PROVIDENCE
Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 243

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This is the January 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-and-provider-information/

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

Recall Alert:

Medtronic has recalled remote controllers for MiniMed insulin pumps for potential cybersecurity risks. Please see FDA announcement (LINK) for more information.

PROVIDENCE Health Plan

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

MEDICAL POLICY COMMITTEE

Effective January 1, 2020

Genetic Testing: Breast Cancer Prognostic Assays (All LOB Except Medicare) **GT157**	**Annual Update** *This policy was updated following NCCN guidelines and recommendations for simplification of the criteria to aid in streamlining implementation.* • Add Breast Cancer Index and EndoPredict to covered assays when criteria are met. This aligns us with NCCN cat 2A recommendations. • Simplify the criteria by moving all covered tests into the same Criterion I. requirements. • Add N1 (less than 4 nodes) to node status sub criterion. This will align several assays to current guidelines. • The above recommendations cause liberalizations for MammaPrint by 1) removing the tumor maximum size criterion, and 2) clinical risk classification requirement. Additionally, the only restrictive impact for MammaPrint results in requiring that tumor be >0.5cm. Not recommending 60-day notice, as this is still generally aligned with practice guideline algorithms. • Move not medically necessary scenarios regarding previous testing and repeat testing into inclusion criteria for coverage under Criterion I. • Remove exclusion of men with breast cancer from not medically necessary criterion. **LOB:** All lines of business except Medicare **Codes/PA:** Add new 1/1/2020 effective code, 81522 to policy. This code will be used for the EndoPredict assay.

Genetic Testing: Breast Cancer Prognostic Assays (Medicare Only)
 	
GT158
	Annual Update
	• Updated all Medicare guidance to current versions where applicable. No significant changes to coverage noted.
	• Removed LCDs 36316 and 36785 related to the Breast Cancer Index (BCI) assay. 36316 replaced with LCD 37913.
	• Added the following local documents and articles:
	  ◦ LCA 57620 for Oncotype DCIS
	  ◦ LCA 57608 for Endopredict
	  ◦ LCA 56335 for BCI
	  ◦ LCA 57364 for Prosigna
	  ◦ LCD 37913 (replaces L36316) for BCI
	LOB: Medicare only
	Codes/PA: Add new 1/1/2020 effective code, 81522 to policy. This code will be used for the EndoPredict assay. Remove PA for all assays with medical necessity criteria, including: 81518, 81519, 81520, and 81521. Policy criteria will remain in effect for post-service claims and those that may come in with unlisted codes.

Deep Brain and Responsive Cortical Stimulation (All Lines of Business Except Medicare) **SUR195** *Previously: Deep Brain Stimulation (All LOB Except Medicare)*	**Annual Update** • Policy expanded to also address responsive cortical stimulation. • Responsive neurostimulation (RNS) (e.g. NeuroPace) now considered medically necessary for the treatment of epilepsy, per evidence review and payer survey. Coverage criteria taken directly from FDA approved indications of use, following most other payers. • No change to criteria for Deep Brain Stimulation as covered for Parkinson's, essential tremor, and primary dystonia. **LOB:** All lines of business except Medicare **Codes/PA:** One code added per coding survey (95971: no PA). PA removed from 5 codes (95971, 95976, 95977, 95983, 95984) – all pertaining to analysis of neurostimulation.
Deep Brain and Responsive Cortical Stimulation (Medicare Only) **SUR395** *Previously: Deep Brain Stimulation (Medicare Only)*	**Annual Update** No change to relevant Medicare coverage criteria. RNS not addressed by coverage documents, ergo RNS will be covered under commercial criteria. **LOB:** Medicare Only **Codes/PA:** One code added per coding survey (95971: no PA). PA removed from 5 codes (95971, 95976, 95977, 95983, 95984) – all pertaining to analysis of neurostimulation.

