Select Health Medical Policies

Neurology/Neurosurgery Policies

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Select Health

MEDICAL POLICY

CERVICAL, LUMBAR, AND THORACIC SPINAL FUSION WITH OR WITHOUT SPINAL DECOMPRESSION

Policy # 622

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Related Medical Policies:
#450 Axial Lumbar Interbody Fusion (AXIALIF)
#320 Interspinous Distraction Devices/Spacers
#558 Interspinous Fixation (Fusion) Devices
#243 Artificial Spinal Disc Replacement
#209 Percutaneous Disc Decompression Procedures

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Cervical and lumbar fusion is a surgery that joins or fuses the vertebrae in the neck and back. It is performed through an incision on the front (anterior) or back (posterior). Fusion is often performed when the vertebrae become damaged due to injury or chronic degenerative changes, leading to compression of the spinal cord or the nerve root. The expected outcome from cervical fusion is stabilization of the vertebrae and alleviation of pain and/or weakness resulting from vertebral instability.

Bone grafts are often used, taken from elsewhere in the body or received from a bone bank. Metal implants can be used to hold the vertebrae together until new bone grows between them. Metal plates can be screwed into adjacent vertebrae to join them.

Clinical complications of fusion surgery include infection, injury to the nerves, broken or loosened plates, screws or implants, injury to the spinal cord, possible need for additional surgery due to non-union of fused material due to adjacent segment breakdown, and/or increased pain.

The lifetime incidence of low back pain (LBP) in the general population is reported to be 60% to 90%. According to the National Center for Health Statistics, each year, 14.3% of new patient visits to primary care physicians are for LBP, and nearly 13 million physician visits are related to complaints of chronic LBP. The causes of LBP are numerous.

The initial evaluation of patients with LBP involves ruling out potentially serious conditions such as infection, malignancy, spinal fracture, a rapidly progressing neurologic deficit suggestive of the cauda equina syndrome, bowel or bladder dysfunction, or weakness, which suggest the need for early diagnostic testing. Patients without these conditions are initially managed with conservative therapy. Chronic LBP that persists despite ongoing conservative treatment and nonsurgical back specialist treatment is best managed using a team approach. This includes physical therapy, physiatry (PM&R), anesthesia with pain subspecialty or neurology with pain subspecialty, and mental health support if indicated. Occasionally, surgical intervention is necessary.

Low back pain stages:

A**cute LBP:** Pain < 6 weeks

Subacute LBP: Continued pain after 6 weeks, but patient continues to function well, and core treatment provides some relief; patient may also be receiving nonsurgical back specialist treatment at this stage.

Chronic LBP: Core LBP treatment has failed, nonsurgical back specialist treatment has not helped, and persistent pain interferes with function and alters the patient's life.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers cervical/lumbar/thoracic spinal fusion and combined decompression/fusion if any one of the following criteria are met (1–7):

1. Acute traumatic spine injury with evidence of instability and stabilization not achievable by closed means and **ANY** one of the following:
    A. Vertebral fracture which includes fracture of vertebral body/posterior elements and subluxation; **or**
    B. Vertebral dislocation; **or**
    C. Ligamentous disruption.
2. Motor deficit or severe radicular pain due to myelopathy with cord compression confirmed by imaging and decompressive surgery expected to result in instability along with **ANY** of the following:
    A. Weakness or severe radicular pain; **or**
    B. Bowel or bladder dysfunction; **or**
    C. Spasticity; **or**
    D. Bilateral loss of dexterity; **or**
    E. Gait disturbance.
3. Vertebral body destruction (confirmed by imaging, for which correction will cause instability) this includes:
    A. Resolved osteomyelitis; **or**
    B. Resolved discitis/epidural abscess; **or**
    C. Tumor of spine or spinal cord.
4. Non-traumatic instability, adult deformity, severe foraminal stenosis, disc disease, or non-union from previous fusion with **motor deficit or severe radicular pain and (either A or B)**:
    A. Motor strength, at least 3/5 weakness
    OR
    B. **ALL** the following:
        i) Interferes with ADLs
        ii) **ANY** one of the following three (i, ii, or iii):
            a. Translation on x-ray or MRI > 3mm, > 15% or 22 degrees for lumbar; **or**
            b. > 3mm, > 20% or 11 degrees for cervical; **or**
            c. Disc disease supported by imaging.
        iii) Pain continues after 6 weeks of non-operative therapy including **ALL** the following (unless contraindicated/not tolerated):
            a. Analgesics, **and**
            b. Activity modification, **and**

c. Physical therapy or chiropractic therapy: minimum of 12 visits within a 6-month period; must have been performed within the previous year (it is recommended that at least four of these visits be performed in-person). After 6 visits, additional therapy is not required if contraindicated or is not recommended by the physical or chiropractic therapist, **and**

d. Evaluation for spinal injection.

5. Non-traumatic instability, adult deformity, severe foraminal stenosis, disc disease, or non-union from previous fusion with **NO motor deficit** and **ALL** the following:
   A. Interferes with ADLs
   B. Instability supported by x-ray with **ANY** one of the following:
      i. Translation on x-ray or MRI > 3mm, > 15% or 22 degrees for lumbar; **or**
      ii. > 3mm, > 20% or 11 degrees for cervical; **or**
      iii. Disc disease supported by imaging.
   C. Pain continues for 6 months or more despite non-operative therapy, including at least 6 weeks of **ALL** the following (unless contraindicated/not tolerated):
      i. Analgesics, **and**
      ii. Activity modification, **and**
      iii. Physical therapy or chiropractic therapy: minimum of 12 visits within a 6-month period; must have been performed within the previous year (it is recommended that at least four of these visits be performed in-person). After 6 visits, additional therapy is not required if contraindicated or is not recommended by the physical or chiropractic therapist, **and**
      iv. Evaluation for spinal injection
   D. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued >/= 3 months
   E. No psychiatric disorder, by history, or currently managed as confirmed by screening. If screening abnormal, must have formal evaluation with behavioral health professional
   F. Weight BMI < 40 (required for lumbar only)
6. Cauda Equina Syndrome with **motor deficit or severe radicular pain and (BOTH A and B)**:
   A. Confirmed by imaging; **AND**
   B. **ANY** of the following:
      i. Bilateral lower extremity weakness or numbness or pain; **or**
      ii. Bowel or bladder dysfunction and other etiologies excluded; **or**
      iii. Diminished rectal sphincter tone by physical examination; **or**
      iv. Perianal or perineal "saddle" anesthesia by physical examination.
7. Pediatric scoliosis surgery, age ≤ 21, with progressive deformity with cobb angle > 50 degrees or rapidly progressive curve and > 40 degrees

Note *- Separate evaluation is needed if any of the following are being used (please see related medical policies above):*

1. Axial lumbar interbody fusion (#450 Axial Lumbar Interbody Fusion (AXIALIF))
2. Interspinous distraction devices/spacers (#320 Interspinous Distraction Devices/Spacers)

3. Interspinous fixation (fusion) devices (#558 Interspinous Fixation (Fusion) Devices)
4. Percutaneous image-guided lumbar decompression (PILD) (#209 Percutaneous Disc Decompression Procedures)
5. Minimally invasive lumbar decompression (MILD) (#209 Percutaneous Disc Decompression Procedures)

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Select Health Community Care will follow the Commercial Plan Policy (Effective May 1, 2019)

Summary of Medical Information
The AANS (American Association of Neurological Surgeons) published guidelines in 2009, that used a systematic review of the National Library of Medicine and Cochrane database, regarding indications for anterior cervical decompression for the treatment of cervical degenerative radiculopathy. They state: “In the acute phase, nonoperative management is the mainstay, with success rates averaging 90%.” The AANS further states: “When clinical cervical radiculopathy is present with active nerve root compression visible on diagnostic imaging, the clinician often recommends surgical decompression if nonoperative measures have failed.” While they state that anterior nerve root decompression via anterior nerve root discectomy with or without fusion for radiculopathy is associated with rapid relief (3–4 months) compared with physical therapy, they acknowledge that at the 12-month point, comparable clinical improvements with PT or cervical immobilization are also present. They also acknowledge that there is insufficient data to factor in the cost of complications and any undesirable long-term effect related to the specific surgical intervention, such as adjacent segment disease.

In 2011, the ACOEM (American College of Occupational and Environmental Medicine) issued guidelines on the diagnostic testing and management of cervical and thoracic spine disorders. MRI received the strongest ACOEM testing recommendation for patients with: acute cervical pain with progressive neurologic deficit, significant trauma with no improvement in significantly painful or debilitating symptoms, a history of neoplasia (cancer), multiple neurological abnormalities that span more than one neurological root level, previous neck surgery with increasing neurologic symptoms, fever with severe cervical pain, symptoms or signs of myelopathy, and subacute or chronic radicular pain syndromes lasting at least 4 to 6 weeks in whom dermatomal and myotomal symptoms are not trending towards improvement if either injection is being considered or both the patient and surgeon are considering early surgical treatment if supportive findings on MRI are found For acute, subacute, and chronic cervicothoracic pain, ACOEM “A” (strong) or “B” (moderate) recommendations included strengthening, endurance and aerobic exercises, proton pump inhibitors, sucralfate, acetaminophen/aspirin, and manipulation/mobilization.

In 2013, Washington State Health Care Authority commissioned the ICER to evaluate the comparative clinical effectiveness and comparative value of spinal fusion and its alternatives in patients with cervical degenerative disc disease (DDD). The focus of this appraisal was on adults (> 17 years of age) with cervical DDD symptoms, including neck pain, arm pain, and/or radiculopathic symptoms (e.g., numbness, tingling); these symptoms could occur with or without the presence of spondylosis. In all cases, the target population was focused on patients whose symptoms have persisted despite an initial short course (i.e., 4–6 weeks) of self-care and conservative management.

ICER (Incremental Cost-Effectiveness Ratio) conferred a “Comparable” rating for spinal fusion vs. conservative management for radiculopathic symptoms. They stated: “For patients with clinical symptoms of radiculopathy and radiographic evidence of nerve root compression there is not a large evidence base comparing outcomes between spinal fusion and conservative management.” We identified only 1 RCT and 1 comparative cohort study, neither of which stood out for their methodologic rigor, size, or generalizability. Despite variability in study design, entry criteria, and outcomes measured, findings were reasonably consistent. Specifically, spinal fusion appeared to provide faster relief of pain and symptoms than conservative management (i.e., physical therapy or cervical collar immobilization) in the short term. Over time, however, these differences diminished and no material differences in outcome were observed by 12 months after intervention. ICER cited a Cochrane review by Nikolaidis and colleagues to determine whether surgical treatment of cervical radiculopathy or myelopathy was associated with improved outcome compared with conservative management. Two trials (N = 149) were included. In both trials, allocation concealment was inadequate and arrangements for blinding of outcome assessment were unclear. One trial (81 patients with cervical radiculopathy) found that surgical decompression was superior to physiotherapy or cervical collar immobilization in the short-term for pain, weakness or sensory loss; at one year, there were no significant differences between groups. One trial (68 patients with mild functional deficit associated with cervical myelopathy) found no significant differences between surgery and conservative treatment in three years following treatment. A substantial proportion of cases were lost to follow-up. The authors concluded that it was unclear whether the short-term risks of surgery are offset by long-term benefits. There was low quality evidence that surgery may provide pain relief faster than physiotherapy or hard collar immobilization in patients with cervical radiculopathy; but there is little or no difference in the long-term. There was very low-quality evidence that patients with mild myelopathy felt subjectively better shortly after surgery, but there was little or no difference in the long-term.

Because of this, and because spinal fusion may cause relatively rare but significant complications, we deemed the overall comparative clinical effectiveness of fusion to conservative management “Comparable.” In some patients, however, neck pain and related symptoms may be so severe and disabling that the faster relief potentially afforded by fusion surgery would also allow a quicker return to work and other normal activities. For such patients, fusion might in fact be considered “Incremental” in comparison to ongoing conservative management.

In analyzing data from randomized controlled trials (RCTs) and comparative cohorts, ICER found that the rate of harm and complications from cervical fusion were significantly greater than those from conservative treatment. Some of the highest rates of potential harm from fusion were events of infection (0–13%), adjacent segment disease (7–16%), paresthesia (14%), dysphagia (3–17%), pseudoarthrosis (8%), and neurological decline (3–23%). Conservative treatment harms were relatively minor, except for neurological decline (14.2%) and paresthesia (8%).

In a meta-analysis, Wu et al. stated that the traditional surgical method of ACDF (Anterior Cervical Discectomy Fusion) carries with it the disadvantages of motion loss at the operative level and accelerated adjacent level disc degeneration. They performed a meta-analysis comparing the long-term outcomes of cervical total disc arthroplasty (TDA) versus fusion. This review was prepared following the standard procedures set forth by the Cochrane Collaboration organization, and preferred reporting items for systematic reviews and meta-analyses (PRISMA). The only studies included were randomized controlled trials with a minimum of 4 years of follow-up data. The meta-analysis included the neck disability index (NDI), visual analog scale (VAS) of neck and arm pain, SF-36 physical component scores (SF-36 PCS), over success, neurological success, work status, implant-related complications, and secondary surgery events. Four randomized controlled trials met the inclusion criteria. The long-term improvement of NDI, VAS of neck and arm pain, SF-36 PCS, over success, and neurological success favored the TDA group. The TDA group also had a lower incidence of secondary surgery for both the index level and adjacent level. In this meta-analysis of 4 including RCTs with a minimum 4 years of follow-ups, total disc

arthroplasty showed improvements over ACDF as measured by the NDI, VAS of neck and arm pain, and SF-36 PCS.

Adjacent segment disease (ASD) development is known to occur after anterior cervical discectomy and fusion. Bydon and colleagues (2014) retrospectively evaluated 888 individuals treated at a single institution over a 20-year period who underwent ACDF for cervical spondylosis. Of these individuals, 108 had re-do surgery as a result of symptomatic adjacent segment disease (ASD). Individuals were followed for an average of 92.4 ± 52.6 months after the index ACDF. Individuals were more likely to develop ASD, known to occur after ACDF, above the index level of fusion. In agreement with previous ACDF case series, they found the highest rate of cervical spinal degenerative disease requiring surgery was at C5/C6, followed by C6/C7. However, neither the inherent location of the index ACDF nor the length of instrumented arthrodesis appeared to correlate with the propensity to develop ASD.

Literature suggests that spinal fusion appears to provide faster relief of pain and symptoms than conservative management (i.e., physical therapy or cervical collar immobilization) in the first several months after the surgery. Over time, however, these differences diminished, and clinical outcomes of cervical fusion and conservative treatment were comparable at 12 months after the intervention. Additionally, spinal fusion may cause relatively rare but significant complications. Therefore, the first line of treatment for chronic cervical pain should be a comprehensive nonoperative approach. A non-emergent cervical spine fusion may be a consideration only after conservative therapy has failed and a physical examination and diagnostic imaging findings indicate neural compression at the appropriate level.

Guidelines for the approach to the initial evaluation of LBP have been issued by the Agency for Healthcare Research and Quality (1994), and similar conclusions were reached in systematic reviews (Jarvik et al., 2002; Chou et al., 2007; NICE, 2009). For adults less than 50 years of age with no signs or symptoms of systemic disease, symptomatic therapy without imaging is appropriate. For patients 50 years of age and older, or those whose findings suggest systemic disease, plain radiography and simple laboratory tests can almost completely rule out underlying systemic diseases. Advanced imaging should be reserved for patients who are considering surgery or for those in whom systemic disease is strongly suspected. Conservative care without immediate imaging is also considered appropriate for patients with radiculopathy, as long as symptoms are not bilateral or associated with urinary retention. Magnetic resonance imaging (MRI) should be performed if the latter symptoms are present, or if patients do not improve with conservative therapy for 4 to 6 weeks. Ninety percent of acute attacks of sciatica will resolve with conservative management within 4 to 6 weeks; only 5 % remain disabled longer than 3 months (Gibson and Waddell, 2007; Lehrich and Sheon, 2007; AHCPR 1994).

