Policy: MP190
Section: Medical Benefit Policy
Subject: Interspinous Distraction Technology

I. Policy: Interspinous Distraction Technology

II. Purpose/Objective:
To provide a policy of coverage regarding Interspinous Distraction Technology

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Interspinous Distraction Technology is a technique in which an oval spacer is inserted between the spinous processes for the treatment of neurogenic intermittent claudication resulting from lumbar spinal stenosis. The implant is thought to act as a physical block in order to prevent extension in the stenotic level and increase dimensions of the spinal canal and intervertebral foramina. The procedure is designed to prevent extension when standing or walking, relieving pressure on the nerves.

Examples of Interspinous Distraction Technology include, but not limited to:
- X STOP® Interspinous Process Decompression System
- ACADIA Facet Replacement System
- ExtenSure Bone Allograft Interspinous Spacer
- TOPS™ (Total Posterior – element System) Spinal System

MEDICARE BUSINESS SEGMENT:
For Medicare beneficiaries, lumbar interspinous process decompression may be considered medically necessary when all of the following criteria are met:

- The member has neurogenic intermittent pain or weakness radiating from the lumbar region into the legs as a result of a confirmed diagnosis of lumbar spinal stenosis; and
- The member has moderately impaired function and experiences relief from leg, buttock, or groin pain, with flexion; and
- The member has undergone at least six months of non-operative treatment (e.g., physical therapy, non-steroidal anti-inflammatory medication) and is a candidate for operative treatment at no more than two lumbar levels.

EXCLUSIONS:
Unless mandated, the Plan does NOT provide coverage for Interspinous Distraction Technology including but not limited to the X STOP® Interspinous Process Decompression System because it is considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

For the Medicare Business Segments – CMS directives may allow these devices to be considered for coverage when used in a hospital outpatient setting. Effective January 1, 2007, the new device pass-through code, C1821, includes device costs for single- and double-level treatments, and is applicable nationally.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED With X STOP® Interspinous Process Decompression System
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

C1821 Interspinous process distraction device (implantable)
0202T 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
0219T Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic

Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic

Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), additional vertebral segment (list separately in addition to code for primary procedure)

Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level

Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level

Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, lumbar; single level

Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


ECRI HTAIS Target Database (online) Interspinous process decompression to treat spinal stenosis. ECRI January 2007.


This policy will be revised as necessary and reviewed no less than annually.

Devised: 09/2006

Revised: 1/10; 12/17 (outline criteria for Medicare coverage)

Reviewed: 03/08, 3/09, 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17, 12/18