PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 254

December 1, 2020

This is the December 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.

FDA Recalls:

BDA Alaris™ System Infusion Pump.
FDA recall information is linked here:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bd-provides-update-previously-disclosed-recall-bd-alaris-system-hardware

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

MEDICAL POLICY COMMITTEE

Effective 1/1/2021, Providence Health Plan and Providence Health Assurance will be integrating behavioral health services into our network. Therefore, the following medical policies (new and existing) have been created and/or annually updated for the 1/1 implementation. *Note: these policies and associated coding configuration will not apply to OHP or the PSJH lines of business.*

Effective January 1, 2021

Cranial Electrical Stimulation BH001	**New Policy** Cranial electrical stimulation will deny not medically necessary and not covered for the treatment of any indication, including but not limited to depression or anxiety disorders. **Codes/PA:** One unlisted code
Ultra-Rapid Detoxification **BH002**	**New Policy** Ultra-rapid detoxification is considered not medically necessary and not covered for the treatment of any indication, including but not limited to, withdrawal from opioid dependence. • Note added to criteria: "This policy does not apply to detoxification or emergency detoxification, which may be considered medically necessary." **Codes/PA:** One unlisted code
Applied Behavior Analysis **BH003**	**New Policy** Applied Behavior Analysis (ABA) will be considered medically necessary and covered when criteria are met, in accordance with the Oregon and Washington state mandates. This includes the ABA assessment, initiation of treatment, and continuation of treatment. **Codes/PA:** ABA will require PA. This includes the ABA assessment, initiation of ABA treatment, and continuation review of ABA treatment every 12 months.
Extended Outpatient Psychotherapy (All Lines of Business Except Medicare) **BH004**	**New Policy** • Implement new BH medical policy for *extended* outpatient psychotherapy that will be used for outlier management and fraud/waste/abuse audits. No PA required, no claim edits. • Policy outlines multiple indications for medically necessary extended psychotherapy (e.g., acute crisis, prolonged exposure therapies, EDMR, etc). All indications based on well-established clinical practice guidelines. **Codes/PA:** No PA or claim edits will be configured. The following codes have been added to the policy and may be used to identify "extended" outpatient psychotherapy. Claims for psychotherapy in excess of 90+ minutes may require medical necessity review. 90837 — Psychotherapy, 60 minutes with patient 90838 — Psychotherapy, 60 minutes with patient when performed with an evaluation and

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<tr><td>Extended Outpatient Psychotherapy (Medicare Only)

BH007</td><td>
New Policy
Recommendation:
• Local Coverage Determination (LCD): Psychiatry and Psychology Services (L34616)
• Local Coverage Article: Billing and Coding: Psychiatry and Psychology Services (A57480)
According to the LCA, “for psychotherapy sessions lasting longer than 90 minutes, reimbursement will only be made if the report is supported by the medical record documenting the face-to-face time spent with the patient and the medical necessity for the extended time.”
Codes/PA: No PA or claim edits will be configured. The following codes have been added to the policy and may be used to identify “extended” outpatient psychotherapy. Claims for psychotherapy in excess of 90+ minutes may require medical necessity review.
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<tr><td>Transcranial Magnetic Stimulation (All Lines of Business Except Medicare)