Conservative management for LBP (Low Back Pain) includes:

- Avoidance of activities that aggravate pain
- Chiropractic manipulation in the first 4 weeks if there is no radiculopathy
- Cognitive support and reassurance that recovery is expected
- Education regarding spine biomechanics
- Exercise program
- Heat/cold modalities for home use
- Limited bed rest with gradual return to normal activities
- Low impact exercise as tolerated (e.g., stationary bike, swimming, walking)
- Pharmacotherapy (e.g., non-narcotic analgesics, NSAIDs [as second-line choices], avoid muscle relaxants, or only use during the first week, avoid narcotics)

In the American Pain Society/American College of Physicians Clinical Practice Guideline on "Nonpharmacological Therapies for Acute and Chronic Low Back Pain," Chou and Huffman (2007), reached the following conclusions: "Therapies with good evidence of moderate efficacy for chronic or subacute low back pain are cognitive-behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation. For acute low back pain, the only therapy with good evidence of efficacy is superficial heat."

According to a draft technology assessment prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Duke Evidence-Based Practice Center on spinal fusion for treatment of

degenerative disease affecting the lumbar spine (AHRQ, 2006), conservative treatments are generally performed routinely before any surgery is considered in axial back pain. These include medical management (such as NSAIDs, etc.), pain management, injections, physical therapy, exercise, and various forms of cognitive rehabilitation. Such conservative treatments are seldom applied in a comprehensive, well-organized rehabilitation program, although some such programs do exist. Conservative treatments are usually tried for at least 6 to 12 months before surgery for any form of lumbar fusion is considered. Several reviews of these therapies noted that there is no evidence about the effectiveness of any of these therapies for low back or radicular pain beyond about 6 weeks. In addition, the assessment stated that almost all lumbar spine surgery, including lumbar fusion, is performed to reduce the subjective individual symptoms of radiculopathy; thus, patient education to inform patients of their treatment options is considered critical. The other indications for lumbar fusion focus on improvement in axial lumbar pain (i.e., near the midline and not involving nerve roots or leg pain). These indications include lumbar instability, such as degenerative lumbar scoliosis, spondylolisthesis for axial pain alone, and for less common problems, such as discitis, lumbar flat back syndrome, neoplastic bone invasion and collapse, and chronic fractures, such as osteoporotic fractures which develop into burst fractures over time. The assessment concluded that: "The evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with non-surgical treatment, especially when considering patients over 65 years of age, for degenerative disc disease; for spondylolisthesis, considerable uncertainty exists due to lack of data, particularly for older patients."

The National Institute for Clinical Excellence's (NICE, 2009) guidance on early management of people with non-specific LBP stated that it is important to help people with persistent non-specific LBP self-manage their condition. The guidance stated that one of the following treatment options should be offered to the patient: (i) an exercise program, (ii) a course of manual therapy (i.e., spinal manipulation, spinal mobilization, and massage), (iii) a course of acupuncture, and (iv) pharmacological therapy. Referral to a combined physical and psychological treatment program may be appropriate for individuals who have received at least one less intensive treatment and have high disability and/or significant psychological distress. The guidance stated: "[t]here is evidence that manual therapy, exercise and acupuncture individually are cost-effective management options compared with usual care for persistent non-specific low back pain. The cost implications of treating people who do not respond to initial therapy and so receive multiple back care interventions are substantial. It is unclear whether there is added health gain for this subgroup from either multiple or sequential use of therapies." In addition, the guidance stated that imaging is not necessary for the management of non-specific LBP. An MRI is appropriate only for people who have failed conservative care, including a combined physical and psychological treatment program, and are considering a referral for an opinion on spinal fusion.

The American Pain Society Clinical Practice Guideline *Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain* (Chou et al., 2009) stated, "Rates of certain interventional and surgical procedures for back pain are rising. However, it is unclear if methods for identifying specific anatomic sources of back pain are accurate, and effectiveness of some interventional therapies and surgery remains uncertain or controversial." Included in the guideline are the following recommendations.

The APS guideline stated that, in patients with chronic non-radicular LBP, provocative discography is not recommended as a procedure for diagnosing LBP (strong recommendation, moderate-quality evidence) (Chou et al., 2009).

In patients with non-radicular LBP who do not respond to usual, non-interdisciplinary interventions, the APS guideline recommended that clinicians consider intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis (strong recommendation, high-quality evidence) (Chou et al., 2009).

In patients with non-radicular LBP, common degenerative spinal changes, and persistent and disabling symptoms, the APS guideline recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence) (Chou et al., 2009).

The guideline recommended that shared decision-making regarding surgery for non-specific LBP include a specific discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus non-interdisciplinary non-surgical therapy, and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome

(defined as minimum or no pain, discontinuation of or occasional pain medication use, and return of high-level function) (Chou et al., 2009).

The APS guideline explained that for persistent non-radicular LBP with common degenerative changes (e.g., degenerative disc disease), fusion surgery is superior to non-surgical therapy without interdisciplinary rehabilitation in 1 trial, but no more effective than intensive interdisciplinary rehabilitation in 3 trials (Chou et al., 2009). Compared with non-interdisciplinary, non-surgical therapy, average benefits are small for function (5–10 points on a 100-point scale) and moderate for improvement in pain (10–20 points on a 100-point scale). Furthermore, more than half of the patients who undergo surgery do not experience an "excellent" or "good" outcome (i.e., no more than sporadic pain, slight restriction of function, and occasional analgesics). Although operative deaths are uncommon, early complications occur in approximately 18% of patients who undergo fusion surgery in randomized trials Instrumented fusion is associated with enhanced fusion rates compared with non-instrumented fusion, but insufficient evidence exists to determine whether instrumented fusion improves clinical outcomes, and additional costs are substantial. In addition, there is insufficient evidence to recommend a specific fusion method (anterior, posterolateral, or circumferential), though more technically difficult procedures may be associated with higher rates of complications.

The APS guideline explained that for persistent and disabling radiculopathy due to herniated lumbar disc, standard open discectomy and microdiscectomy are associated with moderate short-term (through 6 to 12 weeks) benefits compared to non-surgical therapy, though differences in outcomes in some trials are diminished or no longer present after 1 to 2 years (Chou et al., 2009). In addition, patients tend to improve substantially, either with or without discectomy, and continued non-surgical therapy in patients who have had symptoms for at least 6 weeks does not appear to increase risk for cauda equina syndrome or paralysis.

If conservative management fails to relieve symptoms of radiculopathy and there is strong evidence of dysfunction of a specific nerve root confirmed at the corresponding level by findings demonstrated by CT or MRI, further evaluation and more invasive treatment, including spine surgery, may be proposed as a treatment option. The primary rationale of any form of surgery for disc prolapse is to provide decompression of the affected nerve root to relieve the individual's symptoms. It involves the removal of all or part of the lamina of a lumbar vertebra. The addition of fusion with or without instrumentation is considered when there are concerns about instability. Open discectomy, performed with or without the use of an operating microscope, is the most common surgical technique applied, but there are now a number of other less invasive surgical approaches. The surgical treatment of sciatica with discectomy is reportedly ineffective in a sizable percentage of patients, and re-herniation occurs after 5% to 15% of such procedures. Thus, it would be ideal to define the optimal type of treatment for the specific types of prolapse (Carragee et al., 2003).

Different fusion procedures, including anterior lumbar interbody fusion, posterolateral fusion, posterior lumbar interbody fusion and transforaminal lumbar interbody fusion, and anterior-posterior combined fusion, do not vary significantly in pain or disability outcomes, although there are qualitative differences in complications related to the surgical approach. Prior to the 1980's both anterior and posterior non-instrumented lumbar fusions were commonly performed, using primarily bone graft. As pedicle screws became more widely used, it was noted that the rate of fusion increased from 65% with bone graft alone to nearly 95% with the instrumentation to provide internal support for the bone graft. The increased stiffness from the insertion of screws and rods has been hypothesized to lead to increased degeneration at spine segments adjacent to the fusion.

Anterior spine procedures, through either the peritoneum or retroperitoneum, require no posterior muscle and ligamentous dissection and result in less post-operative axial back pain. This approach is generally recommended for the treatment of axial LBP in young individuals. The usual criteria for consideration of an anterior lumbar fusion (or anterior lumbar arthroplasty) include a young person (i.e., age 20 to 40 years), who on MRI scan has either one or two dark discs, a concordant discogram indicating the axial pain is likely arising from the degenerated joints, and failure of previous conservative measures to improve the back pain over a period of time, with a minimum of 6 month conservative treatment. However, according to AHRQ (2006), the discogram remains highly controversial, and recent reports suggest that relying on the MRI findings of a dark disc and limiting the discogram to just those levels may improve the definition of a "positive discogram". The AHRQ assessment stated, "However, the high rate of false positives with normal disc spaces is problematic, as well as the high rate of prevalence

of dark disc syndrome." As patients age into their 40s and 50s the disc and facet degenerative processes slowly worsen, and it is less likely to find patients with isolated arthritis, thus, anterior fusion is less often recommended for older patients. Posterior fusion may be preferable for older individuals in order to stabilize facet joint disease. However, the posterior approach involves significant muscle dissection, resulting in severe back pain in the post-operative period, and is avoided by some surgeons.

The natural history of sciatica is favorable, with resolution of leg pain within 8 weeks from onset in most patients (Peul et al., 2007). Dutch guidelines on the diagnosis and treatment of the lumbosacral radicular syndrome (Stam, 1996) recommended the option of lumbar-disk surgery in patients who have sciatica if symptoms do not improve after 6 weeks of conservative treatment. To determine the optimal timing of surgery, investigators (Peul et al., 2007) randomly assigned patients (n = 283) who had had severe sciatica for 6 to 12 weeks to early surgery or to prolonged conservative treatment with surgery if needed. The primary outcomes were the score on the Roland Disability Questionnaire, the score on the visual analog scale for leg pain, and the patient's report of perceived recovery during the first year after randomization. Repeated-measures analysis according to the intention-to-treat principle was used to estimate the outcome curves for both groups. Of 141 patients assigned to undergo early surgery, 125 (89%) underwent microdiscectomy after a mean of 2.2 weeks. Of 142 patients designated for conservative treatment, 55 (39%) were treated surgically after a mean of 18.7 weeks. There was no significant overall difference in disability scores during the first year ($p = 0.13$). Relief of leg pain was faster for patients assigned to early surgery ($p < 0.001$). Patients assigned to early surgery also reported a faster rate of perceived recovery (hazard ratio, 1.97; 95% confidence interval [CI]: 1.72 to 2.22; $p < 0.001$). In both groups, however, the probability of perceived recovery after 1 year of follow-up was 95%. The investigators concluded that the 1-year outcomes were similar for patients assigned to early surgery and those assigned to conservative treatment with eventual surgery if needed, but the rates of pain relief and of perceived recovery were faster for those assigned to early surgery.

In one study (Weber, 1983) compared the results of surgical versus conservative treatment for lumbar disc herniation confirmed by radiculography (n = 126) with 10 years of follow-up observation. The author reported a significantly better result in the surgically treated group at the 1-year follow-up examination; however, after 4 years the difference was no longer statistically significant. Only minor changes took place during the last 6 years of observation. The trial was not blinded, and 26% of the conservative group crossed over to surgery.

In another study (Greenfield, 2003), available only as an abstract, compared microdiscectomy with a low-tech physical therapy regime and educational approach in patients with LBP and sciatica with a small or moderate disc prolapse. At 12 and 18 months, there were statistically significant differences in pain and disability favoring the surgical group; however, by 24 months there was no difference between the 2 groups.

The Cochrane systematic review (2007) concluded: (i) most lumbar disc prolapses resolve naturally with conservative management and the passage of time; (ii) there is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management. It provides faster relief from the acute attack of sciatica, although any positive or negative effects on the long-term natural history of the underlying disc disease are unclear. There is still a lack of scientific evidence on the optimal timing of surgery. The amount of cross-over in these trials makes it likely that the intent-to-treat analysis underestimates the true effect of surgery; but the resulting confounding also makes it impossible to draw any firm conclusions about the efficacy of surgery.

In a randomized controlled study, Brox et al. (2006) compared the effectiveness of lumbar fusion with posterior transpedicular screws and cognitive intervention and exercises on 60 patients aged 25 to 60 years with LBP lasting longer than 1 year after previous surgery for disc herniation. Cognitive intervention consisted of a lecture intended to give the patient an understanding that ordinary physical activity would not harm the disc and a recommendation to use the back and bend it. This was reinforced by 3 daily physical exercise sessions for 3 weeks. The primary outcome measure was the Oswestry Disability Index (ODI). The success rate was 50% in the fusion group and 48% in the cognitive intervention/exercise group. The authors concluded that for patients with chronic LBP after previous surgery for disc herniation, lumbar fusion failed to show any benefit over cognitive intervention and exercise.

The American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) Guideline's for the Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine (Resnick, 2005), is a series of guidelines that deal with the methodology of guideline formation, the assessment of outcomes following lumbar fusion, recommendations that involve the diagnostic modalities helpful for the pre- and post-operative evaluation of patients considered candidates for or treated with lumbar fusion, followed by recommendations dealing with specific patient populations. Finally, several surgical adjuncts, including pedicle screws, intra-operative monitoring, and bone graft substitutes are discussed, and recommendations are made for their use.

The other randomized trial, by Brox et al. (2003), assigned a specific cognitive and exercise regimen to the non-surgical patients. Enrollment criteria for this study were roughly similar to the other clinical trial, and outcomes were assessed at 1 year. In this study, patients receiving fusion reported improvements ranging from 36 to 49% on pain and disability scales, but patients in the control arm also reported similar improvements in these scores, resulting in differences which were not statistically significant for most outcomes. Although this trial was much smaller (n = 64) than the study by Fritzell et al. (2001), the point estimates of effect for each arm are very similar to each other, and confidence intervals sufficiently narrow to rule out a large clinical benefit of surgery. The authors believed that the difference in results between the 2 studies was caused by the specific intervention used in the non-surgical group, which produced improvements similar to the surgical fusion group.

Brox et al. (2010) compared the long-term effectiveness of surgical and non-surgical treatment in patients with chronic LBP. The study was conducted at 4 university hospitals in Norway. The limitations on study enrollment ensured that patients with more significant symptoms and findings were not included in the protocol. All participants had LBP for at least 1-year, moderate disability, and evidence of disk degeneration at L4-L5 or L5-S1; those with symptomatic spinal stenosis were excluded from study participation. Similarly, patients with disk herniation or lateral recess stenosis plus signs of radiculopathy were excluded, as were those with generalized disk degeneration, ongoing serious somatic or psychiatric disease, or "reluctance" (term not defined) to undergo one of the study treatments. Participants were randomized to receive instrumented transpedicular fusion or non-surgical therapy. The non-surgical therapy was very intensive and included initial education, support, and physical training sessions that lasted an average of 25 hours per week over 3 weeks. There were 4 to 7 participants assigned to this training at a time, and they stayed in a hotel for patients during the 3 weeks. Specialists in physical medicine and rehabilitation guided the program, and participants also met with a peer who had previously completed the non-surgical program. At the end of the 3 weeks, participants were prescribed a home exercise program. The primary study outcome was the Oswestry disability index, which measures both pain and disability. Researchers also followed participants' ratings of treatment effectiveness, quality of life, and effects of the interventions on medication use and time missed from work. The study focused on these results measured at 4 years after randomization, and results were adjusted to account for sex, age, previous surgery for disk herniation, and baseline pain and disability scores. Of 234 eligible patients, 124 were enrolled in the trials. Baseline data were similar for the 2 groups. The mean age of participants was 42 years, and 72% were women. The average duration of LBP was 9 years, and the mean severity of back pain was 64 on a scale of 0 to 100, with 100 being the most severe pain. Both treatment groups professed stronger beliefs in surgical versus non-surgical treatment of chronic LBP at baseline. In the surgical group, the rates of undergoing surgery were 88% at 1 year and 91 % at 4 years. The respective rates of surgery in the non-surgical group were 5% and 24%. Study follow-up was excellent, with rates of 92% and 86% in the surgical and non-surgical groups at 4 years. Beyond comparing surgical and non-surgical treatment for chronic LBP, the study also gave some insight into the use of healthcare and other resources by these patients. Only a slight majority of patients saw a physician for back pain in the year before study follow-up at year 4. Less than 25% received physical therapy. However, the rate of repeat surgery after the initial study surgery was 25% over 4 years. This high repeat surgery rate was recorded, even though no major adverse events related to surgery occurred through year 1 of the study.

