PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 246

April 1, 2020

This is the April 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.

Beginning May 1, 2020:

- ***Site of service criteria will be applied to select surgical procedures including, but not limited to, total knee arthroplasty. These criteria are based on the medical necessity of performing the procedures at an inpatient versus outpatient setting. If a provider would like a copy of the policy, or has any additional questions, please email: PHPMedicalPolicyInquiry@providence.org***
- ***Prior authorization for an insulin pump will only be required for Type 2 diabetes.***

Recall Alert:

Medtronic has issued a class I recall on MiniMed insulin pumps due to incorrect insulin dosing. Please see the FDA announcement (LINK) for more information.

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

Effective June 1, 2020

Minimal Residual Disease Detection in Lymphoid Malignancies (All Lines of Business Except Medicare) LAB425	**New Policy** Minimal residual disease detection (MRD) in lymphoid malignancies using next-generation sequencing (NGS) (i.e. ClonoSeq) is considered investigational and not covered. Note at top of criteria clarifies that other techniques of MRD may be considered medically necessary. Policy is specific to ClonoSeq, the sole FDA-approved NGS assay for addressing lymphoid malignancies. The corresponding CORE will be retired as of effective date. **Evidence:** Hayes conducted an evidence review and assigned a D2 rating (insufficient evidence). "Low-quality" evidence to date has only examined the ClonoSeq assay, and not the sequence generation and downstream data analyses that collectively constitute the ClonoSeq process. Additional studies comparing next-generation sequencing to PCR and flow cytometry are necessary to establish superiority. Studies to determine patient selection criteria are also necessary. **Clinical Practice Guidelines:** In 2020, the NCCN published guidelines supporting the use of MRD testing as an essential component of acute lymphoblastic leukemia (ALL) and multiple myeloma (MM). Nonetheless, authors recommended against NGS assays for the treatment of ALL and, for MM, issued no clear recommendation regarding the role of NGS in MRD detection. The ALL guidance's "discussion section" is currently being updated and further recommendations may be forthcoming. A joint guideline from the ASCO/CCO called for prospective trials validating the efficacy and treatment parameters of NGS assays prior to its utilization in guiding treatment.
Minimal Residual Disease Detection in Lymphoid Malignancies (Medicare Only) LAB424	**New Policy** Minimal residual disease detection (MRD) in lymphoid malignancies using next-generation sequencing (NGS) (i.e. ClonoSeq) is considered medically necessary and covered. **CMS:** • National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) • Local Coverage Article: Billing and Coding: MoIDX: ClonoSEQ Assay for Assessment of Minimal Residual Disease in Patients with Specific Lymphoid Malignancies (A56323)
Bariatric Surgery (All Lines of Business Except Medicare) SUR142	**Annual Update** • Criterion I.C.a has been expanded to include CMS's details of required weight loss program (i.e. must last at least 4 consecutive months). • We will continue to deny adolescent bariatric surgery • Continue to deny BSx in patients with T1D following evidence review.
Bariatric Surgery (Medicare Only) SUR139	**Annual Update** No change in coverage. Bariatric surgery remains covered when criteria are met for Medicare patients. **CMS:** • National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Morbid Obesity (100.1) • Local Coverage Article: Bariatric Surgery Coverage (A53028) • Local Coverage Determination (LCD): Non-Covered Services (L35008)

Effective May 1, 2020

Surgical Site of Service	**Background:** • Centers for Medicare & Medicaid (CMS) policies are increasing opportunity for patient choice under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. • CMS removed total knee arthroplasty from the inpatient only list in 2018, and added TKA to the ambulatory surgical center (ASC) Covered Procedures List (CPL), effective January 1, 2020. • Numerous other procedures including hip arthroplasty have been included in these OPPS and Hospital Inpatient Prospective Payment System (IPPS) • Simultaneously, over the last decade, the ASC market has increased at unprecedented rates. **Policy Changes:** • 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). • As of now, the policy will apply to total knee arthroplasty (TKA) only. We will consider adding other procedures during annual review cycle. ○ We are no longer reviewing for the medical necessity of total knee arthroplasties. The TKA policies will be archived 5/1/2020. ○ 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**. **LOB:** All lines of business **Codes/PA:** All codes from the Total Knee Arthroplasty policies 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 **Evidence:** The evidence regarding patient selection and risk stratification to predict incidence and severity of surgical complications is comprised of pre-surgical, post-procedure, generalized, and procedure-specific tools. Given this breadth in scope, the evidence has been summarized to capture the greatest anesthesia risk based on the American Society of Anesthesiologists and American Heart Association standards and guidelines, along with elements incorporated from American College of Surgeons National Surgical Quality Improvement Program. **Clinical Practice Guidelines:** In addition to the society tools and guidelines referenced in the policy guidelines and evidence, the American Academy of Orthopaedic Surgeons (AAOS) Evidence-based Clinical Practice Guideline for Surgical Management of

