X Stop® Interspinous Process Decompression Device (Kyphon, Inc.) for Lumbar Spinal Stenosis

Policy Number: HS-028

Original Effective Date: 7/3/2008


APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.

BACKGROUND

Each year in the United States, more than 30,000 patients undergo back surgery for lumbar spinal stenosis, an abnormal narrowing or constriction of spaces in the back that provide pathways for spinal nerves. This disorder is the most common reason for back surgery in patients aged > 65 years and it usually develops due to changes in the spinal disks, joints, and/or ligaments. These changes can compress spinal nerves causing pain and difficulty with walking. Many patients with lumbar spinal stenosis benefit from conservative treatments including rest, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and an appropriate program of physical therapy. Steroid injections may also prove to be effective. If conservative treatments do not provide sufficient relief, back surgery may be needed (Hayes, 2013).

The X Stop® Interspinous Process Decompression (IPD) System has been developed as part of a surgical method to treat lumbar spinal stenosis that includes neurogenic intermittent claudication, a disorder in which spinal nerves are compressed or “pinched.” An advantage of the X Stop device is that implantation involves a fairly small incision and little damage to normal back tissue. This device is composed of a T-shaped titanium spacer assembly that is inserted between the parts of the spinal bones that are closest to the skin, at the site in the lower back that appears to be the source of the symptoms. The spacer component of the implant is then connected to a relatively flat wing assembly that locks the entire assembly in place. After implantation, the X Stop device reduces spinal extension to prevent motions that cause neurogenic intermittent claudication. The device also permits spinal flexion, bending, and rotation. For many patients, this device can be implanted by an orthopedic surgeon or neurosurgeon as an outpatient procedure using local anesthesia (Hayes, 2013).

The literature search identified a randomized controlled trial (RCT) and five uncontrolled studies that evaluated the X Stop IPD System for lumbar spinal stenosis. Results of the RCT suggest that this device enables statistically significant improvements in symptom severity and physical function as measured by the Zurich Claudication Questionnaire.

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

The X Stop® Interspinous Process Decompression System (Kyphon Inc.) is considered experimental / investigational and is not a medical benefit.

CODING

Non-Covered CPT® Codes

28899 Unlisted Procedure on Spine for X-Stop

Non-Covered CPT® Category III Codes

0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level (Sunset January 2017)
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) (Sunset January 2017)

Non-Covered HCPCS® Codes
C1821 Interspinous process distraction device (implantable)

Non-Covered ICD-9-CM Procedure Codes
84.80 Insertion or replacement of interspinous process device(s).

Non-Covered DRAFT ICD-10-PCS Codes
0SH00BZ - 0SH04BZ Medical/Surgical, Lower Joints, Insertion, Lumbar Vertebral Joint
0SH30BZ - 0SH34BZ Medical/Surgical, Lower Joints, Insertion, Lumbosacral Joint

Non-Covered ICD-9-CM Diagnosis Code
724.03 Spinal Stenosis of Lumbar Region with neurogenic claudication

Non-Covered ICD-9-CM Diagnosis Codes as outlined above.
038.0 – 038.9 Septicemia; Sepsis
344.61 Cauda equina syndrome with neurogenic bladder
720.0 Ankylosing spondylitis; Rheumatoid arthritis of spine; Spondylitis
733.00 – 733.09 Osteoporosis; Unspecified; Senile; Idiopathic, Disuse; Drug-induced
737.30 Scoliosis; kyphoscoliosis, idiopathic
738.4 Acquired spondylolisthesis; degenerative
756.12 Spondylolisthesis
805.4 Fracture Lumbar vertebra - Closed; without mention of spinal cord injury
805.5 Fracture Lumbar vertebra - Open; without mention of spinal cord injury
995.91 Sepsis (SIRS) due to infectious process without acute organ dysfunction
996.67 Infection/Inflammatory reaction due to other internal orthopedic device, implant and graft
V15.09 Allergy to titanium or titanium alloy
V85.4 Body Mass Index 40 and over; Adult

Non-Covered Draft ICD-10-CM Diagnosis Code
M48.06 Spinal Stenosis, lumbar region

Non-Covered Draft ICD-10-CM Diagnosis Codes
A40.0 - A44.9 Sepsis and Other Sepsis
G83.4 Cauda Equina Syndrome
M41.20 - M41.27 Other idiopathic scoliosis
M41.89 - M41.87 Other forms of scoliosis
M43.00 - M43.09 Spondyloysis
M43.10 - M43.19 Spondylolisthesis
M45.0 - M45.9 Ankylosing spondylitis of unspecified sites in spine
M81.0 Age-related osteoporosis without current pathological fracture
M81.6 Localized osteoporosis [Lequesne]
M81.8 Other osteoporosis without current pathological fracture
S32.000A - S32.059S Fracture of lumbar vertebra
T84.610A - T84.619S Infection and inflammatory reaction due to internal fixation device
Z91.048 Other non-medicinal substance allergy status
Z68.41 - Z68.45 Body mass index [BMI] 40 or greater, adult

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>6/5/2015, 7/10/2014</td>
<td>• Approved by MPC. No changes.</td>
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<tr>
<td>7/11/2013</td>
<td>• Approved by MPC. Status changed to experimental/investigational; non-covered.</td>
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<td>7/5/2012</td>
<td>• Approved by MPC. No changes.</td>
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<td>12/1/2011</td>
<td>• New template design approved by MPC.</td>
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<td>8/2/2011</td>
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