Automated Percutaneous and Percutaneous Endoscopic Discectomy

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

Based on review of available data, the Company considers automated percutaneous discectomy as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine to be **investigational.***

Based on review of available data, the Company considers percutaneous endoscopic discectomy as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine to be **investigational.***

Background/Overview

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy in which the extruding disc material is excised. When performed with an operating microscope, the procedure is known as microdiscectomy.

Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain. In this technique, radiofrequency energy is used to treat the surrounding disc annulus.

Herein we address automated percutaneous and endoscopic discectomy, in which the disc decompression is accomplished by the physical removal of disc material rather than its ablation. Traditionally, discectomy was performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique was modified by automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Endoscopic techniques may be intradiscal or may involve extraction of noncontained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, decompression is performed under visual control.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The Dekompressor®‡ Percutaneous Discectomy Probe (Stryker), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome®‡ (Clarus Medical) are examples of percutaneous discectomy devices that have been cleared for marketing by the U.S. FDA through the 510(k) process. The FDA indication for these products is for "aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine." FDA product code: HRX.

A variety of endoscopes and associated surgical instruments have also been cleared for marketing by FDA through the 510(k) process.

Rationale/Source

Assessment of efficacy for therapeutic intervention involves a determination whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

A 2014 Cochrane review of literature through November 2013 evaluated 11 studies of minimally invasive discectomy (MID) compared with microdiscectomy or open discectomy. Included in the MID category were 8 RCTs or quasi-RCTs on percutaneous endoscopic lumbar discectomy (PELD), 2 studies on transmuscular tubular microdiscectomy, and 1 study on automated percutaneous lumbar discectomy (APLD). Seven of the studies had a high risk of bias. For the analysis, the reviewers combined all MID procedures. They reported that MID may be inferior in terms of relief of leg and low back pain, and rehospitalizations; however, differences in pain relief appeared to be small and may not be clinically meaningful. Potential advantages of minimally invasive discectomy included lower risk of surgical site infection and shorter length of stay (LOS).

AUTOMATED PERCUTANEOUS DISCECTOMY

Systematic Reviews

A 2015 systematic review and network meta-analysis by Lewis et al compared trials of 21 different treatment strategies for sciatica. Examples of the 21 treatment strategies included in the analysis are conservative care, disc surgery, intraoperative interventions, epidural injections, biologic agents, and percutaneous discectomy. Under the category of "percutaneous discectomy," reviewers combined automated percutaneous discectomy, percutaneous automated nucleotomy, nucleoplasty, and laser discectomy. They searched 28 databases and trial registries through December 2009. Ninety studies were included and 10 involved the percutaneous discectomy category as an intervention. Of the 10, 4 are relevant to this evidence review: 2 case-control studies of percutaneous endoscopic discectomy (2006,

2007), 1 RCT of percutaneous endoscopic discectomy (1993), and 1 RCT of automated percutaneous discectomy (1995). The remaining studies were published in a foreign language or involved the comparators nucleolysis and chemonucleolysis, rather than open discectomy or microdiscectomy. The global effects odds ratio for the category of percutaneous discectomy compared with inactive control was 0.82 (95% confidence interval [CI], 0.39 to 1.72), which was inferior to disc surgery, epidural injections, and intraoperative interventions. The pain intensity weighted mean difference for the category of percutaneous discectomy compared with inactive control was 11.5 (95% CI, -18.6 to 41.6). Reviewers concluded that there was no support for the effectiveness of percutaneous discectomy for the treatment of sciatica. Due to the inclusion of additional interventions into the broad category of percutaneous discectomy in this review, the relevance of these results for our evidence review is limited.