	Osteoarthritis of the Knee are included in this new policy draft. The AAOS guidelines are supported by the American Society of Anesthesiologists amongst others, and include recommendations for including BMI and diabetes as risk factors for complications in total knee arthroplasty patients. **CMS:** • Hospital Outpatient Regulations and Notices. Title: Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment (NFRM). Regulation No. CMS-1717-FC. Year: 2020 • Acute Inpatient PPS. FY2020 IPPS Final Rule Home Page. Year: 2020
Diabetes: Insulin Infusion Pumps (External and Implanted) (All LOB Except Medicare) DME208	**Annual Update** The following criteria changes have been made. *General:* • **Policy now solely addresses Type 2 diabetics. Beginning 5/1/2020, Prior Authorization for an insulin pump is only required for Type 2 diabetics.** Note added to top of policy clarifying that pumps (external and internal) may be considered medically necessary for Type 1 diabetics. • Implantable infusion pumps remain investigational (no FDA approved devices). • All Medicare-related language has been removed from criteria, as "CMS only" policy created. • Criteria now apply to all patient populations (previously separated by adults, pregnant women and children). *Specifics (eligibility for Insulin Pumps):* • Requirements for C-peptide testing and beta cell autoantibody testing have been removed. • Criterion I.C.: Patient must have either documented ability to self-adjust insulin dose **or** successfully use a CGM. • Criterion I.D.: Patient must have documented ability to glucose self-test at least 4x daily • Criterion I.E.5.: Documented need for more than 5 daily injections added to list of possible indications • *Removed* "Wide fluctuations in b.g. before mealtime" • *Removed* reference to "dawn phenomenon" • *Removed* criterion mandating visits to treating physician every 3 months • Criterion VII.: Replacement of a pump may be covered when patient either has documented need for a larger insulin reservoir **Codes/PA:** HCPCS codes A9274 (external ambulatory insulin delivery system, disposable) or E0784 (external ambulatory infusion pump, insulin) will be configured to require PA for T2D diagnosis codes only.
Diabetes: Insulin Infusion Pumps (External and Implanted) (Medicare Only) DME414	**New Policy** **Beginning 5/1/2020, Prior Authorization for an insulin pump is only required for Type 2 diabetics.** Medicare criteria now separated out due to differences in coverage criteria. **Codes/PA:** HCPCS E0784 (external ambulatory infusion pump, insulin) will be configured to require PA for T2D diagnosis codes only. Please see policy Billing Guidelines for complete list of diagnosis codes. A9274, which previously denied, will now be handled by pharmacy as disposable insulin pumps are only available through Part D Medicare benefits. **CMS:** • Local Coverage Determination (LCD): External Infusion Pumps (L33794)

	• National Coverage Determination (NCD) for Infusion Pumps (280.14)

Diabetes: Integrated Insulin Infusion and Glucose Monitoring Systems (All Lines of Business Except Medicare)
 	
