PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

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This is the June 1, 2021 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.

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

MEDICAL POLICY COMMITTEE

Lab Management Medical Policies

Effective 6/1/2021, Providence Health Plan will institute the Centers for Medicare & Medicaid (CMS) National Coverage Determination (NCD) Coding Policy Manual of selected lab services for commercial and individual plans.

Q: What is the CMS NCD coding policy manual?
A: The final rule, published in the Federal Register on November 23, 2001 (66 FR 58788), established the national coverage and administrative policies for clinical diagnostic laboratory services. It promoted Medicare program integrity and national uniformity, and simplified administrative requirements for clinical diagnostic services. A total of 23 lab NCDs for diagnostic lab testing services were established as part of this 2001 final rule.

For each of the 23 NCDs, the CMS NCD coding policy manual outlines ICD-10-CM codes that are medically necessary or do not support medical necessity. The coding policy manual also includes limitations to these lab testing services, such as frequency limits.

Q: What is a NCD for diagnostic laboratory testing?
A: A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the clinical circumstances in which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide.

Q: How is Providence Health Plan implementing the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual?
A: Through medical policy, we will create new policies based on the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual. The CPT/HCPCS codes for the various lab testing services are configured to pay or deny (not medically necessary) based on the diagnosis codes outlined in the coding policy manual.

Q: What laboratory services will be affected by this change?
A: For commercial and individual lines of business, we will implement medical policies and coding configuration based on the CMS NCD coding policy manual for the following NCDs:

- Blood Counts (NCD 190.15)
- Glycated Hemoglobin/Glycated Protein (NCD 190.21)
- Thyroid Testing (NCD 190.22)
- Lipids Testing (NCD 190.23)

In the future, we plan to implement all 23 diagnostic laboratory testing NCDs for all lines of business. Provider notice will be provided 60 days in advance of each implementation.

Q: When will the new policies and coding configuration take effect?
A: 6/1/2021* for commercial and individual plans. On this date, the medical policies will be accessible here: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

Q: Where can I access the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual?
A: The NCDs are linked below. Within every NCD there is a section titled "**Covered Code Lists**". Under this section, you may download the most recent version of the CMS NCD coding policy manual.

- Blood Counts (NCD 190.15)
- Glycated Hemoglobin/Glycated Protein (NCD 190.21)
- Thyroid Testing (NCD 190.22)
- Lipids Testing (NCD 190.23)

BEHAVIORAL HEALTH

Effective 7/1/2021

Transcranial Magnetic Stimulation (All Lines of Business Except Medicare) **MP269**	**Interim Update** **Policy changes**: (*provider notice was also given on 5/1/21).* • Expanding requirements to allow psychiatrists and psychiatric nurse practitioners to order transcranial magnetic stimulation (TMS). • Adding requirement that psychiatrist or psychiatric nurse practitioner must oversee the administration of TMS. **Codes/PA:** No coding changes

MEDICAL

Effective 8/1/2021
(Restrictions)

Bariatric Surgery (All Lines of Business Except Medicare) **MP41**	**Annual Update** **Policy changes:** • Note added to top of criteria requiring 6 weeks' cessation for smokers prior to surgery • Non-alcoholic steatohepatitis (NASH) added to list of eligible co-morbidities for patients with BMI between 35 and 39.9 • Expanded language around pre-operative behavioral health/psychological evaluation • Criteria liberalized to allow bariatric surgery for adolescents when criteria are met • Transcatheter bariatric embolotherapy added to list of investigational surgery procedures • Vagus nerve blocking (e.g. Maestro) added to list of "not medically necessary" indications (moved from "investigational" criteria). **Codes/PA:** • Three codes for vagus nerve blocking therapy (0312T, 0313T, 0316T), which currently deny "investigational," will now deny "not medically necessary."
Bariatric Surgery (Medicare Only) **MP37**	**Interim Update** **Policy changes:** • Added transcatheter bariatric embolotherapy to list of procedures unaddressed by CMS that will be reviewed with commercial criteria. **Codes/PA:** One code for vagus nerve blocking therapy (0316T), which currently denies "investigational," will now deny "not medically necessary."
Genetic Testing: Hereditary Breast and Ovarian Cancer (All Lines of Business Except Medicare) **MP143**	**Annual Update** **Policy Changes:** • Added notes to top of policy criteria stating that pharmacogenetic testing and non-covered genetic panels regarding hereditary breast and ovarian cancers are addressed in separate policies. • Added Criterion II.C: Gene testing is specific to the familial pathogenic/likely pathogenic variant. • Removed Criterion VII, which addressed investigational and not covered genetic panels. • Added cross references to the Genetic Testing: Pharmacogenetic Testing and the Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business Except Medicare) policies **Codes/PA:** Removed codes 0102U and 0103U from policy (they will be addressed solely in the Non Covered Genetic Panel policy)