BH005</td><td>
New Policy
Initial and subsequent use of transcranial magnetic stimulation (TMS) may be considered medically necessary and covered for the treatment of major depressive disorder when criteria are met. Use of TMS maintenance therapy, or use of TMS for the treatment of behavioral disorders other than clinical depression (e.g. obsessive-compulsive disorder (OCD) and migraine with aura) are considered not medically necessary.
Codes/PA: TMS will require PA
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<tr><td>Transcranial Magnetic</td><td>New Policy</td></tr>
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Stimulation (Medicare Only) **BH006**	• Local Coverage Determination (LCD): Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L37008) • Local Coverage Article: Billing and Coding: Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (A57693) **Codes/PA:** TMS will require PA
Psychological and Neuropsychological Testing (All Lines of Business Except Medicare) **BH008**	**New Policy** Implement expanded medical policy with medically necessary criteria for psychological and neuropsychological testing when criteria are met. Psychological testing inventories are based on InterQual® Behavioral Health Procedures Psychological Testing policies. Neuropsychological testing criteria, with two new indications included by InterQual®, have been added to the policy from our current "Neuropsychological Testing (All Lines of Business Except Medicare)" policy, which will now be archived. Psychological testing inventories include: • Millon® Adolescent Clinical Inventory (MACI®) • Minnesota Multiphasic Personality Inventory-2® • Minnesota Multiphasic Personality Inventory-Adolescent® (MMPI-A®) • Personality Assessment Inventory™ (PAI®) • Unspecified Symptom Validity Test (SVT) • Unspecified Tests Billing guideline added to policy that psych/neuropsych testing will be limited to 8 hours of testing and only once per calendar year. Anything beyond this may be subject to medical necessity review. **Codes/PA:** As of 1/1, no PA will be required for psych or neuropsych testing. CPT codes will be paired to pay with diagnosis codes for the medically necessary indications for psych and neruopsych testing outlined by the InterQual policies.
Psychological and Neuropsychological Testing (Medicare Only) **BH009**	**New Policy** Psychological and neuropsychological testing is considered medically necessary when Medicare criteria from the documents below are met. • Local Coverage Determination (LCD): Psychological and Neuropsychological Testing (L34646) • Local Coverage Article: Billing and Coding: Psychological and Neuropsychological Testing (A57481) • CMS Publication 100-02; Medicare Benefit Policy Manual, Chapter 15- Covered Medical and Other Health Services: §80.2 Psychological and Neuropsychological Tests Our current "Neuropsychological Testing (Medicare Only)" policy will be archived and now addressed in this policy. **Codes/PA:** As of 1/1, no PA will be required for psych or neuropsych testing.

Biofeedback and Neurofeedback
 	
MED438
	New Policy
	Implement new policy for biofeedback and neurofeedback with the following criteria:
	• Medically necessary criteria for biofeedback includes urinary incontinence, migraine headaches, chronic cancer pain, and chronic constipation
	• Not medically necessary criteria for biofeedback with EEG monitoring/neurofeedback for the following indications:
	  ○ Anxiety
	  ○ Attention deficit hyperactivity disorder
	  ○ Autism spectrum disorder
	  ○ Depression
	  ○ Obsessive-compulsive disorder
	  ○ Post-traumatic stress disorder
	  ○ Substance use disorder
	  ○ Asthma
	  ○ Epilepsy

