Healthcare Services Medical & Pharmacy Policy Alerts

Number 263

October 1, 2021

This is the October 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.

Lab Management FAQ

Effective 11/1/2021, Providence Health Plan and Providence Health Assurance will institute additional CMS National Coverage Determinations (NCDs) of selected lab services for Medicare, 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 and Providence Health Assurance 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 Medicare, 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:

- Prostate Specific Antigen (NCD 190.31)
- Serum Iron Studies (NCD 190.18)
- Partial Thromboplastin Time (NCD 190.16)
- Hepatitis Panel/Acute Hepatitis Panel (NCD 190.33)

Q: When will the new policies and coding configuration take effect?

A: 11/1/2021 for Medicare, commercial, and individual plans. On this date, the medical policies will be accessible here: https://www.providencehealthplan.com/providers/medical-policy--rx-pharmacy-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.

- Prostate Specific Antigen (NCD 190.31)
- Serum Iron Studies (NCD 190.18)
- Partial Thromboplastin Time (NCD 190.16)
- Hepatitis Panel/Acute Hepatitis Panel (NCD 190.33)

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

MEDICAL POLICY COMMITTEE

MEDICAL
Effective 1/1/2022

Intraoperative Monitoring (All Lines of Business Except Medicare) **MP295**	**Policy Updates** • New policy created addressing intraoperative neurophysiological monitoring (IOM). • IOM may be covered when performed as part of monitoring of nerves during various surgeries (e.g. monitoring a cranial nerve during head and/or neck surgery, monitoring of recurrent laryngeal nerve function during high-risk thyroid surgery.) • IOM may be covered when performed during various spinal surgeries (e.g. surgery with instrumentation, high-risk cervical spine surgery.) • IOM will deny as not medically necessary when performed during radiofrequency a Intraoperative Monitoring (Medicare Only) • MP296blation, epidural steroid injections, facet joint injections, spinal cord stimulator placement or when performed during various spine surgeries (e.g. routine decompression, surgery performed below L1/L2. **Codes/PA:** • IOM codes (95940 and G0453) will be configured to pay when billed with certain diagnosis codes, which will be listed in the policy's "Billing Guideline Appendix." • IOM codes (95940 and G0453) will be configured to deny when billed with certain CPT codes (e.g. spinal cord stimulator placement, radiofrequency ablation) or when billed with certain dx codes for indications below L1/L2 or cervical surgery. • IOM codes (95940 and G0453) will require prior authorization when billed with any other diagnosis code

Intraoperative Monitoring (Medicare Only) **MP296**	**Policy Updates** • New policy created addressing intraoperative neurophysiological monitoring (IOM), per the following Medicare guidance documents: ○ National Coverage Determination (NCD) for Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature (160.8) ○ Local Coverage Determination (LCD): Nerve Conduction Studies and Electromyography (L36526) ○ Local Coverage Article: Billing and Coding: Nerve Conduction Studies and Electromyography (A54992) ○ Local Coverage Determination (LCD): Intraoperative Neurophysiological Testing (L34623) ○ Local Coverage Article: Billing and Coding: Intraoperative Neurophysiological Testing (A57604) **Codes/PA:** • IOM codes (95940 and G04539) will be considered medically necessary and covered only when billed with one of the diagnosis codes listed in the Billing Guidelines Appendix, as listed in the relevant LCA.
Hysterectomy for Benign Conditions (All Lines of Business Except Medicare) **MP286** ***Note: Policy effective date may be delayed. If so, an additional provider alert will be issued.***	**Policy Updates** • New policy created addressing hysterectomies for benign conditions, including: ○ Abnormal uterine bleeding ○ Adenomyosis ○ Chronic Pelvic Pain ○ CIN 2, CIN 2,3, and CIN 3 ○ Endometrial hyperplasia ○ Endometriosis ○ Pelvic Inflammatory Disease ○ Uterine Prolapse **Codes/PA:** 24 CPT codes related to hysterectomies will be configured to require prior authorization when billed with diagnosis codes for conditions listed above. These codes will not require prior authorization when billed with other diagnosis codes.

MEDICAL

Effective 12/1/2021

Cosmetic and Reconstructive Surgery (All Lines of Business Except Medicare)	**Policy Updates:** • Add liposuction for treating lipedema as an example of procedures considered to be cosmetic and not covered (below criterion II). • Add to Billing Guidelines: Code 17380 is paired to pay with gender identity disorder diagnosis codes, and deny as cosmetic otherwise. **Codes/PA:**

MP98	• Add note to top of PA coding table stating that codes billed with diagnosis codes F64.0, F64.1, F64.8, or F64.9 do not require PA. • Add note to top of Not Covered coding table stating that codes billed with diagnosis codes F64.0, F64.1, F64.8, or F64.9 may be considered medically necessary and covered. • Move code 17380 from the PA coding table to the No PA required table.
Genetic and Molecular Testing **MP215** *Formerly: Genetic Studies and Counseling*	**Policy Updates:** • Split molecular and genetic testing criteria out from counseling requirements. • Update Documentation Requirements to aid in efficient review. **Codes/PA:** • Panel codes that require PA will stay in this policy for review by CORES or another applicable Medical Policy. • Remove all codes that always deny, single gene or panel. • Remove all codes that do not stop for pre-authorization from this policy. Update all codes that are currently configured to deny for Medicare to require prior authorization.

