INTRODUCTION OF POSTERIOR SPINOUS PROCESS DEVICE

Guideline Number: MPG161.05                                       Approval Date: January 09, 2019

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POLICY SUMMARY

Overview
Interspinous Process Decompression (IPD®) is a less invasive surgical procedure in which a titanium metal implant is placed between the spinous processes of the symptomatic lumbar disc levels. The implant may be placed at two levels if necessary. It is performed as an alternative to laminectomy for patients diagnosed with lumbar spinal stenosis who exhibit symptoms of intermittent neurogenic claudication and are able to relieve their symptoms when bending forward or when the spine is in a flexed position such as when sitting. The implant is designed to limit pathologic extension of the spinal segments and maintain them in a neutral or slightly flexed position which may allow patients to resume their normal posture rather than flex the entire spine to gain symptom relief. IPD is performed in the operating room under local, spinal or general anesthesia. It is done as either an inpatient or outpatient procedure depending upon the number of levels performed and the associated co-morbidities.

Guidelines
UnitedHealthcare will consider IPD medically reasonable and necessary for patients who meet ALL of the following criteria:

• Aged 50 or older suffering from (intermittent neurogenic claudication) secondary to a confirmed diagnosis of lumbar spinal stenosis.
• with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain; and
• Patients who have undergone 3-6 months of non-operative conservative treatment including non-steroidal therapy, comprehensive physical therapy, and epidural injection series.

Limitations
IPD will not be considered medically reasonable and necessary with ANY of the following conditions:

• Allergic to titanium or titanium alloy;
• Spinal anatomy or disease that would prevent implant of the device or cause the device to be unstable in situ, such as significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4); an ankylosed segment at the affected level(s); acute fracture of the spinous process or pars interarticularis;
• Significant scoliosis (Cobb angle greater than 25 degrees);
• Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
• Diagnosis of severe osteoporosis (T-score of -2.5 or less).
• Active systemic infection or infection localized at the site of implantation;
• Body mass index (BMI) > 40kg/m2.

Payment for 22867, 22868, 22869 and 22870 will be an inclusive payment. No additional codes for approach or hardware placement should be billed or paid.

Utilization Guidelines
• It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. This procedure may be performed at one or two spinal levels. When services are performed in excess of established parameters, they may be subject to review for medical necessity.
• It is expected that the patient has not previously received a laminotomy or laminectomy at the same level of the spine as the IPD.
• Services performed on patients who have received another spinal procedure such as any spinal instrumentation (CPT codes 22840-22849) and laminectomy or laminotomy (CPT codes 63001-63048) may be subject to denial.

Documentation Requirements
• The medical record must contain documentation that fully supports the medical necessity of the procedure performed. This documentation includes, but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures and the medical records must be available request.
• Documentation must include evidence of six months of non operative treatment. Examples of non operative treatment include medications, corticosteroid injection therapy, rest or restricted activity, devices designed to help stabilize the spine such as back braces/corsets, and physical therapy/exercises to help stabilize the spine, that help to build endurance and increase flexibility.
• The diagnosis of lumbar stenosis must be confirmed by radiological evidence i.e. a report resulting from a CT scan, MRI, or a myelogram.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0171T</td>
<td>Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level (Expired 12/31/2016- see new codes CPT 22867 and 22869)</td>
</tr>
<tr>
<td>0172T</td>
<td>Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure) (Expired 12/31/2016- see new codes CPT 22868 and 22870)</td>
</tr>
<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 (Effective 01/01/2017)</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 (List separately in addition to code for primary procedure) (Effective 01/01/2017)</td>
</tr>
<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 (Effective 01/01/2017)</td>
</tr>
<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 (List separately in addition to code for primary procedure) (Effective 01/01/2017)</td>
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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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<tr>
<th>ICD-10 Diagnosis Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>M48.06</td>
<td>Spinal stenosis, lumbar region (Expired 09/30/2017-see new codes M48.061, M48.062)</td>
</tr>
<tr>
<td>M48.061</td>
<td>Spinal stenosis, lumbar region without neurogenic claudication (Effective 10/01/2017)</td>
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</tbody>
</table>
ICD-10 Diagnosis Code | Description
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M48.062 | Spinal stenosis, lumbar region with neurogenic claudication *(Effective 10/01/2017)*

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS Local Coverage Determinations (LCDs)

<table>
<thead>
<tr>
<th>LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>L34006 (Interspinous Process Decompression) First Coast</td>
<td>FL, VI, PR</td>
<td>FL, VI, PR</td>
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<tr>
<td>L35942 (Surgery: Fusion for Degenerative Joint Disease of the Lumbar Spine) Cahaba</td>
<td>AL, GA, TN</td>
<td>AL, GA, TN</td>
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*Retired 02/25/2018*

CMS Articles

<table>
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<tr>
<th>Article</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>A52693 (Educational Article - CPT 0171T and 0172T (Insertion of posterior spinous process distraction device)) Cahaba</td>
<td>AL, GA, TN</td>
<td>AL, GA, TN</td>
</tr>
</tbody>
</table>

*Retired 02/25/2018*

CMS Transmittals

Transmittal 237, Change Request 5706, Dated 02/01/2008 (PIMR Annual Update)

MLN Matters

Article MM5438, January 2007 Update of the Hospital Outpatient Prospective Payment System (OPPS): Summary of Payment Policy Changes and OPPS PRICER Logic Changes and Instructions for Updating the Outpatient Provider Specific File (OPSF)

UnitedHealthcare Commercial Policies

Surgical Treatment for Spine Pain

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
</tbody>
</table>
| 01/09/2019 | • Annual review  
| | • Updated HCPCS Coding; removed L8606 |

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.
These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.