Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy #  00221
Original Effective Date:  02/21/2007
Current Effective Date:  06/18/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers interspinous distraction devices as a treatment of neurogenic intermittent claudication to be investigational.*

Based on review of available data, the Company considers the use of an interlaminar device following decompressive surgery to be investigational.*

Background/Overview
Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery.

Interspinous spacers are devices implanted between vertebral spinous processes. Interlaminar spacers are implanted between adjacent lamina and have 2 sets of wings that are placed around the inferior and superior spinous processes. These interspinous implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically, enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication. Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; these are not covered in this policy.

One type of interspinous implant is inserted between the spinous processes through a small (4–8cm) incision and acts as a spacer between the spinous processes, maintaining the flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes. Interlaminar implants are inserted between the adjacent lamina and spinous processes following decompressive surgery.
FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In November 2005, the X-STOP®‡ Interspinous Process Decompression (IPD®‡) System (Kyphon-now part of Medtronic Spine LLC) was approved by the FDA for “treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis.” It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels. The X-STOP PEEK (polyetheretherketone) received approval in 2006 and is a modified version of the X-STOP that includes a PEEK spacer and additional 16-mm spacer size. The indications are the same as for the X-STOP titanium model.

The FDA lists the following contraindications to use of the X-STOP:

- An allergy to titanium or titanium alloy;
- Spinal anatomy or disease that would prevent implantation 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;
  - Significant scoliosis (Cobb angle greater than 25 degrees);
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan [dual energy x-ray absorptiometry] or some comparable study) in the spine or hip that is more than 2.5 [standard deviations] SD below the mean of adult normals in the presence of one or more fragility fractures;
- Active systemic infection or infection localized to the site of implantation.

The Coflex®‡ Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in 2012 (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. This device was previously called the Interspinous U.

The Coflex is indicated for use in 1- or 2-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

The FDA lists the following contraindications to use of the Coflex:

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
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- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 250 degrees).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection - systemic or local.
- Known allergy to titanium alloys or magnetic resonance imaging (MRI) contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

The FDA labeling also contains multiple precautions and the following warnings:
Coflex Interlaminar Technology should only be used by surgeons who are experienced and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the Coflex Interlaminar Technology should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events. Data has demonstrated that spinous process fractures can occur with coflex implantation. Potential predictors for spinous process fractures include:

- Over-decompression during surgery leading to instability in the spine,
- Resection of the spinous process to: 14mm,
- Height of the spinous process 23mm pre-operatively,
- Osteopenia or osteoporosis, and
- "Kissing" spinous processes.

If a spinous process fracture occurs during the surgical procedure, the surgeon should assess if sufficient bone stock exists for Coflex implantation.

Continued FDA approval of the coflex is contingent on annual reports of 2 post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study will provide 5-year follow-up of the cohort in the pivotal investigational device exemption (IDE) trial. The second will be a multi-center trial with 230 patients with follow-up at 5 years that compares decompression alone versus decompression plus Coflex.

The Wallis System (originally from Abbott Spine; currently from Zimmer Spine) was introduced in Europe in 1986. The first generation Wallis implant was a titanium block; the second generation device is composed of a plastic-like polymer that is inserted between adjacent processes and held in place with a flat cord that is wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in an FDA-regulated clinical trial. Also in a FDA-regulated clinical trial is the DIAM Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM system
requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes), Superion® (Vertiflex), and FLEXUS™ (Globus Medical) devices; the comparator in these trials is the X-STOP device.

ExtendSure and CoRoent (both from NuVasive) were launched in Europe in 2005 and 2006. The NL-Prow (Non-Linear Technologies), Aperius (Medtronic Spine), and Falena (Mikai) devices are in trials in Europe.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage decision.
The CMS approved a special add-on payment for hospitals that offer surgery using the patented X STOP(R) IPD(R) System (“X STOP”) in 2007.

Rationale/Source
Literature searches have been dominated by reports from non-U.S. centers of devices that have not received FDA approval, though a number of them are in trials at U.S. centers. As of April 2013, only the X-STOP and Coflex devices have FDA approval for use in the U.S., and this policy does not address other devices. Following is a summary of the key literature to date.

Interspinous Distraction Devices
Systematic Reviews
In 2009, Chou and colleagues presented a review of evidence related to surgical treatments for low back pain for the American Pain Society. They concluded, on the basis of the randomized trial data described below, that the evidence was fair quality and that an interspinous spacer device is superior to nonsurgical therapy for 1- or 2-level spinal stenosis with symptoms relieved with forward flexion but that insufficient evidence exists to judge long-term benefits or harms. Of note, the reviewers considered the Zucherman et al. and Anderson et al. reports as 2 separate studies, while this analysis considers the Anderson et al. to be a subset of the Zucherman et al. study. No trial had compared an interspinous spacer device to standard decompressive surgery.