Participants who received surgery were more than twice as likely to receive a disability pension, regardless of their randomized group. However, it would be wrong to infer that surgery itself promoted a higher rate of disability. These patients had surgery in response to more severe symptoms and were therefore more likely to receive a disability pension in the first place. Moreover, applications for disability pension from patients who had received surgery could have received more favorable reviews. There were no differences between randomized groups in the outcomes of pain and disability in either intent-to-treat or as-treated analyses at 4 years. The mean Oswestry disability index score declined in both groups from

an approximate mean of 44 at baseline to 28 at 4 years. Among secondary outcomes, the only difference between treatment groups was a reduction in fear and avoidance of physical activity, favoring the non-surgical group. Measurements of general function improved by approximately 40% in both groups, and life satisfaction also improved. The number of participants returning to work improved with both treatments to a similar degree, and the proportions of participants rating their treatment as successful at 1 year were 61% and 65% in the surgical and non-surgical cohorts, respectively. Use of pain medication was higher among participants who received surgery, but any difference between treatment groups was not significant on intent-to-treat analysis.

Billing/Coding Information

CPT CODES

0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	, each additional vertebral segment (List separately in addition to code for primary procedure)
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	; each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below C2 segment
22612	; lumbar (with lateral transverse technique, when performed)
22614	; each additional vertebral segment (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22634	; each additional interspace and segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments

Cervical, Lumbar, and Thoracic Spinal Fusion and Combined Decompression/Fusion, continued

22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical
63017	; lumbar
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
63030	; 1 interspace, lumbar
63035	; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63042	; lumbar
63043	; each additional cervical interspace (List separately in addition to code for primary procedure)
63044	; each additional lumbar interspace (List separately in addition to code for primary procedure)
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical
63047	; lumbar
63048	; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)

63056 Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)

63057 ; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)

HCPCS CODES

C2614 Probe, percutaneous lumbar discectomy

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Revision History

Revision Date	Summary of Changes
2/2/23	For Commercial Plan Policy, added language to clarify timeframe requirements in criterion #4-ciii: "Physical therapy or chiropractic therapy (minimum of 4 visits within a 3-month period); ***must have been performed within the previous 2 years. If there have been significant clinical changes or surgery has been performed in the previous 2 years, then repeat physical therapy or chiropractic therapy may be necessary, …"***
5/10/23	Modified title of policy (included "Thoracic" in title of policy).
10/30/24	For Commercial Plan Policy, modified requirements in criterion #5-Ciii: "Physical therapy or chiropractic therapy (minimum of 4 visits within a 3-month period); ***must have been performed within the previous 2 years. If there have been significant clinical changes or surgery has been performed in the previous 2 years, then repeat physical therapy or chiropractic therapy may be necessary, …"***
6/23/25	For Commercial Plan Policy, added language to clarify the type of procedure eligible for coverage described in criterion #7: "***Pediatric scoliosis surgery***, age ≤ 21, with progressive deformity with cobb angle > 50 degrees or rapidly progressive curve and > 40 degrees."
7/22/25	For Commercial Plan Policy, clarified smoking cessation requirement in criterion #5-E: "Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; ***and vaping or inhalation of any other substances for a sustained period***, must be discontinued >/= 3 months."
11/21/25	For Commercial Plan Policy, updated requirements pertaining to attempts at conservative therapy in both criterion #4B-ciii and criterion #5C-iii: "Physical therapy or chiropractic therapy: minimum of 12 visits within a 6-week period; must have been performed within the previous year (it is recommended that at least four of these visits be performed in-person), …"; and removed previous criterion #5D ("Willingness to participate in outcomes database").
3/24/26	For Commercial Plan Policy, clarified requirements outlined in both criterion #4-Biiic and #5-ciii: "Physical therapy or chiropractic therapy:

	minimum of 12 visits within a 6-month period; must have been performed within the previous year (it is recommended that at least four of these visits be performed in-person). **After 6 visits, additional therapy is not required if contraindicated or is not recommended by the physical or chiropractic therapist** …"

Select Health

MEDICAL POLICY

DEEP BRAIN STIMULATION (DBS)

Policy # 205

Implementation Date: 5/1/02
Review Dates: 8/12/02, 10/1/03, 6/24/04, 5/24/05, 5/12/06, 6/11/09, 10/21/10, 10/13/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/17/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/1/24, 10/8/25
Revision Dates: 11/1/03, 7/7/07, 6/19/08, 11/9/09, 5/7/19, 10/23/19

Related Medical Policies:
#186 Vagal Nerve Stimulation (VNS)
#556 Responsive Cortical Neurostimulation in the Treatment of Epilepsy

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description
The DBS System is an implantable, multiprogrammable system that delivers electrical stimulation to selected areas of the brain. An implanted pulse generator (IPG) is connected with a lead extension, to a lead with 4 electrodes. The electrodes contact the patient at a specific anatomical structure within the brain. The IPG is implanted under the skin of either the abdomen or under the clavicle, and sends programmable electrical stimulation pulses to a selected combination of output electrodes within the brain. Two of these device systems may be implanted to stimulate both sides of the brain in order to relieve symptoms or 1 device with 2 lead outputs. A control magnet or therapy controller is used to turn the therapy on and off.

Dystonia is a neurological movement disorder characterized by involuntary muscle contractions that force certain parts of the body into abnormal, contorted—sometimes painful—movements or postures. Dystonia affects approximately 250,000 people in the US, making it the third most common movement disorder, following essential tremor and Parkinson's disease. Essential tremor, sometimes referred to as ET, is a nerve disorder characterized by uncontrollable shaking—or "tremors"—in different parts and on different sides of the body. Areas affected often include the hands, arms, head, larynx, or voice box (making the voice sound shaky), tongue, chin, and other areas. The lower body is rarely affected. Parkinson's disease is a neurodegenerative disorder caused by the loss of cells that produce a chemical called dopamine. The hallmark of Parkinson's disease is a resting tremor, slowness of movement (bradykinesia), and limb rigidity.

Obsessive-Compulsive Disorder (OCD), is an anxiety disorder and is characterized by recurrent, unwanted thoughts (obsessions) and/or repetitive behaviors (compulsions). Repetitive behaviors such as handwashing, counting, checking, or cleaning are often performed with the hope of preventing obsessive thoughts or making them go away.

It is unclear how DBS works for these disorders. An electrical probe is inserted into the brain and it stimulates an area known as the subthalamic nucleus. This can help people overcome the neurological block on movement. Some researchers think the technique stimulates neurons that initiate movement. Others say it blocks inhibitory neurons, allowing brain signals to resume. Another theory holds that it influences the flow of information along axons (fibers that connect neurons to each other).

Approximately 3 million people in the United States have epilepsy and approximately 30% remain resistant to medical treatment. Patients with pharmaco-resistant epilepsy, who are not suitable candidates for resective surgery, should be considered for neurostimulation therapies. Deep brain stimulation (DBS)

and cortical responsive stimulation (CRS) are newer neurostimulation therapies with recently published long-term efficacy and safety data.

Several pilot studies, and recent trials including the Stimulation of the Anterior Nucleus of the Thalamus for Epilepsy (SANTE) trial and a trial of CRS have demonstrated reduction in seizures. The SANTE trial in 110 subjects with localization-related epilepsy found that seizures were significantly reduced by stimulation. The SANTE trial utilized a design with a 3-month baseline, 1-month postoperative recovery, followed by 3 months of double-blind treatment randomized to 5 V or 0 V of stimulation, then an open-label conversion of all subjects to 5-V stimulation for 9 additional months.

The long-term follow-up began at 13 months and continued for an additional 4 years. The primary research question was whether seizure frequency continued to improve over time with open-label anterior thalamic stimulation. Subjects were 18 to 65 years old, with at least 6 partial or secondarily generalized seizures per month, who had failed at least 3 antiepileptic drugs (AEDs) because of lack of efficacy. In the 5 years after implant, 16% (17/109) of randomized subjects reported a seizure-free interval of at least 6 months and 6 subjects were seizure-free for more than 2 continuous years during that time. In addition, 6 subjects had 2 or more seizure-free intervals of at least 6 months. At the 5-year assessment, 11 subjects were seizure-free for at least 6 months. The median percent seizure reduction from baseline at 1 year was 41%, and 69% at 5 years. The responder rate (50% reduction in seizure frequency) at 1 year was 43%, and 68% at 5 years. In the 5 years of follow-up, 16% of subjects were seizure-free for at least 6 months.

There are no head-to-head studies comparing efficacy of types of neurostimulation in refractory epilepsy. All neurostimulation technologies show long-term efficacy, with progressively better seizure control over time. Overall, participants with temporal lobe epilepsy (TLE) who are not suitable for resection may derive the most benefit from vagal nerve stimulation (VNS) or DBS of the anterior nucleus of the thalamus (ANT), also referred to as ANT-DBS. There are data to suggest that VNS and ANT-DBS have the potential to improve seizure control in candidates with failed resections. ANT-DBS has similar potential in previous VNS response failure.

Whether some patients might benefit from VNS after the failure of DBS or CRS has yet to be explored. Future studies may demonstrate that failure of one form of neurostimulation does not preclude use of other forms of neurostimulation for seizure control, given distinct mechanisms of seizure control in each. CRS is at a disadvantage when accurate delineation of the seizure focus is not possible. At present, the use of CRS is also limited to patients with one or two discrete seizure foci. ANT-DBS and VNS are not limited by these factors. Intracranial neurostimulation has a greater side effect profile compared with extracranial stimulation, though all forms of stimulation are considered relatively safe. Pre-existing problems with depression or memory might be of particular concern with regards to ANT-DBS.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers deep brain stimulation when any one of the following criteria are met:

1. **Primary dystonia(s),** including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), with ALL the following:
    a. Age ≥ 7; AND
    b. Chronic intractable (drug refractory) primary dystonia.
2. **Essential tremor**, when the tremor is resistant to all methods of conservative treatment.
3. **Parkinson's disease**, with ALL the following:
    a. Severe disability caused by the disease; and

b. The symptoms are resistant to all methods of conservative treatment, OR the member is developing dystonic reactions to medical therapy.

4. **Epilepsy**, with ALL the following:

   a. Age ≥ 18; and

   b. Evidence of focal/partial onset epilepsy; and

   c. Not a resection candidate for focal epilepsy either due to > 1 focus, or patient unwilling to consider brain resection; and

   d. The patient must have a well-documented seizure disorder with a debilitating effect on the patient's ability to function; and

   e. Failure of 3 or more antiepileptic medications; and

   f. Failure of vagal nerve stimulation (VNS) or responsive neurostimulation (RNS) are not required.

B. Select Health does NOT cover deep brain stimulation for the following conditions:

1. **Obsessive-compulsive disorder.** Limited information concerning efficacy meets the plan definition of experimental/investigational.

2. **Secondary dystonia(s) or any other movement disorders *except* for those associated with Parkinson's disease and essential tremor.** Use of this technology for secondary dystonia(s) other than Parkinson's disease or essential tremor is considered investigational due to a lack of medical literature showing its effectiveness and long-term safety for patients with these conditions.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Deep Brain Stimulation for Dystonia

Nine studies on DBS for dystonia of adequate methodological design have been published since this area of study was last evaluated in 2003. Of these, 1 was a double-blind, randomized controlled trial using sham stimulation as a control group. Kupsch et al. implanted 40 patients with primary dystonia and then randomly assigned them to 3 months neurostimulation or sham stimulation. After 3 months, all patients received neurostimulation. At 3 months, the blinded evaluation revealed improvement on the Burke-Fahn-Marsden Dystonia Rating Scale to be greater in DBS treatment group, compared with the sham control group. At 6 months, after all patients had been on DBS for at least 3 months, all patients continued to experience reduced dystonia symptoms. The sham stimulation patients experienced a similar

improvement in dystonia symptoms. Moreover, patients originally assigned to receive neurostimulation experienced a further, non-statistically significant improvement on the Burke-Fahn-Marsden Dystonia Rating Scale.

The remaining studies in this area are small case series with fewer than 30 patients each. The major weaknesses in this literature continue to be small sample size, lack of control or comparative groups, and lack of blinding. Nevertheless, these studies universally conclude that DBS is effective in treating primary dystonia with few adverse side effects. Most studies were restricted to patients with primary dystonia only. Patients with secondary dystonia were not included in numbers sufficient enough to permit any conclusions regarding the effectiveness of this therapy on patients with this form of dystonia. Studies with the largest periods of follow-up (30–36 months) suggest that the initial improvements observed with DBS are also maintained over time.

Deep Brain Stimulation for Parkinson's Disease

All 3 of the available systematic reviews: Hayes TEC, CMS, and the Australian Medicare suggest that the evidence supporting the effectiveness of deep brain stimulation, while limited, is compelling. Following are summary remarks from the BCBS TEC report; which is not only the most recent but was also commissioned and used by HCFA (CMS) to guide its coverage policy.

"There are no large prospective randomized studies with long-term follow-up of bilateral DBS for treatment of advanced Parkinson's disease. In no published studies are patients randomized to treatment arms to compare DBS with best medical management. Only one small pilot study compares the STN and globus pallidus interna (GPi) targets for DBS using prospective randomization."

Nevertheless, the published scientific evidence is compelling because of the numbers of consecutively treated patients described, the consistency of the findings across studies, and the magnitude of clinical improvements observed on standardized rating scales of neurologic function. More recent evidence suggests that bilateral deep brain stimulation (DBS) of the globus pallidus interna (GPi) or the subthalamic nucleus (STN) may alleviate the entire constellation of Parkinsonian symptoms (tremor, rigidity, and bradykinesia)." Specific indications, including age of candidates and major diagnoses, continue to evolve rapidly."

Studies suggest candidates for DBS with Parkinson's disease should have the following characteristics:

1. The patient has received "maximal medical therapy" and, in spite of such therapy, has shown a substantial (> 50%) increase in "off time"
2. The patient has advanced Parkinsonism, at least Hoehn and/or Yahr (or equivalent scale such the Unified Parkinson disease rating scale) stage III or IV, but is not so severe that this therapy is unlikely to result in significant clinical improvement (Hoehn and/or Yahr stage V)
3. The patient has no other independent diagnosis that could explain the failure to respond to medical therapy
4. The patient exhibits at least 2 of the 4 major symptoms of Parkinsonism (tremor, rigidity, bradykinesia, or gait disturbance of Parkinsonism)
5. The patient currently shows some response or has previously responded to dopaminergic replacement therapy
6. Age < 70 years
7. The patient has completed a formal psychiatric evaluation, documented in the patient's chart, which has determined that the patient does not have any
    - Significant underlying cognitive impairment OR,
    - Any major psychiatric illness such that this therapy is likely to result in significant clinical deterioration.
8. Request is for bilateral deep brain stimulation
9. Stimulator device to be implanted is FDA approved for indication requested

Patients with severe, limiting co-morbidities such as, class III or IV angina pectoris, stage III or higher congestive heart failure, or debilitating arthritis are contraindicated to receive DBS.

Comparison to Alternatives: "The improvements in 'off' period motor function following DBS of the GPi or STN are generally as great as or greater than those typically seen after unilateral pallidotomy."

Deep Brain Stimulation for Essential Tremor
Use of DBS in essential tremor mirrors that of Parkinson's disease. Unilateral and in some cases bilateral pallidal stimulation have been shown to be effective in patients with severe tremor refractory to medical therapy. These patients should have persistent tremor impairing their ability to perform ADLs despite maximally tolerable doses of beta blockers, benzodiazepines, and mysoline or other anti-epileptic medications with a prominent dopaminergic effect.

Deep Brain Stimulation for Obsessive-Compulsive Disorder
As of October 2009, the literature is primarily composed of small case series of limited duration. The largest study was done by Cosyn et al. in 2003 and another smaller study by Greenberg in 2006 involved 8 patients with only the Greenberg study looking at outcomes out to 3 years. All studies have demonstrated a beneficial effect, though significant disease activity continued to persist. All studies were considered preliminary by their authors, though not all recommended larger corroborating studies to prove effectiveness in a larger population.

The single randomized study completed by Mallet et al. in 2008 was remarkable in that the study design used sham therapy, which helps eliminate significant bias and more effectively exclude placebo effect. Though patients experienced a reduction in OCD symptoms, the study size was small with only 16 total patients enrolled. Additionally, the duration was only 10 months, which does not provide information regarding the durability of this technology. Concerning also, was the increased frequency of adverse events, which included 15 serious adverse events overall, including one intracerebral hemorrhage and two infections; there were also 23 minor adverse events. This rate of adverse events was much more than noted in other studies.

