenterology guidelines. |

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| | • Criterion I.B. – Subsequent screening colonoscopies must be performed in alignment with U.S. MSTF guidelines, hyperlinked in "clinical practice guidelines" section.<br>**Codes/PA:** No change to coding or PA |
| **Peroral Endoscopic Myotomy (POEM)**<br><br>**SUR407** | **Annual Update**<br>Liberalize to allow coverage of peroral endoscopic myotomy (POEM) when medical necessity criteria are met. Criteria are focused on guideline recommendations for diagnosis of achalasia. Our clinical subject matter experts, Drs. DeMeester and Dunst have reviewed and approved this updated draft.<br>**Codes/PA:** Unlisted code only, no changes |
| **Gastroesophageal Reflux: Magnetic Esophageal Ring**<br>**SUR229** | • No change to policy criteria. Magnetic sphincter augmentation (MSA) (i.e. LINX Reflux Management System) remains not medically necessary and not covered as a treatment of gastroesophageal reflux (GERD.)<br>• New ECRI review concludes that evidence supporting LINX is "very favorable" on the basis of limited evidence (i.e. 2 systematic reviews of non-randomized studies and 1 RCT with 6 month follow-up.) The first systematic review (Riva et al. 2019) only assessed 35 patients at 1 year follow-up. The second systematic review concluded that MSA appears comparable to laparoscopic fundoplication (Guidozzi et al. 2019) but notes that results may not be generalizable, as meta-analysis was based on results from non-randomized studies with limited follow-up. Investigators concluded that there remains "an urgent need for randomized data directly comparing fundoplication with MSA for the treatment of GERD to truly evaluate the efficacy of this treatment approach."<br>**Codes/PA:** No coding or PA changes<br>**Evidence:** Evidence remains insufficient to support the use of MSA for the treatment of GERD over the current gold-standard treatment, laparoscopic fundoplication. No RCTs comparing the two treatments with long-term follow-up have been published. Consistent but low-quality evidence reports comparable results between the two treatments. ECRI released a new report assessing new safety and efficacy evidence as "very favorable," however, this conclusion is based on non-randomized trials and one RCT with a follow-up of 6 months. No change to Hayes rating of "C" (potential but unproven benefit).<br>**Clinical Practice Guidelines:** In 2019, HERC included magnetic sphincter augmentation (CPT: 43284) among its list of "unproven interventions," citing "insufficient evidence of effectiveness."<br>**CMS:**<br>• Local Coverage Determination (LCD): Non-Covered Services (L35008)<br>• Local Coverage Article: Billing and Coding: Non-Covered Services (A57642) |
| **Celiac Disease Serologic Testing**<br>**LAB404** | **Annual Update**<br>No change to policy criteria or coding configuration. |
| **Gastric Electrical Stimulation**<br>**SUR227** | **Annual Update**<br>No change to policy criteria or coding configuration. |
| **Hyperbaric Oxygen Therapy (All Lines of Business Except CMS)**<br>**MED252** | **Annual Update**<br>No change to policy criteria or coding configuration. |

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| **Hyperbaric Oxygen Therapy (Medicare Only)**<br>**MED420** | **Annual Update**<br>**CMS:**<br>• Continue to reference National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29), and Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797).<br>• Add Local Coverage Article (LCA) Oxygen and Oxygen Equipment - Policy Article (A52514) and LCA: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). |
| **Low-Level and High-Power Laser Therapy**<br>**MED272** | **Annual Update**<br>No change to policy criteria or coding configuration. |
| **Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (All Lines of Business Except Medicare)**<br>**LAB289** | **Annual Update**<br>No change in coverage criteria. Genetic testing of certain genetic alterations in the ALK, *EGFR, BRAF, ROS1, RET, MET and/or HER2* genes and/or testing for PD-L1 protein expression remain medically necessary and covered for guiding targeted therapies for metastatic non-small cell lung cancer (NSCLC). Testing additional mutations in the genes noted above for other genes (e.g. KRAS or PIK3CA) and more comprehensive molecular testing, including expanded gene panels, circulating tumor DNA (ctDNA) tests (e.g. Guardant360), and proteomic and proteogenomic tests remain investigational. Added a ctDNA test (InVisionFirst-Lung) to list of example investigational assays.<br>**Codes/PA:** 12 codes continue to require PA. Added new 07/01/2020 effective code to deny as investigational.<br>• 0179U, Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)<br>LOB<br>**Evidence:** New ECRI and updated Hayes report addressing Guardant360, upgraded from "D2"(insufficient evidence) to "C" (potential but unproven benefit) but clinical utility studies remain lacking in quantity and quality (e.g. retrospective design, small sample size, lack of statistically significant improvement in treatment outcomes). Manufacturer-funded prospective cohort study reported non-inferiority of Guardant360 relative to physician-discretion standard of care tissue genotyping.<br>**Clinical Practice Guidelines:** NCCN recommends against using plasma cell-free/circulating tumor DNA testing (e.g. Guardant360) in lieu of tissue to diagnose NSCLC, but says that it "can be considered in specific clinical circumstances:<br>• If a patient is medically unfit for invasive tissue sampling<br>• In the initial diagnostic setting, if following pathologic confirmation of a NSCLC diagnosis there is insufficient material for molecular analysis, cf/ctDNA should be used only if follow-up tissue-based analysis is planned for all patients in which an oncogenic driver is not identified." |
| **Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (Medicare Only)**<br>**LAB421** | **Annual Update**<br>According to Noridian, our current LCD (L37651) and LCA (A57426) addressing Guardant360 will be archived on May 15th. Noridian announcement includes medical necessity criteria to be used until a future LCD is approved. Policy now includes link to this news alert; links to current LCD and LCA have been removed. Confirmed that referring users to this website this is OK with RCGA. New LCD and LCA addressing a liquid biopsy test (i.e. Inivata) added to coverage criteria (L37899). EGFR testing, next generation sequencing, proteogenomic testing (e.g. OncomineDx) and liquid biopsy remain medically necessary and covered when criteria are met.<br>**Codes/PA:** 12 codes continue to require PA. Added new 07/01/2020 effective code to deny as investigational. |

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| | • 0179U, Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)<br>**CMS:**<br>• National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)<br>• Local Coverage Determination (LCD): MoIDX: Molecular Diagnostic Tests (MDT) (L36256)<br>• Local Coverage Article: Billing and Coding: MoIDX: FDA-Approved EGFR Tests (A54424)<br>• Noridian Healthcare Solutions – Guardant360 and Prospera<br>  ○ *Patient must also meet criteria in NCD for Next Generation Sequencing (NGS) (90.2)*<br>• Local Coverage Article: Billing and Coding: MoIDX: ThermoFisher Oncomine Dx Target Test for Non-Small Cell Lung Cancer (A55888)<br>• Local Coverage Determination (LCD): MoIDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer (L37899)<br>• Local Coverage Article: Billing and Coding: MoIDX: Inivata, InVisionFirst, Liquid Biopsy |
| **Prolotherapy**<br>**MED311** | **Annual Update**<br>No change to policy criteria or coding configuration.<br>**CMS:** No update to non-covered criteria to 2 relevant guidance documents:<br>• National Coverage Determination (NCD) for Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7)<br>• Local Coverage Determination (LCD): Trigger Point Injections (L36859) |
| **Urinary Incontinence Treatments (All Lines of Business Except Medicare)**<br>**SUR359** | **Annual Update**<br>• Add intraurethral valve-pump to the list of investigational services with accompanying 07/01/2020 effective codes.<br>• Add a note to the policy criteria stating that biofeedback for urinary incontinence may be considered medically necessary and the policy need not apply. **LOB:** All lines of business except Medicare<br>**Codes/PA:**<br>• Adding two new codes with quarterly code set update. Both will deny as investigational.<br>  ○ 0596T, Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement<br>  ○ 0597T, Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement |
| **Urinary Incontinence Treatments (Medicare Only)**<br>**SUR440** | **CMS:**<br>• Continue to apply the following Centers for Medicare & Medicaid Services (CMS) guidance<br>  ○ National Coverage Determination (NCD) for Incontinence Control Devices (230.10)<br>  ○ NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18)<br>  ○ NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)<br>  ○ Local Coverage Article (LCA): Posterior Tibial Nerve Stimulation Coverage (A52965)<br>  ○ Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017) |