Genetic Counseling
 	
MP316
	Policy Updates:
	• Split molecular and genetic diagnostic testing criteria out from counseling requirements.
	• Clarify which genetic conditions have specific counseling criteria that do not apply to this general policy. Otherwise any genetic testing request will fall under purview of this policy as previously implemented.
	• The following policies will have genetic counseling criteria removed (also on this Agenda)
	  ○ GT. CADASIL Disease
	  ○ GT. Hereditary Breast and Ovarian Cancer (All LOB except CMS)
	  ○ GT. Inherited Susceptibility to Colorectal Cancer (All LOB except CMS)
	  ○ GT. Reproductive Planning and Prenatal Testing (All LOB Except CMS)
	  ○ GT. Whole Exome, Whole Genome and Proteogenomic Testing
	Codes/PA: This policy has no codes. All codes are in specific policies for genetic testing that will point back to this policy for genetic counseling requirements as needed.

Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business Except Medicare) **MP213**	**Policy Updates:** • Add a number of genetic panels to the list of investigational panels. • Remove a number of genetic panels that are no longer being offered or used. • Add 'Policy Cross-Reference' column to Table in criteria **Codes/PA:** • Add new codes 0249U and 0250U to deny as investigational. • Remove codes for single genes, as this is considered incorrect billing.

<table>
<tr><td></td><td>

Remove PA for codes 81232, 81283, 81287, 81328, and 81346
Remove investigational denial from the following codes:

<table>
<tr><td>0029U</td><td>0030U</td><td>0032U</td><td>0033U</td><td>0050U</td><td>0055U</td><td>0120U</td><td>0135U</td></tr>
<tr><td>0153U</td><td>0173U</td><td>G9143</td><td>0216U</td><td>0217U</td><td>0128U</td><td>0253U</td><td></td></tr>
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<tr><td>Chemoresistance and Chemosensitivity Assays

MP121</td><td>
Policy Updates

Remove Ex-Vivo Analysis assay from criterion G., which was just added in May because this is a duplicate of criterion D.
Add 3D Predict Glioma (KIYATEC®, Inc) as investigational. This assay is represented by code 0248U and is considered investigational per existing policy criteria.
Update Centers for Medicare & Medicaid Services guidance to include the additional assay:

National Coverage Determination (NCD) for Human Tumor Stem Cell Drug Sensitivity Assays (190.7)
Local Coverage Determinations (LCDs): Lab: Special Histochemical Stains and Immunohistochemical Stains (L36353) and In Vitro Chemosensitivity & Chemoresistance Assays (L37630)
For the 3D Predict Glioma test, by KIYATEC®, Inc. (South Carolina): Local Coverage Determination (LCD): In Vitro Chemosensitivity & Chemoresistance Assays (L34554)

Codes/PA:

Add 0248U to list of investigational codes.
Add 0083U with no change to investigational configuration. Code has been reviewed under the Investigational Medical Technologies policy and fits more appropriately under the scope of this policy.

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<tr><td>Colorectal Cancer Screening

MP106</td><td>
Policy Updates

Added blood-based biomarker testing (e.g., Epi proColon®) for colorectal cancer screening is considered investigational and not covered.

Codes/PA: Add G0327, new code for Epi proColon®.
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<tr><td>Genetic Testing: CADASIL Disease

MP238</td><td>
Policy Updates:

Remove criteria for genetic counseling to coordinate with new Genetic Counseling policy which will house all requirements for all policies that require genetic counseling.
Expand on Documentation Requirements to clarify requirements for efficient review and align with other policies.