Essentially, limited studies exist related to deep brain stimulation as applied in the management of treatment resistant obsessive-compulsive disorder. Most of these studies are nonrandomized and not blinded, which introduces significant potential bias as to the conclusions drawn from the studies. This is supported, but the American Psychiatric Association's most recent Guideline Watch (March 2013) for OCD treatments, notes three small studies (Denys 2010, Mallet 2008, and Greenberg 2010) conclude that "the overall strength of evidence for these treatments remains low." Certainly, larger randomized studies of longer duration are warranted to verify the preliminary findings. Until then, the lack of adequate studies fails to prove this therapy's efficacy and safety.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative micro-electrode recording; first array
61864	; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative micro-electrode recording; first array
61868	; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrode
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	; with connection to two or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection

Deep Brain Stimulation (DBS), continued

	algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)

HCPCS CODES

C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

Deep Brain Stimulation (DBS), continued

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Select Health

MEDICAL POLICY

HARDWARE INJECTIONS IN THE ASSESSMENT OF CHRONIC BACK PAIN

Policy # 517
Implementation Date: 12/17/12
Review Dates: 12/19/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/2/19, 2/17/20, 2/16/21, 1/18/22, 2/16/23, 2/15/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Back pain is the second most common symptom-related reason for clinician visits in the United States. Up to 84% percent of adults have low back pain at some time in their lives. The long-term outcome of acute low back pain is generally favorable. Rapid improvement in pain and disability and return to work are the norm in the first month. Further improvement generally occurs over 3 months.

Only a small minority of patients suffering from low back pain ever require surgery. However, rates of surgical procedures are rising in the U.S., particularly for spinal fusion in patients with non-specific back pain. The most common surgery for chronic non-specific low back pain with lumbar disc degenerative changes, is vertebral fusion, a procedure that unites (fuses) 2 or more vertebral bodies together. The goal is to restrict spinal motion and remove the degenerated disc (the presumed pain generator) to relieve symptoms. A variety of fusion techniques are practiced. Fusion can be performed with or without supplemental hardware (instrumentation), such as plates, screws, or cages that serve as an internal splint while the bone graft heals. Fusion alters the normal mechanics of the spine and is associated with an increase in long-term degenerative changes in adjacent spine segments.

Surgical complications include vascular or neurologic injury, pseudarthrosis, infection, graft donor site pain, progressive pelvic obliquity, painful degenerative changes in the segment adjacent to the level of fusion, instability, hardware prominence or failure, and thromboembolism. Hardware complications include slippage of anchoring hooks, fracture of a screw, wire pullout, and migration of the hardware. With instrumentation, there is a 10%–29% incidence of reoperation.

Spinal pain at the surgical site may result from loosening of hardware, non-union, infection, and instability, which could include neurologic deterioration and may also be due to inadequate spinal immobilization. To determine a possible etiology for persisting pain, it has been proposed to inject a local anesthetic agent such as lidocaine and/or corticosteroid alongside the hardware to note, whether there is a decrease in pain. If the pain is temporarily relieved by the injection, it may indicate that the hardware is causing the pain, which may result in removal of the hardware. Failure to reduce the pain is argued to indicate the hardware is not the problem, and thus, hardware removal is not performed.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover hardware injections for diagnostic purposes, symptomatic management, or any other indication. Current medical literature does not demonstrate efficacy and durability of this procedure; this meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A literature review performed in November 2012 did not identify any systematic reviews or published peer-reviewed papers concerning hardware injections for diagnostic purposes, symptomatic management, or any other indication.

Billing/Coding Information

CPT CODES

62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	; with imaging guidance (ie, fluoroscopy or CT)
64450	Injection, anesthetic agent; other peripheral nerve or branch
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)

HCPCS CODES

J2400	Injection, chloroprocaine HCl, per 30 ml

Key References

1. Chou R. (2012). Subacute and chronic low back pain: Surgical treatment. UpToDate. Last Update: September 4, 2012. Available: http://www.uptodate.com/contents/subacute-and-chronic-low-back-pain-surgical-treatment?source=search_result&search=spinal+fusion&selectedTitle=1%7E20. Date Accessed: November 30, 2012.
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Hardware Injections in the Assessment of Chronic Back Pain, continued

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Select Health

MEDICAL POLICY

INTERBODY SPINAL FUSION DEVICES

Policy # 513

Implementation Date: 11/9/12
Review Dates: 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/27/21, 1/18/23, 12/15/23, 12/13/24, 12/12/25
Revision Dates:

Related Medical Policies:
#320 Interspinous Distraction Devices/Spacers
#450 Axial Lumbar Interbody Fusion (AXIALIF)
#558 Interspinous Fixation (Fusion) Devices

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Back pain is the second most common symptom-related reason for physician visits in the United States. Up to 84% of adults have low back pain at some time in their lives. The spectrum of illness and morbidity associated with low back pain is broad. For many individuals, episodes of back pain are self-limited and resolve without specific therapy. For others, however, back pain is recurrent or chronic, causing significant pain that interferes with employment and quality of life. The current accepted treatment algorithm for lumbar spinal stenosis (LSS) begins with non-steroidal anti-inflammatory drugs and narcotics, physical therapy, and pain management modalities such as epidural steroid injections. Over the long term, 15% of patients will improve with nonsurgical modalities, and 70% will continue to experience pain.

When patients fail to respond to conservative measures or develop significant neurological signs and symptoms surgical interventions are considered. Decompression and spinal fusion are the most common surgical procedures for the lower back. Decompression surgery removes a small portion of the bone over the nerve root and/or disc material from under the nerve root, relieving pressure and pain. Microdiscectomy and laminectomy are 2 common procedures for spinal decompression surgery.

In many instances lumbar spinal fusion is necessary to not only treat the patient's underlying problem but also stabilize the spine. There are many approaches to lumbar spinal fusion surgery, and all involve adding bone graft to an area of the spine to set up a biological response that causes the bone graft to grow between the 2 vertebral elements and create a fusion, thereby stopping the motion at that segment.

Fusion can be performed with or without supplemental hardware (instrumentation), such as plates, screws, or cages, which serve as an internal splint while the bone graft heals. Interbody devices create a space to relieve pressure and restore intervertebral disc space. They can be implanted using anterior, lateral, posterior, and transforminal.

The Food and Drug Administration (FDA) defines interbody fusion devices "act as a disc spacer and holds bone graft, also includes some form of integrated fixation to maintain stability by direct purchase into the bony vertebral endplates. They consist of a hollow cylinder or rectangular box made of metal or polymer with integrated fixation." The InterPlate (RSB Spine, LLC, Cleveland, OH) system is made from a titanium alloy and consists of plates, bone screws, and screw covers and uses autografts to facilitate fusion. The Avenue L Interbody Fusion System (LDR Spine USA, Austin, TX) consists of intervertebral cages from PEEK OPTIMA LT1 with an embedded titanium alloy. The Independence Spacer (Globus Medical Inc., Audubon, PA) is made from radiolucent polymer with titanium alloys and integrates a stabilization plate and a PEEK interbody spacer. Polyetheretherketone (PEEK) is a radiolucent

thermoplastic polymer that can be shaped into cages and spacers. PEEK mimics the elasticity, stability, and resistance to compression loading similar to bone.

The StaXx XD Expandable Spacer (Spine Wave Inc., Shelton, CT) is an expandable PEEK spacer adjusts its size during the implantation process. The concave endplates are designed to conform to a patient's anatomy. The StaXx XD device is not approved by the FDA for interbody fusion, only vertebral body replacement.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers interbody devices for FDA approved indications ONLY. All other indications or applications are considered experimental/investigational.

Select Health does NOT cover the StaXx XD Expandable Device when used for interbody fusion procedures as the device is not FDA approved for this indication. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A Select Health Medical Technology Assessment Committee conducted in September 2012 examined the StaXx XD device for interbody spinal fusion procedures. The committee could not identify any systematic reviews or peer-reviewed papers concerning the device being used for any indication other than what was approved by the FDA. Select Health's policy is to only provide coverage of devices that are FDA approved for specific indications.

Billing/Coding Information

CPT CODES

20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
20937	; morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22634	; each additional interspace and segment (List separately in addition to code for primary procedure)

22842	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy (ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar
63048	; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

Key References

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2. Chou, R. (2012). Subacute and chronic low back pain: Surgical treatment. UpToDate. Last Update: September 4, 2012. Available: http://www.uptodate.com/contents/subacute-and-chronic-low-back-pain-surgical-treatment?source=search_result&search=spinal+fusion&selectedTitle=1~20. Date Accessed: September 12. 2012.
3. Food and Drug Administration (FDA). (1996). Premarket Approval (PMA) of Surgical Dynamics, a division of United States Surgical Corporation Ray Threaded Fusion Cage (TFC)™ - ACTION. Department of Health & Human Services. Last Update: October 29, 1996. Available: http://www.accessdata.fda.gov/cdrh_docs/pdf/P950019A.pdf. Date Accessed: October 4. 2012.
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11. Ray, CD. (2009). Spinal Anatomy and its Effects on Types of Spinal Stenosis. Spine-Health. Last Update: August 7, 2009. Available: http://www.spine-health.com/conditions/spinal-stenosis/spinal-anatomy-and-its-effects-types-spinal-stenosis. Date Accessed: August 25. 2012.
12. Spine Wave Inc. (2012). StaXx XD Expandable Device In Situ Distraction, Minimal Retraction Spine Wave Inc. Last Update: 2012. Available: http://www.spinewave.com/products/xd.html. Date Accessed: September 12. 2012.

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Select Health

MEDICAL POLICY

INTRATHECAL BACLOFEN THERAPY

Policy # 137

Implementation Date: 1/4/00
Review Dates: 2/27/01, 6/5/02, 10/23/03, 11/18/04, 11/7/05, 10/19/06, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/16/24, 9/29/25
Revision Dates: 11/18/04, 9/14/06, 9/4/08, 11/12/11, 10/19/17, 10/28/24, 12/15/25

Related Medical Policies:

#609 Infusion Pumps (External or Implantable)

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Intrathecal baclofen therapy is administered to patients with chronic, intractable spasticity. It is based on the surgical implantation of a programmable infusion pump and placement of a catheter into the intrathecal space, the primary site of action, for the delivery of baclofen. The pump is implanted on an indefinite basis, depending on patient response and prognosis. Baclofen (trade name, Lioresal) is a muscle relaxant and anti-spasmodic agent and is the most used anti-spastic drug; other drugs can be added to the pump to improve management of these patients.

In some patients with severe spasticity who are on oral baclofen, the amount of drug that penetrates the blood-brain barrier is insufficient to provide adequate relief. Thus, the achievement of a satisfactory therapeutic response involves high oral dose regimens, which can cause intolerable central nervous system (CNS) side effects or systemic toxicity. Such patients often benefit from long-term intrathecal administration of baclofen.

Intrathecal baclofen (IB) therapy, in contrast to oral baclofen, permits effective levels to be obtained at the site of action without concomitant high levels in non-target tissues (e.g., blood). Thus, plasma concentrations of patients on IB therapy can be 100 times less than those of patients on oral baclofen, with equivalent therapeutic effect, dramatically reducing potential side effects and increasing functional status of the patient.

Side effects of this drug therapy are related to its CNS depressant characteristics and include sedation, drug tolerance, sleepiness, ataxia, and respiratory and cardiovascular depression. The patient population is primarily those with spasticity of spinal or cerebral origin (e.g., due to spinal cord trauma, degenerative spinal disease [multiple sclerosis], stiff person syndrome, hereditary spastic paraplegia, cerebral palsy, or brain injury).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers intrathecal baclofen therapy for the treatment of spasticity in *limited circumstances*.

A. Criteria for placement of trial (temporary) pump:

1. Patient has intractable muscle spasticity.

2. Documentation of failure, contraindication, or intolerance to at least a 6-week trial of oral antispasmodic drugs and physical therapy.

B. Criteria for placement of permanent pump:

1. **ALL** the above, **AND**
2. Patient has a favorable response to a trial using intrathecal dosage of the anti-spasmodic drug prior to pump and demonstrates improvement of the Modified Ashworth Scale, Spasm Scale, or ADLs (Activities of Daily Living) as evidenced by the following:

Modified Ashworth Scale:

1 - No increase in muscle tone

1+ - Slight increase in muscle tone, indicated by a catch followed by minimal resistance throughout range of motion (ROM)

2 - More marked increase through most of the ROM, but the limb easily flexed

3 - Considerable increase in tone; passive movement difficult

4 - Limb rigid in flexion or extension

Spasm Scale:

Spasms are measured by the number of spontaneous muscle spasms that occur over a 1-hour period:

0 - None.

1 - No spontaneous spasms; but vigorous sensory or motor stimulation results in spasms.

2 - Occasional spontaneous spasms or easily induced spasms.

3 - Greater than 1 but less than 10 spontaneous spasms per hour.

4 - Greater than 10 spontaneous spasms per hour.

Contraindications:

- Hypersensitivity to baclofen
- Presence of general contraindications to a surgical procedure (e.g., sepsis, coagulopathy)

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Boviatsis et al. estimated the functional benefit in 22 patients with severe and disabling pharmaceutically intractable spasticity treated with intrathecal baclofen infusion through an implantable pump. Fifteen patients had multiple sclerosis and seven had suffered a spinal cord injury at different levels (from C4 to T11). Postoperatively, all patients reported reduced spasticity, spasm frequency, and pain, improved

functional status, and enhanced quality of life. In a placebo-controlled trial by Van Schaeybroeck et al., 11 patients with spasticity of cerebral origin (mainly cerebral palsy) underwent bolus injections of baclofen and placebo. Eight patients were considered good responders and received a subcutaneous device for intrathecal drug delivery. Six of these were followed-up on for 2 years during which they were subjected to a blinded dose reduction test. The authors reported a noticeable placebo effect on spasticity scores during tests with bolus injections, suggesting the need for double-blind screening in each patient. Eight patients demonstrated a significant beneficial effect of intrathecal bolus injections compared with this placebo effect. Functional improvements were noted in most patients. During continuous infusion, Ashworth scale scores were less favorable but still significantly lower than at baseline.

Sampson et al. conducted a systematic literature review to estimate the effect of continuous intrathecal baclofen infusion on function and quality-of-life (QoL) measures in patients with severe spasticity. Health and cost data were obtained from hospitals in the United Kingdom. Results indicated that intrathecal baclofen improves mobility in bedbound patients and significantly reduce or eliminate pain in persons with severe spasm-related pain. Estimated costs per quality adjusted life year ranged between $10,550 to $19,570. Sampson et al. concluded that in carefully selected patients who have not responded to less invasive treatments, continuous intrathecal baclofen infusion is likely to lead to worthwhile functional benefits. Continuous intrathecal baclofen infusion has an acceptable cost/benefit ratio compared with other interventions that are funded by the health service.

A literature review performed in October 2011 identified Brennan et al. (2010), who found continuous infusion of intrathecal baclofen (ITB) via a subcutaneously implanted pump has developed over the past 2 decades as a powerful tool in the management of spasticity in various adult and pediatric neurological conditions. Acting more focally on spinal GABA receptors, ITB causes fewer systemic side effects than orally administered baclofen. The result is facilitation of daily caring, and symptomatic relief from painful spasm. With increasing experience of ITB use, novel applications and indications are emerging. These include the management of dystonia and chronic neuropathic pain. However, despite some recent authoritative reviews, there is still uncertainty about optimal use and evaluation of this therapy.

