



Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

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

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

X Stop® Interspinous Process Decompression Device 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; 7/5/2012; 7/11/2013; 7/10/2014;
6/5/2015; 6/2/2016; 12/7/2017; 3/1/2018**

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.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

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.³

CMS describes the Interspinous Process Decompression (IPD®) procedure as 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.³

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets except Florida
- Medicare – All Markets

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

Applicable To:

- Medicaid – Florida

Exclusions

Interspinous Process Decompression® **is not considered medically necessary** and not a covered benefit when any of the following conditions apply:

1. Member is allergic to titanium or titanium alloy
2. Member has 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
3. Member has significant scoliosis (Cobb angle greater than 25 degrees)
4. Member has cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction
5. Member has a diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normal in the presence of one or more fragility fractures
6. Member has active systemic infection or infection localized at the site of implantation
7. Member has a body mass index (BMI) > 40kg/m²

Coverage

Interspinous Process Decompression® **is considered medically necessary** and a covered benefit when all of the following criteria apply:

1. Member is aged 50 or older and suffering from (intermittent neurogenic claudication) secondary to a

- confirmed diagnosis of lumbar spinal stenosis; **AND**,
2. Member has moderately impaired physical function and experiences relief from their symptoms of leg/buttock/groin pain, with or without back pain when in flexion; **AND**,
 3. Member has undergone at least 6 months of non-operative treatment.

CODING

Covered CPT® Codes

- 28899** Unlisted Procedure – foot or toes
22867- 22870 Spinal Distraction/Stabilization Device

Covered HCPCS® Code

- C1821** Interspinous process distraction device (implantable)

Covered ICD-10-CM Diagnosis Codes

- M48.061** Spinal stenosis, lumbar region without neurogenic claudication
M48.062 Spinal stenosis, lumbar region with neurogenic claudication

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”

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. X Stop interspinous process decompression system (Medtronic Spine LLC) for lumbar spinal stenosis. Hayes Web site www.hayesinc.com Published December 14, 2012 [archived on January 26, 2016]. Accessed February 14, 2018.
2. X Stop® Spacer. (2013). Main site. Retrieved from <http://www.kyphon.com/sfmt/press/xstop.html>
3. Local coverage determination interspinous process decompression (L34006). Centers of Medicare and Medicaid Services Web site. www.cms.gov. Published October 1, 2017. Accessed February 14, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
3/1/2018	<ul style="list-style-type: none"> • Approved by MPC. Updated guideline to include in coverage for FL.
12/7/2017, 6/2/2016, 6/5/2015, 7/10/2014	<ul style="list-style-type: none"> • Approved by MPC. No changes.
7/11/2013	<ul style="list-style-type: none"> • Approved by MPC. Status changed to experimental/investigational; non-covered.
7/5/2012	<ul style="list-style-type: none"> • Approved by MPC. No changes.
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.