MEDICAL

Effective 6/1/2021

(Liberalizations)

Circulating Tumor Cell and DNA Assays For Cancer Management (All Lines of Business Except Medicare) **MP122**	**Annual Update** **Policy Changes** • Note at top of criteria edited to state that the policy does not address non-small cell lung cancer. • Liberalization: circulating tumor cells (CTCs) or circulating tumor/cell-free DNA (ctDNA or cfDNA) may be covered for assessing PIK3CA mutations in persons with advanced or metastatic HR-positive/HER2-negative breast cancer. • Guardant360 added to list of example investigational tests. **Codes/PA:** • Add 3 codes which already require PA per "Pharmacogenetic Testing" policy (0155U, 0177U, 81309) – specific to PIK3CA testing • Unlisted code (CPT 81479) added to policy.
Circulating Tumor Cell and DNA Assays For Cancer Management (Medicare Only) **MP306**	**New Policy** **Recommendation:** Create new policy due to new LCD covering cell-free DNA tests (also known as circulating tumor DNA tests or liquid biopsies) (e.g. Guardant360) for genomic profiling in solid tumors. Tests may be covered when criteria from following CMS guidance document are met: • National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) • Local Coverage Determination (LCD): MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168) • Local Coverage Article: Billing and Coding: Guardant360® (A58214) • Local Coverage Article: Billing and Coding: MolDX: Circulating Tumor Cell Marker Assays (A57816) • Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36807) • Local Coverage Article: Billing and Coding: MolDX: PIK3CA Gene Tests (A55200) **Codes/PA:** • Three codes will now require PA (CPT: 86152, 86153, 0229U) for Medicare LOB • Three additional codes which already require PA per "Pharmacogenetic Testing" policy (0155U, 0177U, 81309) – specific to PIK3CA testing
Fecal Microbiota Transplantation **MP126**	**Annual Update** **Policy Changes** • Liberalized criteria to allow fecal microbiota transplantation as an option at the 3rd *C. diff* infection, i.e., the 2nd recurrence (criterion I.A.). **Codes/PA:** No changes to coding/PA
Hip: Total Joint Arthroplasty (All Lines of Business Except Medicare) **MP130**	**Annual Update** **Policy Changes:** • Added removal/revision criteria for toxic heavy metals released from hip prostheses. Criteria II.E. to allow for removal/replacement. • Added documentation required for review and policy guidelines to define activities of daily living

	○ *Note*: *No 60-day notice will be given for documents requirement as these are a reiteration of criteria as previously stated and therefore not more restrictive.* • Added criteria notes ○ Total hip arthroplasty performed with a robotic surgical system is considered **not medically necessary and not covered**. ○ This medical policy does not address hip resurfacing which may be considered medically necessary. **Codes/PA:** No changes to coding or PA
Microcurrent Electrical Nerve Stimulation **MP114**	**Annual Update** **Policy Changes:** No changes to criteria. Microcurrent electrical nerve stimulation (MENS), including frequency-specific microcurrent (FSM), is considered to be investigational and not covered as a treatment of any condition. **Codes/PA:** • Billing guideline added, clarifying that CPT 97023 requires PA when billed through eviCore for physical/therapy/occupational therapy services. This code should deny when billed for MENS. • Two miscellaneous DME codes added to policy to include all possible codes with which this service might be billed.
Genetic Testing: Gene Expression Profile Testing for Breast Cancer (All LOB except Medicare) **MP47** *Formerly:* Genetic Testing: Breast Cancer Prognostic Assays (All LOB except Medicare)	**Annual Update** **Policy Changes:** • Policy title changed to better capture scope of the criteria. Profiling assays are recommended and allowed for both prognosis and prediction. • BCI test criteria has been separated out to allow for testing for predicting response to extended adjuvant endocrine therapy in addition to determining prognosis and guiding adjuvant chemotherapy decisions. **Codes/PA:** No recommended changes to coding/PA.
Next Generation Sequencing for Minimal Residual Disease Detection	**Annual Update** **Policy Changes** • Liberalization: allow minimal residual disease (MRD) detection in lymphoid malignancies using next-generation sequencing (i.e. ClonoSeq) for the treatment of acute lymphocytic leukemia or multiple myeloma.