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| | • Add the following CMS guidance<br>○ Medicare Claims Processing Manual. Chapter 32 - Billing Requirements for Special Services. 40 – Sacral Nerve Stimulation which instructs how to process claims for NCD 230.18, Sacral Nerve Stimulation for Urinary Incontinence<br>○ Local Coverage Determination (LCD): Urological Supplies (L33803)<br>○ LCA: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)<br>○ LCA: Urological Supplies - Policy Article (A52521) |
| **Viscosupplementation (All Lines of Business Except Medicare) MED270** | **Annual Update**<br>No change to criteria<br>**Evidence:** Updated Hayes comparative effectiveness review of hyaluronic acid for knee osteoarthritis to the 2020 review date. Conclusions were unchanged from the previously reported review.<br>**Clinical Practice Guidelines:** Updated the American Academy of Orthopaedic Surgeons clinical practice guideline, Management of Glenohumeral Joint Osteoarthritis Evidence-Based Clinical Practice Guideline to the March 2020 version. The guideline gives a four strong recommendation stating that there is no benefit to the use of hyaluronic acid in the treatment of glenohumeral joint osteoarthritis. |
| **Viscosupplementation (Medicare Only) MED271** | **Annual Update**<br>**CMS:** Continue to reference Wisconsin Physicians Service Insurance Corporation Local Coverage Article A56157 |
| **Walkers (All Lines of Business Except Medicare) DME374 & Walkers (Medicare Only) DME419** | **Annual Update**<br>Separate out Medicare criteria per new formatting. Title has been updated to reflect this. No change to criteria.<br>**CMS:** Criteria reference Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): Walkers (L33791) and Local Coverage Article (LCA): Walkers (A52503). |
| **NanoKnife System: Irreversible Electroporation (IRE) SUR284** | **Interim Update**<br>No change to criteria<br>**Codes/PA:** Adding two new codes with quarterly code set update. These are effective 07/01/2020 and will be denied per policy criteria as investigational.<br>• 0600T, Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous<br>• 0601T, Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open |
| **Allergy Testing (All Lines of Business Except Medicare) LAB105** | **Code Set Update**<br>Add bead-based epitope assay (BBEA) to the list of investigational, non-covered tests. CPT code 0165U was added to the policy in April 2020 and represents this type of assay. An additional code (CPT 0178U) is being added with this update that is also representative of this assay. |

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| | **Codes/PA:** Add CPT 0178U, *Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction*, as investigational, non-covered. |
| **Allergy Testing (CMS Only)**<br>**LAB394** | **Code Set Update**<br>• Remove references to Centers for Medicaid & Medicare Services guidance L36402 and A57473 because they are Wisconsin Physician Services publications and Noridian guidance does exist (Noridian takes precedent).<br>• The Noridian Local Coverage Article: Billing and Coding: Non-Covered Services (A57642) and Local Coverage Article: Additional Information Required for Coverage and Pricing for Category III CPT® Codes (A55681) are scheduled to retire on 06/30/2020, however. Both have been added as placeholders in the policy under the assumption that Noridian will add updated articles to replace both as of 07/01/2020, and the analyst will verify on the morning of 07/01/2020 with any update links as necessary.<br>• Add reference to three National Coverage Determinations:<br>○ National Coverage Determination (NCD) for Food Allergy Testing and Treatment (110.11)<br>○ National Coverage Determination (NCD) for Cytotoxic Food Tests (110.13)<br>○ National Coverage Determination (NCD) for Challenge Ingestion Food Testing (110.12)<br>**Codes/PA:** Add CPT 0178U, *Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction*, as investigational, non-covered. |
| **Clinical Trials and Devices (All Lines of Business Except Medicare)**<br>**MED184** | **Annual/Code Set Update**<br>No recommendation for changes to criteria. Continue to follow Oregon Revised Statutes 743A.192; Washington Administrative Code 284-43-5420, Clinical Trials; and United States Code, 2006 Edition, Supplement 4, Title 42, Sec. 300gg-8 - Coverage for individuals participating in approved clinical trials.<br>**Codes/PA:** Add new 07/01/2020 effective code to deny as investigational.<br>• C9760: Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study |
| **Clinical Trials and IDE Studies (Medicare Only)**<br>**MED185** | **Annual/Code Set Update**<br>Continue to implement the following Centers for Medicare & Medicaid guidance:<br>• Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)<br>• Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services<br>• Medicare Benefit Policy Manual, Chapter 14 - Medical Devices<br>• Medicare Benefit Policy Manual, Chapter 4 – Benefits and Beneficiary Protections<br>**Codes/PA:** Add new 07/01/2020 code. Code will deny if not billed with the appropriate Q0 modifier per email attached<br>• C9760: Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography |

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| | (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study |
| **Genetic Studies and Counseling**<br><br>**GT234** | **Annual Update**<br>Update all Centers for Medicare & Medicaid Services references including the following:<br>• Remove reference to A54438 from criterion XIII.A. Article has been retired.<br>• Remove reference to A55147 from criterion XIII.A. The article is from Wisconsin Physicians Service Insurance Corporation, and there is a Noridian article. Noridian takes precedent.<br>• Add Local Coverage Article: Billing and Coding: MolDX: bioTheranostics Cancer TYPE ID® (A54388) and Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256) to criterion XIII.A.<br>• Remove criterion XIII.C. for DecisionDx-UM (Castle Biosciences, Inc). The policies, *Genetic Testing: Gene Expression Profile Testing for Melanoma* address this test.<br>• Remove criterion XIII.D. for Tissue of Origin® (TOO®) (Cancer Genetics Inc. The policies, *Genetic Testing: Non-Covered Genetic Panel Tests* address this test.<br>**Codes/PA:** Add one new CPT with the 07/01/2020 code set. This code will PA.<br>• 0195U, *KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)* |
| **Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business Except Medicare)**<br>**GT235**<br>**&**<br>**Genetic Testing: Non-Covered Genetic Panel Tests (Medicare Only)**<br>**GT420** | **Code Set Update**<br>**Recommendation:**<br>• Add the Genomind Professional PGx Express panels (includes CORE Anxiety & Depression Report [15 Genes] and/or FULL Mental Health Report [24 Genes]) from Genomind, Inc to the non-covered list of panels.<br>• Removed DecisionDx-Melanoma from the policy, and did not mark as a change since this needed to be corrected urgently as a re-publication to the web. Listing here for informational purposes. The DecisionDx-Melanoma panel test has been reviewed under *Genetic Testing: Genetic Expression Profile Testing for Melanoma (All Lines of Business Except Medicare)* since 2019 and was erroneously still listed here. A contact from the Castle Biosciences laboratory brought this to our attention on 06/19/2020.<br>**Codes/PA:** Two new codes with the 07/01/2020 code set updated. Both are non-covered, no PA required.<br>• 0173U, Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes<br>• 0175U, Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes |
| **Genetic Testing: Pharmacogenetic Testing (All Lines of Business Except Medicare)**<br>**GT306**<br>**&** | **Code Set Update**<br>Added *HTR2C* to the list of investigational and not covered examples in criterion IV. per attached consideration.<br>**Codes/PA:** Add two new codes effective 07/01/2020.<br>• 0177U, *Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status.* This is relevant to *therascreen* PIK3CA RGQ PCR Kit from Qiagen, which is the companion diagnostic for PIQRAY (alpelisib) - NDA 212526. |

