PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 247

May 1, 2020

This is the May 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.

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 July 1, 2020

Prostate: Prostatic Urethral Lift SUR318	**Annual Update** Prostatic Urethral Lift (PUL; i.e. UroLift) remains medically necessary and covered for treatment of benign prostatic hyperplasia. Several changes made to criteria based on expanded indications of use: • **I.A**: Patient age lowered from 50 years to 45, based on AUA guideline and expanded indications in 2017 (link) • **I.D.1**: Prostate volume liberalized from <80cc to <100cc based on expanded indications (link) • **I.D.2-5**: Added three FDA contraindications. • **III**. Added criterion addressing repeat PUL procedures as investigational. **Codes:** No coding changes; 4 codes continue to require PA.
Wheelchair and Power Vehicles DME375	**Annual Update** No major changes to criteria. Changes in formatting, phrasing and wording throughout criteria and billing guidelines due to changes in relevant guidance documents. Continue to follow CMS for all LOB. **Codes/PA:** • Adding PA to E1230 and E2331. • Removing PA from 7 accessory codes that currently require PA, since we don't PA accessory codes as a practice. • Removing benefit denial and allow E1031 to pay. • Removing E0985 from policy and adding PA per "Seat Lift Chair Mechanism" policy.
Durable Medical Equipment DME214	**Annual Update** Policy based on CMS guidance. No criteria changes made. "Medical Policy Cross-References" section added and updated with all DME policies. **Effective Date:** 7/1/2020; to be released with "Wheelchairs and Power Vehicles" and "Seat Lift Chair Mechanism." **CMS**: • National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1) • Medicare Benefit Policy Manual: Chapter 15 – Covered Medical and Other Health Services. 110.1 Definition of Durable Medical Equipment (Rev. 228, 10-13-16)
Seat Lift Chair Mechanism DME341	**Annual Update** No substantive changes to criteria. Continue to follow CMS for all LOB. Slight formatting and phrasing changes. **Codes:** 2 codes added to policy, one of which will require PA (E0985). E0167 added per billing guideline update – will deny incidental when billed with E0170 or E0171. E0985 added from "Wheelchair and Power Vehicles" policy: will remove denial and add PA, which is in-line with other seat list codes on the policy (E0627, E0629). **CMS:**

	• National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1) • National Coverage Determination (NCD) for Seat Lift (280.4) • Local Coverage Determination (LCD): Seat Lift Mechanisms (L33801) • Local Coverage Article (LCA): Seat Lift Mechanisms - Policy Article (A52518) • Local Coverage Determination (LCD): Commodes (L33736) • Local Coverage Article (LCA): Commodes - Policy Article (A52461)
Balloon Dilation of the Sinuses or Eustachian Tubes SUR136	**Interim Update** Removed mention of Singulair from criterion I.D.3 and are requiring patient undergo both oral and nasal steroids instead (criterion I.D.2).
Wireless Capsule Endoscopy MED376	**Annual Update** No change to criteria. **Codes/PA:** Coding in the policy remains unchanged. The not covered criteria and coding table include 91111 (Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report) as not covered, however this is erroneously listed on the published PA list, and an updated CRF is being requested. 60-day notice will be given due to this correction. **CMS:** Removed L36219 from the policy which was not applicable to Oregon. Added Local Coverage Article: Billing and Coding: Non-Covered Services (A57642) with the same stance of 0355T being non-covered.

Effective May 1, 2020

Surgical Site of Service UM387	**NEW Policy** • Adopt this new Surgical Site of Service policy, which specifies patient criteria to support the medical necessity of an inpatient surgical procedure. The expectation is that patients not meeting these criteria would be acceptable candidates for surgery outside of the inpatient setting (alternative site is not specified in the policy). • Roll policy out for total knee arthroplasty (TKA), only. Consider other procedures after piloting TKA during annual review cycle. ○ We are no longer reviewing for the medical necessity of total knee arthroplasties. The TKA policies were approved for archive on April MPC agenda. ○ Instead, we are only going to focus on applying medical necessity of the site of service. This will be done at the PA level, so **providers will still need to submit a PA when requesting a TKA**. ▪ We are working with SA to determine if we can PA by location code. This would allow us to only require PA on TKAs requested at an inpatient facility and would significantly decrease our PA volume. **Codes/PA:** All codes from the Total Knee Arthroplasty policies (recommended for archive in 04/01/2020 MPC Agenda) are moving into this policy, and remain unchanged in PA or configuration. PA is required for the following: • 27445 Arthroplasty, knee, hinge prosthesis (eg, Walldius type)

	• 27447 Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty) • 27486 Revision of total knee arthroplasty, with or without allograft; 1 component • 27487 Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
Blood Brain Barrier Disruption and Bypass DME148	**Annual Update** No change to criteria **Codes/PA:** No change to coding or PA
Cardiac: Disease Risk Screening (All Lines of Business Except Medicare) LAB173	**Annual Update** No change to criteria. **Codes/PA:** Two codes will deny investigational for all LOB—0423T and 83876. This was already indicated in policy criteria, but the denial was never added to the codes.
Cardiac: Disease Risk Screening (Medicare Only) LAB422	**Annual Update** Update to new Medicare policy format. Added a service section for Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C), and associated Local Coverage Article (LCA) A54976. This is a non-coverage statement, and the LCA is referenced in GT420, *Genetic Testing: Non-Covered Genetic Panel Tests (Medicare Only)* as well. Reference to the Medicare Claims Processing Manual has been moved into criteria. This contains specific billing limits for screening. Continue to apply LCD's L36362 and L36256. Add applicable reference Local Coverage Articles (LCAs), A57055, and A54976. Moved NCD 190 out of billing guidelines and into criteria reference. **Codes/PA:** Add 81479 (unlisted molecular pathology procedure) to the policy, which may be used for any number of molecular tests, though this code is specifically referenced by LCA A54976. **CMS:** • Continue to apply: ○ Medicare Claims Processing Manual, Chapter 18 - Preventive and Screening Services, Section 100 – Cardiovascular Disease Screening ○ National Coverage Determination (NCD) for Lipid Testing (190.23) • Continue to apply LCDs: ○ L36362, MolDX: Biomarkers in Cardiovascular Risk Assessment ○ L36256, MolDX: Molecular Diagnostic Tests (MDT) • Add LCAs: ○ A54976, MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing Billing and Coding Guidelines (A54976) ○ A57055, Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment. ○ A57527, Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
Compression Bandages, Stockings, and	**Annual Update** • Splitting this policy up by line of business, and putting Medicare in a separate policy.