(All Lines of Business Except Medicare) **MP110** *Previously:* *Minimal Residual Disease Detection in Lymphoid Malignancies (All Lines of Business Except Medicare)*	• Denying as investigational two new MRD assays using next-generation sequencing (i.e. Signatera, Guardant Reveal) specific to solid tumors. • Changed policy title to encompass broadened scope. **Codes/PA**: No coding changes.
Next Generation Sequencing for Minimal Residual Disease Detection (Medicare Only) **MP111** *Previously:* *Minimal Residual Disease Detection in Lymphoid Malignancies (Medicare Only)*	**Annual Update** **Policy Changes** Added 2 new guidance documents addressing minimal residual disease detection for colorectal cancers. Continue to follow current two CMS guidance documents: • National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) • Local Coverage Article: Billing and Coding: MolDX: ClonoSEQ Assay for Assessment of Minimal Residual Disease in Patients with Specific Lymphoid Malignancies (A56323) • Local Coverage Determination (LCD): MolDX: Minimal Residual Disease Testing for Colorectal Cancer (L38431) • Local Coverage Article: Billing and Coding: MolDX: Minimal Residual Disease Testing for Colorectal Cancer (A57104) **Codes/PA:** No coding changes
Prostate: Prostatic Urethral Lift **MP161**	**Annual Update** **Policy Changes:** • Removed maximum implant number for urethral lift procedure in criterion I. • Changed criterion III to allow for repeat prostatic urethral lift procedures. **Codes/PA:** No changes to codes or PA

Wireless Capsule Endoscopy (All Lines of Business Except Medicare) **MP134** *Previously: Wireless Capsule Endoscopy*	**Annual Update** **Policy Changes:** • Separated policy into commercial and Medicare policies due to new Medicare guidance, which was effective 4/1/2021. • Added criterion V.C for esophageal varices in cirrhotic members with compromised liver function in which sedation or anesthesia is contraindicated. • Edited criterion VI.C (investigational indications) to exclude esophageal varices in which upper endoscopy is contraindicated. **Codes/PA:** No changes to codes or PA
Genetic Testing: Pharmacogenetic Testing (All Lines of Business Except Medicare) **MP216**	**Interim Update** **Policy Changes:** • Liberalizing coverage to now allow genetic testing of POMC, PCSK1 and/or LEPR for diagnosis of obesity and hyperphagia (chronic weight management) to be treated by Imcivree® (setmelanotide). **Codes/PA:** No changes to codes or PA
Genetic Testing: Thyroid Nodules (All Lines of Business Except Medicare) **MP39**	**Interim Update** **Policy Changes:** • Criterion II: Removed II.C, which states that Afirma GSC or GEC is considered investigational when used in combination with add on tests. • Criterion III: Added Afirma BRAF, Afirma MTC, and Afirma Xpression Atlas to list of E/I tests. **Codes/PA:** No changes to codes or PA.