Two systematic reviews by Manchikanti et al were published in 2013. One investigated the effectiveness of APLD, with a search of databases from 1966 to September 2012. Studies were included if the following criteria were met: for RCTs, greater than 50% of the criteria adapted from the Cochrane Back Review Group; for cohort studies, 7 of 10 criteria from the Newcastle-Ottawa Scale (NOS) for assessing the quality for cohort studies; and for case-control studies, 5 of 10 criteria from the NOS for case-control studies. No RCTs met the inclusion criteria. Nineteen observational studies met the criteria and were identified for this review. With no RCTs meeting the criteria, meta-analysis could not be performed. Within the 19 observational studies, 5515 patients underwent automated percutaneous discectomy, with 4412 reporting positive results. The range of positive results reported in the studies was 45% to 88%. Despite the large number of studies, the reviewers concluded that the literature was limited, because no RCTs met quality inclusion criteria and because the most recent study, published in 2010, reported results from a study conducted in 2000-2002. The second review by Manchikanti focused specifically on disc decompression using the Dekompressor. This review used the same criteria described above. No RCTs met the study inclusion criteria; 3 observational studies did and were included. Reviewers acknowledged that the Dekompressor appeared to decrease pain, but because meta-analysis could not be conducted, the 3 trials selected were relatively small (total N=164 patients), and none provided follow-up data beyond 8 years, they concluded that the evidence was limited for use of the Dekompressor device for the treatment of lumbar disc herniation.

Vorobeychik et al (2012) and Singh et al (2009) also conducted reviews on the Dekompressor. Vorobeychik identified the same 3 observational studies as Manchikanti plus a case series while Singh identified the same observational studies as Manchikanti. The authors of both reviews also concluded that pain relief was achieved, but the evidence lacked sufficient rigor to support conclusions.

In 2009, Hirsch et al published a systematic review on APLD, searching databases from 1966 to April 2009. Cochrane review criteria (50 of 100 points were needed for inclusion) were used to assess quality of RCTs and Agency for Healthcare Research and Quality criteria (50 of 100 points were needed for inclusion) were used to assess observational studies. Reviewers assessed 4 RCTs and 76 observational studies evaluating APLD. One RCT (by Revel et al [1993]) met inclusion criteria and is detailed in the next section on RCTs. The other 3 RCTs failed to meet study quality criteria. In discussing the results of the Revel trial, which

showed a lower success rate than the observational studies, reviewers noted that APLD might not have been successful in this trial due to inappropriate patient selection, failure to recruit the number of patients indicated by sample size calculations, and lack of follow-up beyond 6 months. Ten observational studies met methodologic quality criteria for inclusion. Results were consistent among the observational studies, showing APLD effective among approximately 75% of patients. APLD appears to compare favorably compared with open discectomy, microdiscectomy, and chymopapain injection, though evidence lacked RCTs. The evidence for the use of APLD for short- and long-term pain relief is considered level II-2 (well-designed cohort or case-control studies), using the U.S. Preventive Services Task Force criteria.

Freeman and Mehdian assessed the evidence for 3 minimally invasive techniques used to treat discogenic low back pain and radicular pain: electrothermal therapy (intradiscal electrothermal therapy), percutaneous discectomy, and nucleoplasty in a 2008 article. They reported that trials of automated percutaneous discectomy suggested clinical outcomes are at best fair and often worse than with microdiscectomy.

In 2007, Gibson and Waddell updated a Cochrane review on surgical interventions for lumbar disc prolapse, concluding that there was insufficient evidence on percutaneous discectomy techniques to draw firm conclusions. In the same year, a task force of the American Society of Interventional Pain Physicians (ASIPP) reported that percutaneous disc decompression remains controversial. Although all observational studies provided positive findings, the evidence from 4 randomized trials was negative. Questions also remain about appropriate patient selection criteria for this procedure, particularly related to the size and migration of the disc herniation.

The RCTs are described next are considered poor quality and, in general, did not meet most inclusion criteria of the above systematic reviews.

Randomized Controlled Trials
The 2002 LAPDOG trial compared automated percutaneous discectomy with open discectomy in patients with lumbar disc herniation. Enrolled patients had no prior lumbar spinal surgery, no coexistent lumbar spinal disease, and radiographic evidence of disc herniation. The trial was designed to recruit 330 patients but enrolled 36 patients for reasons not readily apparent. Twenty-seven patients were available at follow-up, with efficacy reported by 41% of those undergoing automated percutaneous discectomy and by 40% of those undergoing open discectomy. The authors concluded that “It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation.”