Wraps (All Lines of Business Except Medicare) DME188 ***Previous title: Compression Bandages, Stockings, and Wraps***	• Update the title according to the recommendation, above. • In follow-up to the attached email, revise the criteria note to clarify that compression bandages, stockings and wraps following mastectomy is medically necessary. This revision was reviewed and approved by regulatory compliance. • Continue to base this policy off of CMS LCD L33831 and LCA A54563 for commercial. No change to coverage. CMS updated verbiage from "ordering physician" to "treating practitioner", though this did not affect implementation. • Add one reference to LCA A55426, which contains documentation requirements for all claims submitted for DME. **Codes/PA:** No change to PA or coding **CMS**: The policy is based on CMS guidelines, only, hence no evidence or clinical practice guidelines are included in this entry. • Continue to apply Local Coverage Determination (LCD): L33831, Surgical Dressings • Continue to apply Local Coverage Article (LCA): A54563, Surgical Dressings - Policy Article • Add reference to LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs
Compression Bandages, Stockings, and Wraps (Medicare Only) DME415	**NEW Policy** • Splitting DME188 up by line of business, this is the Medicare only policy. • The same note has been added to this new policy in follow-up to the attached email, which states that compression bandages, stockings and wraps following mastectomy is medically necessary. This revision was reviewed and approved by regulatory compliance. • Continue to use LCD L33831 and LCA A54563 for Medicare. No change to coverage since the last review of DME188. CMS updated verbiage from "ordering physician" to "treating practitioner", though this did not affect implementation. Add one reference to LCA A55426, which contains documentation requirements for all claims submitted for DME. **Codes/PA:** No change to PA or coding, moved all codes from the previous policy into this one, maintaining all of the CMS configuration. **CMS**: • Continue to apply Local Coverage Determination (LCD): L33831, Surgical Dressings • Continue to apply Local Coverage Article (LCA): A54563, Surgical Dressings - Policy Article • Add reference to LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs
Compression: Outpatient Pneumatic Devices (All Lines of Business Except Medicare) DME191	**Annual Update** • Splitting this policy up by line of business, and putting Medicare in a separate policy. • Update the title according to the recommendation, above. • No change to intent of criteria. Coverage remains unaffected by this format change. Continue to reference National Coverage Determination (NCD): Pneumatic Compression Devices (280.6), Local Coverage Determination (LCD): L33829, Pneumatic Compression Devices, and Local Coverage Article (LCA): A52488, Pneumatic Compression Devices - Policy Article. Add reference to LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs. • Revise the criteria note to clarify that outpatient pneumatic compression devices following mastectomy is medically necessary. This revision is in alignment with the update to DME188 also presented in this agenda.

	• The word "physician" was updated to "treating practitioner" wherever LCA52488 made updates in the article. **Codes/PA:** No change to coding or PA. Commercial lines of business will continue to process all codes the same. E0676 had PA removed in 01/2019, however, the code erroneously stayed in the PA required section of the policy. This draft shows the code moved to the appropriate coding box, with no change requests to configuration needed. **CMS:** This policy is based on the following CMS guidance. • Continue to apply NCD: Pneumatic Compression Devices (280.6) • Continue to apply LCD: L33829, Pneumatic Compression Devices • Continue to apply LCA: A52488, Pneumatic Compression Devices - Policy Article • Add reference to LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs
Compression: Outpatient Pneumatic Devices (Medicare Only) DME416	**NEW Policy** • Splitting DME191 up by line of business, this is the Medicare only policy. • No change to intent of criteria. Coverage remains unaffected by this format change. Continue to reference National Coverage Determination (NCD): Pneumatic Compression Devices (280.6), Local Coverage Determination (LCD): L33829, Pneumatic Compression Devices, and Local Coverage Article (LCA): A52488, Pneumatic Compression Devices - Policy Article. Add reference to LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs. • Including the criteria note to clarify that outpatient pneumatic compression devices following mastectomy is medically necessary. This is in alignment with the update to DME191 also presented in this agenda. • The word "physician" was updated to "treating practitioner" wherever the references made updates. **Codes/PA:** No change to coding or PA. Medicare business will continue to process codes as before. **CMS:** • Continue to apply NCD: Pneumatic Compression Devices (280.6) • Continue to apply LCD: L33829, Pneumatic Compression Devices • Continue to apply LCA: A52488, Pneumatic Compression Devices - Policy Article • Add reference to LCA: A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs
Genetic Testing: Hereditary Breast and Ovarian Cancer (All Lines of Business Except Medicare) GT155	**Annual Update** No substantive changes made to policy criteria. Table of contents added to criteria section to facilitate reading. Hyperlinks redirecting to “policy guidelines” now replace asterisks throughout. One genetic panel test added to list of example investigational panels. **Codes/PA:** No coding changes. 3 codes (81164, 81166, 81167) that were incorrectly under the “PA required” section of the coding table on the policy have been relocated under the “No PA Required” header.
Genetic Testing: Hereditary Breast	**Annual Update**

and Ovarian Cancer (Medicare Only) **GT380**	No change to coverage criteria. BRCA1 and BRCA2 Genetic Testing remain medically necessary and covered for patients suspected of hereditary breast and/or ovarian cancer. Genetic testing for susceptibility to breast or ovarian cancer with multigene NGS Panels also remain medically necessary. **Codes/PA:** No coding changes. 3 codes (81164, 81166, 81167) that were incorrectly under the "PA required" section of the coding table on the policy have been relocated under the "No PA Required" header. **CMS:** • Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) • National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) • Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355)
NanoKnife System: Irreversible Electroporation (IRE) **SUR284**	**Annual Update** No change to criteria **Codes/PA:** No change to coding, all relevant codes are unlisted.
Nerve Conduction Studies (All LOB Except Medicare) **MED285**	**Annual Update** No change to criteria. Non-automated nerve conduction studies remain medically necessary and covered for the diagnosis of peripheral nervous system disorders. Automated nerve conduction studies, quantitative sensory testing and sensory nerve conduction threshold testing remain investigational. **Codes:** No coding changes. No codes require PA.
Nerve Conduction Studies (Medicare Only) **MED425**	**Annual Update** No change to criteria. Nerve conduction studies (automated and non-automated) remain medically necessary and covered when criteria are met. Quantitative sensory testing and sensory nerve conduction threshold testing remain investigational. **Codes:** No coding changes. No codes require PA. **CMS:** • National Coverage Determination (NCD): Sensory Nerve Conduction Threshold Tests (sNCTs) (160.23) • Local Coverage Determination (LCD): Nerve Conduction Studies and Electromyography (L36526) • Local Coverage Determination (LCD): Non-Covered Services (L35008)
Prostate: High-Intensity Focused Ultrasound (HIFU) (All Lines of Business Except Medicare) **SUR420**	**Annual Update** No change to criteria **Codes/PA:** No change to coding or PA