	○ Fibromyalgia ○ Primary headaches ○ Traumatic brain injury **Codes/PA:** Add 4 new codes: 90875, 90876, 90901, and E0746 • 90875, 90876, and 90901 would be configured to deny NMN with diagnosis codes for the non-covered indications above.
Drug Testing for Therapeutic or Substance Use Monitoring (All Lines of Business Except Medicare) **LAB361**	**Annual Update** • Title change to reflect the addition of hair and oral fluid drug testing. These testing methodologies will be considered not medically necessary. • Definitive UDT in excess of 7 drug classes (G0481) will now deny not medically necessary. • All other existing UDT limits will stay in effect. These are as follows: ○ Covered presumptive UDT is limited to CPT codes 80305, 80306, and 80307 (PHP Payment Policy 28.0) when medical policy criteria are met. ○ Covered definitive UDT is limited to CPT code G0480 (PHP Payment Policy 28.0) when an unexpected presumptive test warrants further, specific definitive testing (i.e., presumptive testing must precede definitive testing). ○ Definitive testing may only be performed by an independent laboratory or outpatient hospital (PHP Payment Policy 28.0). ○ Covered definitive UDT is limited to 14 tests in a 12-month period (PHP Payment Policy 28.0). **Codes/PA:** ○ 0227U (presumptive testing of 30 or more analytes) adding to policy to deny NMN; new code for 1/1. ○ G0481 (definitive testing for 8-14 drug classes) will now deny NMN ○ Two codes are being added that are specific to drug testing using "oral fluid". These are proprietary lab codes and can only be billed for the lab tests they are specific to. ▪ 0011U: Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites ▪ 0116U: Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications ○ Both 0011U and 0116U will be configured to deny NMN. 0116U is already denying per the Investigational Medical Technologies policy. The code will be removed from the IMT policy and will now deny per the drug testing policy.
Drug Testing for Therapeutic or Substance Use Monitoring (Medicare Only) **LAB414**	**Annual Update** No change to relevant Medicare guidelines. Policy updated to new Medicare format. • Local Coverage Determination (LCD): Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (L36707) • Local Coverage Article: Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (A55030) Medicare does not address drug testing using oral fluid or hair samples; therefore, commercial criteria should be followed. ○ 0227U (presumptive testing of 30 or more analytes) adding to policy to deny NMN; new code for 1/1. ○ G0481 (definitive testing for 8-14 drug classes) will now deny NMN ○ Two codes are being added that are specific to drug testing using "oral fluid". These are proprietary lab codes and can only be billed for the lab tests they are specific to. ▪ 0011U: Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites ▪ 0116U: Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications ○ Both 0011U and 0116U will be configured to deny NMN. 0116U is already denying per the Investigational Medical Technologies policy. The code will be removed from the IMT policy and will now deny per the drug testing policy.
Vagus Nerve Stimulation	**Annual Update**

(All Lines of Business Except Medicare) **SUR363**	Liberalization of criterion I. to remove the specificity of partial onset (focal) seizures, and broaden to "treatment of seizures" when criteria are met. Vagus nerve stimulation remains investigational and not covered for the following indications: • Refractory depression • Alzheimer's disease • Obesity • Migraine headaches • Essential tremor **Codes/PA:** No change to coding/PA.
Vagus Nerve Stimulation (Medicare Only) **SUR446**	**Annual Update** No recommended changes to criteria. • Continue to apply Centers for Medicare & Medicaid Service (CMS) National Coverage Determination 160.18. ○ Per the NCD, as of February 15, 2019, CMS provides coverage for FDA-approved VNS devices for treatment resistant depression when criteria are met. This was in draft at the last annual review of this policy, and was implemented by CMS on 07/22/2020. See the NCD for details.
Deep Brain and Responsive Cortical Stimulation (All Lines of Business Except Medicare) **SUR195**	**Annual Update** No recommended changes to criteria. Deep brain stimulation remains investigational and not covered for the following indications: • Chronic Pain • Multiple Sclerosis • Epilepsy • Depression • Obsessive Compulsive Disorder • Tourette's Syndrome **Codes/PA:** No changes to coding or PA
Deep Brain and Responsive Cortical Stimulation (Medicare Only) **SUR395**	**Annual Update** No recommended changes to criteria. • Continue to apply the following Centers for Medicare & Medicaid Service (CMS) National Coverage Determinations: ○ Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24) ○ Electrical Nerve Stimulators (160.7) ○ Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2) **Codes/PA:** No changes to coding or PA
Complementary and Alternative Medicine **MED437**	**New Policy** • Adopting a new policy with an investigational statement for complementary and alternative medicine therapies. • Medicare guidance exists for some codes in this policy given the broad nature of the codes listed (unlisted codes, and infusion and injection codes). No specific guidance was identified for the specific services listed, however a National Coverage Determination or Local Coverage Determination/Article may still be applicable. A note to this effect was included in the Medicare section of the policy with a link to the Medicare website for searching the applicable document.

	Codes/PA: No PA or coding configuration will be implemented for this policy.