Kabir et al., in a 2010 systematic review, observed that apart from the 2 randomized controlled trials (RCTs), other studies with X-STOP were not of high methodologic quality. The authors observed that results at 2 years were analyzed using only the Zurich Claudication Questionnaire (ZCQ), while analysis of 1-year results also included the Short-Form 36 (SF-36). They also noted concerns about the trial raised by the FDA: First, the block randomization employed could potentially be used to select patients more likely to respond to the intervention. Second, outcomes in both groups were worse than expected, suggesting that power calculations were invalid. Third, results from one center were clearly superior to those of other centers. Four-year follow-up included only 18 of the original 100 patients, and Oswestry Disability Index (ODI) scores were reported instead of ZCQ scores. Studies of the other devices (DIAM, Coflex, Wallis, DIAM) included in the review showed satisfactory outcomes to varying degrees; however, it was stated that “due to small numbers and poor design of studies, it is difficult to clearly define indications for their use in lumbar degenerative disease”. The authors concluded that X-STOP may improve outcomes compared to nonoperative treatment in a select group of patients 50 years of age or older with radiologically confirmed lumbar canal stenosis and neurogenic claudication who have improvement of symptoms on flexion;
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However, they suggest that further good quality trials are required to clearly identify indications for the use of the devices.

Randomized Controlled Trials
Multiple reports have been published from the single prospective randomized trial, conducted for FDA approval, that compared the X-STOP device to medical therapy.

This study randomized 191 patients from 9 clinical centers in the U.S. to implantation of the X-stop device or medical therapy. Inclusion criteria were neurogenic intermittent claudication caused by lumbar spinal stenosis, age at least 50 years or older, and able to walk at least 50 feet. The primary outcome measure was the ZCQ, which consists of a physical function domain, a symptom severity domain, and a patient satisfaction domain. Outcomes were assessed at 6 weeks, 6 months, 1 year and 2 years.

Using the entire study population of 191 patients in this multicenter trial, Zucherman et al. reported an improvement of 45% over the mean baseline Symptom Severity Score in the treated patients at 2 years compared with 7% improvement in the control group, which had medical (nonoperative) therapy including epidural injection. In a separate paper, Anderson and colleagues, reporting on a subset of 75 randomized patients who had spondylolisthesis (out of the total group of 191 patients with 1- or 2-level lumbar spinal stenosis), found a success rate of 63% in treated patients compared with 13% in controls. Four-year follow-up was reported for 18 of the treated patients in the study. Hsu et al. reported quality-of-life data (SF-36) from the same trial. The patients, who had to meet a number of inclusion/exclusion criteria, were assessed at baseline and at 6 weeks, 6 months, 1 year, and 2 years following the initial treatment. The X-STOP group showed improvements (by single-factor ANOVA or t-test) in both physical and mental component scores compared to both baseline and control subjects. There was a large loss to follow-up (42%) in the medical-treatment group; 6% of the experimental and 26% of the control subjects underwent laminectomy.

A randomized non-inferiority trial of the X-STOP compared to decompressive surgery was published by Bjorn et al. in 2013. One hundred patients with symptomatic one- or two-level lumbar spinal stenosis and neurogenic claudication relieved on flexion were included in the study. Blinding of patients and evaluators was not described. There was a decrease in surgical time (62 vs. 98 minutes) and blood loss (54 vs. 262) with insertion of the X-STOP, although statistical analysis was not reported. Both intention-to-treat analysis and as-treated analysis at 6, 12, and 24 months found no significant differences between the groups on the patient-reported ZCQ, visual analog score (VAS) for leg and back pain, or SF-36. Thirteen patients (26%) in the X-STOP group had additional surgery (typically decompression) compared to 3 patients (6%) in the decompression group, and there was 1 spinous process fracture. The X-STOP patients who later underwent decompression were not considered to be treatment failures.

Preliminary results have been published from a U.S. FDA-regulated multicenter randomized IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP. Non-blinded results at 6-month follow-up showed similar efficacy for the 2 devices. Twenty percent of patients in the Superion group and 23% of patients in the X-STOP had complications. The FDA-mandated primary endpoint of this trial is non-inferiority to X-STOP at 2 years, with additional postmarketing surveillance for 10 years. Over 300
Uncontrolled Series

Several large case series of patients implanted with X-STOP devices have been reported.