Surface Electromyography (sEMG) Testing **MED349**	**Annual Update** No change to investigational status. **Codes/PA:** Removing investigational denial of 94006 - *Physician review and interpretation of comprehensive computer based motion analysis, dynamic plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report*. This code may be used for physician review and interpretation of services that are considered medically necessary in addition to the investigational application of surface electromyography. Since the code is not routinely submitted on the same claim as the originating service, configuration would not appropriately capture the potential situations where this code is truly medically necessary or investigational. **CMS:** • Continue to reference Noridian Local Coverage Determination L36526, Nerve Conduction Studies and Electromyography and accompanying Local Coverage Article, A54992: Billing and Coding: Nerve Conduction Studies and Electromyography which both state necessity and reasonableness of surface and macro EMGs "have not been established." • Removed reference to LCD L34594 because it is from contractor, Wisconsin Physicians Service Insurance Corporation, and Noridian takes precedent when both contractors publish guidance for Oregon.
Back: Stabilization Devices and Interspinous Spacers **SUR126**	**Annual Update** No changes to criteria. Stabilization devices and interspinous spacers remain investigational and not covered for all indications. **Codes/PA:** No coding or PA changes.
Pelvic Congestion Syndrome Treatment **SUR340**	**Annual Update** No changes to criteria. Vascular embolization with percutaneous catheter techniques of the ovarian and/or internal iliac vein remains investigational and not covered for the treatment of pelvic congestion syndrome. **Codes/PA:** No coding or PA changes.

April 1, 2020 New Code Updates

Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies **LAB403**	**Interim Update** The following code will deny E/I per the policy for all LOB 0164U — Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
Inflammatory Bowel Disease: Serologic Testing	**Interim Update** The following code will deny E/I for all LOB

and Therapeutic Monitoring LAB312	0169U — NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
Genetic Testing: Reproductive Planning and Prenatal Testing (All Lines of Business Except Medicare) GT236 & Genetic Testing: Reproductive Planning and Prenatal Testing (Medicare Only) GT384	**Interim Update** The following code will require PA for all LOB 0168U — Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy
Genetic Testing: JAK2, CALR, and MPL (All Lines of Business Except Medicare) & GT400 Genetic Testing: JAK2, CALR, and MPL (Medicare Only) GT399	**Interim Update** The following code will require PA 0171U — Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence
Allergy Testing (All Lines of Business Except Medicare) LAB105 & Allergy Testing (Medicare Only) LAB394	**Interim Update** The following code will deny as E/I 0165U — Peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and interpretation

<table>
<tr>
<td>Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) & Investigational and Non-Covered Medical Technologies (Medicare Only)</td>
<td>Interim Update
The following codes will deny E/I for all LOB
<table>
<tr><td>0166U</td><td>Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation</td></tr>
<tr><td>0167U</td><td>Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood</td></tr>
<tr><td>0170U</td><td>Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis</td></tr>
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Archived Policies as of May 1, 2020

Prostate: High-Intensity Focused Ultrasound (HIFU) (Medicare Only) SUR430	**Archive** The Centers for Medicare & Medicaid Services retired the coverage article addressing HIFU, Local Coverage Article A56019. Recommend archiving this policy and cease review of applicable code for Medicare members. Regulatory and Compliance has been consulted and agree with this recommendation. **Codes/PA:** Remove PA of C9747 - *Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance* for Medicare members.
Knee: Total Joint Arthroplasty (All Lines of Business Except Medicare) SUR268	**Archive** Total knee arthroplasty will be archived for medical necessity review of the procedure, though appropriate site of care will still be reviewed under a new policy, Surgical Site of Service, UM387. **Codes/PA:** No change to coding. Continue to PA as site of service will be reviewed for these procedures.
Knee: Total Joint Arthroplasty (Medicare Only) SUR269	**Archive** Total knee arthroplasty will be archived for medical necessity review of the procedure, though appropriate site of care will still be reviewed under a new policy, Surgical Site of Service, UM387. **Codes/PA:** No change to coding. Continue to PA as site of service will be reviewed for these procedures.
Stereotactic Computer Assisted Volumetric (Navigational) Procedure	**Archive** Policy is currently based on a retired LCD, which doesn't/didn't list "Oregon" as one of the states to which the document applied. No recent evidence assesses this procedure. **Codes:** Discussion with coding folks: relevant payments policies and coding configurations will be updated/removed.

SUR347	

VENDOR UPDATES

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Effective for dates of service on and after May 17, 2020, the following updates will apply to the AIM Advanced Imaging: Vascular Imaging Clinical Appropriateness Guidelines.

Updates by section:

Aneurysm of the abdominal aorta or iliac arteries

- Added new indication for asymptomatic enlargement by imaging
- Clarified surveillance intervals for stable aneurysms as follows:
- Treated with endografts, annually
- Treated with open surgical repair, every 5 years

Stenosis or occlusion of the abdominal aorta or branch vessels, not otherwise specified

- Added surveillance indication and interval for surgical bypass grafts

Code changes

- None

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.