Effective 1/1/2021
Back Pain and Procedures Medical Policies

Back: Fusion and Decompression Procedures **SUR120**	**Annual Update** • ***Documentation requirements***: we have added the following documentation requirements: ○ Clinical notes documenting that the individual has been evaluated at least once by the requesting surgeon before submitting a request for surgery. ○ Medical records must document that a physical examination has been performed or reviewed by the operating surgeon within 3 months prior to surgery. ○ Clinical documentation of ***extent and response to*** conservative care (see Policy Guidelines), as applicable to the policy criteria, ***including outcomes of any procedural interventions, medication use and physical therapy notes*** ○ Imaging reports ○ Evaluation and documentation of ***the extent and specifics of one or more*** of the functional impairments or disabilities ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present ○ Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms ▪ Imaging must be performed and read by an independent radiologist ▪ If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede • ***More restrictive pain and disability requirements***: We have added the following language to criterion I. (cervical laminectomy), criterion III. (thoracic/lumbar laminectomy) and criterion IV.D and IV.F(thoracic/lumbar fusion)((e.g. Criterion I.A.1a.-b): ○ Persistent, debilitating, neck or cervicobrachial radicular pain, secondary to spinal cord or nerve root compression; **and** ○ Documentation that age-appropriate activities of daily living have been moderately or severely impacted (see Policy Guidelines); **or** ○ Moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition) • ***Smoking abstinence before cervical fusion****:* Per evidence review, we are requiring smoking abstinence for at least 4 weeks prior to cervical fusion. One non-evidence based clinical practice guideline (North American Spine Society (2013) does not required abstinence prior to cervical fusion. We already require abstinence prior to lumbar fusion. • ***II. Cervical laminectomy/fusion:*** Expanded list of eligible indications • ***IV.D***.: Deleted requirement that scoliosis must cause "functional impairment" prior to thoracic or lumbar fusion; "functional impairment" language now captured in prior criterion IV.D.1-2. ("spinal instability with disabling pain that in*terferes with age-appropriate activities of daily living "; or 2. severe disability as measured by the Oswestry Disability Index* (this is defined in the "policy guidelines" section)

	• ***Conservative treatment:***
	  ○ Conservative treatment lengthened from 6 weeks to 3 months prior to thoracic or lumbar laminectomy
	  ○ Specific indications for which conservative treatment may be waived now listed in the “policy guidelines”
	  ○ Requirement of at least 3 physical therapy visits
	  ○ Added language specifying that patients’ “symptoms must have failed to improve” and that conservative care is intended "as part of pre-operative surgery planning."
	  ○ Other requirements in policy guideline
	  ▪ Participation in a physical therapy program must last for the duration of conservative management (i.e. 3 months before surgery depending on the indication for surgery), including at least 3 physical therapy visits
	  ▪ Oral analgesics (including anti-inflammatory medications, if not contraindicated) or participation in an interdisciplinary pain management program
	  ▪ Oral corticosteroids (if not contraindicated)
	• ***Annulus repair devices (e.g. Barricaid):*** Added to list of investigational procedures per evidence review and plan survey. 4 of 4 payers deny annular closure devices as investigational. One large (manufacturer-funded) RCT showing good results, but with no long-term follow-up.
	• ***Repeat surgery*****:** Added to "policy guidelines": Repeat fusion may only be covered in the event that new symptoms have returned following resolution from prior surgery. Residual deficits from prior surgery will not be considered.
	  ○ No payers address in criteria; one NASS clinical practice guideline (not evidence-based) approved for cervical fusion.
	• ***New Policy Guidelines:***
	  ○ Activities of daily living
	  ○ Conservative treatments
	  ▪ Indications which may be exempt from conservative care requirements
	  ○ Low back pain
	  ○ Myelopathy
	  ○ Radiculopathy added from 2020 North American Spine Society guideline, per input from LS.
	  ○ Persistent, debilitating pain (measured by VAS)
	  ○ Neck Disability Index: Definition and scoring guide added to aid in interpretation of new "moderate to severe disability" requirement.
	  ○ Oswestry Disability Index: Definition and scoring guide added to aid in interpretation of new "severe disability" requirement.
	  ○ Repeat fusion
	Codes/PA:
	• 2 codes (0274T and 62380) which currently deny “not medically necessary” and “not a covered benefit” for CMS lines of business, will be configured to deny investigational.

