MEDICAL COVERAGE POLICY	
SERVICE:	**Interspinous Process Decompression System**
Policy Number:	**056**
Effective Date:	**01/01/2020**
Last Review:	**10/31/2019**
Next Review Date:	**10/31/2020**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Interspinous Process Decompression System

PRIOR AUTHORIZATION: Not applicable.

POLICY: Scott and White Health Plan considers interspinous process spacer devices and interspinous/interlaminar stabilization/distraction devices such as X-Stop®, Coflex®, etc., experimental, investigational and unproven because there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, durability, and long-term outcome of these devices, or to determine how the use of these devices compares to alternative medical, interventional, or surgical treatment.

OVERVIEW: An interspinous process spacer device is an implant designed to preserve motion and provide symptomatic relief of pain associated with degenerative disc disease or spinal stenosis, with or without degenerative spondylolisthesis. Spinal stenosis is a narrowing of the vertebral canal that may lead to compression of the spinal nerves or nerve roots, especially in the lumbar vertebrae. Lumbar stenosis is commonly seen in an aging or degenerative spine. Bony overgrowth and ligament enlargement into the spinal canal, intervertebral disc herniation, or vertebral slippage (i.e., spondylolisthesis) may cause nerve compression resulting in low back pain, leg fatigue and pain, and reduced capacity for physical activity. Neurogenic claudication is a combination of low back and leg pain, with numbness and motor weakness when standing or walking that is relieved by sitting or lying. Treatment for back pain may include pharmacological therapy (e.g., non-steroidal anti-inflammatory drugs (NSAIDs), analgesics, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy. Various interventional and surgical procedures may be considered if these measures are unsuccessful. Surgical options include decompressive procedures (e.g., laminectomy) alone, or decompression and fusion. Fusion is frequently performed with rigid implant fixation systems, including pedicle screws and interbody cages. The use of interspinous process spacer devices has been proposed as a less invasive dynamic stabilization alternative.

The X-STOP® System is a titanium implant with two components: a spacer assembly consisting of a tissue expander, an oval spacer and a fixed wing; and a wing assembly consisting of an adjustable wing and locking screw. The X-STOP® procedure is performed under general or local anesthesia. A midline incision is made over the appropriate spinal level to display the spinous processes and their interspinous ligaments. The X-STOP® device is positioned in the space between the flexed spinous processes to act as a physical block in order to prevent extension at the stenotic level and increase the dimensions of the spinal canal and intervertebral foramina. The procedure is designed to prevent extension when standing or walking, relieving pressure on the nerves.

Although the results of the available studies are promising, the overall quality of the body of evidence is low since most of the studies are uncontrolled and/or retrospective, and most of the existing studies are small or moderate in size. Additional clinical trials are needed to further evaluate the efficacy and safety of the X Stop system and to compare it with standard treatment and other alternatives. Studies with long-term follow-up are needed to ascertain the clinical longevity and durability of any beneficial effects of the X Stop device, and to evaluate safety. Clear patient selection criteria for X Stop therapy have not been established, and it remains unclear whether the efficacy and safety of the X Stop device are sufficient to allow patients to undergo this treatment instead of decompression laminectomy.

Technology Assessment Committee decision regarding Coflex follows:

Scott&White HEALTH PLAN
PART OF BAYLOR SCOTT & WHITE HEALTH

September 12, 2017

Dr. John Peloza
Center for Spine Care
17980 Dallas Pkwy # 300
Dallas, TX 75287

RE: SWHP TAC review of Coflex

Dr. Peloza,

The Scott and White Health Plan ("SWHP") Technology Assessment Committee ("TAC") would like to thank you for the presentation you gave to the TAC on July 17, 2017. We appreciate your time and effort.

After discussion with the voting members of the TAC, a decision to recommend that Coflex not be considered eligible for coverage by SWHP. This recommendation will be communicated with the Medical Director Committee for acceptance or rejection based on the individual health care needs of our members who have coverage through a SWHP Commercial fully-insured product. As always, medical necessity is required for individual approval to use approved technologies. For Medicare and Medicaid, we will continue to follow their published coverage guidelines.

Please realize the TAC's decision explained above applies only to SWHP members; other insurers may have different requirements or may not cover the [procedure/technology]. It is always prudent to check with every patient's carrier to learn if they are covering the procedure/technology and what their specific requirements are before planning a specific procedure.

Sincerely,

Mary Davis, MD
Chief Medical Officer
Scott and White Health Plan

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MANDATES: none

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
CPT Not Covered:	22867 - Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar, single level 22868 - Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar, second level 22869- Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar, single level 22870 - Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar, second level
ICD-10 codes:	M48.06 - Spinal stenosis, lumbar region
HCPCS Codes:	C1821- Interspinous process distraction device (implantable)

CMS: No NCD. Novitas Solutions LCD L32594 was retired 10/31/2013

POLICY HISTORY:

Status	Date	Action
New	11/24/2010	New policy
Reviewed	12/16/2011	Reviewed.
Reviewed	11/15/2012	Reviewed.
Reviewed	11/14/2013	Revised criteria. Updated CMS information
Reviewed	09/25/2014	Reviewed
Reviewed	10/22/2015	Status changed to E&I - “Not Covered”
Reviewed	10/27/2016	No changes
Reviewed	09/26/2017	References and codes updated
Reviewed	08/07/2018	Updated policy statement to include Coflex device. TAC letter added
Reviewed	10/31/2019	No changes

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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