Sleep Disorder Testing (All LOB Except Medicare)
MED343
	Annual Update
	• *Criterion V.*: Full-Night Facility Based Polysomnography for non-OSA sleep disorders.
	  ○ Content was previously dispersed throughout criteria V.-VIII.
	  ○ Covered when a comorbid sleep-related disorder other than OSA is suspected, including but not limited to, hypersomnia, narcolepsy, parasomnia and periodic limb movement disorder.
	  ▪ Checked AASM, no specific criteria given for these non-OSA sleep disorders, state that a proper dx is necessary.
	• *Criteria X.*: Multiple Sleep Latency Testing
	  ○ Content previously dispersed throughout criteria XIV.-XV.
	  ○ Covered when used as part of the evaluation of patients with suspected narcolepsy to confirm dx, and is completed in conjunction with polysomnography conducted no more than 24 hours prior to MSLT; or for patients with suspected hypersomnia, to help differentiate between hypersomnia from narcolepsy.
	  ▪ Based on AASM guidance (2005)
	• *Criteria XII* **(new)**.: Multiple Sleep Latency Testing Repeat Testing

	○ Covered when initial test was affected by extraneous circumstances; or appropriate study conditions were not present during initial testing; or patient is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation. ▪ Based on AASM guidance (2005) Consideration-based updates • Per consideration, criterion XVI. added: remote-controlled titration of an oral appliance (e.g. the MATRx oral appliance titration study) is considered not medically necessary. • Per consideration, Billing Guideline added clarifying that initial PA approval is for either 95810 or 95811, with any additional sleep disorder testing requires submission of a new PA.
Sleep Disorder Testing (Medicare Only) **MED415**	**Annual Update** No changes to applicable Medicare coverage criteria. **LOB:** Medicare Only **CMS:** • **National Coverage Determination (NCD) FOR Sleep Testing for Obstructive Sleep Apnea (OSA)** (240.4.1) • **Local Coverage Determination (LCD): Polysomnography and Other Sleep Studies** (L34040) • **Local Coverage Article (LCA): Abbreviated Daytime Sleep Study (e.g. PAP-NAP)** (A55479)
Sleep Disorder Treatment: Oral Appliances (All LOB Except Medicare) **DME411**	**Annual Update** Fabricated oral appliances (mandibular advancement devices (MAD)) remain medically necessary and covered for the treatment of obstructive sleep apnea. Prefabricated MAD remain investigational. The following changes have been made: • Replacement of Oral Appliance: Per consideration, note added before criterion III. clarifying that, to receive a replacement device, the patient must receive a prescription from the doctor/dentist who initially made (synthesized) the oral appliance. • Per MD input, added criterion V. denying dual PAP and oral appliance therapy as not medically necessary and not covered, including but not limited to, when used as a convenience item (e.g. travel). • Per consideration, "bite deprogrammers" are now addressed and considered investigational (criterion VII.). • Sleep position trainers now considered investigational (new HCPCS code added per 1/1/20 update) (criterion VIII.)
Sleep Disorder Treatment: Oral Appliances (Medicare Only) **DME412**	**Annual Update** No changes to applicable Medicare coverage criteria. Oral appliances remain medically necessary for the treatment of OSA. **LOB:** Medicare Only **CMS:** • Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611) • Local Coverage Article (LCA): Oral Appliances for Obstructive Sleep Apnea (A52512)
Sleep Disorder Treatment: Positive Airway Pressure (All Lines of Business Except Medicare) **MED416**	**Annual Update** Per MD input, added criterion XVI. denying dual PAP and oral appliance therapy as not medically necessary and not covered, including but not limited to, when used as a convenience item (e.g. travel). Note added to top of policy stating that "positive airway pressure (PAP) therapy would be considered a duplicative service and not covered in mild OSA if member chose oral appliance therapy." Per MD input, non-OSA criteria (IX.-XII.) now clarified to include AVAPS (i.e. states "BiPAP/BiPAP AVAPS" instead of "BiPAP". **LOB:** All Lines of Business Except Medicare