	• Removing PA from posterior cervical fusion codes (22590, 22595 and 22600) and removing codes from the policy. We would never deny these due to patients' severe spinal instability. We will be removing PA for these codes and let them pay. In 2019, we received only 88 PA's, only 6 of which denied (5 for OHP).
Back: Artificial Intervertebral Discs (All Lines of Business Except Medicare) **SUR138**	**Interim Update** Interim update to criteria to make consistent with changes in "Back: Fusion and Decompression Procedures" and "Back: Epidural Steroid Injections" policies. **We have liberalized and will consider cervical hybrid fusion procedures medically necessary when criteria are met for both an artificial disc and fusion.** **Documentation requirements***:* WE have added the following documentation requirements (based on "Back: Fusion and Decompression Procedures"): ○ Indication for the requested surgery ○ Clinical notes documenting that the individual has been evaluated at least twice by the requesting surgeon before submitting a request for injection. ○ Medical records must document that a detailed neurological examination has been performed by, or reviewed by the provider performing the injection, within 3 months prior to procedure. ○ Clinical documentation of extent and response to conservative care (see Policy Guidelines for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes ○ Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present ○ Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms ▪ Imaging must be performed and read by an independent radiologist ▪ If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede • **More restrictive pain and disability requirements**: we have replaced several criteria addressing conservative care and symptomology with criteria taken from "Back: Fusion and Decompression Procedures" • **Hybrid procedures:** We will cover cervical hybrid procedures (cervical fusion with cervical artificial intervertebral disc implantation) when criteria for artificial disc replacement are met. This recommendation is made on the basis of comparable safety and efficacy to fusion at 2-year follow-up. ○ III. "Cervical hybrid procedures (cervical fusion with cervical artificial intervertebral disc implantation) may be considered **medically necessary and covered** when both of the following criteria are met (A.-B.): A. For the artificial disc component of the hybrid procedure, criterion I. above is met; **and** B. For the cervical fusion component of the hybrid procedure when criteria in the policy "Back: Fusion and Decompression Procedures" are met. • The following criteria have been copied over from relevant Fusion/Decompression criteria sections. See below:

Cervical Artificial Disc Replacement

- Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see Policy Guidelines))
- At least one of the following criteria are met (1.-2.):
    - Imaging shows severe stenosis with cord signal changes;or
    - Exam shows major, progressive neurologic changes such as myelopathy or progressive weakness; o
    - Patient meets both of the following (a.-b.):
        - a. Persistent, debilitating, neck or cervicobrachial radicular pain (see Policy Guidelines), secondary to spinal cord or nerve root compression; and
        - b. Documentation that age-appropriate activities of daily living have been moderately or severely impacted (see Policy Guidelines); or Moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition); or
    - Symptoms have failed to improve after 3 months **(up from 6 weeks**) conservative treatment (see Policy Guidelines for all requirements), as part of pre-operative surgery planning unless there is intolerable radicular pain (see Policy Guidelines), significant motor dysfunction, or progressive neurologic changes; and
- All other reasonable sources of radicular pain have been formally evaluated and ruled out; and