Billing/Coding Information

CPT CODES

Catheter Placement

62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy
62351	; with laminectomy
62355	Removal of previously implanted intrathecal or epidural catheter

Reservoir/Pump Placement

62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	; non-programmable pump
62362	; programmable pump, including preparation of pump, with or without programming
62365	Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion

Analysis/Reprogramming

62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill
62368	; with reprogramming
62369	; with reprogramming and refill
62370	; with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

Refilling

95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed
95991	; requiring physician's skill or other qualified health care professional
96521	Refilling and maintenance of portable pump
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (eg, intravenous, intra-arterial)

HCPCS CODES

This list is not all-inclusive

J0475	Injection, baclofen, 10 mg
J0476	Injection, baclofen, 50 mcg for intrathecal trial
A4220	Refill kit for implantable infusion pump
A4221	Supplies for maintenance of drug infusion catheter, per week (list drug separately)
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, non-programmable, permanent (implantable)
C2626	Infusion pump, non-programmable, temporary (implantable)
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement.
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

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Revision History

Revision Date	Summary of Changes
10/28/24	For Commercial Plan Policy, replaced the Ashworth Scale with the Modified Ashworth Scale in criteria #B-2 for evaluation of this therapy.
12/15/25	For Commercial Plan Policy, modified requirements in criterion #A-1: "Patient has intractable muscle spasticity."; and clarified requirements in criterion #B-2: "Patient has a favorable response to a trial ***using*** intrathecal dosage of the anti-spasmodic drug prior to pump …"

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Select Health

MEDICAL POLICY

MIGRAINE HEADACHE SURGERY

Policy # 291
Implementation Date:1/20/06
Review Dates: 12/21/06, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 10/13/11, 11/29/12, 10/24/13, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/18/19, 2/17/20, 2/23/21, 1/18/22, 2/17/23, 2/21/24, 2/9/25
Revision Dates: 1/17/14

Related Medical Policies:

#559 Sphenopalatine Ganglion (SPG) Injection in the Management of Headaches

#420 Peripheral Nerve Stimulation for Occipital Neuralgia and Chronic Headaches

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Migraine is a common, often disabling, episodic headache disorder that occurs in up to 17% of women and 6% of men each year. The World Health Organization (WHO) ranks migraines 19th among all diseases worldwide that cause disability. Migraines are thought to have a polygenetic and multifactorial etiology. Migraine sufferers may have a genetic threshold making them prone to migraines, which may be triggered by "neuronal dysfunction" (i.e., the balance between excitation and inhibition) occurring at various levels of the nervous system that activates a cascade of neural changes to produce migraine symptoms. A variety of theories postulate several possible pathways of migraine pathogenesis that involve trigeminal nerve stimulation, cortical hypoperfusion and cortical spreading depression (CSD), and the action of serotonin and calcitonin gene-related peptide (CGRP) on cerebral vasculature.

Several surgical procedures have been developed to prevent chronic migraine headaches. A summary of the more common procedures follows.

Cardiac shunt closure (PFO Closure) is often done percutaneously on an outpatient basis. The procedure involves inserting a catheter into the heart through an incision in the femoral vein. The PFO is measured and a closure device (e.g., Amplatzer Septal Occluder CardioSEAL Septal Occlusion System) is moved through the catheter to the location of the PFO. Once in the correct location, the PFO closure device is allowed to expand its shape to straddle each side of the hole. The device remains in the heart permanently to stop the abnormal flow of blood between the two atria.

Cranial Muscle Surgery aims to reduce compression of certain nerves that traverse the surface of the cranial muscles. Patients undergo multiple botulinum toxin A injections (Botox) to identify headache trigger points. Botox responders (at least 50% reduction in intensity or frequency lasting at least 4 consecutive weeks) are surgery candidates. Surgery involves removal of the corrugator supercilii, depressor supercilii, and procerus muscles for frontal headaches, removal of a portion of the zygomaticotemporal branch of the trigeminal nerve for temporal headaches, and removal of a small portion of the semispinalis capitis muscle for occipital migraines.

Intranasal surgery assumes that some migraine headaches arise from pressure on nasal mucosa from anatomical variations in the nasal cavity (e.g., deviated septum). Patients undergo radiographic imaging to identify contact points between the septum (thin wall of cartilage that divides the nasal cavities) and turbinates (bony plates within the nasal cavity). Patients who report migraine improvement when a topical anesthetic is applied to the contact area are candidates for surgery. Patients with such triggers accompanied by intranasal abnormality undergo septoplasty, in which portions of the nasal septum are removed or repositioned, and/or turbinectomy, in which the inferior and/or middle turbinates are removed or reduced in size.

The PREMIUM (Prospective, Randomized Investigation to Evaluate Incidence of Headache Reduction in Subjects with Migraine and PFO Using the AMPLATZER PFO Occluder to Medical Management) was a double-blind study investigating migraine characteristics over 1 year in subjects randomized to medical therapy with a sham procedure (right heart catheterization) versus medical therapy and PFO closure with the Amplatzer PFO Occluder device (St. Jude Medical, St. Paul, Minnesota). Subjects had 6 to 14 days of migraine per month, had failed at least 3 migraine preventive medications, and had significant right-to-left shunt defined by transcranial Doppler. Primary endpoints were responder rate defined as 50% reduction in migraine attacks and adverse events. Secondary endpoints included reduction in migraine days and efficacy in patients with versus without aura.

Of 1,653 subjects consented, 230 were enrolled. There was no difference in responder rate in the PFO closure (45 of 117) versus control (33 of 103) groups. One serious adverse event (transient atrial fibrillation) occurred in 205 subjects who underwent PFO closure. Subjects in the PFO closure group had a significantly greater reduction in headache days (–3.4 vs. –2.0 days/month, p ¼ 0.025). Complete migraine remission for 1 year occurred in 10 patients (8.5%) in the treatment group versus 1 (1%) in the control group (p ¼ 0.01). Conclusion: PFO closure did not meet the primary endpoint of reduction in responder rate in patients with frequent migraine.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover any currently available surgical techniques when used primarily for the treatment of migraine headaches, including but not limited to: PFO closure, corrugator/frontalis muscle resection, and 'contact point' intranasal surgery. Current evidence is inconclusive as to the safety and efficacy of any surgical intervention in the treatment of migraine headaches; therefore, this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Patent Foramen Ovale Closure

Six studies examining the effect of PFO closure on frequency of migraine headaches were found when conducting a literature review. All were retrospective clinical reports of patients who underwent closure of a PFO or atrial septal defect. Most patients were diagnosed with or were suspected of having paradoxical cerebral embolism. None of the patients in these studies was reported to have undergone PFO closure primarily for migraine prophylaxis nor were patients selected for surgery based on the presence of migraine symptoms. None of these studies measured any utilization outcomes-related migraines (e.g., medication use, office visits, ER visits).

The extant literature generally supports some association between PFO closure and migraine pain relief. Azarbal et al., for example, reported that in PFO closure patients in whom migraine was also present (n = 37), 75% of those with aura and 31% without aura experienced complete remission of migraine symptoms at 3 months post-surgery. Of the remaining migraineurs, 40% reported significant improvement

in migraine symptoms. Morandi et al. studied 17 migraine patients scheduled for PFO closure. Six months after surgery, 5 patients no longer complained of migraine, 10 were substantially improved, and 2 were unchanged. A 1-year retrospective study of 50 migraineurs by Reisman et al. found complete resolution of migraine symptoms in 56% of patients and 14% experienced significant reduction in migraine frequency. Overall, the mean number of migraine episodes per month decreased from 6.8 + 9.6 to 1.4 + 3.4 after surgery. Schwerzmann et al.'s study of 48 migraine patients found that PFO closure reduced the frequency of attacks by 54% and 62% in those with and without aura, respectively. In contrast, a 2005 survey of 75 PFO closure patients by Mortelmans et al. found that PFO closure was not related to a decrease in the prevalence of migraine (median follow-up time was 29 months). In fact, 10 patients experienced new-onset migraine after surgery.

The rate of migraine among PFO closure patients from these studies ranged from 11%−57%. However, evidence based on randomized, prospective studies is not yet available to allow conclusions as to whether this therapy indeed is cost-effective in treating migraine headaches, let alone effective.

Cranial Surgery

Four studies involved corrugator muscle resection and other surgical procedures for treatment of migraine headaches, 3 of which were conducted by Bahman Guyuron, a primary developer of this technique. All these studies involved relatively small sample sizes and most lacked adequate strategies for assuring homogeneity of the study sample.

The most recent study, a 2005 investigation of 125 migraine patients, randomly assigned 100 patients to surgery while the remaining 25 served as no treatment controls. Depending on individual trigger sites, surgery involved resection of the corrugator supercilii, depressor supercilii, and procerus muscles, removal of a section of the zygomaticotemporal branch of the trigeminal nerve, or a portion of the semispinalis capitis muscle. Many of these patients also underwent intranasal surgery as well. Of the 89 who completed the study, 31 (35%) reported elimination of migraine symptoms and 51 (57%) demonstrated at least 50% reduction in migraine headache frequency, duration, or intensity over a mean follow-up period of 396 days. Conversely, 3 of 19 controls (15.8%), recorded reduction in migraine headaches during the 1-year follow-up, but in none were migraines eliminated. The mean annualized cost of migraine care for the treatment group ($925.00) was reduced significantly compared with the baseline expense ($7,612.00 dollars) and the control group ($5,530.00). How these costs were calculated was not reported, however. The mean monthly number of days lost from work for the treatment group (1.2) was reduced significantly compared with the baseline data (4.41) and the control group (4.4) ($p = 0.003$).

Dirnberger et al. examined 60 consecutive patients who underwent corrugator muscle resection for migraines. Of these, 28.3% reported a total relief from migraine, 40% reported some improvement, and 31.7% experienced minimal or no change in symptoms. Patients with more mild migraine headaches had a higher likelihood of experiencing an improvement or total elimination of migraine than those patients with severe migraine. Eleven patients who had a favorable response within the first weeks experienced a gradual return of their headaches to preoperative intensity after about 4 weeks. Investigator bias and the lack of adequately controlled and powered studies limit the conclusion obtained from this body of literature.

Intranasal Surgery.

Seven studies were found in the literature regarding the use of intranasal surgery in treatment of migraine headache. Most of these were retrospective clinical reports in which surgery was conducted as part of clinical care, rather than a research protocol. Consequently, none of the studies was controlled in that they lacked random subject selection, standard study procedures, or consistent measurement strategies. The procedures administered in these studies included septal correction, resection of the turbinates, ethmoidectomy, and sphenoidectomy.

Results from these studies suggest that intranasal surgery relieves headache pain in migraine patients with radiographic evidence of intranasal contact points between the septum, turbinates, and surrounding sinuses. Behin et al. have published the most recent research in this area. Their 2005 chart review involved 21 subjects with refractory migraine and intranasal contact points, which, when treated with topical anesthesia, produced headache relief. Surgery to correct these contact points resulted a decline in mean headache frequency from 17.7 to 7.7 headache days per month and a decrease in mean headache severity from 7.8 to 3.6 (0−10 scale). Headache-related disability declined from 5.6 to 1.8 (0−10 scale). A second chart review by Behin et al. reported that 80% of migraine patients who underwent surgery to

correct intranasal contact points experienced improvement in their headaches. The authors concluded that contact point headaches should be evaluated as an alternative diagnosis in the patient with chronic migraines.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproven for this indication

CPT CODES

Forehead/Brow Lift

15824 Rhytidectomy, forehead

Excision or Submucous Resection of Nasal Turbinates

30130 Excision turbinate, partial or complete, any method

30140 Submucous resection turbinate, partial or complete, any method

Nasal Septum Repair

30520 Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft

Patent Foramen Ovale

93580 Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant

Additional Procedures

93315 Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report

93320 Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to code for echocardiographic imaging); complete

93321 ; follow-up or limited study (List separately in addition to codes for electrocardiographic imaging)

93325 Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)

93533 Combined right heart catheterization and transseptal left heart catheterization through existing septal opening, with or without retrograde left heart catheterization, for congenital cardiac anomalies

HCPCS CODES

C1817 Septal defect implant system, intracardiac

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Select Health

MEDICAL POLICY

PROGRESSIVE ADOLESCENT IDIOPATHIC SCOLIOSIS

Policy # 662

Implementation Date: 6/8/23
Review Dates: 9/18/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Scoliosis is a musculoskeletal disorder characterized by abnormal lateral curvature of the spine measuring more than 10 degrees in the coronal plane. The spinal curve may develop as a single curve (shaped like the letter C) or as 2 curves (shaped like the letter S). Adolescent Idiopathic Scoliosis (AIS) is by far the most common type of scoliosis, affecting children between ages 10 to 18; it is found in as many as 4 in 100 adolescents. In general, AIS curves progress during the rapid growth period of the patient. While most curves slow their progression significantly at the time of skeletal maturity, some, especially curves greater than 60°, continue to progress during adulthood. Many theories exist with regards to the cause of AIS, including hormonal imbalance, asymmetric growth, and muscle imbalance.

AIS is usually confirmed through a physical examination, an x-ray, spinal radiograph, computed tomography (CT) scan, or magnetic resonance imaging (MRI). Imaging tests take a closer look at the spine to determine whether there are any problems with the bones and to measure the curvature of the spine. The curve is measured in degrees commonly referred to as the Cobb angle. A positive diagnosis of scoliosis is made based on a coronal curvature measured on a posterior-anterior radiograph of > 10°. In general, a curve is considered significant if it is greater than 25° to 30°. Curves exceeding 45° to 50° are considered severe and often require more aggressive treatment.

The goal of treatment in AIS is to correct the spinal deformity while allowing for thoracic growth for optimal cardiopulmonary function. Treatment options include observation, bracing or casting, or surgery. The type of treatment chosen depends on several factors, including etiology, severity of the spinal curve, curve pattern, and remaining growth of the patient. Spinal fusion surgery is often recommended for individuals with severe scoliosis. However, if performed too early, fusion surgery can lead to arrested development, thoracic insufficiency syndrome (TIS), and loss of mobility over the fused section.

The ApiFix System is indicated for AIS patients with deformity classified as Lenke type 1 and 5 and a Cobb angle up to 60 degrees. Both major and secondary curves must be flexible, confirmed using Lateral Bending X-rays, to allow gradual correction over time. For patients with these indications, the surgical procedure is less invasive, compared to the traditional standard of care. The unilateral implant system is attached to the spine on the concave side of the major curve using only two to three screws. There is an insufficient quantity of published, peer-reviewed, human clinical data to evaluate the Minimally Invasive Deformity Correction (MID-C)/ApiFix System for adolescent idiopathic scoliosis in a health technology assessment.

Vertebral body tethering (VBT) is a fusionless surgical technique to modulate spine growth, provide spinal curve correction, and preserve spine mobility in skeletally immature patients with severe, progressive, idiopathic scoliosis who have failed or are intolerant to bracing. Placement of The Tether VBT system can

be performed thoracoscopically, which is less invasive than the open surgical technique used for posterior spinal fusion (PSF) and prompts faster recovery.

The Tether (Zimmer Biomet Spine Inc.) is one of several spinal tethering systems currently available or in clinical trials and is the only anterior VBT system allowed for in use in the United State outside a clinical trial setting (H190005). The Tether is indicated for treatment of idiopathic scoliosis* in skeletally immature patients who have failed or are intolerant to bracing, have a major Cobb angle of 30° to 65°, and have adequate vertebral bone structure to support necessary screws.

VBT, a nonfusion technique first published in 2010 by Crawford and Lenke (in human patients; animal model studies published earlier), modulates spinal growth by using an internal mechanical restraint in the form of a flexible cord that is anchored by screws placed into several adjacent vertebrae. The cord applies a compressive force to the convex side of the anterior aspect of the spine, which slows growth of the concave side of the spine, allowing it to grow relatively more than the convex side, thus creating conditions for a straighter spine to develop over time. Procedures are performed under general anesthesia using a thoracoscopic or mini-open approach. There is a known learning curve for surgeons new to this surgical technique that may affect operative time (including time patient spends intubated and under anesthesia), estimated blood loss for the patient, and hospital length of stay. VBT may also be referred to as dynamic spinal stabilization, soft stabilization, dynamic growth modulation, fusionless anterior scoliosis correction, or spine ligamentoplasty. VBT is not the same procedure as vertebral body stapling.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover posterior dynamic deformity correction devices (e.g., MID-C/ApiFix System) for the treatment of progressive adolescent idiopathic scoliosis. There is insufficient clinical data available to support improved outcomes or long-term safety; therefore, this meet's the plan's definition of experimental/investigational.