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| **Genetic Testing: Pharmacogenetic Testing (Medicare Only)**<br>**GT423** | • 0172U, *Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score*. This is relevant to the Myriad myChoice® CDx companion diagnostic for Zejula® (niraparib) - NDA 208447 and Lynparza (olaparib) - NDA 208558. |
| **Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies**<br><br>**LAB403** | **Annual Update**<br>Add measurement of antibodies to ustekinumab (Stelara) to the investigational criteria, i.e., Anser UST Assay (Prometheus Laboratories, Inc.).<br>**Codes/PA:**<br>• No changes to PA.<br>• Removed CPT 0164U from policy, as this code is not for a test that measures antibodies to immunosuppressive therapies. The code has been placed in the Investigational and Non-covered Medical Technologies policies and remains investigational.<br>**Evidence:**<br>• Added an ECRI report (2018) evaluating the Anser UST Assay (Prometheus Laboratories, Inc.). The assay proposes to optimize treatment of inflammatory bowel disease (IBD) by monitoring serum ustekinumab (Stelara®) and anti-ustekinumab antibody levels in patients receiving this immunotherapy. Only one study evaluating the assay has been published, and it was a conference abstract with 59 participants.<br>• All other ECRI and Hayes reports are up to date with no changes to the summaries. |
| **Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) and (Medicare Only)** | **Interim Update for New Codes**<br>The following codes will deny investigational:<br>• 0594T - Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device. May be used for FITBONE® System and PRECICE UNYTE® Nail. These date back to mid-2000's in the literature and FDA approvals though most data are related to lower limb lengthening, not upper extremity.<br>• 0598T – Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity). May be used for MolecuLight's handheld fluorescence imaging device, the i:X. Limited data on this new device, and did not identify predecessor devices for comparison.<br>• 0599T - Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure). See previous code.<br>• 0602T - Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent. This GFR device from MediBeacon has been designated a combination device and fast-tracked with the FDA. The device will provide continuous real-time GFR measurement in patients with impaired or normal renal function without any need for blood sampling or urine collection. They system is not available for sale as it is not yet FDA-approved.<br>• 0603T - Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours. See previous.<br>• 0604T, 0605T, 0606T: Code is for a Home Optical Coherence Tomography device for the diagnosis of neovascular retina diseases. The device has not been granted FDA approval and therefore should be denied as investigational. |

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| | • 0607T, 0608T: The Cardio-Pulmonary Stethoscope (CPS) uses radiofrequency signals to measure changes in the amount of water present in the lungs via a "chest patch" sensor and can wirelessly transmit the data to a mobile device for remote patient monitoring. No evidence assessing this device was identified and it is unclear if it has received FDA approval and therefore should be denied as investigational.<br>• 0609T, 0610T, 0611T, 0612T: Codes are used to report the determination and localization of discogenic pain using magnetic resonance spectroscopy (MRS). This new technology uses existing MR technology and a proprietary software program, the NOCISCAN™ Suite, to conduct MRS exams of lumbar disc. Evidence supporting safety and efficacy is insufficient and therefore should be denied as investigational.<br>• 0613T: Code is for percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist. Code may be used to report the InterAtrial Shunt device, which has not been granted FDA approval and therefore should be denied as investigational.<br>• 0614T: Code is for the removal and replacement of substernal implantable defibrillator pulse generator. Code may be used to report the use of extravascular implantable cardioverter defibrillator (EV ICD) system, which has not been granted FDA approval and therefore should be denied as investigational.<br>• 0615T: Code is for eye-movement analysis without spatial calibration, with interpretation and report. Code may be used to report the EyeBOX exam, which was granted marketing authority by the FDA in December 2018. Due to limited research and unimpressive trial results, we recommend that this code be denied as investigational.<br>• 0616T, 0617T, 0618T: Codes are for insertion of iris prosthesis, including suture fixation and repair or removal of iris. Code may be used for the CustomFlex Artificial Iris, approved in 2018. Little research has been conducted on the CustomFlex, and Hayes found that there is insufficient evidence to assess safety and/or impact of the product. Therefore, CustomFlex Artificial Iris should be denied as investigational.<br>• 0164U, Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results<br>• 0174U, Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents<br>• 0176U, Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)<br>• C9759, Transcatheter intraoperative blood vessel microinfusion(s) (e. g. , intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed<br>• C9764, Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed<br>• C9765, Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed<br>• C9766, Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed<br>• C9767, Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed |

PROVIDENCE Health Plan

## VENDOR UPDATES

*Updates to AIM Advanced Imaging Clinical Appropriateness Guideline*

Effective for dates of service on and after **August 16, 2020**, the following updates will apply to the AIM Advanced Imaging of the Chest and AIM Oncologic Imaging Clinical Appropriateness Guidelines.

**Advanced Imaging of the Chest updates by section:**
Tumor or Neoplasm

- Allowed follow up of nodules less than 6 mm in size seen on incomplete thoracic CT, in alignment with follow up recommendations for nodules of the same size seen on complete thoracic CT
- Added new criteria for which follow up is indicated for mediastinal and hilar lymphadenopathy
- Separated mediastinal/hilar mass from lymphadenopathy, which now has its own entry

Parenchymal Lung Disease – not otherwise specified

- Removed as it is covered elsewhere in the document (parenchymal disease in Occupational lung diseases and pleural disease in Other thoracic mass lesions)

Interstitial lung disease (ILD), non-occupational including idiopathic pulmonary fibrosis (IPF)

- Defined criteria warranting advanced imaging for both diagnosis and management

Occupational lung disease (Adult only)

- Moved parenchymal component of asbestosis into this indication
- Added Berylliosis

Chest Wall and Diaphragmatic Conditions

- Removed screening indication for implant rupture due to lack of evidence indicating that outcomes are improved
- Limited evaluation of clinically suspected rupture to patients with silicone implants

**Oncologic Imaging updates by section:**
MRI breast

- New indication for BIA-ALCL
- New indication for pathologic nipple discharge

- Further define the population of patients most likely to benefit from preoperative MRI

Breast cancer screening

- Added new high risk genetic mutations appropriate for annual breast MRI screening

Lung cancer screening

- Added asbestos-related lung disease as a risk factor

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

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## Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting June 5, 2020

Go-Live Date: Saturday, August 01, 2020, unless otherwise noted

### Special Announcement: Opioid Medications for Commercial Patients

Effective September 1st 2020 for our Commercial patients, authorization will be required for patients that have cumulative opioid doses exceeding a daily morphine milligram equivalent (MME) of 90. Please note, this will **not** affect patients that are currently exceeding this threshold in order to provide continuity of care.