Lumbar Artificial Disc Replacement

- Persistent, debilitating, radicular pain (see Policy Guidelines) and at least one of the following criteria are met (1.-3.):
    - Documented moderate to severe interference of radicular pain with age-appropriate activities of daily living (see Policy Guidelines); or
    - Severe disability as measured by the Oswestry Disability Index (see Policy Guidelines) ; and
    - Neurological exam abnormalities and symptoms that correlate with spinal cord or nerve root compression that has been identified on neurological imaging studies; and
- Symptoms have failed to improve after 3 months (**down from 6 moths)** of conservative treatment (see Policy Guidelines for all requirements and exceptions), as part of pre-operative surgery planning, including but not limited to physical therapy (unless there is intolerable radicular pain (see Policy Guidelines)), significant motor dysfunction, or progressive neurologic changes); and
- Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see Policy Guidelines); and
- Imaging studies (e.g., CT or MRI) indicate stenosis, or nerve root compression, or spinal cord compression at the level corresponding with above clinical findings; and
- All other reasonable sources of radicular pain and/or neurological changes have been ruled out

	New Policy Guidelines: ○ Activities of daily living ○ Conservative treatments and list of example indications for which conservative care may be waived ○ Myelopathy ○ Radiculopathy ○ Persistent, debilitating pain (measured by VAS) ○ Neck Disability Index ○ Oswestry Disability Index
Back: Epidural Steroid Injections (All Lines of Business Except Medicare) **MED123**	**Annual Update** • **Documentation requirements***:* We have added the following documentation requirements (based on "Back: Fusion and Decompression Procedures"): ○ Indication for the requested procedure ○ Clinical notes documenting that the individual has been evaluated at least once by the requesting provider before submitting a request for injection (except in cases of malignancy, trauma, infection or rapidly progressive neurologic symptoms) ○ Medical records must document that a detailed neurological examination has been performed by, or reviewed by the provider performing the injection, within 3 months prior to procedure. ○ Clinical documentation of extent and response to conservative care (see Policy Guidelines for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes ○ Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present ○ Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms • Imaging must be performed and read by an independent radiologist • If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. ***Initial Injections*** • **More restrictive pain and disability requirements**: We have added the following language to criterion I. B. "initial injections" (based on "Back: Fusion and Decompression Procedures"): B. Persistent, debilitating, radicular pain (see Policy Guidelines) and at least one of the following criteria are met (1.-3.): 1. Documented moderate to severe interference of radicular pain with age-appropriate activities of daily living (see Policy Guidelines); or

2. For thoracic/lumbar epidural steroid injections (ESIs), severe disability as measured by the Oswestry Disability Index (see Policy Guidelines); or
3. For cervical ESIs, moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition).

- **Moved criteria:**
  - **I.D. is now I.F.** The injection is targeted to the documented impingement and/or contact point
- **Conservative treatment**: new requirements per North American Spine Society (NASS) guidelines

E. Symptoms have failed to respond to 6 weeks of conservative treatment (see Policy Guidelines for all requirements) within the last 6 months, including both of the following(1.-2.):

1. Physical therapy including either one the following (a.-b.)
   a. At least 3 physical therapy visits (including active muscle conditioning) over a course of 6 weeks or less; or
   b. Physical therapist's notes, or a physician's statement in the documentation explaining why physical therapy is contraindicated (e.g. progressively worsening pain and disability); and
2. Documented medication usage (e.g. narcotic analgesics, muscle relaxants, non-steroidal anti-inflammatory drugs) or participation in an interdisciplinary pain management program; and

- **Max number of nerve root levels per session:** New requirement per NASS guidelines.

I.G. No more than the maximum number of nerve root levels per session is performed (1.-2.)

1. Caudal and interlaminar: No more than 1 level per session may be performed and not in conjunction with an transforaminal injection.
2. Transforaminal: No more than 2 transforaminal ESIs may be performed at a single setting (e.g. single level bilaterally or two nerve root levels unilaterally)

- **New Policy Guidelines**:
  - Activities of daily living
  - Conservative treatments with list of example indications for which conservative care may be waived
  - Maximum number of nerve root levels per session
  - Repeat injections
  - Radiculopathy
  - Persistent, debilitating pain (measured by VAS)
  - Neck Disability Index
  - Oswestry Disability Index