DME112
 	
Previously titled:
Diabetes: Artificial Pancreas Devices and Other Integrated Systems (All Lines of Business Except Medicare)
	Annual Update
	The following criteria changes have been made. All have been approved by Dr. Halperin and our subject matter expert (SME; Dr. Elizabeth Stephens).
	• Note with hyperlinks to FDA websites moved to Table 1.
	• Title change and language change throughout criteria. "CSII-CGM system, including APDs," replaced with "integrated insulin infusion and glucose monitoring system" – per feedback that "integrated systems" is more apt nomenclature.
	• **Criterion I.C.: *Documented history of inadequate glycemic control despite:***
	  ○ *(Removed)* requirement for compliance with frequent self-monitoring;
	  ○ *(Added)* "despite multiple daily injections and a medically necessary CGM for at least 3 months"
	  ○ *(Added)* note explaining that patients may require simultaneous placement on an IP and glucose monitoring system
	• (*Removed)* criteria addressing type 1 diabetes (formerly I.D.) per feedback from RH
	• **Criterion II**. Overhauled investigational criteria for integrated insulin infusion and glucose monitoring system, per feedback from RH. Now investigation for off-label uses, non-insulin dependent patients and individuals with gestational diabetes
	• **Upgrade/Replacement criteria** – removed requirement that health care provider manage the diabetes within the last 6 months and recommend new system, per feedback from RH.
	Codes/PA: Seven codes will continue to PA. 2 codes (A9274 and E0784) will now only PA when paired with specific dx code for T2D. See billing guideline for more info.

Diabetes: Integrated Insulin Infusion and Glucose Monitoring Systems (Medicare Only) **DME397** Previously titled: *Diabetes: Artificial Pancreas Devices and Other Integrated Systems (Medicare Only)*	**Annual Update** No relevant changes to guidance or coverage. **Codes/PA:** 7 codes will continue to PA. E0784 will now only PA when paired with specific dx code for T2D. See billing guideline for more info. **CMS:** • National Coverage Determination (NCD) for Infusion Pumps (280.14) • Local Coverage Determination (LCD): External Infusion Pumps (L33794) • Local Coverage Determination (LCD): Glucose Monitors (L33822) • Local Coverage Article: External Infusion Pumps – Policy Article (A52507) • Local Coverage Article: Glucose Monitor – Policy Article (A52464)

Effective April 1, 2020

Ambulance Transport **UM386**	**Annual Update** • Criteria continue to be based on the CMS Medicare Benefit Policy Manual; Chapter 10 – Ambulance Services and the Medicare Learning Network Booklet: Medicare Ambulance Transports. • All medical necessity language was removed and criteria now state "covered/not covered". • Additionally, the sections from the CMS manual on which the individual criteria are based on has been added for reference.
Circulating Tumor Cell and DNA Assays for Cancer Management **LAB151**	**Annual Update** Criteria updated to include circulating tumor/cell-free DNA (ctDNA;cfDNA). Both ctDNA and circulating tumor cells (CTCs) will continue to deny investigational. List of example investigational assays now included in criteria.

Previously: Circulating Tumor Cell Assays for Cancer Management	**Evidence:** Several systematic reviews added to the references section, which evaluate CTCs or ctDNA for the management of various cancers. All studies conclude that elevated levels of the biomarkers were associated with poor prognosis but noted a lack of demonstrated clinical utility. **Clinical Practice Guidelines:** NCCN guidelines updated, no change in recommendation against CTC for the management of metastatic breast cancer. Three guidelines from the American Society of Clinical Oncology recommending against CTCs or ctDNA biomarkers for cancer management **CMS:** • Local Coverage Determination (LCD): MolDX: Circulating Tumor Cell Marker Assays (L34066) • Local Coverage Article: Billing and Coding: MolDX: OncoCee™ (A55598) • Local Coverage Article: Billing and Coding: MolDX: Circulating Tumor Cell Marker Assays (A57816)
Anesthesia Care with Diagnostic Endoscopy **MED108**	**Annual Update** Current language in criteria has been edited for clarity. The only content change: • Criterion II.C.4: removed requirement that patients with sleep apnea must submit a copy of the PSG. **Codes/PA: Removing PA from 00813**
Auricular Electrostimulation (All Lines of Business Except Medicare) **MED115**	**Annual Update** No change to criteria designating auricular electrostimulation as investigational and not covered.
Auricular Electrostimulation (Medicare Only) **MED435**	**New Policy** New "Medicare Only" policy. No change designating auricular electrostimulation as not medically necessary and not covered. **CMS:** • National Coverage Determination (NCD) for Acupuncture (30.3) • National Coverage Determination (NCD) for Acupuncture for Fibromyalgia (30.3.1) • National Coverage Determination (NCD) for Acupuncture for Osteoarthritis (30.3.2)
Chemoresistance and Chemosensitivity Assays **LAB169**	**Annual Update** No change to criteria CMS: • National Coverage Determination (NCD) for Human Tumor Stem Cell Drug Sensitivity Assays (190.7) • Local Coverage Determination (LCD): Lab: Special Histochemical Stains and Immunohistochemical Stains (L36353)
Colorectal Cancer Screening: FIT and Cologuard **LAB187**	**Annual Update** No change to criteria. **CMS:** No changes to the National Coverage Determination for Colorectal Cancer Screening Tests (210.3).
Fecal Microbiota Transplantation **MED223**	**Annual Update** No changes to criteria – fecal microbiota transplantation (FMT) remains medically necessary and covered for the treatment of C. difficile infection, and investigational for all other indications.
Genetic Testing: Inherited Susceptibility to Colorectal Cancer (All Lines of Business Except Medicare) **GT388**	**Annual Update** No change to criteria.