PROVIDENCE Health Plan

## Table of Contents:



## New Drugs and Combinations:

| **Trastuzumab Biosimilars (Herzuma, Ontruzant, Trazimera)** |
|---|
| **Indication:**<br>• Adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature breast cancer:<br>  ○ as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel<br>  ○ as part of a treatment regimen with docetaxel and carboplatin<br>  ○ as a single agent following multi-modality anthracycline based therapy.<br>• Metastatic Breast Cancer<br>  ○ In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer<br>  ○ As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.<br>• Metastatic Gastric Cancer<br>  ○ In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.<br><br>**Formulary Alternatives:** trastuzumab (Herceptin®), bevacizumab (Avastin®), pegfilgrastim (Neulasta®), or rituximab (Rituxan®) |
| • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br><br>**Prior Authorization Criteria:**<br>• Commercial/Medicaid/Medicare Part B: Added to Injectable anti-cancer agents policy |

PROVIDENCE Health Plan

**Bevacizumab-bvzr (Zirabev)**

**Indication:**

- In combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC).
- In combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab product-containing regimen.
- In combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer (NSCLC).
- Treatment of recurrent glioblastoma (GBM) in adults.
- In combination with interferon alfa, is indicated for the treatment of metastatic renal cell carcinoma (mRCC)
- In combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer

**Formulary Alternatives:** Avastin

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

**Prior Authorization Criteria:**

- Commercial/Medicaid/Medicare Part B: Added to Injectable anti-cancer agents policy

**Rituximab-pvvr (Ruxience)**

**Indication:**

- Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent.
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens.
- In combination with fludarabine and cyclophosphamide (FC), is indicated for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.

- In combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

**Formulary Alternatives:** Rituxan

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

**Prior Authorization Criteria:**

- Commercial/Medicaid/Medicare Part B: Add to Rituximab policy

**Pegfilgrastim-bmez (Ziextenzo)**

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

**Formulary Alternatives:** Neulasta

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

**Bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) Tablet**

**Indication:** Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

**Formulary Alternatives:** ezetimibe, evolocumab (Repatha®), alirocumab (Praluent®)

- Commercial: Non-formulary, Prior Authorization
- Medicaid: Non-formulary, Prior Authorization
- Medicare Part D: Formulary, Tier 4, Prior Authorization

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

| | |
|---|---|
| PA PROGRAM NAME | Nexletol/Nexlizet |
| MEDICATION NAME | Nexletol™ and Nexlizet™ |
| COVERED USES | All FDA-approved indications not otherwise excluded from the benefit. |
| EXCLUSION CRITERIA | N/A |

| | |
|---|---|
| REQUIRED MEDICAL INFORMATION | Fasting LDL-C<br>For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. |
| AGE RESTRICTIONS | Approved for adults 18 years of age and older |
| PRESCRIBER RESTRICTIONS | Must be prescribed by or in consultation with a cardiologist |
| COVERAGE DURATION | Initial authorization will be approved for 6 months and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication |
| OTHER CRITERIA | For Initial Authorization:<br>1. Confirmed diagnosis of clinical ASCVD or Familial Hypercholesterolemia<br>2. Fasting LDL-C ≥70 mg/dL despite treatment with therapies below<br>3. One of the following:<br>a. Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily<br>b. Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin 5 mg daily) and any other statin at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations in creatinine kinase) that decrease or resolve after discontinuation of therapy with a statin.<br>4. Current use of ezetimibe 10 mg daily for at least 3 months, or documented intolerance/contraindication to its use.<br>5. Documentation of current use of a formulary PCSK-9 inhibitor (e.g., Repatha®) or intolerance/contraindication to its use.<br><br>Reauthorization requires documented response to therapy, as defined by a reduction in fasting LDL-C |

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

| | |
|---|---|
| PA PROGRAM NAME | Nexletol/Nexlizet |
| MEDICATION NAME | Nexletol™ and Nexlizet™ |
| PA INDICATION INDICATOR | 1 - All FDA-Approved Indications |

| | |
|---|---|
| OFF-LABEL USES | N/A |
| EXCLUSION CRITERIA | N/A |
| REQUIRED MEDICAL INFORMATION | For Initial Authorization:<br>1. Confirmed diagnosis of clinical ASCVD or Familial Hypercholesterolemia<br>2. Fasting LDL-C ≥70 mg/dL despite treatment with therapies below<br>3. One of the following:<br>a. Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily<br>b. Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin 5 mg daily) and any other statin at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations in creatinine kinase) that decrease or resolve after discontinuation of therapy with a statin.<br>4. Documentation of current use of a formulary PCSK-9 inhibitor (e.g., Repatha®) or intolerance/contraindication to its use.<br><br>Reauthorization requires documented response to therapy, as defined by a reduction in fasting LDL-C |
| AGE RESTRICTIONS | N/A |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, a cardiologist |
| COVERAGE DURATION | Initial authorization will be approved for 6 months and reauthorization will be approved until no longer eligible with the plan |
| OTHER CRITERIA | N/A |

| **Isatuximab-irfc (Sarclisa) Vial** |
|---|
| **Indication:** Isatuximab-irfc is indicated, in 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<br><br>**Formulary Alternatives:** N/A |
| • Commercial: Medical Benefit, Prior Authorization<br>• Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization |

**Prior Authorization Criteria:**

- Added to Injectable Anti-Cancer Medications policy

**Cenobamate (Xcopri) Tablet and Tab DS PK**

**Indication:** Treatment of partial-onset seizures in adult patients.

**Formulary Alternatives:** Aptiom, Banzel, clobazam, Fycompa, Oxtellar ER, pregabalin, topiramate ER, vigabatrin, Vimpat

- Commercial: Formulary, Tier 4, Step Therapy
- Medicaid: Formulary, Step Therapy
- Medicare Part D: Formulary, Tier 5, Prior Authorization

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

- Added to the Antiepileptic Medications Step Therapy Policy

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

- Added to the Antiepileptic Agents Prior Authorization Program

**Selumetinib sulfate/vitamin e tpgs (Koselugo) Capsule**

**Indication:** Treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

**Formulary Alternatives:** N/A

- Commercial: Formulary, Tier 5, Prior Authorization
- Medicaid: Formulary, Specialty, Prior Authorization
- Medicare Part D: Formulary, Tier 5, Prior Authorization

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

| | |
|---|---|
| PA PROGRAM NAME | Koselugo |
| MEDICATION NAME | Selumetinib capsule |
| COVERED USES | All FDA-approved indications not otherwise excluded from the benefit. Add additional off-label/compendia uses if needed |
| EXCLUSION CRITERIA | N/A |

| | |
|---|---|
| REQUIRED MEDICAL INFORMATION | For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. |
| AGE RESTRICTIONS | Approved for ages 2 years and older |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with an oncologist, neuro-oncologist, neurology, neurosurgery or a provider at a neurofibromatosis center. |
| COVERAGE DURATION | Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication. |
| OTHER CRITERIA | For initial authorization:<br>1. Documentation of inoperable neurofibromatosis type 1 (NF1) plexiform neurofibroma (PN) (defined as one that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN)<br>2. Patient has significant morbidity related to the target PN (i.e. motor dysfunction, pain, airway dysfunction, visual impairment, and bladder/bowel dysfunction)<br><br>For reauthorization: Documentation of adequate response to the medication must be provided. |