Sleep Disorder Treatment: Positive Airway Pressure (Medicare Only) MED417	**Annual Update** No change to applicable Medicare coverage criteria. PAP devices remain covered for the treatment of OSA. **LOB:** Medicare Only **CMS:** • Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) • Local Coverage Article (LCA): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (A52467) • Local Coverage Determination (LCD): Respiratory Assist Devices (L33800) • Local Coverage Article: Respiratory Assist Devices - Policy Article (A52517) • National Coverage Determination (NCD): Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (240.4)
Balloon Dilation of the Sinuses or Eustachian Tubes SUR136	**Annual Update** Clarifying language edits have been made to criteria I.D. and I.E regarding medical management and requiring imaging findings. Neither is more restrictive to existing criteria. No other changes to criteria. **LOB:** All lines of business
Breast Cancer: Focused Microwave Phased Array Thermotherapy for Breast Cancer MED154	**Annual Update** No change to criteria denying focused microwave phased array thermotherapy as investigational and not covered as a treatment of breast cancer. **LOB:** All lines of business
Breast Cancer: Radiofrequency Ablation of Breast Tumors MED159	**Annual Update** No change to criteria denying radiofrequency ablation as investigational and not covered as a treatment of breast cancer. **LOB:** All lines of business
Salivary Hormone Testing (All Lines of Business Except Medicare) LAB339	**Annual Update** No change to criteria considering salivary hormone testing medically necessary for the diagnosis of Cushing's disease. Salivary hormone testing remains investigational for all other indications. **LOB:** All lines of business except Medicare **Codes/PA:** S3650 and S2652 will now be configured to deny E/I (salivary hormone testing for menopause and preterm labor)
Salivary Hormone Testing (Medicare Only) LAB387	**Annual Update** No change to relevant Medicare guidance. Policy put in new Medicare policy format. **LOB:** Medicare only **Codes/PA:** S3650 and S2652 will now be configured to deny E/I **NCD/LCDs:** Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Measurement of Salivary Hormones (L36857)(**Link**)
Port-Wine Stain Laser Treatment MED308	**Annual Update** No change to existing criteria **LOB:** All lines of business

Cold Therapy and Cooling Devices in the Home Setting DME303	**Annual Update** No change to existing criteria. **LOB:** All lines of business
Interferential Stimulation DME256	**Annual Update** No change to existing criteria **LOB:** All lines of business
Skin and Tissue Substitutes MED378	**Interim Update** • Removed investigational indication for "prevention of parotidectomy complications (e.g., Frey syndrome)". • To be in-line with updated Gender Affirming Surgical Interventions policy, added criterion addressing skin substitutes as a component of genital surgery. These may be considered medically necessary for surgical wound coverage prior to skin grafting. **LOB:** All LOBs
Percutaneous Neuromodulation Therapy (PNT) MED305	**Annual Update** No change to criteria designating PNT/PENS as investigational for all indications **LOB:** All lines of business **CMS:** The Centers for Medicare & Medicaid (CMS) Local Coverage Determination (LCD) Non-Covered Services (L35008) indicates PNT is not covered.
Ovarian Cancer: Multimarker Serum Testing LAB299	**Annual Update** Multianalyte serum biomarker testing (i.e., OVA1®, Overa, and ROMA®) remain investigational and not covered for ovarian cancer. **LOB:** All lines of business
Rehabilitation: Mechanical Stretching Devices for Joints of the Extremities DME333	**Annual Update** No change to investigational status of static progressive and patient-actuated stretch devices. **LOB:** All lines of business
Dental Anesthesia Services MED203	**Annual Update** No major changes to criteria covering dental anesthesia services in ambulatory surgical center or hospital facility. Changes to wording and flow. Note to top of criteria added per consideration to clarify CMS coverage stance: "Please see medical policy "MED428: Dental Services: Administrative Guidelines (Medicare Only)" for guidance regarding Medicare coverage of other dental services." **LOB:** All lines of business
Definition: Medical Necessity MED199	**Annual Update** **Criteria:** Per Medicaid guidance, the highlighted language below has been added to the definition of "medical necessity". Accompanying reference has been added as well.