PHARMACY & THERAPEUTICS COMMITTEE

Oregon Region P&T Committee Meeting April 3, 2020
Go-Live Date: Monday, June 01, 2020, unless otherwise noted

PROVIDENCE Health Plan

New Drugs and Combinations:

Avapritinib (Ayvakit) Tablet
Indication: Treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. **Formulary Alternatives:** imatinib, sunitinib (Sutent)
• Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization Effective 05/01/2020 **Prior Authorization Criteria:** • For Commercial/Medicaid: Added to Oral Anti-Cancer Medications • For Medicare Part D: Added to Anti-Cancer PA Program

Enfortumab vedotin-ejfv (Padcev) Vial
indication: Locally Advanced Or Metastatic Urothelial Cancer (Muc) Who Have Previously Received A PD-1 Or PD-L1 inhibitor and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting • Indication 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 a confirmatory trial **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 **Prior Authorization Criteria:** • For Commercial/Medicaid/Medicare Part B: Added to Injectable Anti-Cancer Medications

Fam-trastuzumab deruxtecan-nxki (Enhertu) Vial

Indication: Unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer in adults who were previously treated with 2 or more anti-HER2-based regimens in the metastatic setting
- Indication 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 a confirmatory trial

Formulary Alternatives: ado-trastuzumab emtansine (Kadcyla®)

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

PRIOR AUTHORIZATION CRITERIA:
- For Commercial/Medicaid/Medicare Part B: Added to Injectable Anti-Cancer Medications

Diroximel fumarate (Vumerity) Capsule DR

Indication: Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Formulary Alternatives: Tecfidera®, Rebif®, Avonex®, Gilenya®

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

Givosiran sodium (Givlaari) Vial

Indication: Treatment of adults with acute hepatic porphyria (AHP)

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

Prior Authorization Criteria For Commercial/Medicaid/Medicare Part B:

PA Program Name	Givosiran sodium (Givaari) Vial
Medication Name	Givosiran sodium (Givaari) Vial
Covered Uses	All FDA-approved indications not otherwise excluded from the benefit.
Exclusion Criteria	Use post liver transplant
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 a hepatologist, gastroenterologist, or hematologist
Coverage Duration	Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.
Other Criteria	Initial authorization: 1. Documentation of diagnosis with acute hepatic porphyria (*i.e.,* acute intermittent porphyria, hereditary corproporhyria, variegate porphyria, ALA dehydratase deficient porphyria) **AND** 2. Active disease defined as two documented porphyria attacks within the past 6 months which required either hospitalization, urgent care visit, or intravenous hemin administration at home Reauthorization criteria: documentation of reduction in the number or severity of porphyria attacks, reduction in number of hospitalizations due to acute porphyria attacks, or decreased hemin administration from baseline

Golodirsen (Vyondys-53) Vial

Indication: Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VYONDYS 53. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Formulary Alternatives: prednisone, deflazacort (Emflaza®)

- Commercial: Medical Benefit, Prior Authorization
- Medicaid: Medical Benefit, Prior Authorization

- Medicare Part D: N/A
- Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria For Commercial/Medicaid/Medicare Part B:

PA Program Name	Exon-Skipping Therapies for Duchenne Muscular Dystrophy – New policy name, formerly called EXONDYS® 51
Medication Name	eteplirsen vial (Exondys® 51), golodirsen vial (Vyondys® 53)
Policy	Eteplirsen (Exondys® 51) and golodirsen (Vyondys® 53) are not considered medically necessary and will not be covered at this time, due to the lack of clinical evidence of improved outcomes and safety.

Lumateperone tosylate (Caplyta) Capsule

Indication: Schizophrenia in adult patients

Formulary Alternatives: risperidone, aripiprazole, Latuda®, Vraylar®

- Commercial: Formulary, Tier 4, Step Therapy
- Medicaid: Non-Formulary (Covered by DMAP)
- Medicare Part D: Formulary, Non-Preferred Drug tier, Prior Authorization

Prior Authorization Criteria For Commercial:

- For Commercial: Added to Antipsychotics Step Therapy
- For Medicare Part D: Added to Antipsychotics Prior Authorization Program

Crizanlizumab (Adakveo) Vial

Indication: To reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease

Formulary Alternatives: generic hydroxyurea capsule 200 mg, 300 mg, 400 mg and 500 mg, Siklos oral tablet 100 mg and 1000 mg

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

- Medicare Part B: Medical Benefit, Prior Authorization

Prior Authorization Criteria:

- For Commercial/Medicaid/Medicare Part B:

PA Program Name	Adakveo
Medication Name	Crizanlizumab (Adakveo®)
Covered Uses	All FDA-approved indications not otherwise excluded from the benefit.
Exclusion Criteria	Use in combination with voxelotor
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 patients 16 years of age and older
Prescriber Restrictions	Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of Sickle Cell Disease
Coverage Duration	Initial authorization and reauthorization will be approved for one year
Other Criteria	Initial authorization: 1. Confirmed medical history or diagnosis of sickle cell disease 2. Patient has experienced at least two (2) sickle cell-related pain crises in the prior year 3. Documentation that patient meets one of the following: a. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least 6 months b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least 6 months c. Patient has had an intolerance or contraindication to hydroxyurea (For many patients myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose Reauthorization: Documentation that the number or severity of sickle cell-related pain crises has decreased from baseline

Voxelotor (Oxbryta) Tablet
Indication: Treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Formulary Alternatives: generic hydroxyurea capsule 500 mg, Siklos oral tablet 100 mg and 1000 mg

- Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (3 tablets per day)
- Medicare Part D: Non-Formulary

Prior Authorization Criteria:

PA Program Name	Oxbryta
Medication Name	Oxbryta
Covered Uses	All FDA-approved indications not otherwise excluded from the benefit.
Exclusion Criteria	Used in combination with crizanlizumab (Adakveo®)
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 patients 12 years of age and older
Prescriber Restrictions	Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of Sickle Cell Disease
Coverage Duration	Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year
Other Criteria	Initial authorization: 1. Confirmed medical history or diagnosis of sickle cell disease 2. Documented hemoglobin of less 10.5 g/dL taken within one month prior to initiating therapy 3. Documentation that patient meets one of the following: a. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least 6 months b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least 6 months c. Patient has had an intolerance or contraindication to hydroxyurea (For many patients myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments) Reauthorization: For initial reauthorization documentation of an increase in hemoglobin from baseline of at least 1 g/dL and for subsequent reauthorization documentation that an increase of at least 1 g/dL from baseline has been maintained

Lasmiditan (Reyvow) tablet

Indication: Acute treatment of migraine with or without aura in adults. Not indicated for the preventive treatment of migraine.

