Automated percutaneous discectomy is considered investigational 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.

Endoscopic discectomy is considered investigational 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.

Percutaneous discectomy may be performed by surgeons, but anesthesiologists or other physicians whose practices focus on pain management may also perform this procedure.

The following CPT code specifically describes a percutaneous decompression procedure of the lumbar spine:

- **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 the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
Although most percutaneous discectomies are performed on lumbar vertebrae, FDA labeling of the Stryker Dekompressor Percutaneous Discectomy Probe includes the thoracic and cervical vertebrae. Code 62287 includes procedures performed using endoscopic approaches.

Percutaneous discectomy is also a component of the following CPT codes:

- **0274T**: 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 (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

- **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 (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

**Background**

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, a 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 material is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Ablative techniques include laser discectomy and radiofrequency decompression (see Blue Shield of California Medical Policy: Decompression of the Intervertebral Disc Using Laser Energy [Laser Discectomy] or Radiofrequency Coblation [Nucleoplasty]). In addition, 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 (see Blue Shield of

This policy addresses 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 is performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique has been 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 the extraction of noncontained and sequestered disc fragments from inside the spinal canal using an interlaminar or transfominal approach. Following insertion of the endoscope, the decompression is performed under visual control.

Regulatory Status

The Stryker Dekompressor® Percutaneous Discectomy Probe (Stryker) and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process. Both have the same labeled intended use (i.e., “for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine”).

A variety of endoscopes and associated surgical instruments have received marketing clearance through FDA’s 510(k) process.

Traditional and Minimally Invasive Open Discectomy

In 2012, Dasenbrock et al reported a meta-analysis of 6 trials (837 patients) of minimally invasive discectomy compared with traditional open discectomy. (1) Open discectomy could be conducted with or without an operating microscope. Minimally invasive treatments included microendoscopic discectomy (3 studies), operating microscope with a tubular retractor system (2 studies), and full endoscopy (1 study). All of the included studies reported visual analog scale (VAS) scores for pain with a minimum follow-up of 1 year. Meta-analysis found similar operative time for the open and minimally invasive approaches. Although intraoperative complications (incidental durotomies, nerve root injuries) were more common in patients undergoing minimally invasive discectomy (relative risk, 2.01), total complications were similar for the 2 procedures. At 1- to 2-year follow-up, the mean VAS had improved to 1.6 in both cohorts.

The largest study included in the systematic review is a randomized double-blind trial by Arts et al, with 1-year outcomes reported in 2009 and 2-year outcomes reported in 2011. (2,3) A total of 328 patients who had persistent leg pain due to lumbar disc herniations were randomized to tubular discectomy or conventional microdiscectomy and followed for 2 years. The median time to recovery was not significantly different (2.1 weeks for conventional, 2.0 weeks for tubular treatment). At 8 weeks and through the first year, there was no significant difference between groups in the Roland-Morris Disability Questionnaire (RMDQ) for sciatica. At 1 year, intention-to-treat analysis showed significantly better RMDQ scores for conventional discectomy than tubular discectomy (3.4 vs 4.7); however, the difference in scores is less than the minimal clinically important difference of 3 to 5 points. The change in the VAS pain score was statistically better in the conventional discectomy group, with a mean difference in improvement between the 2 groups of 4.2 for leg pain and 3.5 mm for back pain. On a 100-mm scale, the clinical significance of this finding is uncertain. Similar results were obtained at 2-year follow-up. There was no significant difference between the groups in complications (intraoperative or postoperative) or in reoperation rate.
Ryang et al reported a trial of 60 patients randomized to conventional microdiscectomy or tubular discectomy. The method of randomization and blinding of the investigators was not described. There was no significant difference between the 2 groups for operative time, intraoperative blood loss, or complication rate, or in postoperative VAS for pain, Oswestry Disability Index (ODI), or Short-Form (SF)-36.

**Automated Percutaneous Discectomy**

**Systematic Reviews**

A literature search for the period of 1990 to February 2005 focused on controlled clinical trials comparing percutaneous discectomy with either open discectomy or conservative therapy. The literature search identified a large number of case series but only 5 controlled trials, 4 of which were reviewed in a 2000 Cochrane report by Gibson et al. The Cochrane review concluded, “Three trials of percutaneous discectomy provided moderate evidence that it produces poorer clinical outcomes than standard discectomy or chymopapain.”

In 2007, Gibson and Waddell published an updated Cochrane review of surgical interventions for lumbar disc prolapse, concluding that there is 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 reported that percutaneous disc decompression remains controversial; although all observational studies were positive, the evidence from 4 of 4 randomized published studies was negative. Questions also remained about the appropriate patient selection criteria (particularly related to the size and migration of the disc herniation) for this procedure.

Freeman and Mehdian assessed the current 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 suggest that clinical outcomes are at best fair and often worse when compared with microdiscectomy.