A series of 175 patients were treated at a German center between February 2003 and June 2007. Mean VAS score was reduced from 61.2 to 39 on a 100-point scale at 6 weeks postoperatively and maintained to the 2-year evaluation. Mean ODI scores were 32.6 (range 8-80, SD: 16.0) preoperatively, 22.7 (range 0-85, SD:15.6) at 6 weeks postoperatively, and 20.3 (range 0-42, SD:17.5) at 2 years. No complications were associated with use of the device. Eight patients required removal of the device and microsurgical decompression because of unsatisfactory outcome.

Case series from other institutions have found good outcomes in only about a third of patients treated with the X-STOP. For example, one study found that by 12 months, clinically significant improvement in symptoms and physical function was reported by 54% and 33% of the 24 patients, respectively, and 29% of patients required caudal epidural after 12 months for recurrence of symptoms of neurogenic claudication. In another series with 46 patients the overall clinical success rate, defined as an improvement of the ODI by at least 15 points or a satisfaction rating of “very satisfied”, was 36%. A third series of 65 patients found that a good outcome was achieved in 31% of patients.

In a 2010 paper, Rolfe and colleagues evaluated outcomes of a series of 179 patients with and without scoliosis in order to test a contraindication which limits X-STOP use to patients with a maximum scoliosis of 25 degrees. Patients, who received the device between January 2006 and May 2007, were divided into 3 groups: Group 1 without scoliosis (controls, n = 116), Group 2 patients with low scoliosis (11-25 degrees, n = 41), and group 3 (high scoliosis, n = 22). At 1 year, 56% of Group 1 and Group 2 patients, but only 18% of Group 3 patients, achieved improvement of 15 or more points on ODI. Satisfaction rates were 76% for Group 1, 78% for Group 2, and 59% for Group 3. On average, all 3 groups improved for each outcome: Group 1 (ODI 17.3, VAS 2.0, standing time 39 minutes, and walking time 43 minutes), Group 2 (ODI 20.0, VAS 1.9, standing time 65 minutes, and walking time 64 minutes), Group 3 (ODI 7.2, VAS 0.9, standing time 18 minutes, and walking time 16 minutes). The authors conclude that surgeons and patients must be aware that overall lumbar scoliosis greater than 25 degrees may portend less favorable outcomes.

Adverse Events

A number of papers focus on complications with the X-STOP device.

Barbagallo et al. analyzed complications in a series of 69 patients and proposed an anatomic scoring system for patient selection. At a mean follow-up of 23 months, 8 complications (11.5%) were recorded: 4 device dislocations and 4 spinous process fractures.

Bowers et al. reviewed records of 13 patients implanted with the X-STOP device at one U.S. center. Nine patients had severe and 4 had moderate stenosis. Average follow-up was 42.9 months (range, 3-48 months). Initially, pain improved an average of 72%; however, preoperative pain returned in 77% of the
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patients. The overall complication rate was 38%, including 3 spinous process fractures and 2 instances of new onset radiculopathy. Eleven of the 13 patients required additional spinal surgery.

A prospective observational study found a high rate of spinous process fractures in 38 patients (50 implants, 97.4% follow-up) after implantation of the X-STOP titanium (n = 34), X-STOP PEEK (n = 8), or Aspen (n = 8) devices. Although no fracture was identifiable on plain radiographs, postoperative computed tomography (CT) identified nondisplaced spinous process fractures in 11 patients (28.9% of patients, 22% of levels). Direct interview of patients and review of medical records indicated that 5 fractures were associated with mild to moderate lumbar back pain, and 6 fractures were asymptomatic. Three of the 11 patients underwent device removal and laminectomy for persistent pain. Fractures in 3 other patients had healed by 1 year.

Verhoof et al. reported that, in a cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis who were treated with X-STOP and followed up for a mean of 30.3 months, 8 patients had complete relief of symptoms postoperatively while 4 had no relief. Recurrence of pain, neurogenic claudication, and worsening of neurologic symptoms were observed in 3 patients within 24 months. Postoperative radiographs and MRI did not show changes in percentage of slip or spinal dimensions. Seven patients had posterior fusion within 24 months. The authors did not recommend the device for treatment of spinal stenosis complicating degenerative spondylolisthesis.

