Common Name: Spinal Devices

Definition:
- Implanted devices for treatment of spinal stenosis are spacers used to help open narrowed canals in the spine to relieve compression of nerve roots or the spinal cord.
- Intervertebral stabilization devices are flexible implants that can be used with spinal fusion procedures to stabilize the backbones and allow for some flexibility after fusion.
- Interspinous process fixation devices are attached to the bone protrusion in the middle of each backbone to keep the backbones from moving apart from each other.
- Facet joint allografts are materials taken from outside the body and surgically implanted into the facet joints (where the individual backbones meet) to treat pain arising from these joints.

Device Capture: Product Line + Devices

I. Criteria for Inclusion
Static/nonflexible implanted devices (not intended for use in conjunction with laminectomy) for treatment of spinal stenosis are considered medically necessary for the following indications:

A. Degenerative lumbar stenosis when ALL of the following criteria are met:
   1. Stenosis is confirmed by imaging
   2. Symptoms correlate with imaging findings and claudication is relieved by lumbar flexion
   3. Age greater than 50 years
   4. Failed conservative therapy for a minimum of 6 weeks (i.e. medications, injections)
   5. There is no more than 25 degrees of degenerative scoliosis
   6. There is no more than grade 1 degenerative spondylolisthesis
   7. Open procedure for treatment of stenosis, such as a laminectomy, is not indicated due to significant comorbid condition(s)

II. Criteria for Exclusion
A. Static/nonflexible implanted devices for treatment of spinal stenosis are considered not medically necessary when the above criteria are not met, or for the following:
   1. Patients less than 50 years of age
   2. Mainly axial back pain that is not related to activity
   3. Lumbar flexion does not relieve symptoms
   4. Patient is a candidate for direct decompression (such as a laminectomy)
   5. Presence of degenerative spondylolisthesis above grade 1, or degenerative scoliosis with greater than 25 degree curve

B. Due to lack of sufficient evidence to establish safety and efficacy, dynamic/flexible implanted devices for treatment of spinal stenosis are considered investigational and not medically necessary. Static/nonflexible devices are considered investigational and not medically necessary when done in conjunction with fusion or laminectomy.
C. Due to lack of sufficient evidence to establish safety and efficacy, intervertebral stabilization devices are considered investigational and not medically necessary.

D. Due to lack of sufficient evidence to establish safety and efficacy, interspinous process fixation devices are considered investigational and not medically necessary.

E. Due to lack of sufficient evidence to establish safety and efficacy, facet joint arthroplasty or allograft implants are considered investigational and not medically necessary.

F. For persons with significant co-morbidities or complications, the medical record must contain documentation of the risk/benefit of surgery.

III. Device Considerations
A. Only implants with FDA approval are considered to be medically appropriate

IV. Surgical Considerations
A. Pre-Operative Considerations:
   1. Preoperative care planning needs may include:
      a. Routine preoperative evaluation
      b. Diagnostic test scheduling, including:
         i. MRI or CT scan
         ii. Laboratory testing (CBC, erythrocyte sedimentation rate, C-reactive protein) for suspected infection
      c. Preoperative discharge planning as appropriate

B. Intra-Operative Considerations:
   1. Antibacterial wipes
   2. Antibacterial nasal swab

C. Post-Operative & Inpatient Considerations:
   1. Hospital evaluation and care needs may include:
      a. Treatment and procedure scheduling and completion, including:
         i. Imaging (e.g., x-ray, MRI)
         ii. Arthrocentesis
         iii. IV antibiotics
         iv. DVT prophylaxis
         v. Physical therapy
      b. Monitoring patient's status for deterioration and comorbid conditions