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

| | |
|---|---|
| PA PROGRAM NAME | Koselugo |
| MEDICATION NAME | Selumetinib capsule |
| PA INDICATION INDICATOR | 1 - All FDA-Approved Indications |
| OFF-LABEL USES | N/A |
| EXCLUSION CRITERIA | N/A |
| REQUIRED MEDICAL INFORMATION | For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. |
| AGE RESTRICTIONS | Approved for ages 2 years and older |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with an oncologist, neuro-oncologist, neurology, neurosurgery or a provider at a neurofibromatosis center. |

| | |
|---|---|
| COVERAGE DURATION | Authorization will be approved until no longer eligible with the plan |
| OTHER CRITERIA | For initial authorization:<br>1. Documentation of inoperable NF1 plexiform neurofibroma (PN) (defined as one that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN)<br>2. Patient has significant morbidity related to the target PN (i.e. motor dysfunction, pain, airway dysfunction, visual impairment, and bladder/bowel dysfunction) |

**Tazemetostat hydrobromide (Tazverik) Tablet**

**Indication:** Treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection

**Formulary Alternatives:** N/A

- Commercial: Formulary, Tier 6, Prior Authorization
- Medicaid: Formulary, Specialty, Prior Authorization
- Medicare Part D: Formulary, Tier 5, Prior Authorization

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

- Added to Oral Anti-Cancer Medications policy

**Prior Authorization Criteria for Medicare:**

- Added to Anti-Cancer Agents Prior Authorization Program

**Teprotumumab-trbw (Tepezza) Vial**

**Indication:** Thyroid eye disease

**Formulary Alternatives:** N/A

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

PROVIDENCE Health Plan

**Prior Authorization Criteria:**

| | |
|---|---|
| PA PROGRAM NAME | Tepezza |
| MEDICATION NAME | Tepezza |
| COVERED USES | All FDA approved indications not otherwise excluded from the benefit |
| EXCLUSION CRITERIA | N/A |
| REQUIRED MEDICAL INFORMATION | For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. |
| AGE RESTRICTIONS | N/A |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, an ophthalmologist |
| COVERAGE DURATION | Authorization will be approved for six (6) months for a total of eight (8) infusions |
| OTHER CRITERIA | All of the following criteria must be met:<br>1. Confirmed diagnosis of moderate-to-severe thyroid eye disease/Grave's Orbitopathy, as defined by one (1) of the following:<br>a. Sight-threatening disease (e.g., dysthyroid optic neuropathy, corneal breakdown)<br>b. Eye disease significantly impacts quality of life and at least two of the following:<br>i. Lid retraction of at least 2 mm, marginal reflex distance-1 (MRD1) greater than 4, or presence of lagophthalmos<br>ii. Moderate or severe soft-tissue involvement (e.g. swelling or redness of the eyes)<br>iii. Inconstant diplopia (*i.e.,* diplopia at extremes of gaze) or constant diplopia (*i.e.,* continuous diplopia in primary or reading position)<br>2. Documentation of active disease, defined as a Clinical Activity Score of at least three (3)<br>3. Laboratory evidence of euthyroid state<br>4. Inadequate response to at least two weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) or inability to use this therapy (e.g., evidence of recent viral hepatitis, significant hepatic dysfunction, severe cardiovascular morbidity or psychiatric disorders)<br><br>Reauthorization is not considered medically necessary and will not be covered. |

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| **Eptinezumab-jjmr (Vyepti) Vial** |
|---|
| **Indication:** Preventive treatment of migraine in adults.<br><br>**Formulary Alternatives:** topiramate, valproate, divalproex, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, Aimovig®, Ajovy®, Emgality® |
| • Commercial / Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization<br><br>**Prior Authorization Criteria:**<br>• Added to Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis policy as non-preferred agent |

| **Rimegepant sulfate (Nurtec ODT) Tab Rapdis** |
|---|
| **Indication:** For the acute treatment of migraine with or without aura in adults. Not indicated for the preventive treatment of migraine.<br><br>**Formulary Alternatives:** triptans, ergot alkaloids, Ubrelvy®, Reyvow® |
| • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (8 tablets per 30 days)<br>• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (8 tablets per 30 days)<br>• Medicare Part D: Non-Formulary, Quantity Limit (15 tablets per 30 days)<br><br>**Prior Authorization Criteria:**<br>• Added to Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Acute Migraine Treatment policy |

| **Afamelanotide acetate (Scenesse) Implant** |
|---|
| **Indication:** To increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).<br><br>**Formulary Alternatives:** N/A |
| • Commercial / Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization<br><br>**Prior Authorization Criteria:** |

PROVIDENCE Health Plan

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|---|---|
| PA PROGRAM NAME | Scenesse |
| MEDICATION NAME | Afamelanotide acetate implant (Scenesse®) |
| COVERED USES | All FDA-approved indications not otherwise excluded from the benefit. |
| EXCLUSION CRITERIA | 1. Current Bowen's disease, basal cell carcinoma, or squamous cell carcinoma<br>2. Personal history of melanoma or dysplastic nevus syndrome<br>3. Erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) with significant hepatic involvement |
| REQUIRED MEDICAL INFORMATION | For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. |
| AGE RESTRICTIONS | May be approved for members 18 years of age or older |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with a dermatologist or porphyria specialist |
| COVERAGE DURATION | Initial and reauthorization will be approved for 6 months for 3 implants (Medical justification is required for requests beyond 3 implants for seasonal coverage) |
| OTHER CRITERIA | **Initial authorization:**<br>1. Confirmed diagnosis of erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) by one of the following:<br>a. Gene sequencing showing an FECH, CLPX, or ALAS2 mutation<br>b. Elevated total erythrocyte protoporphyrin greater than 80 mcg/dL<br>c. Erythrocyte fractionation shows ≥ 50% metal-free vs. zinc protoporphyrin<br>2. Documentation of characteristic symptoms of EPP/XLP phototoxicity (e.g. intolerance to light with symptoms including itching, burning, pain, erythema, or scarring of the skin on contact with sunlight)<br>3. Documentation that sun avoidance and use of sunscreen and protective clothing have proven inadequate in controlling EPP/ XLP -associated painful skin reactions<br>4. Documentation that the condition is having a significant impact on quality of life (QOL)<br><br>For reauthorization:<br>1. Documentation of a positive response to therapy by of one of the following:<br>a. Decreased severity and number of phototoxic reactions<br>b. Increased duration of sun exposure<br>c. Increased quality of life<br>2. For request of more than 3 implants per year: medical justification must be provided addressing why member needs coverage for more than 6 months out of the year |

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|---|---|
| | (afamelanotide is typically given during periods of high sunlight exposure, e.g. from spring to autumn) |