Formulary Alternatives: triptans, ergot alkaloids

- Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 tablets per 30 days)
- Medicare Part D: Non-Formulary, FDA Max Quantity Limit (4 tablets per 30 days)

Effective 05/01/2020

Prior Authorization Criteria:

PA Program Name	Lasmiditan
Medication Name	Lasmiditan succinate (Reyvow) tablet
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, a neurologist.
Coverage Duration	Initial Authorization will be approved for 6 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.
Other Criteria	Diagnosis of migraine headaches **AND one of the following:** 1. Trial of and inadequate response or intolerance to two (2) oral triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) **and** one (1) additional triptan formulation (e.g. oral disintegrating tablet, nasal spray, injection) **OR** 2. One of the following cardiovascular or non-coronary vascular contraindications to use of triptans: ▪ Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina) ▪ History of stroke or transient ischemic attack (TIA) ▪ Peripheral vascular disease ▪ Ischemic bowel disease ▪ Uncontrolled hypertension

	Reauthorization: Documentation of treatment success as demonstrated by a reduction of migraine pain or freedom from migraine symptoms

Ubrogepant (Ubrelvy) Tablet

Indication: acute treatment of migraine with or without aura in adults. Not indicated for the prevention of migraines.

Formulary Alternatives: triptans, ergot alkaloids

- Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (8 tablets per 30 days)
- Medicare Part D: Non-Formulary, FDA Max Quantity Limit: 50 mg: 32 tablets per 30 days, 100 mg: 16 tablets per 30 days

Effective 05/01/2020

Prior Authorization Criteria:

PA Program Name	Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Acute Migraine Treatment
Medication Name	ubrogepant tablet
Covered Uses	All FDA-approved indications not otherwise excluded from the benefit.
Exclusion Criteria	Concurrent use of a strong CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, clarithromycin) Concurrent use with a CGRP used for migraine prophylaxis
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, a neurologist.
Coverage Duration	Initial Authorization will be approved for 6 months. Reauthorization will be reviewed annually to assess continued medical necessity and effectiveness of medication.
Other Criteria	Diagnosis of migraine headaches **AND one of the following:** 1. Trial of and inadequate response or intolerance to two (2) oral triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) **and** one (1) additional triptan formulation (e.g. oral disintegrating tablet, nasal spray, injection) **OR** 2. One of the following cardiovascular or non-coronary vascular contraindications to use of triptans: ▪ Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina) ▪ History of stroke or transient ischemic attack (TIA)

	▪ Peripheral vascular disease ▪ Ischemic bowel disease ▪ Uncontrolled hypertension Reauthorization: Documentation of treatment success as demonstrated reduction of migraine pain or freedom from migraine symptoms and, if applicable, demonstration that additional quantities continue to be medically necessary Quantity Limit: Quantities up to double the formulary quantity limit will be approved if requested by a provider with supporting medical rationale that the patient is on prophylactic therapy (e.g. injectable CGRPs, divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, or venlafaxine), the patient is still experiencing more than 2 headache days per week regardless of prophylactic therapy, and policy criteria are met.

New Strengths and Formulations:

Testosterone undecanoate (Jatenzo) Capsule
Indication: Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: • Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. • Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. **Formulary Alternatives:** testosterone gel, testosterone injection • Commercial: Non-Formulary, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary **Prior Authorization Criteria:**

- Commercial/Medicaid: Added to Testosterone Replacement Therapy

New Indications:

1. **TECENTRIQ®** ATEZOLIZUMAB
   TECENTRIQ® NEW INDICATION UPDATE (PLUS PRIOR INDICATIONS)
   - Non-Small Cell Lung Cancer (NSCLC)
     - in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations (1.2)

RECOMMENDATION: Inform prescribers via MD alert. 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.

2. VASCEPA® ICOSAPENT ETHYL
   VASCEPA® NEW INDICATION UPDATE
   - adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
     - established cardiovascular disease or
     - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
   - as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

   Limitations of Use:
   - The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

RECOMMENDATION: Inform prescribers via MD alert. The Vascepa Commercial/Medicaid policy was updated in December 2019 to include the new indication; therefore, no changes to Commercial/Medicaid criteria coverage are warranted.

3. XTANDI® ENZALUTAMIDE
   New indication approved 12/16/2019:
   XTANDI® NEW INDICATION UPDATE (PLUS PRIOR INDICATIONS)
   - metastatic castration-sensitive prostate cancer.

RECOMMENDATION: Inform prescribers via MD alert. 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.

4. TRUXIMA® RITUXIMAB-ABBS

TRUXIMA® NEW INDICATION UPDATE (PLUS PRIOR INDICATIONS)

- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids.

RECOMMENDATION: Inform prescribers via MD alert. The Truxima Commercial/Medicaid/Medicare Part B policy was updated in January 2020 to include the new indication; therefore, no changes to Commercial/Medicaid/Medicare Part B criteria coverage are warranted.

5. FIASP®/FIASP FLEXTOUCH®/ FIASP PENFILL® INSULIN ASPART

FIASP®/FIASP FLEXTOUCH®/ FIASP PENFILL® NEW PATIENT POPULATION UPDATE

- to improve glycemic control in adult and pediatric patients with diabetes mellitus

RECOMMENDATION: Inform prescribers via MD alert. The Non-Preferred Insulin Commercial policy does not include age restrictions; therefore, no changes to Commercial criteria coverage are warranted.

6. MYCAMINE® MYCAFUNGIN SODIUM

MYCAMINE® NEW INDICATION UPDATE

- Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses in adult and pediatric patients 4 months of age and older.
- Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses without meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.
- Treatment of Esophageal Candidiasis in adult and pediatric patients 4 months of age and older.
- Prophylaxis of Candida Infections in adult and pediatric patients 4 months of age and older undergoing Hematopoietic Stem Cell Transplantation (HSCT).
- Limitations of Use
- The safety and effectiveness of MYCAMINE have not been established for the treatment of candidemia with meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age as a higher dose may be needed.
- MYCAMINE has not been adequately studied in patients with endocarditis, osteomyelitis or meningoencephalitis due to Candida.

- The efficacy of MYCAMINE against infections caused by fungi other than Candida has not been established.

RECOMMENDATION: Inform prescribers via MD alert.