	• Health care services are determined to be **medically necessary** if they are healthcare services or products that a physician, exercising prudent clinical judgement, would provide to a patient for the purpose of evaluating, diagnosing, preventing, or treating illness (including mental illness), injury, disease or its symptoms, and that are: A. In accordance with generally accepted standards of medical practice*; **and** B. Clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the patient's medical condition; and C. Not primarily for the convenience of the patient, physician, or other health care provider; **and** D. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis, prevention, or treatment of that patient's illness, injury, or disease. **In addition, medical necessity determination standards and any other quantitative or non-quantitative treatment limitations applied to Covered Services may be no more restrictive than those applied to Fee-for-Service Covered Services.**
Surgical Treatment for Skin Redundancy (All LOB Except Medicare) **SUR145**	**Annual Update** No major changes made to criteria. Panniculectomy and surgical treatment of other anatomical areas (criterion IV.) remain medically necessary. All CMS-related language has been excised due to creation of new "Medicare Only" policy. **LOB:** All lines of business except Medicare
Surgical Treatment for Skin Redundancy (Medicare Only) **SUR446**	**New Policy** **Recommendation:** New policy due to differences in criteria specificity. **LOB:** CMS Only **CMS:** • Local Coverage Determination (LCD): Plastic Surgery (L37020) • Local Coverage Determination (LCD): Cosmetic and Reconstructive Surgery (L34698) • Local Coverage Article (LCA): Billing and Coding: Cosmetic and Reconstructive Surgery (A57475) • Local Coverage Article (LCA): Billing and Coding: Plastic Surgery (A57222)
Genetic Testing: Thyroid Nodules (All Lines of Business Except Medicare) **GT352**	**Annual Update** No change to policy criteria. Afirma gene expression classifier remains medically necessary to assess fine needle aspirates of thyroid nodules. The use of all gene expression classifiers (other than Afirma) remain investigational. Mutation analysis of fine needle aspirates also remain investigational. **LOB:** All lines of business except Medicare
Genetic Testing: Thyroid Nodules (Medicare Only) **GT419**	**Annual Update** No change in coverage criteria. Afirma remains medically necessary for assessing potentially cancerous thyroid nodules. Mutation analysis of BRAF V600E remains covered. NRAS testing of proliferative thyroid lesions remains non-covered. Several guidance documents currently listed on policy have been retired since the last update, including the "MolDX: Excluded Test List" **LOB:** Medicare Only **CMS:** • Local Coverage Determination: MolDX: Molecular Diagnostic Tests (MDT) (**L36256**)

	• Local Coverage Article: MolDX: Afirma™ Assay by Veracyte Update (**A55139**) • Local Coverage Determination: MolDX: NRAS Genetic Testing (**L36339**)
Rehabilitation: Acute Inpatient **MED329**	**Annual Update** No criteria changes. Acute in-patient rehabilitation services remain medically necessary. Medicare benefit manual upon which policy is based remains unchanged. **LOB:** All lines of business **CMS:** • Medicare Benefit Policy Manual Chapter 1, Inpatient Hospital Services Covered Under Part A. Section 110 Inpatient Rehabilitation Facility (IRF) Services; Rev. 234 (link)

Effective February 1, 2020

Vagus Nerve Stimulation (All Lines of Business Except Medicare) **SUR363** ***Previously: Vagus Nerve Stimulation***	**Annual Update** • Remove Medicare criteria from the policy. A Medicare-only version of the policy has been created. • Simplify/restructure criteria, moving medically necessary indications all to the top two criteria and combining all investigational indications to a single statement. No changes to the intent have been made, thus none of these impacts are more restrictive. **LOB:** All LOB except Medicare **Codes/PA:** • Add 0466T, 0467T, 0468T to the policy which are initial insertion, revision/replacement, and removal of a chest wall respiratory sensor electrode or electrode array. These codes already PA effective 12/1/2019 for hypoglossal nerve stimulation, but are also applicable to VNS. Of note, 0466T is to accompany 64568, which already PA's in this policy. • Remove PA of 64553 for percutaneous VNS, and deny per new Criterion III. • Removing PA from 95974 and 95975 for analysis of implanted neurostimulator. Per consideration from PA team and we already don't PA the other analysis codes.
Vagus Nerve Stimulation (Medicare Only) **SUR446**	**NEW Medicare Policy** Created new Medicare specific version of the vagus nerve stimulation policy. **LOB:** Medicare only **Codes/PA:** Adopt same codes as Commercial version (i.e., sur363) for PA. Other services will point to the Commercial version for lack of CMS guidance. **CMS:** Continue to reference the National Coverage Determination (NCD): 160.18 for Vagus Nerve Stimulation (VNS) covers implantable VNS for those with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.

VENDOR UPDATES

None

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PHARMACY & THERAPEUTICS COMMITTEE

None