Codes/PA: No recommended changes to coding/PA.
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<tr><td>Genetic Testing: Gene Expression</td><td>Policy Updates:</td></tr>
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Profile Testing for Breast Cancer (All Lines of Business Except Medicare) **MP47**	• Add Theralink® Reverse Phase Protein Array (RPPA) (Theralink® Technologies, Inc) to Criterion IV. as investigational. This assay is represented by code 0249U and is considered investigational per existing policy criteria. • Add Documentation Requirements to clarify requirements for efficient review. **Codes/PA:** • Add 0249U to the investigational codes. This code will also appear on the GT Non-Covered Panels (All Lines of Business Except Medicare) policy, effective 12/01/2021.
Genetic Testing: Gene Expression Profile Testing for Breast Cancer (Medicare Only) **MP48**	**Policy Updates:** • Changes made to this policy due to Q3 2021 Code updates. **Codes/PA:** • Code 0249U: Add code to the policy, with PA edits.
Genetic Testing: Hereditary Breast and Ovarian Cancer (All Lines of Business Except Medicare) **MP143**	**Policy Updates:** • Add back criterion regarding genetic panel testing, which was erroneously removed in previous version. • Remove criteria for genetic counseling to coordinate with new Genetic Counseling policy which will house all requirements for all policies that require genetic counseling. • Expand on Documentation Requirements to clarify requirements for efficient review and align with other policies. **Codes/PA**: Add four (4) codes, 0102U, 0103U, 0132U and 0131U to policy to deny as investigational.
Genetic Testing: Inherited Susceptibility to Colorectal Cancer (All Lines of Business Except Medicare) **MP115**	**Policy Updates:** • Remove criteria for genetic counseling to coordinate with new Genetic Counseling policy which will house all requirements for all policies that require genetic counseling. • Add Documentation Requirements to clarify requirements for efficient review. **Codes/PA:** Add CPT 0130U to the investigational codes. This code represents test, ColoNext® (Ambry) which is investigational per existing policy criteria.
Genetic Testing: Reproductive Planning and Prenatal Testing	**Policy Updates:** • Remove criteria for genetic counseling though added references to new Genetic Counseling policy which will house all requirements for all policies that require genetic counseling. Note that new criteria number XIX has no genetic counseling requirement as per the new policy (non-heritable conditions, e.g., trisomies, are excluded for counseling requirements).

(All Lines of Business Except Medicare) **MP78**	• Expand on Documentation Requirements to clarify requirements for efficient review and align with other policies. **Codes/PA:** No recommended changes to coding/PA.
Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing **MP219**	**Policy Updates:** • Remove criteria for genetic counseling to coordinate with new Genetic Counseling policy which will house all requirements for all policies that require genetic counseling. • Expand on Documentation Requirements to clarify requirements for efficient review and align with other policies. **Codes/PA:** Add CPT 0209U to the investigational codes. This code represents the test, CNGnome (PerkinElmer Genomics®) which is investigational per existing policy criteria and is already mentioned by name in the Policy Guidelines.
Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring **MP218**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** • Add code 81335 to policy configured to PA. This codes represents single gene testing for *TPMT*, which the current policy considers to be medically necessary when criteria are met. • Move 81306 to PA section of policy from investigational section. This code represents single-gene testing for *NUDT* which the current policy considers to be medically necessary when criteria are met.
Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (All Lines of Business Except Medicare) **MP194**	**Policy Updates:** • Add PGDx elio™ tissue complete (Personal Genome Diagnostics, Inc.) to Criterion V. as investigational. This assay is represented by code 0250U and is considered investigational per existing policy criteria. • Add Documentation Requirements to clarify requirements for efficient review. **Codes/PA:** • Add 0250U to the investigational codes. This code will also appear on the GT Non-Covered Panels (All Lines of Business Except Medicare) policy, effective 12/01/2021. • Add 0048U to the investigational codes. This code represents the test, Memorial Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Targets™ (MSK-IMPACT™) which is investigational per existing policy criteria and is referenced on GT Non-Covered Panels (All Lines of Business Except Medicare) policy.
Non-Small Cell Lung Cancer: Molecular Testing	**Policy Updates:** • Changes made to this policy due to Q3 2021 Code updates. **Codes/PA:**

for Targeted Therapy (Medicare Only) **MP193**	• Code 0250U: Add code to the policy, with PA edits.
Residential Mental Health Treatment Facilities **MP307** ***Note: Policy effective date may be delayed. If so, an additional provider alert will be issued.***	**Policy Updates** **Recommendation:** Create policy with medically necessary criteria for residential mental health treatment centers in general as well as specific criteria for level 3.5 and level 3.7 centers for substance use disorders (SUDS). **Codes/PA:** No CPT or HCPCs codes apply to the policy.

