



**X STOP® INTERSPINOUS PROCESS
DECOMPRESSION DEVICE (KYPHON, INC.)
FOR LUMBAR SPINAL STENOSIS
HS-028**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

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WellCare Prescription Insurance, Inc.

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

Policy Number: HS-028

Original Effective Date: 7/3/2008

**Revised Date(s): 7/21/2009; 7/28/2010;
8/2/2011**

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.

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.

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, 2007).

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, 2007).

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

The X Stop® Interspinous Process Decompression System (Kyphon Inc.) **is considered medically necessary** if ALL of the following criteria are met:

- Member is aged 50 or older; **AND**,
- Member has intermittent neurogenic claudication secondary to a confirmed diagnosis of lumbar spinal stenosis – (724.02); **AND**,
- Member has moderately impaired physical function, experiencing relief in flexion from their symptoms of leg, buttock or groin pain, with or without back pain; **AND**,
- Members have undergone at least 6 months of non-operative treatment (e.g. NSAIDs, muscle relaxants, steroid injections, rest, physical therapy).

The X Stop® Interspinous Process Decompression System (Kyphon Inc.) **may NOT be considered medically necessary and NOT a covered benefit** if the member has ANY of the following conditions:

- Allergic to titanium or titanium alloy-(V15.09); **OR**,
- Spinal anatomy or disease that would prevent implant of the device or cause the device to be unstable in situ. This may include significantly instability of the lumbar spine (e.g. isthmic spondylolisthesis-(756.12) or degenerative spondylolisthesis-(738.4) greater than grade 1.0 (on a scale of 1 to 4); an ankylosed-(720.0) segment at the affected level(s); acute fracture of the spinous process or pars interarticularis-(805.4, 805.5) **OR**,
- Significant scoliosis-(737.30) (Cobb angle greater than 25 degrees); **OR**,



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- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction-(344.61) ; **OR**,
- Diagnosis of severe osteoporosis-(733.00), defined as bone mineral density (from DXA scan or comparable study) in the spine or hip that is more than 2.5 standard deviations below the mean of adult norms in the presence of one or more fragility fractures; **OR**,
- Active systemic infection-(038, 995.91) or infection localized at the site of implantation (996.67); **OR**,
- Body mass index (BMI) > 40 kg/m² -(V85.4)

Physician Requirements

Implantation must be performed by an orthopedic surgeon or neurosurgeon with experience in spinal surgery.

CODING

CPT® Codes

- 28899** Unlisted Procedure on Spine for X-Stop
0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
0172T 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)

HCPCS® Codes

- C1821** Interspinous process distraction device (implantable)

Covered ICD-9-CM Procedure Codes

- 84.80** Insertion or replacement of interspinous process device(s).
84.81 Revision of interspinous process device(s)

Covered ICD-9-CM Diagnosis Code

- 724.02** Spinal Stenosis of Lumbar Region

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

Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

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Government Agencies, Professional and Medical Organizations

1. Centers for Medicare and Medicaid Services. LCD for Interspinous Process Decompression (L25281). 2007.
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Other

1. X Stop®, Kyphon Inc. website. Available at <http://www.kyphon.com/sfmt/press/xstop.html>

HISTORY AND REVISIONS

| Date | Action |
|-----------|--|
| 12/1/2011 | <ul style="list-style-type: none">• New template design approved by MPC. |
| 8/2/2011 | <ul style="list-style-type: none">• Approved by MPC. No changes. |