Repeat Injections

	• **III.A.:** Criteria for initial injections must now be met prior to offering a repeat injection (defined as an injection via same technique (e.g. interlaminar, caudal) at same location as past injection).
	• **III.B.** Language changes
	  ○ "Documentation of clinically relevant sustained pain reduction" now replaced with "documentation that initial injection resulted in greater than 50% radicular pain relief as measured by a standardized rating scale (e.g. ODI and NDI).
	  ○ "Improvement in patient's activities of daily living" replacing "improvement in the patient's functional abilities.
	Frequency Limitations
	• Per NASS guidelines (2020), no more than 4 ESIs may be performed in a 6-month period; no more than 6 ESIs should be performed per 12-month period, regardless of the number of levels involved.
	
	Non-Covered Indications
	• Interlaminar ESI's performed above C7 now called out as not medically necessary, per NASS guidelines
	• Changing denial from investigational to not medically necessary for ESIs with ultrasound guidance and various contraindications (expanded list per NASS).
	• Conscious sedation, Monitored Anesthesia Care (MAC), and intraoperative neuromonitoring (IONM) is considered **not medically necessary and not covered** when performed with an epidural steroid injection.
	Codes/PA:
	• **New billing guideline:** The following codes for monitored anesthesia and moderate sedation (CPT: 00300, 00600, 00620, 00630, 00640, 01992, 99152, 99153, 99156, 99157) will deny "not medically necessary" when billed with an epidural steroid injection(CPT: 62321, 64479, 64480, 62323, 64483, 64484).
	• 0228T-0231T: denials will change from "investigational" to "not medically necessary" per input from Dr. Soot.

Back: Epidural Steroid Injections (Medicare Only)
 	
MED391
	Annual Update
	• We changed the formatting to our new Medicare policy format
	• We continue to follow the following CMS guidance:
	  ○ **Cervical and Thoracic Injections**
	  ▪ Local Coverage Determination (LCD): Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457)
	  ▪ Local Coverage Article: Billing and Coding: Nerve Blockade for Treatment of Chronic Pain and Neuropathy (A52725)
	  ○ **Lumbar Injections**
	  ▪ Local Coverage Determination (LCD): Lumbar Epidural Injections (L34980)
	  ▪ Local Coverage Article: Billing and Coding: Lumbar Epidural Injections (A57203)
	Codes/PA:
	• 2 codes added to policy, per inclusion on A57203 (CPT: 62326, 62327)

Back: Implantable Spinal Cord and Dorsal Ganglion Stimulation (All Lines of Business Except Medicare)
 	
SUR133
	Annual Update
	Criteria have been updated to match language of our other policies addressing pain (e.g. Back Fusion)
	• **Documentation requirements** section has been added to the policy, including medical records of indication, medical records of neurological exam performed within 3 months prior to implantation, clinical documentation of conservative care, documentation of extent and specifics of functional impairments or disabilities, documentation of cognitive and behavior health evaluation, and other appropriate medical records.
	• **Criterion I.A:** Language has been changed to require that patient experiences 'persistent debilitating' neuropathic pain. Definition added to Policy Guidelines.
	• **Criterion I.B:** "Documentation that age-appropriate activities of daily living have been moderately or severely impacted" has been added as a criterion. Definition of "activities of daily life" has been added to Policy Guidelines.
	• **Criterion I.C.1:** Added the presence of radicular pain to Failed Back Surgery Syndrome indication. Added definition of radicular pain to the Policy Guidelines.
	• **Criterion I.D:** Changed language to "conservative treatment" and added definition to the Policy Guidelines, rather than listing it in the criteria section.
	• **Conservative Treatment:** Removed narcotic drugs and spinal injections from the conservative treatment requirements. Neither have shown to be effective in this population. Included physical therapy visits, cognitive therapy, and therapy with NSAIDs, antidepressants, and anticonvulsants, which are commonly used to treat radicular nerve pain.
	• **Criterion I.D:** "Surgical intervention is not indicated and spinal cord stimulation treatment is used only as last resort" was added as a criterion.
	• **Criterion I.F:** Added that a psychological evaluation identifies no problematic emotional reactions, maladaptive thinking and behavior, and/or social problems that may contribute to pain and disability.* The psychological evaluation should include documentation of valid and reliable assessments of all of the following (1.-5.):
	  ○ subjective pain intensity; and
	  ○ mood and personality; and
	  ○ activity interference; and
	  ○ pain beliefs; and
	  ○ coping
	• **Criterion II:** Initial trial period length was changed from ≤ 2 days to 3-7 days, based on FDA and UpToDate recommendations.
	• **Criterion III:** "Chronic" was added to "non-specific back and leg pain" as an investigational condition
	• CARF-accredited management programs were removed from the requirements in the criteria and were removed from Policy Guidelines, due to the lack of access
	Codes/PA: No changes to codes or PA