7. ZILRETTA® TRIAMCINOLONE ACETATE

ZILRETTA® NEW INDICATION LIMITATION OF USE UPDATE

- Management of osteoarthritis pain of the knee.
- Limitation of Use The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

RECOMMENDATION: Inform prescribers via MD alert.

8. LYNPARZA® OLAPARAIB

LYNPARZA® NEW INDICATION UPDATE (PLUS PRIOR INDICATIONS)

- Pancreatic cancer
  - for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

RECOMMENDATION: Inform prescribers via MD alert. 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.

9. KEYTRUDA® PEMBROLIZUMAB

KEYTRUDA® NEW INDICATION UPDATE (PLUS PRIOR INDICATIONS)

- Urothelial Carcinoma
  - for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

RECOMMENDATION: Inform prescribers via MD alert. 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.

10. OZEMPIC® SEMAGLUTIDE

OZEMPIC® NEW INDICATION UPDATE

- 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 and established cardiovascular disease.

Limitations of Use:

- Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy.

- Not indicated for use in type 1 diabetes mellitus or treatment of diabetic ketoacidosis

RECOMMENDATION: Inform prescribers via MD alert. Update policy with new indication. No changes to criteria coverage are warranted.

11. SABRIL® VIGABATRIN

SABRIL® PATIENT POPULATION UPDATE

- Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; SABRIL is not indicated as a first line agent
- Infantile Spasms -monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss

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

PA Program Name	NEUROMUSCULAR DRUGS
Medication Name	**SABRIL® (vigabatrin tablet, powder pack)**
Covered Uses	All Food and Drug Administration (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	For complex partial seizures: approved for ages ~~10~~ 2 years and older. For infantile spasms: approved for ages 1 month to 2 years old.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
Coverage Duration	Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.
Other Criteria	For refractory complex partial seizures: 1. Must be at least ~~10~~ 2 years of age AND 2. Documentation of trial and failure, contraindication, or intolerance to 2 alternative formulary generic antiepileptic medications For infantile spasms: 1. Must be between 1 month and 2 years~~'~~ old

12. DIFICID® FIDAXOMICIN

DIFICID® PATIENT POPULATION UPDATE

- Adult and pediatric patients 6 months of age and older for the treatment of C. difficile-associated diarrhea.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of DIFICID and other antibacterial drugs, DIFICID should be used only to treat infections that are proven or strongly suspected to be caused by C. difficile.

RECOMMENDATION: Inform prescribers via MD alert. The Dificid policy does not include age restrictions; therefore, no changes to Commercial/Medicaid coverage criteria are warranted.

13. INVOKAMET®/INVOKAMET XR® CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE

INVOKAMET®/ INVOKAMET XR® NEW INDICATION UPDATE (PLUS PRIOR INDICATIONS)

- Canagliflozin is indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria

RECOMMENDATION: Inform prescribers via MD alert. Update SGLT-2 Inhibitors Commercial and Medicaid policy with new indication. No changes to coverage criteria are warranted.

Drug Safety Monitoring:

1. Belviq, Belviq XR (lorcaserin) : Drug Safety Communication – Due to Possible Increased Risk of Cancer

ISSUE: The FDA is alerting the public that results from a clinical trial assessing safety show a possible increased risk of cancer with the weight management medicine Belviq, Belviq XR (lorcaserin). At this time, the cause of the cancer is uncertain, and the FDA cannot conclude that lorcaserin contributes to the cancer risk. However, the FDA wanted to make the public aware of this potential risk. The FDA is continuing to evaluate the clinical trial results and will communicate their final conclusions and recommendations when they have completed their review.

FDA RECOMMENDATION: Health care professionals should consider if the benefits of taking lorcaserin are likely to exceed the potential risks when deciding whether to prescribe or continue patients on lorcaserin.
Patients currently taking lorcaserin should talk to their health care professionals about the potential increased risk of cancer with use of lorcaserin.

HEALTH PLAN RECOMMENDATION:
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

2. Clozaril, Fazaclo ODT, Versacloz (clozapine): Drug Safety Communication – FDA Strengthens Warning That Untreated Constipation Can Lead to Serious Bowel Problems

ISSUE: FDA is strengthening an existing warning that constipation caused by the schizophrenia medicine clozapine (Clozaril, Fazaclo ODT, Versacloz, generics) can, uncommonly, progress to serious bowel complications. This can lead to hospitalization or even death if constipation is not diagnosed and treated quickly.

FDA RECOMMENDATION: Mavyret, Zepatier, and Vosevi are FDA-approved to treat chronic hepatitis C in patients without liver impairment or with mild liver impairment (Child-Pugh A).
Health professionals should:

- Evaluate bowel function before starting a patient on clozapine.
- Avoid co-prescribing clozapine with other anticholinergic medicines that can cause gastrointestinal hypomotility.
- Advise patients frequently of the significant risk of constipation and life-threatening bowel issues and the need to stay hydrated to prevent constipation.
- Question patients about the frequency and quality of their bowel movements throughout treatment.
- Advise patients to contact a health care professional right away if they have difficulty having a bowel movement or passing stools, do not have a bowel movement at least three times a week or less than their normal frequency, or are unable to pass gas.
- Monitor patients for symptoms of potential complications associated with gastrointestinal hypomotility such as nausea, abdominal distension or pain, and vomiting.
- Consider prophylactic laxative treatment when starting clozapine in patients with a history of constipation or bowel obstruction.

Patients should contact their health care professional if:

- their bowel movements are less frequent than normal.
- they do not have a bowel movement at least three times a week.
- they have hard or dry stools.
- they have difficulty passing gas.

Patients should contact your health care professional right away if you have symptoms which can be associated with serious bowel problems such as:

- nausea
- vomiting
- bloating or belly swelling, or belly pain

HEALTH PLAN RECOMMENDATION:
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

3. FDA Updates and Press Announcements on NDMA in Metformin

ISSUE: The U.S. Food and Drug Administration posted laboratory results showing N- Nitrosodimethylamine (NDMA) levels in some metformin products approved in the U.S. FDA has determined that the levels of NDMA in metformin products tested

range from not detectable to low levels. To date, no sample of metformin that FDA has tested exceeds the acceptable daily intake for NDMA. FDA has not recommended metformin recalls in the U.S.