VENDOR UPDATES

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Advanced Imaging Clinical Appropriateness Guidelines. Part of the AIM guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services

Advanced Imaging of the Spine – updates by section

Congenital vertebral defects
- New requirement for additional evaluation with radiographs

Scoliosis
- Defined criteria for which presurgical planning is indicated
- Requirement for radiographs and new or progressive symptoms for postsurgical imaging

Spinal dysraphism and tethered cord
- Diagnostic imaging strategy limiting the use of CT to cases where MRI cannot be performed
- New requirement for US prior to advanced imaging for tethered cord in infants age 5 months or less

Multiple sclerosis
- New criteria for imaging in initial diagnosis of MS

Spinal infection
- New criteria for diagnosis and management aligned with IDSA and University of Michigan guidelines

Axial spondyloarthropathy
- Defined inflammatory back pain
- Diagnostic testing strategy outlining radiography requirements

Cervical injury
- Aligned with ACR position on pediatric cervical trauma

Thoracic or lumbar injury
- Diagnostic testing strategy emphasizing radiography and limiting the use of MRI for known fracture
- Remove indication for follow-up imaging of progressively worsening pain in the absence of fracture or neurologic deficits

Syringomyelia
- Removed indication for surveillance imaging

Non-specific low back pain
- Aligned pediatric guidelines with ACR pediatric low back pain guidelines

<u>Advanced Imaging of the Extremities</u>– updates by section

Osteomyelitis or septic arthritis; myositis
- Removed CT as a followup to nondiagnostic MRI due to lower diagnostic accuracy of CT

Epicondylitis and Tenosynovitis – long head of biceps
- Removed due to lack of evidence supporting imaging for this diagnosis

Plantar fasciitis and fibromatosis
- Removed CT as a followup to nondiagnostic MRI due to lower diagnostic accuracy of CT
- Added specific conservative management requirements

Brachial plexus mass
- Added specific requirement for suspicious findings on clinical exam or prior imaging

Morton’s neuroma
- Added requirements for focused steroid injection, orthoses, plan for surgery

Adhesive capsulitis

- Added requirement for planned intervention (manipulation under anesthesia or lysis of adhesions)

Rotator cuff tear; Labral tear – shoulder; Labral tear - hip

- Defined specific exam findings and duration of conservative management
- Recurrent labral tear now requires same criteria as an initial tear (shoulder only)

Triangular fibrocartilage complex tear

- Added requirement for radiographs and conservative management for chronic tear

Ligament tear – knee; meniscal tear

- Added requirement for radiographs for specific scenarios
- Increased duration of conservative management for chronic meniscal tears

Ligament and tendon injuries – foot and ankle

- Defined required duration of conservative management

Chronic anterior knee pain including chondromalacia patella and patellofemoral pain syndrome

- Lengthened duration of conservative management and specified requirement for chronic anterior knee pain

Intra-articular loose body

- Requirement for mechanical symptoms

Osteochondral lesion (including osteochondritis dissecans, transient dislocation of patella)

- New requirement for radiographs

Entrapment neuropathy

- Exclude carpal and cubital tunnel

Persistent lower extremity pain

- Defined duration of conservative management (6 weeks)
- Exclude hip joint (addressed in other indications)

Upper extremity pain

- Exclude shoulder joint (addressed in other indications)
- Diagnostic testing strategy limiting use of CT to when MRI cannot be performed or is nondiagnostic

Knee arthroplasty, presurgical planning

- Limited to MAKO and robotic assist arthroplasty cases

Perioperative imaging, not otherwise specified

- Require radiographs or ultrasound prior to advanced imaging

<u>Vascular Imaging</u> – updates by section

- Alternative non-vascular modality imaging approaches, where applicable

Hemorrhage, Intracranial

- Clinical scenario specification of subarachnoid hemorrhage indication.
- Addition of Pediatric intracerebral hemorrhage indication.

Horner's syndrome; Pulsatile Tinnitus; Trigeminal neuralgia

- Removal of management scenario to limit continued vascular evaluation

Stroke/TIA; Stenosis or Occlusion (Intracranial/Extracranial)

- Acute and subacute time frame specifications; removal of carotid/cardiac workup requirement for intracranial vascular evaluation; addition of management specifications
- Sections separated anatomically into anterior/posterior circulation (Carotid artery and Vertebral or Basilar arteries, respectively)

Pulmonary Embolism

- Addition of non-diagnostic chest radiograph requirement for all indications
- Addition of pregnancy-adjusted YEARS algorithm

Peripheral Arterial Disease

- Addition of new post-revascularization scenario to both upper and lower extremity PAD evaluation

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 (P&T) Committee

None