Back: Implantable Spinal Cord and Dorsal Ganglion	**Annual Update**
	• We changed the formatting to our new Medicare policy format
	• We continue to follow the following CMS guidance:
	  ○ National Coverage Determination (NCD) for Electric Nerve Stimulators (106.7)
	  ○ Local Coverage Determination (LCD): Spinal Cord Stimulators for Chronic Pain (L36204)

Stimulation (Medicare Only) **SUR134**	○ Local Coverage Article: Spinal Cord Stimulators for Chronic Pain (A57792) **Codes/PA:** No changes to codes or PA

Effective January 1, 2021
Other Policies

Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery (All Lines of Business Except Medicare) **SUR438**	**Annual Update** • Policy criteria continue to be based on ASTRO policies for SBRT and SRS. ASTRO's SBRT policy was recently updated, and we have updated our criteria accordingly (see Criteria I-II) **Codes/PA:** New diagnoses codes were added to configure to pay with SBRT codes, based on ASTRO policy. See Billing Guidelines for added ICD-10 codes.
Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery (Medicare Only) **SUR 439**	**Annual Update** • We changed the formatting to our new Medicare policy format • We continue to follow the following CMS guidance: ○ Local Coverage Determination (LCD): Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151) ○ Local Coverage Article: Billing and Coding: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (A57461) **Codes/PA:** No changes to codes or PA
Fecal Incontinence Treatments (All Lines of Business Except Medicare) **SUR224**	**Interim Update** • Add criterion VII: "Peristeen anal irrigation system is considered **not medically necessary and not covered** for the treatment of fecal incontinence." • Add note below criterion VII to explain that the least costly anal irrigation devices will be covered, and that higher end devices such as the Peristeen system are not necessary. **Codes/PA:** Add A4459 to policy to deny as not medically necessary. **Evidence:** Added two randomized trials and 3 retrospective studies on Peristeen and bowel issues. All studies included similar limitations, including small sample size and a lack of long-term safety data.
Wireless Capsule Endoscopy **MED376**	**Interim Update** New criterion (III.B.): Small-bowel wireless capsule endoscopy may be considered medically necessary and covered in patients with Crohn's disease ***to ensure medication response and adequate mucosal healing after medical intervention.*** **Codes/PA:** No coding changes **Clinical Practice Guidelines:** Two new clinical practice guidelines added to evidence section, which support repeat endoscopy even in the absence of symptoms: • NICE (2019) guideline recommends endoscopy to ensure medication response.

	• ACR (2019) states that both endoscopy and imaging are "central tools" in CD to detect active inflammation despite clinical resolution of symptoms.

VENDOR UPDATES

AIM Speciality Health

AIM Specialty Health© (AIM) has updated 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:

- Imaging of the Chest
- Imaging of the Head and Neck
- Imaging of the Brain
- Oncologic Imaging
- Imaging of the Heart, including echocardiography

These enhancements are scheduled to be **effective on March 14, 2021.** Please **submit your questions or feedback to** AIM.guidelines@aimspecialtyhealth.com

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Pharmacy & Therapeutics (P&T) Committee

No Updates