FDA RECOMMENDATION: None

HEALTH PLAN RECOMMENDATION:
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Diazepam (Valtoco) Spray	New route and dosage form. • Commercial: Formulary, Tier 4, Prior Authorization, Quantity Limit (1 pack or 2 doses per 30 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 pack or 2 doses per 30 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 packs or 10 dose)	Commercial/Medicaid: Nayzilam (to be renamed Rescue Medications for Epilepsy)

Prior Authorization Criteria for Medicare Part D:

PA Program Name	V*altoco*
Medication Name	Valtoco
Pa Indication Indicator	1 - All FDA-Approved Indications (New Starts only)
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	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist
Coverage Duration	Authorization will be approved until no longer eligible with the plan
Other Criteria	N/A

Elapegademase-LVLR (Revcovi) Vial	Add to Medicare Part D formulary: Formulary, Tier 5, Prior Authorization	• Medicare Part D: Revcovi
Isotretinoin, micronized (Absorica LD) Capsule	New strengths (8mg, 16mg, 24mg, 32mg). • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations Without Established Benefit • Medicare Part D: N/A
Bevacizumab Syringe	New Strength Medical Benefit for all lines of business	N/A
Butorphanol tartrate Spray	Commercial/Medicaid: Change quantity limit from 2.5 ml per 30 days to 5 ml per 30 days.	N/A
Budesonide-formoterol flumarate	First generic (Symbicort). • Commercial/Medicare Part D: Non-Formulary • Medicaid: Formulary	N/A
Celecoxib Capsule	Commercial/Medicaid: remove quantity limit. Effective: 5/1/2020	N/A
Danazol Capsule	Add to Medicaid formulary	N/A
Oxandrolone Tablet	Add to Medicaid formulary	N/A
Cetirizine hcl (Quzyttir) Vial	New route (IV) and dosage form (Vial). • Commercial/Medicaid: Medical Benefit, Remove Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	• Commercial/Medicaid: **Remove from** New Medications and Formulations Without Established Benefit • Medicare Part D: N/A
Midazolam syringe, cartridge, vials	Add to Formulary • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Omeprazole magnesium/amoxicillin trihydrate/rifabutin (Talicia) Cap IR DR	New combination. • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Collagenase clostridium hist. (Xiaflex) Vial	Add prior authorization. • Commercial: Medical Benefit, Prior Authorization • Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Xiaflex (see policy section for criteria)

	• Medicare Part B: Medical Benefit, Prior Authorization Effective 07/01/2020	
Ketorolac tromethamine (Ketorolac) Spray	Authorized Generic (Sprix). • Commercial: Non-Formulary, Quantity Limit (5 bottles per 30 days) • Medicaid: Non-Formulary, Quantity Limit (5 bottles per 30 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 bottles per 30 days)	• Commercial/Medicaid: N/A • Medicare Part D: Sprix
Methylphenidate ER 72 mg (Relexxi)	Remove from Commercial Formulary: None-Formulary, Quantity Limit (1 tablet per day) Effective 07/01/2020	N/A
Tramadol hcl Tablet	New Strength (100mg). • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations Without Established Benefit • Medicare Part D: N/A
Diclofenac (Solaraze) Gel	Change tiers: • Commercial (WA): Formulary, Tier 3 (from Tier 4), **Retire** Prior Authorization • Medicare Part D: Formulary, Tier 3 (from Tier 4), Prior Authorization	Medicare Part D: Actinic Keratosis Agents
Somatropin: • **Genotropin Cartridge; Disp Syrin** • **Nutropin Vial** • **Nutropin AQ Nuspin Cartridge**	• Medicaid: add to Formulary: Specialty, Prior Authorization	• Human Growth Hormones for Pediatrics
Thyroid, pork (Armour Thyroid) Tablet	• Medicare Part D: add to Formulary, Tier 4	N/A
Aimovig/Emgality	For all lines of business, add to formulary • Commercial/Medicare Part D: Formulary, Tier 3, Prior Authorization • Medicaid: Formulary, Prior Authorization	• Commercial/Medicaid: Calcitonin Gene-Related Peptide Receptor (CGRP) Inhibitors for Migraine Prophylaxis • Medicare Part D: See below
Prior Authorization Criteria for Medicare Part D:		

PA PROGRAM NAME	Calcitonin gene-related peptide (CGRP) Inhibitors for Migraine Prophylaxis
MEDICATION NAME	Aimovig, Emgality
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concomitant use with another calcitonin gene-related peptide (CGRP) agent
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	N/A
COVERAGE DURATION	Initial approval will be for 6 months. Reauthorization will be approved until no longer eligible with the plan.
OTHER CRITERIA	Initial authorization for migraine prophylaxis (Aimovig and Emgality): 1. Diagnosis of migraine headaches with at least four (4) headache days per month 2. One of the following: a. Trial and failure of at least 6 weeks of at least one conventional migraine prophylaxis medication [e.g., anticonvulsants (divalproex, topiramate), beta-blockers (propranolol)] b. Documented intolerance or contraindication to an anticonvulsant and beta blocker 3. Documentation that if the patient is currently receiving CGRP therapy, treatment with the other CGRP will be discontinued. Initial authorization for cluster headache prophylaxis (Emgality only): 1. Diagnosis of episodic cluster headaches and both of the following: a. A history of at least five (5) cluster headache attacks with at least two of the cluster periods lasting at least 7 days b. Cluster periods are separated by at least three (3) months of pain-free remission Reauthorization for all indications: Documented reduction in the severity or frequency of headaches

The formulary status for the following drugs was line extended in accordance with

PROVIDENCE Health Plan

Providence Health Plan Pharmacy Operational Policy ORPTCOPS062
INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Estradiol (Divigel) Gel Packet	New Strength (1.25mg). Line extend with other Divigel strengths; • Non-Formulary for all lines of business	N/A
Imipenem/cilastatin sodium/relebactam (Recarbrio) Vial	New Combination. Medical benefit for; • Commercial, Medicaid, and Medicare Part B	N/A
Fofacitinib citrate (Xeljanz XR) Tab ER	New Dosage Form (XR) and Strength (22mg). Line extend with Xeljanz XR 11mg tablet; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 tab per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tab per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tab per day)	• Commercial: Therapeutic Immunomodulators (TIMs) • Medicaid: Therapeutic Immunomodulators (TIMs) – Medicaid • Medicare Part D: Xeljanz/Xeljanz XR
Antihemophilic factor (fviii) rec, b-dom truncated peg-exei (Esperoct) Vial	New Formulation Medical; Line extend with other anti-hemophilic factor (FVIII). Medical benefit for; • Commercial, Medicaid, and Medicare Part B	N/A
Mometasone furoate (Asmanex HFA) HFA AER AD	New Strength (50mcg). Line extend with other Asmanex strengths; • Commercial/Medicare Part D: Formulary, Tier 3 • Medicaid: Formulary	N/A
Mometasone furoate/formoterol fumarate (Dulera) HFA AER AD	Line extend with other Dulera strengths; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**