In 1995, Chatterjee et al reported on 71 patients with lumbar disc herniation randomized to percutaneous discectomy or to lumbar microdiscectomy. A satisfactory outcome was reported in 29% of patients undergoing percutaneous discectomy compared with 80% in the microdiscectomy group. The trial was terminated early due to the inferior outcome.
Revel et al compared percutaneous discectomy with chymopapain injection in 141 patients with disc herniation and sciatica in a 1993 randomized trial. Treatment was considered successful in 61% of patients

in the chymopapain group and in 44% of patients in the percutaneous discectomy group. Thirty-two patients withdrew from the trial, citing therapeutic failure. Within 6 months of the trial, 20% of the patients underwent open laminectomy.

No additional RCTs have been identified since the 2002 LAPDOG trial. All trials have focused on lumbar disc herniation. There were no RCTs of percutaneous discectomy for cervical or thoracic disc herniation. A 2013 review of the evidence from ASIPP noted that "even though Dekompressor may be considered a new interventional modality, the early studies were published approximately 8 years ago. Consequently, one would expect that the technique's continued use would be supported by more recent, high-quality evaluations."

Section Summary: Automated Percutaneous Discectomy
The evidence for automated percutaneous discectomy in individuals who have herniated intervertebral disc(s) includes small RCTs and systematic reviews of RCTs. Evidence from small RCTs does not support the use of this procedure. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure.

PERCUTANEOUS ENDOSCOPIC DISCECTOMY
Systematic Reviews
In 2017, Phan et al published a systematic review and meta-analysis comparing full endoscopic discectomy (FED) and microendoscopic discectomy (MED) with open discectomy for the treatment of lumbar disc herniation. A database search through February 2016 identified 23 studies for inclusion. FED was favorable compared with open discectomy in surgery duration, hospital LOS, and blood loss. MED was favorable compared with open discectomy in terms of LOS and blood loss. Both endoscopic procedures were comparable to open discectomy, as measured on a visual analog scale (VAS) for leg pain and Oswestry Disability Index (ODI) score. In terms of patient satisfaction, FED was more favorable than open discectomy, and MED was comparable to open discectomy.

A 2016 systematic review and meta-analysis published by Li et al compared FED with traditional discectomy surgery. A literature search was conducted in January 2015 and resulted in the inclusion of 4 RCTs and 2 non-RCTs. FED for herniation (both cervical and lumbar) was favorable compared with traditional discectomy in surgery duration, blood loss, LOS, and return to work days. Clinical outcomes were comparable between FED and traditional discectomy.

A 2016 meta-analysis identified 9 RCTs (total N=1092 patients) through August 2014 that compared endoscopic to open discectomy for lumbar disc herniation. Endoscopic discectomy resulted in clinical outcomes similar to open discectomy, but had significantly greater patient satisfaction, lower intraoperative blood loss, and shorter hospital LOS.
In 2013, Smith et al published a systematic review of endoscopic discectomy for lumbar disc herniation. A search for controlled trials published through September 2012 identified 4 RCTs. None found a significant difference in ODI scores for endoscopic discectomy compared to open discectomy or microdiscectomy. The

largest study (Teli et al [2010], described below; N=240) reported an increase in the number of severe complications in the MED group. Another study (Garg et al [2011], also described below; N=112) found a shorter hospital LOS with no significant changes in ODI scores or complication rates, but recommended that microendoscopic discectomy not be attempted without appropriate training. The 2 other trials included in the review were small, with 22 and 40 patients.

Several of the larger trials included in the systematic reviews above, larger trials on cervical disc herniation, and trials published subsequent to the systematic review literature searches are described in the next section.

Randomized Controlled Trials

In 2017, Gibson et al published an RCT comparing transforaminal endoscopic discectomy (TED) with microdiscectomy. Patients with single-level lumbar prolapse and radiculopathy were randomized to TED under conscious sedation (n=70) or to microdiscectomy under general anesthesia (n=70). Both procedures resulted in comparable improvements in outcomes (ODI scores, VAS back pain, VAS leg pain, 36-Item Short-Form Health Survey [SF-36] scores) at 3 months, 1 year, and 2 years compared with baseline.