Select Health does not cover anterior vertebral body tethering (e.g., Zimmer Biomet/The Tether) for the treatment of progressive adolescent idiopathic scoliosis. There is insufficient clinical data available to support improved outcomes or long-term safety; therefore, this meet's the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information
Not covered for the indications listed above

CPT CODES

0656T Vertebral body tethering, anterior; up to 7 vertebral segments
0657T Vertebral body tethering, anterior; 8 or more vertebral segments
20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only
20931 Allograft, structural, for spine surgery only
20936 Autograft for spine surgery only; local
20937 Autograft for spine surgery only; morselized (through separate skin or fascial incision)
20938 Autograft for spine surgery only; structural bicortical or tricortical (through separate skin or fascial incision)
22612 Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
22800 Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments (levels)
+22840 Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)
+22842 Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments
+22843 Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments
22899 Unlisted procedure, spine [when specified as vertebral body stapling or implantation of a posterior (dynamic) distraction device]

Key References

1. Hayes, Inc. Minimally Invasive Deformity Correction System (ApiFix) for Adolescent Idiopathic Scoliosis. Evidence Analysis Research Brief. Nov. 20, 2020.
2. Hayes, Inc. The Tether (Zimmer Biomet) for Skeletally Immature Patients With Progressive Idiopathic Scoliosis. Evolving Evidence Review. Apr. 7, 2022.
3. Hayes, Inc. Evidence Analysis Research Brief. ApiFix (ApiFix Ltd.) for Treatment of Adolescent Idiopathic Scoliosis. Dec. 11, 2023.

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Select Health

MEDICAL POLICY

PERIPHERAL NERVE STIMULATION FOR OCCIPITAL NEURALGIA AND CHRONIC HEADACHES

Policy # 420

Implementation Date:8/13/09

Review Dates: 8/19/10, 9/15/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 11/28/18, 12/18/19, 12/16/20, 11/28/21, 11/17/22, 12/20/23, 12/26/24

Revision Dates: 3/17/10

Related Medical Policies:

#162 Percutaneous Electrical Nerve Stimulation (PENS)

#559 Sphenopalatine Ganglion (SPG) Injection in the Management of headaches

#221 Botulinum Toxin Injections

#291 Migraine Headache Surgery

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Peripheral nerve stimulation (PNS) is a neuromodulation technique in which an electrical current is applied to the peripheral nerves to reduce or eliminate chronic pain. It is most applied to patients with chronic neuralgia or headache conditions. After a trial period in which temporary electrodes and an external generator are applied for ~1 week, a standard 4–8 contact electrodes are typically used; the electrodes are passed in the epifascial plane under the skin but above the muscles. Patients routinely undergo a psychological screening to rule out psychological amplifiers of pain, such as depression, substance abuse, behavioral problems, etc. For the permanent procedure, the electrodes used include cylindrical "wire" types (such as Quad, Octad, Quad Plus, or Quad Compact [Medtronic, Inc.]; Qattrode, Octrode, or Axxess [Advanced Neuromodulation Systems]; and Linear [Advanced Bionics]). The electrodes or extension cables are tunneled toward the generator pocket. The tunneling step is quite painful and necessitates the use of general anesthesia. Location of the pocket is chosen based on the patient's and surgeon's preference. The infraclavicular area is most used for occipital nerve stimulation systems, and in this way the procedure is similar to the one used for placement of deep brain stimulation generators.

A new neurostimulator, the Bion microstimulator, manufactured by Advanced Bionics, is currently in U.S. clinical trials for the treatment of urinary urge incontinence through pudendal nerve stimulation (for which it has already received the CE Mark), and for the treatment of chronic headache through occipital nerve stimulation. Several other indications are being explored for this revolutionary micro-bionic technology. This small leadless rechargeable device weighing 0.75 g with an overall volume of only 0.19 cm^3 (3 mm x 28 mm), the microstimulator is a tiny fraction of the size of other neurostimulators. Its small size enables the microstimulator to be implanted with the use of a custom needle-like insertion tool (4 mm in diameter) in the subcutaneous space above the trapezius muscles; this is proposed to offer an advantage over implantable pulse generator (IPG) systems, since it is immune from problems like lead migration and stress fracturing. IPG advocates stress the greater proximity of electrical energy to the target nerve possible with leads.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover peripheral nerve stimulation for occipital neuralgia or chronic headaches. This procedure meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Select Health identified 13 studies for this report. Overall, this literature consists of small case series of generally limited follow-up periods. One of these was a comparative trial. These studies conclude that PNS results in pain reduction and functional improvements relative to baseline assessments. Ahmed et al. reported on 30 patients who underwent PNS for tension headache, migraine, or posttraumatic headache. In this unblended study, patients were randomized to receive PENS (needles with electricity) or "needles alone" according to a crossover study design. All treatments were administered for 30 minutes, 3 times a week for 2 consecutive weeks, with 1 week off between the 2 different treatments. Compared with the needles alone, PENS therapy was significantly more effective in decreasing the overall VAS pain scores for tension-type headache, migraine, and posttraumatic headache (58%, 59%, and 52% vs. 20%, 15%, and 20%, respectively). Similarly, PENS therapy produced greater improvement in the patients' physical activity (41%–58% for PENS vs. 11%–21% for needles only) and quality of sleep (41%–48% for PENS vs. 12%–20% for needles only). However, there were no differences in the pattern of the response to PENS therapy among the three headache groups.

Burns et al. administered PNS (Bion) to 6 patients with hemicrania continua in crossover fashion: the device was on for the first three months, off for the fourth month, and on again during long-term follow-up. All phases were unblinded. At the median 13.5-month follow-up, there was a significant effect of the Bion being on or off for the entire cohort (Wald $\chi^2 2 = 13.1$, $p = 0.001$). A study-day term in the model was used to account for the baseline period ($\chi^2 1 = 0•01$, $p = 0.92$). The results of this analysis suggest that the Bion intervention reduces pain levels in this group. The overall estimated effect of the Bion was a reduction in pain score of 5.8 points on the Migraine Disability Assessment Scale (95% CI 4.7–6.9 points).

Kapural et al. reported a case series involving 6 patients who underwent PNS implantation for occipital neuralgia who were followed for 3 months after implantation. Patients experienced significant decreases in VAS pain ratings over time (8.66–2.5) and improved functional capacity as measured by the Pain Disability Index. A 2007 study by Melvin et al. prospectively evaluated PNS in 11 patients with C2-mediated occipital headaches. At 12 weeks, scores on the Short-Form McGill Pain Questionnaire (-64%), Visual Analog Scale (-67%), and the Present Pain Index (-67%) all declined significantly from baseline. Moreover, 91% of patients reported using less medication for headache pain and 64% reported having fewer headaches. Finally, the impact of headaches on ADLs (-34%), recreation (-35%), and work productivity (-40%) also declined over time.

Slavin et al., conducted a retrospective review of 30 patients with craniofacial pain who underwent PNS of the supraorbital (7 patients), infraorbital (6), and occipital (21) nerves. In 19 patients, more than one nerve was stimulated. Outcomes by stimulation site were not reported. Of the 30 implanted, 22 (73%) experienced more than a 50% reduction in pain intensity and went on to have a permanent system implanted. At an average 35-month follow-up, 2 devices had been removed because of improved pain

and three were removed because of loss of effectiveness. Altogether, of 22 patients in whom PNS devices were implanted, 16 (73%) experienced significant (> 50%) improvement in pain intensity (14 with and 2 without stimulation); 3 patients (13.5%) reported less than 50% pain improvement; and 3 (13.5%) continued to experience pain after their devices were removed due to either loss of effect or infection.

Though some literature suggests peripheral nerve stimulation may be effective in treating chronic intractable headaches, these studies were of small sample size and none were blinded, including the 2 crossover ones. Additionally, there are few comparative trials from which to draw firm conclusions about the efficacy of this treatment, especially as it compares to alternative treatments. The pre-post design utilized by most studies is a weak method for testing treatment effects as it is susceptible to regression toward the mean. For greater certainty, blinded comparative studies are particularly important in pain-related treatment studies to rule out the placebo effect. Therefore, until larger, blinded, comparative studies are completed, PNS cannot be considered a valid alternative in the treatment of chronic intractable headache/neuralgia and remains investigational.

The Congress of Neurological Surgeons published guidelines regarding PNS in 2015. The guideline outlined nine smaller published studies on the use of occipital nerve stimulation (ONS) for occipital neuralgia (ON). The studies are all small (< 15 patients), and most of them have no comparison or control population (in one study treatment patients served as their own controls). The level of evidence in all the studies is Level III (case series, case reports, or comparative studies with historical controls). Based on the review, the authors state that: "The use of ONS is a treatment option for patients with medically refractory ON." The ONSTIM study published in 2011 defined responders as a patient achieving > 50% reduction in headache days/month or a > 3-point reduction in pain severity. The responder rate in this trial was 39% for active stimulation, 6% for sham, and 0% for medical management. The study was not powered for efficacy evaluation. The response rates are comparable to medical preventative chronic migraine treatments and suggests that additional study is warranted.

Lipton et al., reported the results of the PRISM study in abstract only as part of a conference presentation. The abstract reportedly failed to demonstrate statistically significant improvement compared to sham for occipital nerve stimulation. The trial results have not yet been published in a peer-reviewed journal. A St. Jude study also did not meet statistical significance for its' primary endpoint of active treatment responders achieving > 50% reduction in daily headache scale scores. Further statistical analysis showed a statistical difference at > 30% reduction, but this was not the primary trial endpoint. Another trial (Silberstein) did not reach statistical significance for its primary endpoint.

Chen et al., published meta-analysis as part of procedural guidance for the UK National Institute for Health and Care Excellence (NICE). The meta-analysis includes analysis of the three multicenter RCTs previously mentioned. The meta-analysis concluded that mean headache day reduction in those three multicenter trials was 2.56 days per month with active ONS compared to sham control. The analysis goes on to conclude: "The average effect size is modest and may be exaggerated by bias as achieving effective blinding remains a methodological challenge." This review also noted safety concerns with common lead migration and infections potentially requiring revision surgery. For example, in the ONSTIM trial, lead migration occurred in 24% of patients at 3 months follow-up and it occurred in 18% of the St Jude trial at 1-year follow-up. The meta-analysis concluded: "Current evidence on the effectiveness and safety of ONS is still limited in quantity and remains inconclusive given the challenges in trial methodology and patient selection."

A 2017 literature search found a review (Robbins et al., 2017) in the Journal of Head and Face Pain (Headache) summarizing the 3 main trials for stimulation in chronic headache which found this conclusion: "The 3 clinical trials for minimally invasive occipital nerve stimulation for migraine did not clearly demonstrate efficacy but show promising trends. High rates of adverse effects … are serious concerns." There is a prospective ONS trial for chronic migraine (Rodrigo et al., 2017) that shows benefit, however, because it is open-label and uncontrolled, the level of evidence is not strong. Another small case series suggested medical benefit (Keifer et al., 2017) but like most of the other studies suggesting clinical benefit, it is limited by design and small sample size.

Billing/Coding Information
Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95975	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

HCPCS CODES

C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)

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Select Health

MEDICAL POLICY

QUANTITATIVE ELECTROENCEPHALOGRAPHY (QEEG)

Policy # 319

Implementation Date:10/25/06

Review Dates: 10/18/07, 10/23/08, 12/17/09, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 6/21/18, 4/12/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23, 4/19/24, 4/10/25

Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Electroencephalogram (EEG) refers to the continuous recording of brain electrical activity. This can be recorded onto a paper chart, or more commonly, digitized into a computer for frequency analysis. The continuous EEG is made up of waves of different frequencies that each relate to different aspects of mental activity. Quantitative EEG (QEEG) is the digitization of the EEG signal and mathematical analysis of the data and patterns of the signal through various manipulations of the data to help in the diagnosis and prognosis of illness, whether neurological or cognitive (e.g., head trauma or learning disorders). The heart of QEEG lies with the underlying computerized analytic and statistical techniques.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover quantitative electroencephalography (QEEG) testing. There is a lack of literature supporting its use as an effective assessment tool; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Much of the research on quantitative EEG continues to be in its formative stages and its relevance to clinical practice cannot be evaluated. Most of this cross-sectional research involved small sample sizes with the aim of describing EEG abnormalities in different diagnosis groups. For many conditions, very few

additional articles were published in the four years since our last review. Consequently, for most potential applications of QEEG, the literature does not support its incorporation into clinical practice.

For several conditions such as attention deficit-hyperactivity disorder/attention deficit disorder (ADHD/ADD) and dementia, QEEG has received more study. The test has also been examined as a means to track response to psychotropic medications. Chabot et al. reviewed the use of QEEG for these and other psychiatric indications.

ADHD: QEEG abnormalities may help to differentiate between childhood and adolescent ADHD/ADD and other learning disorders. Chabot et al. concluded that an increased theta-beta power ratio (i.e., high theta power relative to low beta power) in the frontal and temporal regions distinguishes children with ADHD from normal controls. More recent research is consistent with this observation. Barry et al., for example, found decreased levels of alpha and beta activity in 40 children with ADHD, compared with 40 matched controls. Hermens et al. found that children with ADHD had increased (primarily left) frontal theta relative to normal controls. Furthermore, this abnormality predicted performance on cognitive performance tasks. While initial data on adults with ADHD suggest a similar EEG profile, the data are insufficient to conclude whether these findings are reliable, particularly as other research evidence cited by Chabot et al. demonstrated age-related changes in EEG results.

In November 2016, the American Academy of Neurology released a guideline advising against using QEEG for the diagnosis of ADHD (Gloss et al.). Specifically, it states: "Clinicians should inform patients with suspected ADHD and their families that the combination of EEG theta/beta power ratio and frontal beta power should not replace a standard clinical evaluation. There is a risk for significant harm to patients from ADHD misdiagnosis because of the unacceptably high false-positive diagnostic rate of EEG theta/beta power ratio and frontal beta power."

Some of the technical issues raised in the AAN practice guideline for ADHD are likely to be concerns with using QEEG for other conditions. "Theta activity is increased by drowsiness and medication effects and is increased in many neurologic disorders. Theta power is known to be a highly nonspecific feature of EEGs. Likewise, there are many reasons (other than ADHD) why frontal beta power values may be higher or lower than average in certain individuals. These values also change with the patient's state of awareness, so values may differ when a patient is retested just minutes after the previous testing."

Dementia: Chabot et al. reported that increased delta or theta power, decreased mean frequency, decreased beta power, and decreased occipital dominant frequency may be indicative of dementia and may help differentiate dementia from other cognitive disorders (e.g., depression). In a more recent research, Kai et al. compared QEEG results from patients with either Alzheimer's disease (AD) or dementia with Lewy Bodies (DLB). Relative to AD patients, DLB patients had higher delta and theta band intrahemispheric coherence values in the fronto-temporo-central regions and lower beta band in almost all temporo-centro-parieto-occipital regions. In 44 elderly patients with memory complaints, Onishi et al. found that QEEG power did not correlate with scores on the Mini-Mental Status Exam (MMSE), though a combination of QEEG and gender predicted 48% of the variance in MMSE scores. Sneddon et al. used QEEG to discriminate patients with AD and Related Disorders (ADRD) from patients with mild cognitive impairment (MCI) and normal aging. QEEG measured while performing a delayed recognition task correctly identified 30/32 normal aging subjects (94% specificity) and 14/16 MCI-to-mild ADRD (88% sensitivity).

Further literature searches showed a few additional small studies, such as Bonanni et al. from 2016, support the validity of QEEG analysis as a tool for diagnosis in DLB patients. These are small studies, not at a level that would justify using QEEG. The Bonanni study had low correct classification at 90% and 64%.

Psychotropic Medication Response: Use of QEEG to evaluate treatment response has been evaluated for a variety of conditions including dementia, depression, ADHD, obsessive-compulsive disorder (OCD), and schizophrenia. Generally, these studies have been done to examine the neurological basis underlying the cognitive, affective, and behavioral effects of psychotropic medications. These studies suggest that psychotropic medications do produce effects on the brain that can be detected with QEEG. For example, Song et al. obtained QEEG measurements from 20 boys with ADHD before and after administration of methylphenidate. This medication produced a significant increase in alpha band activity in both the right and left frontal and occipital areas, an increase of beta band activity in almost all areas except for the temporal region, a decrease of theta band activity in both the occipital and right temporo-

parietal areas, a mild decrease of delta band activity in the occipito-parietal areas, and an increase of the theta/beta ratio in the right frontal and parieto-occipital, and left temporal areas during the CPT state. Adler et al. administered neuropsychological testing and QEEG prior to 20 AD patients' initiating treatment with rivastigmine. After 2 weeks of therapy, patients with greater decrease in theta power responded more favorably than did those with a smaller theta power decrease. Responders also had better short term memory at baseline. In 50 adults with ADHD and 50 controls, Bresnahan et al. used QEEG to evaluate response to treatment with dexamphetamine. Following medication, ADHD patients experienced a decline in slow wave activity to levels that were similar to that seen in controls. A study by Crumbley et al. examined the validity of QEEG results for predicting response to treatment with psychotropic medication in 70 adolescent inpatients. Their retrospective analysis revealed that treatment concordant with QEEG results was no more effective than treatment discordant with QEEG results.