## New Drug Strengths and Formulations: See Other Formulary Changes

## Other Formulary Changes:

| Drug Name | Action Taken | Policy Name |
|---|---|---|
| **Tazarotene (Arazlo) Lotion** | New Dosage Form (Lotion) and Strength (0.045%):<br>• Non-Formulary for all lines of business | N/A |
| **Moxifloxacin 0.2% drops (generic for Moxeza®)** | Remove from Commercial formulary | N/A |
| **Metformin hcl (Riomet ER) Sus ER Rec** | New Dosage Form:<br>• Non-Formulary for all lines of business | N/A |
| **Darunavir/cob/emtri/tenofalaf (Symtuza) Tablet** | Add to Commercial and Medicaid formulary:<br>• Commercial: Formulary, Tier 6<br>• Medicaid: Formulary, Specialty<br>• Medicare Part D: Formulary, Tier 5 | N/A |
| **Diroximel fumarate (Vumerity) Capsule DR** | • Commercial: Formulary, Tier 5<br>• Medicaid: Formulary, Specialty<br>• Medicare Part D: Formulary, Tier 5 | N/A |
| **Midostaurin (Rydapt) Capsule** | Remove quantity limit from Commercial and Medicaid. | • Commercial/Medicaid: Oral ANTI-cancer Medications<br>• Medicare Part D: N/A |
| **Oxycodone hcl (Oxycontin)** | Removed from Medicaid formulary:<br>Non-Formulary, Prior Authorization, Quantity Limit (90 MME per day) | Long Acting Opioids |
| **Ubrogepant (Ubrelvy) Tablet** | • Commercial/Medicaid: Increase Quantity Limit from eight (8) tablets per 30 days to ten (10) tablets per 30 days | Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists For Acute Migraine Treatment |

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| Drug Name | Action Taken | Policy Name |
|---|---|---|
| **Dalfampridine (Ampyra) Tablet ER 12H** | Remove prior authorization for all lines of business and change tier:<br>• Commercial:<br>  ○ OR: Formulary, **change** from Tier 6 to Tier 2, Quantity Limit (2 tablets per day)<br>  ○ WA: Formulary, **change** from Tier 6 to Tier 4, Quantity Limit (2 tablets per day)<br>• Medicaid – Remove from specialty: Formulary, Quantity Limit (2 tablets per day)<br>• Medicare Part D: Formulary, Tier 3, Quantity Limit (2 tablets per day)<br>Effective 7/1/2020 | Ampyra |
| **Empagliflozin/linagliptin/metformin hcl (Trijardy XR) Tab BP 24H** | New combination:<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: DPP-4 Inhibitors<br>• Medicare Part D: N/A |
| **Elexacaftor/tezacaftor/ivacaftor (Trikafta) Tablet SEQ** | • Commercial: Change from Tier 6 to Tier 5 | CFTR Modulators |
| **Cetirizine hcl (Zerviate) Droperette** | New Route (ophthalmic), Dosage form (droperette), and strength (0.24%);<br>• Commercial: Non-Formulary, Prior Authorization<br>• Medicaid/Medicare Part D: Non-Formulary | • Commercial: Bepreve, Lastacaft, Pazeo<br>• Medicaid/Medicare Part D: N/A |
| **Hydrocodone ER (Zohydro) Capsule** | Add generic for Zohydro® (hydrocodone ER) to Medicare Part D.<br>• Medicare Part D: Formulary, Tier 4, Prior Authorization | Long Acting Opioids |
| **Famotidine Susp** | Add to Medicaid Formulary | N/A |
| **Insulin Lispro/Insulin Lispro Mix 75-25 KWKPN** | Converted to Biologic; Non-formulary for all lines of business | N/A |

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

**INFORMATIONAL ONLY**

| **NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS** |
|---|

PROVIDENCE Health Plan

| Drug Name | Action Taken | Policy Name |
|---|---|---|
| **Cysteamine bitartrate (Procysbi) Granule PKT** | New Strength (300mg) and Dosage Form (Granule packet). Line extend with Procysbi Capsule;<br>• Commercial: Formulary, Tier 6, Prior Authorization<br>• Medicaid: Formulary, Specialty, Prior Authorization<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization<br>Effective 6/1/2020 | • Procysbi |
| **Palbociclib (Ibrance) Tablet** | New dosage form; Line extend with Ibrance capsule;<br>• Commercial: Formulary, Tier 6, Prior Authorization<br>• Medicaid: Formulary, Specialty, Prior Authorization<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization | • Commercial/Medicaid: Oral Anti-Cancer Medications<br>• Medicare Part D: Anti-Cancer Agents |
| **Meloxicam (Anjeso) Vial** | New Route (IV), Dosage Form (vial), and Strength (30mg/ml). Line extend as medical;<br>• Commercial/Medicaid: Medical Benefit<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit | N/A |
| **Eltrombopag olamine (Promacta) Powd Pack** | New Strength (25mg suspension packet). Line extend with Promacta 12.5mg susp packet;<br>• Commercial: Formulary, Tier 6, Prior Authorization;<br>• Medicaid: Formulary, Prior Authorization;<br>• Medicare: Formulary, Tier 5, Prior Authorization | Promacta |
| **Fremanezumab-vfrm (Ajovy) Auto Injct** | New Dosage Form (Autoinject). Line extend with Ajovy syringe;<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization;<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists<br>• Medicare Part D: N/A |
| **Immune globulin,gamma (igg)/proline/iga 0 to 50 mcg/ml (Hizentra) Syringe** | New Dosage Form (syringe). Line extend with Hizentra Vial;<br>• Commercial: Formulary, Tier 6, Prior Authorization<br>• Medicaid: Formulary, Specialty, Prior Authorization<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Immune Gamma Globulin (IGG)<br>• Medicare Part D: N/A |
| **Romidepsin Vial** | New Dosage Form (vial); New Strength (27.5mg/5.5ml). Line extend with Romidepsin kit;<br>• Commercial/Medicaid/Medicare Part B: Medical Benefit; | N/A |

| | | |
|---|---|---|
| | • Medicare Part D: Non-formulary | |
| **Prenatal vitamins no.165/ferrous fumarate/folic ac (Azeschew) Tab Chew** | New Combination; Line extend with prenatal vitamins with folic acid of 1mg;<br>• Non-Formulary for all lines of business | N/A |

## New Generics:

| Drug Name | Action Taken | Policy Name |
|---|---|---|
| **Cysteamine bitartrate (Procysbi) Granule PKT** | New Strength (300mg) and Dosage Form (Granule packet). Line extend with Procysbi Capsule;<br>• Commercial: Formulary, Tier 6, Prior Authorization<br>• Medicaid: Formulary, Specialty, Prior Authorization<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization<br>Effective 6/1/2020 | • Procysbi |
| **Palbociclib (Ibrance) Tablet** | New dosage form; Line extend with Ibrance capsule;<br>• Commercial: Formulary, Tier 6, Prior Authorization<br>• Medicaid: Formulary, Specialty, Prior Authorization<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization | • Commercial/Medicaid: Oral Anti-Cancer Medications<br>• Medicare Part D: Anti-Cancer Agents |
| **Meloxicam (Anjeso) Vial** | New Route (IV), Dosage Form (vial), and Strength (30mg/ml). Line extend as medical;<br>• Commercial/Medicaid: Medical Benefit<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit | N/A |
| **Eltrombopag olamine (Promacta) Powd Pack** | New Strength (25mg suspension packet). Line extend with Promacta 12.5mg susp packet;<br>• Commercial: Formulary, Tier 6, Prior Authorization;<br>• Medicaid: Formulary, Prior Authorization;<br>• Medicare: Formulary, Tier 5, Prior Authorization | Promacta |
| **Fremanezumab-vfrm (Ajovy) Auto Injct** | New Dosage Form (Autoinject). Line extend with Ajovy syringe; | • Commercial/Medicaid: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists |

| | | |
|---|---|---|
| | • Commercial/Medicaid: Non-Formulary, Prior Authorization;<br>• Medicare Part D: Non-Formulary | • Medicare Part D: N/A |
| **Immune globulin,gamma (igg)/proline/iga 0 to 50 mcg/ml (Hizentra) Syringe** | New Dosage Form (syringe). Line extend with Hizentra Vial;<br>• Commercial: Formulary, Tier 6, Prior Authorization<br>• Medicaid: Formulary, Specialty, Prior Authorization<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Immune Gamma Globulin (IGG)<br>• Medicare Part D: N/A |
| **Romidepsin Vial** | New Dosage Form (vial); New Strength (27.5mg/5.5ml). Line extend with Romidepsin kit;<br>• Commercial/Medicaid/Medicare Part B: Medical Benefit;<br>• Medicare Part D: Non-formulary | N/A |
| **Prenatal vitamins no.165/ferrous fumarate/folic ac (Azeschew) Tab Chew** | New Combination; Line extend with prenatal vitamins with folic acid of 1mg;<br>• Non-Formulary for all lines of business | N/A |

## Clinical Policy Changes:

| PHARMACY CLINICAL POLICIES – MAJOR CHANGES | |
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| **Policy Name** | **Summary of Change** |
| **Adakveo** | After P&T discussion in April 2020, the policy was updated by chair vote to further clarify an adequate trial of hydroxyurea. |
| **Alpha-1 Proteinase Inhibitors** | The policy was updated to align with current treatment guidelines, including forced expiratory volume in one second (FEV1) range for emphysema and phenotype for alpha 1-antitrypsin (AAT) deficiency. |
| **Antiepileptic Medications** | New drug Xcopri added to policy. Additionally, added levetiracetam or clobazam as preferred generic options for step therapy. |
| **Aranesp, Epogen, Procrit, Retacrit - Medicare Part B** | The policy for Medicare Part B was split out from other lines of business, as the health plan is required to follow National Coverage Determination (NCD) criteria from the Centers for Medicare & Medicaid Services (CMS). Policy criteria related to Erythropoiesis stimulating agent (ESA) use in oncologic conditions were updated to align with the NCD. |
| **Bepreve, Lastacaft, Pazeo** | Added Zerviate to commercial policy and criteria. |

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| **Botulinum Toxin** | Position statement was updated to included information used to create migraine prophylaxis criteria. Clarified that combination therapy with CGRPs is considered investigational and is not covered. |
| **Buprenorphine** | Policy wording changed from requiring that these products be given as part of an "evidence based treatment program" to requiring that they are used along with counseling and/or psychosocial support. |
| **Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists For Acute Migraine Treatment** | The quantity limit was increased from eight (8) tablets per 30 days to ten (10) tablets per 30 days due to the package size available at retail pharmacies. |
| **Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis** | The prescriber restrictions were updated to reflect that a specialist is not required for the diagnosis of episodic migraine prophylaxis. In addition, topiramate was added as a prerequisite option for cluster headaches. |
| **CFTR Modulators** | Reauthorization criteria was updated to allow for reduced respiratory symptoms. |
| **Daliresp** | Removed asthma without COPD from exclusion criteria and extended initial authorization duration from 3 months to 12 months. |
| **DPP-4 Inhibitors** | Adding new combination formulation to policy. |
| **Esbriet, Ofev** | For Ofev, add new FDA-approved indication of chronic fibrosing ILD with progressive phenotype with specific criteria. |
| **Fentanyl Citrate** | Added Abstral, Fentora, Lazanda, Subsys to fentanyl citrate policy. Updated policy criteria to require one short-acting narcotic in addition to inadequate control with long acting-narcotics. In addition, Abstral, Lazanda, Fentora, and Subsys will continue to require a trial of generic fentanyl citrate lozenge/troche. |
| **Infertility and Related Medications** | Policy updated to simplify criteria. |
| **Infusion Therapy Site of Care** | There are new medications that have been added to the site of care program (intravenous immune gamma globulin, Crysvita, and Enzyme Replacement Therapy (e.g., Nagalzyme®, Elelysio®). In addition, some criteria were updated for clarification. |
| **Ketorolac Intramuscular Injection** | Updated policy to cover all FDA approved indications and off-label use migraine. Due to safety of this medication, an age restriction, policy criteria addressing contraindications per the package insert, and criteria addressing 5-day max use were added. |
| **Krystexxa** | Trial and failure of Febuxostat (Uloric) was removed from criteria due to the FDA report of increased heart related death and death from all causes. |
| **Long Acting Opioids** | Added palliative care with a terminal diagnosis, sickle cell disease or severe burns under the cancer pain criteria. Added requirement of non-opioid therapy for new starts for chronic pain. Added migraine and headaches as an exclusion. Clarified reauthorization criteria. |

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| **Long-Acting Opioids – Medicaid** | Policy updated to align with commercial long-acting opioid policy and OHA opioid requirements. |
| **Maximum Allowable Opioid Dose – Commercial** | Added palliative care with a terminal diagnosis, sickle cell disease or severe burns under the cancer pain section. Clarified reauthorization criteria and criteria for dose increases. Please note, a cumulative MME 90 edit will be put into effect for the commercial line of business effective 9/1/2020 |
| **Maximum Allowable Opioid Dose – Medicaid** | Minor updates to policy to align with OHA policies for opioids. Further clarification of funded and unfunded conditions. Added palliative care with a terminal diagnosis, sickle cell disease or severe burns under the cancer pain section. |
| **Medicaid Intranasal Medications** | Removed Veramyst from the policy, as this drug has been discontinued. |
| **Medically Infused Therapeutic Immunomodulators (TIMs) - Medicare Part B** | Policy was updated to clearly reflect that the preferred agents (Remicade, Simponi aria) require prior authorization for Medicare Part B (effective 9/1/20). |
| **Miacalcin** | Policy criteria for osteoporosis was updated to align with other therapies (such as Tymlos, Forteo) |
| **Nucynta ER** | Updated trial and failure criteria to allow pregabalin for the treatment of diabetic peripheral neuropathy. |
| **Oxbryta** | After P&T discussion in April 2020, the policy was updated by chair vote to further clarify an adequate trial of hydroxyurea. In addition, the reauthorization criteria was updated to include specific hemoglobin levels required. |
| **Oxymorphone (Opana)** | Added criteria for cancer diagnosis requiring documentation of active cancer pain. |
| **Reblozyl** | Policy was updated to reflect the new indication for patients with anemia due to myelodysplastic syndrome (MDS) |
| **The following policies were retired**<br>• Ampyra: Effective 07/01/2020<br>• Abstral, Fentora, Lazanda, Subsys<br>  ○ Combined with Fentanyl Citrate policy | |

## New Indications:

1. **TRULICITY®**
   DULAGLUTIDE
   **New indication approved 02/21/2020:**
   - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
   - **To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors**

Limitations of Use:
- Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy.
- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- Not for patients with pre-existing severe gastrointestinal disease

**DECISION:** Inform prescribers via MD alert. The GLP-1 Agonist Commercial and Medicaid policies position statements have been updated to include the new indication; therefore, no changes to the Commercial/Medicaid criteria coverage or position statement are warranted.