Eight-year follow-up from a quasi-RCT assessing endoscopic lumbar discectomy and open discectomy was reported by Hussein et al in 2014. The trial included 185 patients with a large uncontained lumbar disc herniation. Surgery times were similar for both groups. Postsurgical mean hospital LOS was 10.4 hours for the endoscopic group and 82.38 hours ($p<0.05$) for the open group. Mean time to return to work/normal activities after endoscopic surgery (8.5 days) was significantly shorter than after open surgery (31.4 days; $p<0.05$). The percentages of adverse events were similar between groups, and 8.1% of patients in each group required reoperation during the follow-up. Improvements in leg pain, back pain, and ODI scores (1.05, 1.43, 21.5%, respectively) persisted at 8 years in the endoscopic group, but deteriorated for back pain (7.53) and ODI scores (59.6%) in the open group.

Garg et al (2011) reported on a trial randomizing 112 patients with a single-level disc herniation to microendoscopic lumbar discectomy or to open discectomy. The method of randomization and whether patients and assessors were blinded were not reported. Surgical time was significantly longer in the endoscopic group (84 minutes vs 56 minutes) while blood loss (41 mL vs 306 mL) and hospital LOS (3 days vs 12 days) were reduced. ODI scores were similar at baseline (endoscopic, 25.78 vs open discectomy, 21.02) and all follow-up visits through 1 year postoperatively (endoscopic; 1.75 vs open discectomy 2.14).
In 2010, Teli et al reported on an RCT comparing endoscopic discectomy to microdiscectomy or open discectomy in 240 patients with posterior lumbar disc herniation. Most herniations (60%) were extrusions. The average surgical time was longer in the endoscopic group (56 minutes) than in the micro- or open discectomy groups (43 minutes and 36 minutes, respectively). Follow-up assessments were performed at 6, 12, and 24 months by an independent investigator; 212 (91%) patients completed the 24-month evaluation. Intention-to-treat analysis showed no significant differences in the outcome variables (VAS, ODI, and SF-36 scores). The endoscopic procedure led to more dural tears (8.7% vs 2.7% or 3%), root injuries (3% vs 0%

or 0%), and recurrent herniations (11.4% vs 4.2% or 3%) than the microdiscectomy or open approaches, respectively, although differences were not statistically significant.

In 2008 and 2009, Ruetten et al published 4 RCTs comparing FED with conventional techniques in the lumbar and cervical spine. All studies were randomized or quasi-randomized, with assignment described as either order of presentation or balanced block. Follow-up examinations were conducted at day 1 and at months 3, 6, 12, and 24 by physicians not involved in the surgeries. The 4 trials were not blinded due to observable differences in the surgical approaches, and are described below.

- Patients with mediolateral cervical disc herniations (N=120) were randomized to full endoscopic anterior decompression (FACD) or to conventional anterior cervical decompression with fusion (ACDF). Mean surgery time was 32 minutes for FACD and 62 minutes for ACDF. At 24 months, 103 (86%) patients were available for follow-up examinations. Revision rates for ACDF (6.1%) and FACD (7.4%) did not differ significantly. There were no significant differences in clinical outcomes (pain, VAS arm, VAS neck) between groups.
- Patients with clinically symptomatic lateral cervical disc herniation (N=200) were randomized to full endoscopic posterior cervical foraminotomy or conventional microsurgical ACDF. At 24 months postsurgery, 175 (88%) patients were available for follow-up. Ten patients had revisions due to persistent arm pain, recurrences of herniation, or failure of the implant (6 endoscopic patients, 4 ACDF). Postoperative pain was significantly reduced in the endoscopic group (data not reported), and postoperative work disability was shorter (19 days vs 34 days). Other clinical outcomes (VAS scores for neck and arm pain, a German version of the North American Spine Society [NASS] Instrument [Hilibrand criteria]) were similar between groups throughout the 24-month follow-up.
- Patients with clinically symptomatic lumbar disc herniation (N=200) were randomized to FED or to conventional microdiscectomy. Mean surgery time for endoscopic discectomy (22 minutes) was nearly 50% faster than for conventional microdiscectomy (43 minutes), and the complication rate was significantly lower. Postoperative pain and pain medication usage were significantly reduced in the endoscopic group (data not reported), and the postoperative work disability was shorter (25 days vs 49 days). At 24 months after surgery, 178 (89%) patients were available for follow-up. The 2 groups had similar improvements in leg pain, with 85% of endoscopic discectomy and 79% of microdiscectomy patients reporting being pain-free. More patients in the microdiscectomy group (5% vs 1%) underwent revision spinal canal expansion and fusion.
- Patients with recurrent lumbar disc herniation following conventional discectomy who were in need of a revision (N=100) were randomized to FED or to conventional microdiscectomy. Surgery time was significantly shorter with the endoscopic approach (24 minutes vs 58 minutes), and access-related osseous resection was much less frequent in the endoscopic group (3 [6%] cases vs 47 [94%] cases). There were 4 cases of dura injury (1 endoscopic discectomy, 3 microdiscectomy). Overall, serious complication rates were significantly higher in the microdiscectomy group (21% vs 6%). Postoperative pain and pain medication usage were significantly reduced in the endoscopic group, as was postoperative work disability (28 days vs 52 days). At 24 months, 87 (87%) patients were available for follow-up. Seventy-nine percent had no