D. Discharge Planning & Considerations:
   1. Discharge planning includes:
      a. Assessment of needs and planning for care, including:
         i. Develop treatment plan (involving multiple providers as needed).
         ii. Evaluate and address preadmission functioning as needed.
         iii. Evaluate and address patient or caregiver preferences as indicated.
         iv. Identify skilled services needed at next level of care, with specific attention to:
            ➢ Neurovascular status assessment
            ➢ Rehabilitation therapy or equipment coordination
            ➢ Wound or dressing management
         v. Evaluate and address psychosocial status issues as indicated
      b. Early identification of anticipated discharge destination; options include:
         i. Home, considerations include:
            ➢ Access to follow-up care
            ➢ Home safety
            ➢ Self-care ability, if appropriate
            ➢ Caregiver need, ability, and availability
         ii. Post-acute skilled care or custodial care, as indicated
c. Transition of care plan complete, which may include:
   i. Patient and caregiver education complete
   ii. Medication reconciliation completion includes:
      ➢ Compare patient's discharge list of medications (prescribed and over-the-counter) against physician's admission or transfer orders.
      ➢ Assess each medication for correlation to disease state or medical condition.
      ➢ Report medication discrepancies to prescribing physician, attending physician, and primary care provider, and ensure accurate medication order is identified.
      ➢ Provide reconciled medication list to all treating providers.
      ➢ Confirm that patient, family, or caregiver can acquire medication.
      ➢ Educate patient, family, and caregiver.
         1. Provide complete medication list to patient, family, or caregiver.
         2. Confirm that patient, family, or caregiver understands importance of presenting personal medication list to all providers at each care transition, including all physician appointments.
         3. Confirm that patient, family, or caregiver understands reason, dosage, and timing of medication (eg, use "teach-back" techniques).
   iii. Plan communicated to patient, caregiver, and all members of care team, including:
      ➢ Inpatient care and service providers
      ➢ Primary care provider
      ➢ All post-discharge care and service providers
   iv. Post-discharge appointment plans made as needed, which may include:
      ➢ Primary care provider
      ➢ Orthopedic surgeon
      ➢ Rehabilitation therapy services
   v. Post-discharge testing and procedure plans made
   vi. Referrals made for assistance or support, which may include:
      ➢ Financial, for follow-up care, medication, and transportation
      ➢ Smoking cessation counseling or treatment
   vii. Medical equipment and supplies coordinated (ie, delivered or delivery confirmed) which may include:
      ➢ Ambulation devices (eg, cane, crutches, walker)
      ➢ Wound care supplies

V. Length of Stay Considerations
   A. Goal length of stay: Not available
   B. Facility type criteria: Not available

VI. Coding
   A. CPT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
<tr>
<td>22868</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level</td>
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<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
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<tr>
<td>22870</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level</td>
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<tr>
<td>22899</td>
<td>Unlisted procedure, spine [when specified as one of the procedures covered in this policy]</td>
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<td>0202T</td>
<td>Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine</td>
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<td>0219T</td>
<td>Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical</td>
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<td>0220T</td>
<td>Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic</td>
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<td>0221T</td>
<td>Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar</td>
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<td>0222T</td>
<td>Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment</td>
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B. HCPCS

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<tr>
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<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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C. ICD-10 Procedure

No ICD-10 Procedure Codes

D. ICD-10 Diagnosis

All associated ICD-10 Diagnosis codes
References

CLINICAL POLICY
Spinal Devices

Regulatory Data

<table>
<thead>
<tr>
<th>Policy Number/Name:</th>
<th>PA.CP.MP.OR.1037 Spinal Devices</th>
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<tr>
<td>Initial Approval and Effective Date:</td>
<td>5/3/2018</td>
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<td>4/30/2018; 2/25/2019</td>
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<td>5/3/2018; 2/27/2019</td>
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URAC Standards:

State Requirements:

CMS/Federal Requirements:

Corresponding policies:

Reviews, Revisions, and Approvals

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<td>03/20</td>
<td>7/8/2020</td>
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• New Policy created.
• Policy administered by Turning Point Healthcare Solutions

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by PA Health & Wellness, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.
This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at [http://www.cms.gov](http://www.cms.gov) for additional information.

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