Overall, the strength of the research supporting most psychiatric indications for QEEG continues to be sparse. For most indications, additional studies are needed with larger and more diverse sample sizes to prospectively investigate the relationship between QEEG and symptom presentation, comorbid conditions, and treatment response. Even for studies with a larger body of literature supporting the association between QEEG findings and clinical diagnosis, the role of QEEG in the diagnostic workup for ADHD remains unclear.

Several issues need to be addressed for QEEG to be incorporated into standard clinical practice: 1) How might QEEG supplement or replace standard diagnostic tests?; 2) How would treatment be altered based on QEEG results?; 3) How should results be interpreted in light of other EEG abnormalities?; 4) How might QEEG results be affected in additional medical or psychiatric comorbidities?; and 5) Which patients are likely candidates for QEEG? Until these issues are more completely addressed in the research literature, QEEG will remain primarily an investigational modality.

Billing/Coding Information
Not Covered: Investigational/Experimental/Unproven for this indication

CPT CODES

95955	Electroencephalogram (EEG) during nonintracranial surgery (e.g., carotid surgery)
95957	Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)
95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional
95962	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure)

HCPCS CODES

S8040	Topographic brain mapping

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Select Health

MEDICAL POLICY

RESPONSIVE CORTICAL NEUROSTIMULATION IN THE TREATMENT OF EPILEPSY

Policy # 556

Implementation Date:9/16/14

Review Dates: 10/15/15, 10/20/16, 10/19/17, 4/9/18, 10/15/18, 10/13/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/24/24

Revision Dates: 11/15/24, 12/5/24

Related Medical Policies:
#186 Vagal Nerve Stimulation (VNS)
#205 Deep Brain Stimulation (DBS)

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

A seizure is defined by transient focal or generalized signs or symptoms due to abnormal excessive or synchronous neuronal activity in the brain. Focal seizures, which originate within neuronal networks limited to one cerebral hemisphere, produce signs and symptoms corresponding to the specific region of the brain that is affected by the seizure.

There are three broad categories of seizures: focal, multifocal, and generalized. Focal onset seizures start in one area and can spread across the brain and cause mild or severe symptoms, depending on how the electrical discharges spread. Multifocal seizures originate in multiple areas of the brain. Generalized seizures can start as focal seizures that spread to both sides of the brain.

Seizure disorders are typically treated with antiepileptic medications alone or combination. The management of patients with epilepsy is focused on three main goals: controlling seizures, avoiding treatment side effects, and maintaining or restoring quality of life. The optimal treatment plan is derived following an accurate diagnosis of the patient's seizure type(s), an objective measure of the intensity and frequency of the seizures, awareness of medication side effects, and an evaluation of disease-related psychosocial problems. Despite advances in anti-epileptic drug therapy, epilepsy surgery, and vagus nerve stimulation, approximately 30% of patients continue to have seizures.

The NeuroPace stimulator is a small, battery-powered device neurostimulator is surgically implanted in the skull. Leads that are connected to the neurostimulator are placed on and/or inside the brain. The neurostimulator monitors the electrical activity of the brain and detects abnormal activity that could lead to a seizure. If abnormal activity is detected, the neurostimulator delivers electrical stimulation to the brain through the leads to help prevent the seizure before it occurs. The neurostimulator is programmed for initial use by the doctor after it is surgically implanted, then the neurostimulator settings will be adjusted on an ongoing basis as needed. A computer (called the NeuroPace Programmer) lets the doctor do the initial programming and follow-up adjustments to the neurostimulator. Adjustments are based on brain activity and response to stimulation, which are both stored in the neurostimulator.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers responsive cortical neurostimulation in the treatment of epilepsy, when all the following criteria are met:

1. 12 years of age or older; and
2. Partial onset seizures; and
3. Undergone diagnostic testing that localized no more than two (2) epileptogenic foci; and
4. Refractory to two or more antiepileptic medications; and
5. Currently having an average of one (1) or more disabling seizures (for example, motor partial seizures, complex partial seizures, or secondary generalized seizures) per month over the most recent three months; and
6. Documentation specifies that the care team has considered vagus nerve stimulation (VNS), or surgical ablation of epileptogenic focus, and outlines the reasons they are not candidates based upon surgical risk or other clinical factors.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
To date, no systematic reviews and three primary literature articles met inclusion criteria for this report. A total of 390 patients with partial epilepsy were studied, however, it is important to note that the papers by Heck et al. and Morrell et al. reported on the same cohort of 191 patients in a randomized, multicenter, double blind, and sham-controlled trial. Follow-up times were between 9.2 and 24 months.

There is a long-term open labeled follow-up study by Bergey, et al. in 2015 of patients initially reported in a double-blinded pivotal study. Patients were followed up to 7 years. This study showed ongoing benefits of the RNS device with seizure reduction of 48–66% over post-implant years 3–6; the device appears to be safe over an extended period. The most common adverse event was noted to be infections at the surgical sites of stimulator replacements, indicating relative long-term safety. Limits of the study are its lack of blinding, and significant dropouts, but the authors attempted to compensate for this through statistical analysis.

The evidence has demonstrated the following regarding safety, efficacy, and durability of effect of the NeuroPace device:

Safety and Efficacy – Heck et al. compared the safety of the device to sham and noted that there was no difference between the groups. All three papers illustrated statistically significant reductions in seizures compared with baseline measurements. Heck et al. and Morrell et al. showed that this decrease was present against sham. Morrell et al. reported the top five device-related adverse events in ≥ 2.5% of subjects at 1 year were as follows:

1. Headache (10%)
2. Complex partial seizures (8%)
3. Complex partial seizures increased (8%)
4. Dysesthesia (7%)
5. Implant site pain (7%)

Durability of Effect – Approximately 50% of the seizures were eliminated in patients who received the NeuroPace device at either a 2-month follow-up or at a 24-month follow-up. No evidence of durability of effect exists past 24 months.

In conclusion, the few papers that have been published on the NeuroPace device have demonstrated statistically significant improvements in seizure diminution out to two years. Safety of NeuroPace is commensurate with DBS and its efficacy is on par with vagus nerve stimulation.

Billing/Coding Information
Covered for the indications outlined above when criteria are met
CPT CODES

61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or caniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or received, direct or inductive coupling; with connection to a single electrode arrays
61886	Insertion or replacement of cranial neurostimulator electrodes
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation,

detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)

HCPCS CODES

C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator, electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator radiofrequency receiver
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

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Revision History

Revision Date	Summary of Changes
11/15/24	For Commercial Plan Policy, changed requirement in criterion #5 from 3 disabling seizures to 1 disabling seizure per month in the most recent three months, and modified criterion #6 to require the ***care team*** as opposed to the individual to have considered other options prior to this treatment.
12/5/24	For Commercial Plan Policy, changed age requirement in criterion #1 from at least 18 years of age or older ***to at least 12 years of age or older***.

Select Health

MEDICAL POLICY

SPHENOPALATINE GANGLION (SPG) INJECTIONS IN THE MANAGEMENT OF PAIN

Policy # 559

Implementation Date: 11/5/14
Review Dates: 8/25/16, 8/17/17, 8/13/18, 8/7/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 8/22/24, 8/18/25
Revision Dates: 5/15/15, 4/4/24

Related Medical Policies:
#221 Botulinum Toxin (e.g., Botox) Injections
#291 Migraine Headache Surgery

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description
The sphenopalatine ganglion (SPG) is located with some degree of variability near the tail or posterior aspect of the middle nasal turbinate. The SPG has been implicated as a strategic target in the treatment of various headache and facial pain conditions. It is part of the autonomic nervous system. A sphenopalatine ganglion (SPG) block has been introduced as a quick, minimally invasive procedure. A local anesthetic, currently Marcaine but historically Lidocaine, is introduced intranasally for topical administration. Access to this structure can be gained via a small area of mucosa just posterior and superior to the tail of the middle turbinate on the lateral nasal wall. At this aspect, there is no bony boundary to the SPG.

More recently, the introduction of a new medical device specific for medication delivery to the nasal passageway has renewed interest in performing SPG blocks to treat migraine and other headache conditions. The Tx360 nasal applicator, developed by Tian Medical in 2011, and the SphenoCath are promoted as making injections of the SPG easier and more effective. SphenoCath is an FDA Class I therapeutic "ear, nose, and throat drug administration device" and is not marketed as a migraine treatment. It is marketed as a general use drug administration device, which can be used to facilitate sphenopalatine ganglion (SPG) circuit neuromodulation.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover sphenopalatine ganglion (SPG) blocks for any indication, including but not limited to, the treatment of acute or chronic headaches and complex regional pain syndrome (CRPS), as current evidence is insufficient to determine the efficacy and safety of this procedure.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their

search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
Current evidence related to the use of sphenopalatine ganglion block in headache management is very limited with few published studies. Narouze (2010) explored the use of SPG ablation for chronic cluster headache. Percutaneous radiofrequency ablation of the SPG was shown to have encouraging results in those patients with intractable cluster headaches.

Ansarinia et al. (2010) examined the effects of electrical stimulation of SPG for acute treatment of cluster headaches. A total of 6 patients with refractory CCH were treated with short-term (up to 1 hour) electrical stimulation of the SPG during acute cluster headaches. Headaches were spontaneously present at the time of stimulation or were triggered with agents known to trigger cluster headaches in each patient. A standard percutaneous infra-zygomatic approach was used to place a needle at the ipsilateral SPG in the pterygopalatine fossa under fluoroscopic guidance. Electrical stimulation was performed using a temporary stimulating electrode. Stimulation was performed at various settings during maximal headache intensity. Five patients had cluster headaches during the initial evaluation. Three returned 3 months later for a second evaluation. There were 18 acute and distinct cluster headache attacks with clinically maximal VAS intensity of 8 (out of 10) and above. Electrical stimulation of SPG resulted in complete resolution of the headache in 11 attacks, partial resolution (greater than 50 % VAS reduction) in 3, and minimal-to-no relief in 4 attacks. Associated autonomic features of cluster headache were resolved in each responder. Pain relief was noted within several minutes of stimulation. The authors concluded that SPG stimulation can be effective in relieving acute severe cluster headache pain and associated autonomic features. They stated that chronic long-term outcome studies are needed to determine the utility of SPG stimulation for management and prevention of cluster headaches.

Magis and Schoenen (2011) reviewed the latest clinical trial results in anti-migraine treatment. Sphenopalatine ganglion stimulation, and other neuromodulation techniques were reviewed and were noted to be promising treatments for medically refractory patients; but large controlled trials are needed.

One of the most recent studies by Cady et al. (2014) in their double-blind, parallel-arm, placebo-controlled, randomized pilot study using a novel intervention for acute treatment in CM performed a series of 12 SPG blocks with 0.3 cc of 0.5% bupivacaine or saline provided 2 times per week for 6 weeks. Subjects were re-evaluated at 1 and 6 months post final procedure. SPG blockade with bupivacaine delivered repetitively for 6 weeks with the Tx360® device demonstrates promise as an acute treatment of headache in some subjects with CM. Statistically significant headache relief is noted at 15 and 30 minutes and sustained at 24 hours for SPG blockade with bupivacaine vs. saline. But duration of the effect beyond this level was not measured. The Tx360® device was simple to use and not associated with any significant or lasting adverse events. They concluded further research on sphenopalatine ganglion blockade is warranted.

A follow-up publication to the Cady study from 2014 (Cady 2015) shows secondary end points: headache days, quality of life (HIT score), acute pain, and acute medication usage in the study population. None of these endpoints met statistical significance, but there were favorable trends in all categories. The authors noted in their conclusion that: "… data from this exploratory pilot study does not establish efficacy, but suggests the possibility that there may be long-term clinical benefits in the use of repetitive SPG blockade." A more complete study was recommended.

The American Headache Society also released guidelines for treatment of cluster headaches in 2016. In these guidelines (Robbins 2016), SPG electric stimulation for cluster headaches is given a level B (probably effective) rating. This is based on a single, class-controlled trial done in 28 patients with

sphenopalatine ganglion stimulation. The study showed efficacy in acute treatment of cluster headache. However, the guidelines note that this treatment is not routinely available in the United States.

A further review (Robbins 2016) from the Headache Journal outlines SPG pathophysiology and treatment approaches. Studies of SPG blockade for cluster headache are reviewed, the paper notes that: "the majority of those studies were open and uncontrolled." SPG blockade studies for migraine are also reviewed. The controlled studies are noted to have had mixed results (one in 1196 by Maizels with intranasal lidocaine had brief headache relief but unsustained treatment benefit; another 1999 trial showed lidocaine superior to placebo; another 2001 trial of intranasal lidocaine in the ER found it not superior to placebo; a 2012 randomized trial found intranasal ketorolac with lidocaine was superior to lidocaine alone). The review also outlines Sphenopalatine Blocking Catheters (like Cady et al. discussed above) and neurostimulation.

A new review by Tepper et al. was published in 2017, focused on SPG Stimulation primarily as it impacts cluster headaches. This was a prospective cohort study of patients followed in a registry. Initial one-year data was presented at a meeting in 2016, and a responder rate of 68% was reported. However, this study had multiple methodological flaws as it lacks randomization and blinding, which introduces bias into the conclusions. There is an ongoing randomized controlled study in the US right now, the CH-2 study with an estimated completion date of January 2019. Overall, the current evidence has not established efficacy, durability, or reliability of this treatment in migraine management.

Billing/Coding Information

CPT CODES

64505 Injection, anesthetic agent, sphenopalatine ganglion

HCPCS CODES

No specific codes identified

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Revision History

Revision Date	Summary of Changes
4/4/24	Modified title of policy (was previously titled, Sphenopalatine Ganglion (SPG) Injection in the Management of Headaches), and for Commercial Plan Policy, clarified that this therapy is not covered for any indication, including but not limited to, the treatment of acute or chronic headaches and complex regional pain syndrome (CRPS).

Select Health

MEDICAL POLICY

TUMOR-TREATMENT FIELDS FOR THE TREATMENT OF GLIOBLASTOMA MULTIFORME

Policy # 496

Implementation Date: 12/5/11
Review Dates: 7/18/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/25/18, 6/18/19, 6/14/20, 8/19/21, 7/26/22, 8/16/23, 8/15/24, 8/21/25
Revision Dates: 10/20/16

Description

Gliomas are the most common primary tumors of the brain, with an incidence of about 25,000 new cases per year in the United States, and are malignant gliomas occur in all age groups but predominate in the fifth and sixth decades. They are the dominant primary intracranial tumors, accounting for 35% to 45% of all adult brain tumors. At least half of all gliomas exhibit aggressive, malignant behavior. Glioblastoma multiforme (GBM), is particularly clinically and pathologically malignant. Patients with GBM have a poor prognosis, with a median survival of one year with aggressive therapy; fewer than 5% will survive 5 years. Despite its seemingly low incidence, mortality from GBM accounts for 3% to 4% of all cancer deaths each year in the US. These tumors occur in the cerebral hemispheres as sizable, rapidly growing lesions with a characteristic ring-like, enhancing appearance on CT or MRI, with central necrosis, infiltrating margins and surrounding low-density changes.

The NovoTTF-100A System (NovoCure, Ltd., Haifa, Israel), which received an FDA PMA on April 8, 2011, for the treatment of recurrent GBM, is a portable battery- or power supply- operated device which produces alternating electrical fields, called tumor treatment fields ("TTFields") within the human body. TTFields are applied to the patient by electrically-insulated surface electrodes. Research studies demonstrate that TTFields can disrupt the rapid cell division exhibited by cancer cells. The NovoTTF-100A produces alternating electrical fields within the human body that are believed to disrupt the rapid cell division exhibited by cancer cells, with the alternating electrical fields applied to the brain through electrodes placed on the scalp.

The Optune System (NovoCure, Portsmouth, NH), which is a second-generation system developed for the treatment of recurrent GBM, is a portable battery- or power supply-operated device which produces alternating electrical fields, called tumor treatment fields ("TTFields") within the human body. It became available for distribution on July 25, 2016. TTFields are applied to the patient by electrically-insulated surface electrodes. Research studies demonstrate that TTFields can disrupt the rapid cell division exhibited by cancer cells.