leg pain at follow-up, and there were no significant differences between groups in clinical outcomes (VAS, NASS Instrument, ODI scores).

A 1999 RCT by Hermantin et al was rated as having a low risk of bias in the 2014 Cochrane review. Sixty patients who had objective evidence of a single intracanalicular herniation of a lumbar disc were randomized into 2 groups: endoscopic microdiscectomy or open laminotomy and discectomy. A similar percentage of patients was considered to have a satisfactory outcome (97% of the microendoscopic group vs 93% of the open group). The mean duration of narcotic pain-relief use (7 days vs 25 days) and return to work (27 days vs 49 days) were significantly lower in the microendoscopic group. This trial did not use validated outcome measures.

Observational Studies
In 2016, Gotecha et al published a prospective study on the use of transforaminal PELD for the treatment of lumbar disc herniation. Efficacy and limitations of the procedure were studied on 120 patients with lumbar disc herniation. Using McNab criteria, 89% achieved excellent (no pain or restrictions) or good (occasional back/leg pain) status at 6 months of follow-up. The authors noted that a limitation of the procedure is that, during surgery on patients with L5 through S1 lumbar disc herniation, the iliac crest may interfere with the angle necessary to perform successful discectomy.

A number of observational studies have also assessed the learning curve and the need for longer follow-up for endoscopic discectomy. The largest and longest follow-up to date has been reported by Choi et al (2015), who examined 10,228 patients at their institution who had had PELD over a 12-year period. They found that 4.3% of cases required reoperation in the first 6 weeks due to incomplete removal of herniated discs (2.8%), recurrence (0.8%), persistent pain (0.4%), and approach-related pain (0.2%).

Section Summary: Percutaneous Endoscopic Discectomy
The evidence for percutaneous endoscopic discectomy in individuals who have herniated intervertebral disc(s) includes a number of RCTs and systematic reviews of RCTs. Many of the RCTs were conducted at a single center in Europe. Some trials have reported outcomes at least as good as traditional approaches with an open incision, while an RCT from a different center in Europe reported a trend toward increased complications and reherniations using an endoscopic approach. There are few reports from the United States. Reporting from a number of moderately large ongoing RCTs is anticipated in the next 2 to 3 years.

SUMMARY OF EVIDENCE
For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on net health outcomes. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

Original Effective Date: 07/24/2006

Current Effective Date:	10/01/2018
03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee approval
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. No change to coverage.
03/05/2010	Medical Policy Committee approval
03/19/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Rationale updated.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coding update.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Changed investigational statements to track BCBSA. Title changed to “Automated Percutaneous and Percutaneous Endoscopic Discectomy.”
10/01/2018	Coding update
Next Scheduled Review Date:	07/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Automated Percutaneous and Percutaneous Endoscopic Discectomy

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Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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

Code Type	Code
CPT	0274T, 0275T, 62287, 62380
HCPCS	C2614 Code deleted eff 10/1/18: S2348
ICD-10 Diagnosis	M51.06 M51.36 M51.37

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

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

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