Calcipotriene/ betamethasone dipropionate	Authorized Generic (Taclonex). Line extend as generic;
	• Commercial:
	  ○ OR: Formulary, Tier 2, Prior Authorization
	  ○ WA: Formulary, Tier 4, Prior Authorization
		• Commercial/Medicaid: Enstilar, Taclonex, Taclonex Scalp
		• Medicare Part D: N/A

(Calcipotriene) Suspension	• Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	
Calcipotriene Foam	Authorized Generic (Sorilux). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Diltiazem hcl (Tiadylt ER) Cap SA 24H	Line extend with generic diltiazem ER 420; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Indomethacin, submicronized (Indomethacin) Capsule	Authorized Generic (Tivorbex). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Penicillamine Tablet	First generic (Depen). Line extend as generic; • Commercial: Formulary, Tier 5 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 5	N/A
Simvastatin Oral Susp	Line extend as generic; • Non-formulary for all lines of business	N/A
Doxepin hcl	Authorized generic for Silenor. Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Insomnia Agents • Medicare Part D: N/A

Health Plan Clinical Policy Changes:

PHP CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Evenity	Policy criteria were updated to align with the latest Endocrine Society guidelines. Use of osteoanabolic agents prior to anti-resorptive therapies may be covered in certain, high-risk patients.

Forteo	Policy criteria were updated to align with the latest Endocrine Society guidelines. Use of osteoanabolic agents prior to anti-resorptive therapies may be covered in certain, high-risk patients.
Human Growth Hormones for Adults	The policy was updated to reflect changes outlined in the American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) 2019 guideline update for the management of growth hormone deficiency in adults.
Human Growth Hormones for Pediatrics	Policy was updated to reflect current guidelines for pediatrics. Specifically, the use of stimulation tests can be avoided in some patients, so criteria were updated to reflect these patient populations.
Tymlos	Policy criteria were updated to align with the latest Endocrine Society guidelines. Use of osteoanabolic agents prior to anti-resorptive therapies may be covered in certain, high-risk patients.
Emflaza	Policy updated to further clarify appropriate trial and failure of predinsone.
Non-Preferred Insulins	Added generic Novolog (insulin aspart) to the policy. No other changes to the criteria.
Crysvita	Updated covered uses to align with FDA-approved indications and updated criteria to differentiate between those with fused growth plates and those not fused. Removed exclusion criteria as not necessary with covered uses update.
Sandostatin Injection, Sandostatin LAR Depot	Added covered diagnosis of oncology conditions with criteria that the condition must be FDA labeled indication or meets NCCN recommendation of 2A or higher.
Signifor	Added prescriber restriction requiring endocrinologist to prescribe or consult.
GLP-1 Agonists **GLP-1 Agonists – Medicaid**	Remove Tanzeum from policy, as it is discontinued. Updated Position Statement to include latest evidence on cardiovascular outcomes.
Infertility Medications	Revised criteria to meet updated practice guidelines.
Kuvan	Revised criterion for pretreatment baseline Phe level to 600 micromol/L for ages 12 years and older to align with current guidelines. Prescriber restrictions were added and exclusion for concomitant use of Palynziq.
Palynziq	Added Reauthorization criteria to allow for patients who are still up-titrating dose and have not met goal Phe levels.
Increlex	Exclusion criteria updated to include malignant neoplasia as an exclusion to align with FDA label.
Strensiq	Policy updated with additional criteria for adult patients that had perinatal/infantile or juvenile-onset hypophosphatasia. Given high cost of therapy and limited evidence in adults, this therapy should be reserved for adult patients with clear evidence of onset in childhood with significant disability as adults. Adult onset and odontohypophosphatasia were added to the policy as an exclusion as these are non-FDA approved indications.
Relistor	Removed trial of stool softener from criteria; only require trial of stimulant laxative alone instead of combination. For Medicaid, constipation agents may be covered if treatment of opioid-induced constipation if patient has active cancer pain or drug is part of palliative care regimen.

Constipation Agents	Removed trial of stool softener from criteria; only require trial of stimulant laxative alone instead of combination. For Medicaid, constipation agents may be covered if treatment of opioid-induced constipation if patient has active cancer pain or drug is part of palliative care regimen.
Sublingual Immunotherapy	Updating reauthorization criteria from 1 year to lifetime approval. In addition, the criterion related to trial of prerequisite therapy was updated to require a trial of both an oral antihistamine and a nasal steroid.
Evzio	Generic Evzio auto-injector is now available which is much lower in cost than the brand, however, more expensive than naloxone syringes and nasal spray. The generic was added to this policy and the branded product will require medical justification as to why the generic auto-injector cannot be used.
Nayzilam	Change policy name to Rescue Medications for Epilepsy and add intranasal diazepam (Valtoco) to the policy.
Xhance	New policy
Oral ANTI-cancer Medications	The changes approved at February P&T meeting were intended to be for Commercial only; therefore, the criteria were updated to reflect that.
Xiaflex	New policy – Dupuytren's contracture will be covered subject to criteria outlined in policy. Other indication (Peyronie's disease) will not be covered, as considered benefit exclusion for all lines of business.
Infusion Therapy Site of Care	Clarified clinical requirements to continue receiving infusions at an unapproved site of care.
Calcitonin Gene-Related Peptide Receptor (CGRP) Inhibitors for Migraine Prophylaxis	Criterion for prerequisite therapy was updated from three (3) classes of conventional prophylactic medications to one class, or contraindication/intolerance to all three (3) classes. In addition, a requirement was added to evaluate for medication overuse headache. Aimovig® and Emgality® will be preferred agents and non-preferred agents will require trial of both preferred agents.