MEDICAL

Effective 11/1/2021

Proton Beam Radiation Therapy **MP167**	**Policy Updates:** • Add criteria that finds proton beam radiation therapy medically necessary for treating prostate cancer • Remove prostate cancer from Criterion VI, listing indications that are not medically necessary **Codes/PA:** • For all codes on policy, configure with diagnosis code C61 to be medically necessary with no PA, all other diagnosis codes will continue to require prior auth. • Add note to coding table and billing guideline reflecting this new configuration

MEDICAL
Effective 10/1/2021

Back: Epidural Steroid Injections	**Policy Updates** • Add language clarifying that physical examinations, which are required for initial and repeat epidural steroid injection(s), may be performed in-office or via video telehealth visit. • Update the following policy sections with revised language: "Documentation Requirements", "Initial Injection(s)" (I.A.) and "Repeat Injections" (III.C.) **Codes/PA:** No changes to codes/PA

VENDOR UPDATES

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Call to Action:

Clinical review and comment on guideline updates by *October 18, 2021*
Implementation of several high-impact expansive changes – *November 7, 2021*
Implementation of remaining changes – *March 13, 2022*
Provider communications consideration – recommending notification be shared by *December 1, 2021* if 90-day notice is required)

Dear Colleague,

AIM Specialty Health© (AIM) is pleased to provide for your review updates to the AIM Clinical Appropriateness Guidelines. As always, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services. The updates, part of the AIM guideline annual review process, enhance the text related to the following guidelines:

Cardiac Imaging
Oncologic Imaging
Brain Imaging
Head and Neck Imaging
Chest Imaging
Abdomen/Pelvis Imaging

Notes on the effective dates:

- Expansive changes: We are pleased to announce new functionality that will allow earlier adoption of several high-priority expansive changes. These changes are primarily the result of seminal new literature or guidelines and make it easier to obtain authorization in specific clinical scenarios. Early implementation of these changes will help to streamline the PA process with a system solution as soon as possible. These changes will be adopted November 7th 2021, with the remaining changes effective on March 13, 2022 per our standard timeline. Because these changes are universally more expansive in their coverage, they should not require additional provider notification. These changes are highlighted in green in the review materials
- Restrictive Changes: To allow time for your provider notifications requirements, the remaining changes will be effective on March 13, 2022. In October, following your review and comment period, we will supply a proposed provider notification copy for a projected December 1st provider notification publication.

These updates include code changes that will be effective March 13, 2022. These code changes are noted in the redlined version of the guideline and may or may not apply to your program. Your AIM client director will work with your team to determine what changes will be implemented.

If you have any questions, please do not hesitate to contact my colleague Andrea Garren at garrena@aimspecialtyhealth.com.

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.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee

Go-Live Date: Saturday, January 01, 2022, unless otherwise noted

Medicare Calendar Year (CY) 2022 Updates:

Annually, Medicare Part D plans are required to submit a formulary to the Centers for Medicare & Medicaid Services (CMS) for the upcoming calendar year. As part of this annual review, the formulary is reviewed in its entirety and changes are made based on the safety, comparative efficacy, and cost-effectiveness of therapies.

On October 1st 2021 the CMS approved Providence Health Assurance CY2022 Medicare formularies will be available for review on the Providence Health Assurance website: https://www.providencehealthplan.com/medicare/medicare-advantage-plans/formulary-list-of-approved-drugs

- Patients and providers are encouraged to review the formularies for changes to their medications prior to the new year

A high-level summary of changes for CY2022 include:

- Examples of medications moved to lower tiers (lower cost-share)
  - Alendronate
  - Fluoxetine capsules
  - Olmesartan
- Examples of medications moved to higher tiers (higher cost-share)
  - High-risk medications in the elderly (e.g., oral contraceptives, amitriptyline, nitrofurantoin)
  - Acute-use therapies (e.g. high-cost antibiotics/NSAIDs with lower cost alternatives)
  - More cost-effective alternatives or formulations available on lower tiers (e.g., naproxen delayed-release, buprenorphine/naloxone film, metronidazole lotion, diclofenac ER tablets)
- Drugs Removed from Formulary, based on several reasons, including:
  - Drugs that are considered a medical benefit, typically covered by Part B (e.g., piggy-back formulations, IV solutions)
  - A generic version has become available and was added to formulary in place of the brand (e.g., Lotemax® ophthalmic gel)
  - Drug is obsolete
  - More cost-effective alternatives or formulations available on the formulary (e.g., carvedilol ER, betamethasone topical foam, doxycycline monohydrate 150 mg tablet)

CY2022 Part B Step Therapy:

Providence Health Assurance will be participating in the Centers for Medicare & Medicaid Services (CMS) Part B Step Therapy Program (ST) for CY2022.

1. The ST program applies to drugs covered under the Part B benefit (outpatient healthcare administered medications)
2. If a drug is part of the ST program, it requires a trial of a preferred drug to treat a medical condition before covering a non-preferred drug
   a. Both preferred and non-preferred drugs may still be subject to prior authorization medical necessity criteria or quantity limits
3. ST program requirements for preferred therapies will only be for members being initiated on therapy; patients established on the requested medication within the previous 365 days will not be subject to ST requirements
   a. Prior authorization medical necessity criteria or quantity limits may still apply

Details of the Part B ST program are available on the Providence Health Assurance website at:
https://www.providencehealthplan.com/providers/medical-policy--rx-pharmacy-and-provider-information#8B73CB96FAB24891B9792ED270E5B1D8