Genetic Testing: Inherited Susceptibility to Colorectal Cancer (Medicare Only) **GT413**	**Annual Update** Update to new Medicare policy format. No change to coverage. Continue to use LCD L36884, LCAs: A57353, A57527, and A56104. These LCAs are referenced by the LCD for additional claims processing guidance. **CMS:** • Continue to apply LCD L36884, MolDX: APC and MUTYH Gene Testing • Add LCAs: ○ A57353, Billing and Coding: MolDX: APC and MUTYH Gene Testing ○ A57527, Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) ○ A56104, Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors
Genetic Testing: Inherited Thrombophilias (All Lines of Business except Medicare) **GT401**	**Annual Update** No change to criteria.
Genetic Testing: Inherited Thrombophilias (Medicare Only) **GT402**	**Annual Update** Update to new Medicare policy format. Continue to use LCD L36159. No change to coverage, add LCA: A57424. Remove LCD L36400 from the policy. **CMS:** • Continue to apply LCD L36159, MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) from Noridian, LLC. • Remove reference to LCD L36400 from the policy. This LCD is published by Wisconsin Physicians Services Insurance Corporation, and would not be applicable given the LCD listed above. • Add LCA A57424, Billing and Coding: MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) from Noridian, LLC.
Hip: Total Joint Arthroplasty (All Lines of Business Except Medicare) **SUR247**	**Annual Update** **Recommendation:** InterQual criteria is no longer utilized for total hip arthroplasty. Policy criteria are generally the same, though simplified in presentation.
Hip: Total Joint Arthroplasty (Medicare Only) **SUR248**	**Annual Update** No change to coverage. Updated LCD to current version, and added complimentary Local Coverage Article (LCA). **CMS**: • Continue to use Noridian LCD L36573, Total Hip Arthroplasty. • Add LCA A57684, Billing and Coding: Total Hip Arthroplasty
Lyme Disease **MED277**	**Annual Update** No change to diagnostic testing for Lyme disease as medically necessary when done in accordance with the CDC two-step lab testing process. Other forms of diagnostic testing and non-antimicrobial alternative therapies remain investigational. ZEUS ELISA test systems added to list of investigational diagnostic tests per consideration.
Microcurrent Electrical Neuromuscular Stimulation (MENS) **DME280**	**Annual Update** No change to criteria **CMS:** No CMS guidance identified

Subcutaneous Hormone Pellet Implant MED418	**Annual Update** No change to criteria designating subcutaneous estrogen or testosterone pellet in females is considered investigational **CMS:** No relevant CMS guidance identified as of 1/8/2020.
Vectra DA Test for Rheumatoid Arthritis (All Lines of Business Except Medicare) LAB366	**Annual Update** No change to criteria. Vectra DA Test remains investigational and not covered for the treatment of any condition.
Vectra DA Test for Rheumatoid Arthritis (Medicare Only) LAB423	**New Policy** New "Medicare Only" policy format. No change to criteria covering Vectra DA as covered for Medicare patients. **Codes/PA:** Codes will now be configured to pay only when billed with one of the 200 dx codes listed in the below LCD. Codes will deny NMN when not billed with a proper dx code. See LCA for full list of dx codes. Requesting frequency limit configuration – limit 2 per rolling calendar year. **CMS:** • Local Coverage Article: Billing and Coding: MolDX: Vectra™ DA (A54505)

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

None