Treatment parameters are preset by NovoCure such that there are no electrical output adjustments available to the patient. Based on detailed training provided by the physician, the patient will learn to change and recharge depleted device batteries and to connect to an external power supply overnight. In addition, the electrodes need to be replaced once to twice a week and the scalp re-shaved in order to maintain optimal contact. Patients carry the device in an over-the-shoulder bag or backpack and receive continuous treatment without changing their daily routine.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers tumor field therapy for the treatment of glioblastoma multiforme in *limited* circumstances when criteria are met for medically necessity.

Select Health does NOT cover tumor treatment field therapy outside its FDA approved indications or for any other tumor type or location.

Coverage Criteria (ALL must be present)

1. Tumor Treatment field therapy is being used in one of the following FDA approved indications:
    a. Histologically-confirmed glioblastoma multiforme (GBM), following histologically- or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy and is being used as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.
    b. Use with temozolomide (TMZ) is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.
2. The individual receiving therapy is > 22 years of age
3. The member does not have an active implanted medical device (e.g., deep brain stimulators, spinal cord stimulators, pacemakers, defibrillators)
4. No bullet fragments in the area
5. No intraventricular shunts are present
6. No skull defects (e.g., missing bone with no replacement) are present

Authorization of rental equipment used in tumor treatment field is limited to 6 months and that re-authorization of the device is contingent on use of the device a minimum of 18 hours/day and evidence for disease stabilization or improvement confirmed by MRI.

Select Health does NOT cover electrical field therapy for any other tumor type or circumstance as current evidence in other malignancies is insufficient to reach conclusions regarding efficacy and safety in these circumstances.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
Current evidence related to tumor treatment fields has evolved since initial FDA approval in 2011. In a 2016 review, two systematic reviews and 8 primary studies were identified on the topic. These encompassed results from approximately 1,418 patients (intervention and controls) studied between 2012 and 2016.

The 2 systematic reviews were published in 2016 and were generally favorable in their assertions for efficacy of the therapy. The Hayes review was the most thorough assessment of the literature. In all, the systematic reviews found the technology to be both safe and effective in treating GBM with side-effects not exceeding what would be observed in standard treatments.

Six of the 8 (75%) primary studies were comparative to physician's best choice or standard treatment regimens. The studies examined the following:

- Intra- and inter-rater reliability of MRI for transducer placement
- Management treatment of sequelae
- Overall and progression-free survival
- Post-chemo patients treated with either TTF + temozolomide (TMZ) or TMZ alone
- TTF + bevacizumab (Bev) or TTF + combination therapy
- TTF alone or chemo alone
- TTF vs. best physician's choice

Three studies particularly illustrated best the outcomes associated with TTF treatment, namely those by Stupp et al. (2012) (2015) and Wong et al. All 3 of these studies addressed progression free survival (PFS) and/or overall survival (OS). The studies all illustrated an improvement in PFS and OS where reported, though not all reports met statistical significance.

It is important to know from the 3 comparative effectiveness studies that none of them were used as first-line treatments for GBM. That said, 2 of the 3 showed better- or non-inferior PFS and OS in patients who added TTF to their treatment regimen than did patients who underwent standard therapy. The third study (Wong et al.) spoke more to the virtues of an augmented treatment regimen with the inclusion of TTF and showed substantial but not statistically significant improvements in OS.

In conclusion, evidence obtained for this review has demonstrated the safety of TTF for the treatment of GBM. The evidence of improved patient outcomes, especially as a first-line therapy, is more limited but has shown an improvement in OS and PFS.

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

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Tumor-Treatment Fields for the Treatment of Glioblastoma Multiforme, continued

Select Health

MEDICAL POLICY

VAGUS NERVE STIMULATION (VNS)

Policy # 186
Implementation Date:7/5/00
Review Dates: 7/17/00, 2/27/01, 8/15/01, 10/4/01, 8/27/02, 12/11/03, 1/9/07, 6/19/08, 6/11/09, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 6/21/18, 4/12/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23, 4/19/24, 4/10/25
Revision Dates: 8/1/24

Related Medical Policies:
#205 Deep Brain Stimulation (DBS)
#556 Responsive Cortical Neurostimulation in the Treatment of Epilepsy

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The vagus nerve is the tenth and longest cranial nerve. Its name is derived from the Latin meaning "wandering," due to its complex path through the body from the brain stem through organs in the neck, thorax, and abdomen. The vagus nerve innervates vital structures in the body such as the heart, intestines, esophagus, stomach, liver, and muscles of vocalization. In the brain, the vagus nerve forms connections with the medulla, but most connections are to the nucleus tractus solaritus (NTS). The NTS is connected to a wide range of nerve projections from and to other areas of the brain. The vagus nerve is the primary sensory organ of the NTS. It is also capable of processing extensive information and has been likened to a small brain within the larger brain.

LivaNova markets the VNS Therapy System, the only device currently approved for VNS. The device was initially approved in 1997 for epilepsy, but during these clinical trials investigators observed that VNS improved mood and cognition in epilepsy patients. The exact mechanism of action by which VNS is thought to reduce the symptoms of depression is yet unknown, but it has been shown that VNS has an effect on brain metabolism and brain function.

The VNS Therapy System consists of a programmable pulse generator, similar to a pacemaker, which is implanted subcutaneously in the chest and delivers pulses of current via electrodes attached to the vagus nerve in the left side of the neck. Left VNS is preferred to right VNS because the heart rate is mostly influenced by the right vagus nerve, and stimulation could induce cardiovascular complications. The VNS Therapy System includes a handheld computer, programming software, and a programming wand; these components are used to interrogate the pulse generator and modify stored simulation parameters.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers vagus nerve stimulation (VNS) for patients with intractable epilepsy, who meet criteria as outlined below:

Criteria for use of VNS in patients with intractable epilepsy require the patient to meet all the following:

1. The patient must be one year of age or older;

2. The patient must have a well-documented, seizure disorder with a debilitating effect on the patient's ability to function;
3. The patient must be unresponsive to an appropriate trial of anti-convulsant medications or be unable to tolerate therapeutic levels of AEDs (meaning a minimum of a 3-month course of at least 3 different classes of anti-epileptic drugs [AEDs] at therapeutic doses);
4. The VNS implantation is recommended by the patient's neurologist/epileptologist;
5. The patient must either:
   - Not be a good candidate for other, more effective anti-seizure surgical therapy;

   OR

   - Have refused anti-seizure surgical (resective) therapy;
6. Have a surgeon experienced with implantation of the vagus nerve stimulator device (has performed at least 2 previous VNS implants) perform the implantation procedure, using an FDA-approved vagus nerve stimulator device;
7. Be managed by a neurologist/epileptologist familiar with the protocols for use of the device.

Select Health does NOT cover vagus nerve stimulation for any other indication; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Vagus Nerve Stimulation in Depression

Current literature demonstrates variable efficacy for short-term effects in the treatment of therapy-resistant major depression. Marnagell, Rush et al., in 2002, first published 12-month outcomes for VNS in patients with major depressive disorder. These studies suggested a statistically significant ($p = 0.045$) benefit in remission rates compared with placebo. George et al., in an open trial in 2005 confirmed these results, demonstrating a response rate of 27%, twice the placebo control group. Both these trials were limited by their open nature and relatively small sample sizes ($n = 2.05$). Additionally, the remission rates were low at 29% and 27% respectively. These results do not reach the same level of effectiveness as ECT therapy. Two-year outcome studies published by Nahas, Marangell et al., in 2005, however, suggested a falloff in efficacy to 22%. This study was small, and definitive conclusions could not be reached. Further questions related to long-term efficacy and safety were raised in a study published by Rush, Marnagell, et al., in 2005. This 10-week randomized trial found response rates much lower than previous uncontrolled studies at 15.2%, compared with a placebo rate at 10% ($p = 0.251$). Additionally, there is insufficient information about the long-term effect of this treatment on depression. Though short-term safety does not seem to be an issue, long-term safety has not yet been fully addressed, and thus, questions in this area also remain. These questions remained unanswered in Sackeim, Rush et al., in their studies published in 2001.

Subsequent reviews, such as a 2006 BCBS TEC review concluded that clinical trial data offered only weak evidence for the efficacy of the procedure and that the effectiveness outside investigational settings has not been established. A review published by the University Health System Consortium offered a similar conclusion—that the literature on VNS for depression offered "inadequate proof of efficacy." A 2006 review from the California Technology Assessment Forum noted that it is premature to conclude that VNS is equally as or more effective than established therapies for treating depression. Finally, an evaluation by CMS conducted to inform its recent national coverage decision noted that treatment-resistant depression is a poorly defined construct and stated that: "CMS does not believe there is a treatment effect directly attributable to VNS therapy based on the current evidence."

Since the last M-Tech review in 2005, 2 empirical studies have been published. The first study was an observational study of 205 patients who had previously undergone VNS implantation for treatment-resistant depression; Burke et al. evaluated the use of ECT in non-responsive patients. Of 205 patients who were followed, 55 (27%) were responders, (> 50% reduction in self-rated depression), and 14 (7%) experienced depression severe enough to warrant ECT during the 12 months following implantation. By 12 months, 11 of these 14 patients (79%) were still considered "non-responders" to VNS.

The other study published in 2006 by Corocoan et al., involved 11 patients with treatment-resistant depression, 55% of whom had received ECT previously. Patients underwent a 12-week acute phase of treatment, which commenced 2 weeks after implantation, and 40 weeks of long-term stimulation. Stimulation levels were set during the first 2 weeks of the acute phase and were not adjusted thereafter. At 1 year, all measures of depression had declined, and 6 patients were considered to be "responders" (Hamilton Rating Scale for Depression score < 10). During the follow-up period, one non-responder died by suicide.

Of note, Dunner et al. reported on the natural outcomes of treatment-resistant depression, which they tracked in 124 patients over a 2-year period. Treatment was uncontrolled (i.e., depression was treated on an individual basis as determined by patients' individual physicians. During that 2-year period, 18.4% (19/103) experienced a response (≥ 50% decrease in depression) and 7.8% experienced remission. The authors noted that response and remission were typically intermittent and transient.

Based upon the inconclusive nature of the currently available studies, vagus nerve stimulation remains unproven for the treatment of depression.

Vagus Nerve Stimulation in Epilepsy

There is substantial evidence that VNS can reduce seizure frequency, with approximately 30% of patients experiencing at least a 50% mean reduction. In some patients, the effect can be much greater, and patients who respond often experience sustained benefits. However, most studies to date have included patients with a broad range of epilepsy syndromes associated with intractable partial seizures classified as simple, complex, or secondarily generalized. Since specific details regarding each patient were not included in the reports, it is difficult to determine which patients derived the most benefit from the therapy.

The placebo effect may have contributed to the observed improvement in patient status during VNS, since some patients derived benefit from the low-level VNS used as a presumed placebo control. However, it is unclear whether the response seen in these patients was due to a strong placebo effect or whether it represented a true treatment effect of low-level stimulation.

The use of VNS in children has not been well-studied and, at present, the NCP system is approved only for patients over the age of 12. However, results of initial pilot pediatric studies have been promising. In a study by Murphy et al., VNS was particularly beneficial for patients with Lennox-Gastaut syndrome, a rare but particularly severe form of childhood epilepsy, and for children who had previous corpuscallosotomy. Hornig et al. note that there are significant advantages to the use of VNS treatment in children compared with medical management alone—no adverse cognitive effects, no drug interactions, and no issues of patient compliance—as therapy is involuntary and automatic. Nine studies and 1 technology assessment met criteria for inclusion in this report. Hayes' Medical Technology Directory from 2007 gave a 'B' rating to VNS in patients > 12 years with medically intractable partial-onset seizures who are not suitable candidates for surgery or in whom surgical treatment has failed. However, it assigned a 'C' rating for VNS in patients with generalized epilepsy who are not suitable candidates for surgery or in whom surgical treatment has failed due to the paucity of clinical evidence regarding the efficacy of VNS for generalized

seizures. The available evidence consists of a small number of uncontrolled studies involving few patients and retrospective analyses of patient medical history data.

Nine studies published, and all conclude that VNS is a safe and effective therapy for seizures that are refractory to medication. These studies included patients with partial and generalized seizures. For example, Abubakr et al. implanted VNS in 31 patients with refractory generalized and partial seizures who were not candidates for resective surgery. At 6 months, 22 patients (73%) showed considerable improvement in terms of feeling better, being more alert and having fewer seizures; they were considered to be responders to VNS therapy. Among those who initially responded to VNS, 20 patients (66%) demonstrated > 50% reduction in seizure frequency at 6 months (good responders) and 16 of them (53.3%) continued to have sustained improvement (> 50% reduction in seizure frequency) 4 years later. However, none of the patients attained seizure freedom during the follow-up period. In four patients (13.3%) seizures increased in frequency and severity and they were considered poor responders to VNS therapy. Separate results were not reported for generalized versus partial seizures.

Kostov et al. implanted 12 patients with drug-resistant idiopathic generalized epilepsy. At a mean follow-up of 23 months, overall seizure reduction was 61% with a 62% reduction in generalized tonic-clonic seizures, 58% of absences, and 40% of myoclonic seizures. Eight patients were considered responders (> 50% seizure reduction); 2 of these patients became seizure-free. Five out of 7 patients with juvenile myoclonic epilepsy were responders. At the last follow-up visit, the patients had reduced the anti-epileptic drug (AED) usage from an average of 2.3 to 1.7 AED per patient (p = 0.0625). Two patients are currently being treated with VNS therapy only. Nine patients reported side effects, which were mostly mild and tended to diminish over time.

You et al. involved 28 children with refractory epilepsy. Of these, 15 (53.6%) showed a > 50% reduction in seizure frequency and 9 (32.1%) had a > 75% reduction. The reduction in frequency did not differ across seizure type and etiology. There was no correlation between the length of the stimulation period and treatment effect. The seizure reduction rate, however, tended to be inversely related to the seizure duration before VNS implantation and age at the time of VNS therapy. VNS also improved quality of life in this group of patients, including improved memory in 9 (32.1%), improved mood in 12 (42.9%), improved behavior in 11 (39.3%), improved alertness in 12 (42.9%), improved achievement in 6 (21.4%), and improved verbal skills in 8 (28.6%). Adverse events included hoarseness in 7 patients, dyspnea at sleep in 2 patients, and wound infection in 1 patient, but all were transient and successfully managed by careful follow-up and adjustment of parameters.

Orosz et al reported long term followup in 347 children with VNS for intractable seizures. She found that seizure frequency was reduced over a 2 year follow up period with no new safety issues. Finally, Klinkenberg et al evaluated VNS in a randomized trial of 41 children with intractable seizures. VNS reduced seizures by 50% or more in 16% of children in the high-output stimulation group and 21% of the low-output stimulation group with overall severity of seizures statistically improved.

The existing literature supports the use of VNS for treatment of seizures that are refractory to medications. The literature also indicates that adverse effects from implantation are minimal and that use of VNS results in significant reduction in seizure frequency and severity and more rapid recovery. While most patients continue to have seizures even after treatment, they report better control over seizure-activity and improved quality of life. Though current evidence in support of the procedure for therapy-resistant generalized seizures remains limited, available evidence suggests benefit in this population.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

Implantation

61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve

64568 Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

Revision or Removal

64585 Revision or removal of peripheral neurostimulator electrodes array

64569 Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

64570 Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

61880 Revision or removal of intracranial neurostimulator electrodes

61888 Revision or removal of cranial neurostimulator pulse generator or receiver

Analysis/Programming

95970 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

95974 ;complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour

95975 ;complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

HCPCS CODES

C1767 Generator, neurostimulator (implantable), nonrechargeable

C1778 Lead, neurostimulator (implantable)

C1823 Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads

L8680 Implantable neurostimulator electrode, each

L8681 Patient programmer (external for use with implantable programmable neurostimulator pulse generator

L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

L8685 Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

L8686 Implantable neurostimulator pulse generator single array, on rechargeable, includes extension

L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

L8688 Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

L8689 External recharging system for implanted neurostimulator replacement only

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Revision History

Revision Date	Summary of Changes
8/1/24	Retitled policy as “Vagus Nerve Stimulation (VNS)” (this policy was previously titled as “Vagal Nerve Stimulation (VNS)”); and incorporated this new wording throughout the remainder of the policy as well.

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