Interlaminar Stabilization Devices
Randomized Controlled Trials
The pivotal IDE trial for Coflex Interlaminar Technology was a non-blinded randomized multi-center non-inferiority trial of Coflex compared to posterolateral fusion with pedicle screw fixation. A total of 344 patients were randomized in a 2:1 ratio (215 Coflex and 107 fusion controls, with 22 protocol violators). This study was conducted in a restricted population with numerous exclusion criteria. Compared to fusion, implantation of the Coflex device required less operative time (98.0 vs. 153.2 minutes) and resulted in less blood loss (109.7 vs. 348.6 cc) and a shorter hospital stay (1.9 vs. 3.2 days). Composite clinical success (a combination of a minimum 15-point improvement in ODI, no reoperations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months achieved non-inferiority compared to posterolateral fusion (66.2% Coflex and 57.7% fusion). Secondary effectiveness criteria, which included the ZCQ, VAS for leg and back pain, Short Form-12 (SF-12), time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the Coflex group by Bayesian analysis. (In this analysis, non-overlapping confidence intervals (CIs) imply statistically reliable group differences.) For example, ZCQ composite success was achieved in 78.3% of Coflex patients (95% CI: 71.9%, 84.7%) compared to 67.4% of controls (95% CI: 57.5%, 77.3%). The percentage of device-related adverse events was the same for the 2 groups (5.6% Coflex and 5.6% control), and a similar percentage of asymptomatic spinous process fractures were observed. The FDA considered the data in this non-blinded study to support reasonable assurance of safety and effectiveness for device approval, but approval is conditional on 2 additional studies that will provide longer-term follow-up (in the IDE cohort) and evaluate device performance under actual conditions of use (decompression alone vs. decompression with Coflex).
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Controlled Cohort Studies
In 2010, Richter et al. reported a prospective case control study of the Coflex device in 60 patients who underwent decompressive surgery. Two-year follow-up from this study was published in 2012/2013. Decompression involved a partial laminotomy, removal of ligamentum flavum, and undercutting facetectomy. The surgeon determined whether the midline structures were preserved or resected and whether the Coflex device was implanted (1 or 2 levels). The indications for the two groups were identical, and use of the device was considered incidental to the surgery. No significant differences were observed between the groups on the ODI, the Roland-Morris disability questionnaire (RMS), VAS for pain, and pain-free walking distance. At 2-year follow-up, there were no significant differences between the 2 groups for any of the outcome measures in this non-randomized controlled cohort study, suggesting that additional placement of the Coflex device does not improve the clinical outcome of decompressive surgery. Randomized controlled trials are needed to determine the efficacy of the Coflex interlaminar implant with greater certainty.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009
In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Differing input was received; several reviewers felt data were sufficient to demonstrate improved outcomes.

2011
In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in March 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes including durability. Two reviewers did not consider this investigational but felt the technology had a role in the treatment of selected patients with neurogenic intermittent claudication.

Summary
Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Although the randomized device trials report short-term improvements in symptoms and functional status when compared to non-operative therapy, a number of questions remain. Overall, high-quality comparative data are limited. There is a need for longer-term (more than 2 years) outcome data on symptom relief, the need for repeat procedures, and implant survival. Future studies need to better control for potential biases and avoid other methodologic issues, including follow-up of patients in the control group and consistent use of outcome measurements. There are also questions about patient section criteria; for instance, whether patients with any degree of spondylolisthesis should be excluded from this treatment. In addition, comparisons with decompressive surgery without an interlaminar implant are...
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lacking, and recent case series indicate that outcomes may be less favorable than those reported in the multi-center randomized trial. Because the impact of this technology on net health outcome is not known, these devices are considered investigational.

References
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Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Policy History
Original Effective Date:  02/21/2007
Current Effective Date:  06/18/2014
02/07/2007  Medical Director review
02/21/2007  Medical Policy Committee approval.
02/04/2009  Medical Director review
02/19/2009  Medical Policy Committee approval. No change to coverage.
02/04/2010  Medical Policy Committee review
02/17/2010  Medical Policy Implementation Committee approval. No change to coverage.
02/03/2011  Medical Policy Committee review
02/16/2011  Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012  Medical Policy Committee review
02/15/2012  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2013  Medical Policy Committee review
06/25/2013  Medical Policy Implementation Committee approval. Title changed from “Interspinous Distraction Devices (Spacers)” to “Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)”. Removed “secondary to lumbar stenosis” from the first investigational statement. Added that the use of an interlaminar device following decompressive surgery is considered to be investigational. Updated FDA section with new approval for Cotflex.
06/05/2014  Medical Policy Committee review
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06/18/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 06/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. reference to federal regulations.

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