2. **NERLYNX®**
NERATINIB MALEATE
**New indication approved 02/25/2020:**
- **As a single agent, for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab based therapy.**
- **In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.**

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

3. **SYMTUZA®**
COBICISTAT; DARUNAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE
**New indication approved 03/02/2020:**
SYMTUZA® is indicated for as a complete regimen for the treatment of HIV-1 infection in adults **and pediatric patients weighing at least 40 kg**:
- who have no prior antiretroviral treatment history or
- who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir

**DECISION:** Inform prescribers via MD alert.

4. **OFEV®**
NINTEDANIB ESYLATE
**New indication approved 03/09/2020:**
- Treatment of idiopathic pulmonary fibrosis (IPF).
- **Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.**
- Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

**DECISION:** Inform prescribers via MD alert. The Ofev Commercial/Medicaid policy was updated in March 2020 to include the new indication; therefore, no changes to the Commercial/Medicaid criteria coverage are warranted.

5. **YERVOY®**

**New indication approved 03/10/2020 (plus prior indications):**

- **Treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib, in combination with nivolumab. 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.**

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

6. **OPDIVO®**

NIVOLUMAB

**New indication approved 03/10/2020 (plus all prior indications):**

- patients with hepatocellular carcinoma who have been previously treated with sorafenib**, as a single agent or in combination with ipilimumab.**[a]

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

7. **EPCLUSA®**

SOFOSBUVIR; VELPATASVIR

**New indication approved 03/19/2020:**

- treatment of adult and **pediatric patients 6 years of age and older or weighing at least 17 kg** with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection:
  - without cirrhosis or with compensated cirrhosis
  - with decompensated cirrhosis for use in combination with ribavirin

**DECISION:** Inform prescribers via MD alert. The Hepatitis C – Direct Acting Antivirals Commercial and Medicaid policy does not include age restrictions; therefore, no changes to the Commercial or Medicaid criteria coverage are warranted.

8. **EUCRISA®**

**New indication approved 03/23/2020:**

- topical treatment of mild to moderate atopic dermatitis in adult and **pediatric patients 3 months of age and older.**

**DECISION:** Inform prescribers via MD alert. Update Commercial/Medicaid policy as follows:

| | |
|---|---|
| PA PROGRAM NAME | TOPICAL PRODUCTS |
| MEDICATION NAME | EUCRISA® (crisaborole 2% ointment) |

| | |
|---|---|
| COVERED USES | All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.<br><br>Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services. |
| EXCLUSION CRITERIA | N/A |
| REQUIRED MEDICAL INFORMATION | For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. |
| AGE RESTRICTIONS | ~~Approved for age 2 years and older~~<br>N/A |
| PRESCRIBER RESTRICTIONS | N/A |
| COVERAGE DURATION | Initial authorization will be approved for 3 months. Reauthorization will be approved for 12 months. |
| OTHER CRITERIA | 1. Documentation of trial and failure of an adequate treatment course (2 weeks or longer) of two (2) topical corticosteroids, including one (1) high potency corticosteroid (such as betamethasone dipropionate augmented ointment, clobetasol propionate cream or ointment, or halobetasol cream/ointment), unless member has a contraindication (such as an affected area that is not amenable to topical corticosteroid)<br>**AND**<br>2. Documentation of trial, failure, intolerance or contraindication to topical tacrolimus |

9. **SAXENDA®**

LIRAGLUTIDE RECOMBINANT

**New indication approved 03/25/2020:**

As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of

- 30 kg/m2 or greater (obesity) (1) or
- 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia) (1).

**Limitations of Use:**

- **Saxenda is not indicated for the treatment of type 2 diabetes.**
- **Saxenda should not be used in combination with any other GLP-1 receptor agonist.**
- **The safety and efficacy of co-administration with other products for weight loss have not been established.**

**DECISION:** Inform prescribers via MD alert.

10. **TALTZ®**
IXEKIZUMAB
**New indication approved 03/26/2020:**
- **patients aged 6 years or older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.**
- adults with active psoriatic arthritis.
- adults with active ankylosing spondylitis.

**DECISION:** Inform prescribers via MD alert. Update the Therapeutic Immunomodulators (TIMs) Commercial and Medicaid policy with new indication. The Therapeutic Immunomodulators (TIMs) Commercial and Medicaid policy does not include age restrictions; therefore, no changes to the Commercial or Medicaid criteria coverage are warranted.

11. **IMFINZI®**
DURVALUMAB
**New indication approved 03/27/2020:**
Treatment of adult patients for the treatment of adult patients
- Locally advanced or metastatic urothelial carcinoma who:
  - have disease progression during or following platinum-containing chemotherapy.
  - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

  This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- for the treatment of adult patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- **in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).**

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

## Drug Safety Monitoring:

1. **Belviq, Belviq XR (lorcaserin) by Eisai: Drug Safety Communication - FDA Requests Withdrawal of Weight-Loss Drug**

ISSUE: FDA has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the U.S. market because a safety clinical trial shows an increased occurrence of cancer. The drug manufacturer, Eisai Inc,. has submitted a request to voluntarily withdraw the drug.
When FDA approved lorcaserin in 2012, we required the drug manufacturer to conduct a clinical trial to evaluate the risk of cardiovascular problems. A range of cancer types was reported, with several different types of cancers occurring more frequently in the lorcaserin group, including pancreatic, colorectal, and lung.

FDA RECOMMENDATION:
In January 2020, the FDA announced reviewal of clinical trial data and alerted the public about a possible risk of cancer associated with lorcaserin based on preliminary analysis of the data.

**Patients** should stop taking lorcaserin and talk to their respective health professional about alterative weight-loss medications and weight management programs.

**Healthcare professionals** should stop prescribing and dispensing lorcaserin to patients. Contact patients currently taking lorcaserin, inform them of the increased occurrence of cancer seen in the clinical trial, and ask them to stop taking the medicine. Discuss alternative weight-loss medicines or strategies with your patients.

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

2. **Singulair (montelukast) and All Montelukast Generics: Strengthened Boxed Warning - Due to Restricting Use for Allergic Rhinitis**

ISSUE: FDA is strengthening existing warnings about serious behavior and mood-related changes with montelukast (Singulair and generics), which is a prescription medicine for asthma and allergy. FDA is taking this action after a review of available information that led us to reevaluate the benefits and risks of montelukast use. Montelukast prescribing information already includes warnings about mental health side effects, including suicidal thoughts or actions; however, many health care professionals and patients/caregivers are not aware of the risk. We decided a stronger warning is needed after conducting an extensive review of available information and convening a panel of outside experts, and therefore determined that a Boxed Warning was appropriate.

FDA RECOMMENDATION:
**Patients** should talk with their health care professional about:

- The benefits and risks of montelukast, as many other safe and effective allergy medicines are widely available
- Any history of mental illness before starting treatment

**Healthcare professionals** should:

- Ask patients about any history of psychiatric illness prior to initiating treatment
- Consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine

- Advise all patients of the risk of neuropsychiatric events when prescribing montelukast. Warnings about these side effects are included in the existing prescribing information; however, many health care professionals and patients/caregivers are not aware of this risk, and suicides and other adverse events continue to be reported
- Advise patients and parents/caregivers that the patient should stop taking montelukast and contact a health care professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.
- Monitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease.
- Encourage patients and parents/caregivers to read the Medication Guide they receive with their montelukast prescriptions, which explains the safety risks and provides other important information.

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