Systematic reviews have analyzed the literature for different devices. Singh et al and Vorobeychik et al performed a systematic analysis of studies in which the Dekompressor device was used; no randomized controlled trials (RCTs) were identified. In 2009, Hirsch et al reviewed 4 RCTs and 76 observational studies in their analysis of studies in which the Nucleotome was used. One of those RCTs is described next. The other 3 RCTs failed to meet study quality criteria. Two systematic reviews by Manchikanti et al in 2013 found limited evidence for percutaneous mechanical discectomy (including the Nucleotome®) or for disc decompression with the Dekompressor®. There were no RCTs that met the study inclusion criteria.

Examples of studies included in these systematic reviews are described next.

**Randomized Controlled Trials**

Revel et al compared the outcomes of percutaneous discectomy with chymopapain injection in 141 patients with disc herniation and sciatica in a randomized study from 1993. Treatment was considered successful in 61% of patients in the chymopapain group compared with 44% in the percutaneous discectomy group. Chatterjee et al reported on the results of a study that randomly assigned 71 patients with lumbar disc herniation to undergo either percutaneous discectomy or lumbar microdiscectomy in 1995. A successful outcome was reported in only 29% of those undergoing percutaneous discectomy compared with 80% in the microdiscectomy group. The trial was halted early due to this inferior outcome.
The LAPDOG study was the only RCT published between the 2000 Cochrane review and the 2005 update and compared percutaneous and open discectomy in patients with lumbar disc herniation. This trial was designed to recruit 330 patients but was only able to recruit 36 patients, for reasons that were not readily apparent to the authors. Of the evaluable 27 patients, 41% of the percutaneous discectomy patients and 40% of the conventional discectomy patients were assessed as having successful outcomes at 6 months. The authors concluded that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion. The authors state, “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.”

No additional RCTs have been identified in literature updates since the 2002 LAPDOG study. In addition, all of the trials reviewed here focused on lumbar disc herniation. There were no RCTs of percutaneous discectomy of cervical or thoracic disc herniation.

**Endoscopic Discectomy**

**Systematic Reviews**

In 2010, Nellensteijn et al published a systematic review of the literature on transforaminal endoscopic surgery for symptomatic lumbar disc herniations that included English, German, and Dutch language articles published through May 2008. One RCT, 7 non-RCTs, and 31 observational studies were identified. Analysis of the 8 controlled trials found no significant differences between the endoscopic and open microdiscectomy groups for leg pain reduction (89% vs 87%), overall improvement (84% vs 78%), reoperation rate (6.8% vs 4.7%) or complication rate (1.5% vs 1%, all respectively). The methodologic quality of these studies was described as poor, providing insufficient evidence to support or refute this procedure.

In 2013, Smith et al published a systematic review of microendoscopic discectomy for lumbar disc herniation. A search for controlled trials published through September 2012 identified 4 RCTs. None of the studies found a significant difference in ODI scores compared with open discectomy or microdiscectomy. The largest study with 240 patients (Teli et al, described next) reported an increase in the number of severe complications in the microendoscopic discectomy group. Another large study with 112 patients (Garg et al, also described next) found a shorter hospital stay with no significant changes in ODI or complication rates but recommended that microendoscopic discectomy should not be attempted without appropriate training. The 2 other trials included in the review were small with 22 and 40 patients.

**Randomized Controlled Trials**

Included in the systematic review by Nellensteijn was a 1999 RCT by Hermantin et al that was rated as the only study with a low risk of bias. 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 were considered to have a satisfactory outcome (97% of the microendoscopic group, 93% of the open group). The mean duration of use of narcotics (7 vs 25 days) and return to work (27 vs 49 days) were significantly less in the microendoscopic group. This study is limited by the lack of validated outcome measures.

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

In 1 study, 200 patients with clinically-symptomatic lateral cervical disc herniation were assigned to decompression via endoscopic posterior cervical foraminotomy or conventional microsurgical anterior cervical discectomy and fusion (ACDF). Patients with medial localization of the disc herniation were excluded. At 24 months after surgery, 175 patients (88%) were available for follow-up. Fifteen patients were lost to follow-up, and 10 patients had a revision with conventional ACDF due to persistent arm pain, recurrences, or failure of the implant (6 endoscopic patients, 4 ACDF). Postoperative pain was significantly reduced in the endoscopic group (data not reported), and the postoperative work disability was shorter (19 vs 34 days). Other clinical outcomes (VAS for neck and arm pain, a German version of the North American Spine Society (NASS) Instrument (Hilibrand criteria) were similar in the 2 groups throughout the 24-month follow-up.

A 2009 report compared anterior endoscopic discectomy with ACDF in 120 patients with mediolateral cervical disc herniations. The duration of pain ranged from 4 to 128 days. The mean operating time was 32 minutes for endoscopic discectomy compared with 62 minutes for ACDF. In the endoscopic discectomy group, bone resection was required to reach the epidural space or the foramen in 55% of cases. At 24 months, 103 patients (86%) were available for follow-up examinations. The revision rate was 6.1% for ACDF and 7.4% for endoscopic discectomy; these were not significantly different. Excluding 4 patients who were revised by ACDF, 85 patients (85.9%) had no arm pain; there were no significant differences in clinical outcomes between the 2 groups. Advantages and disadvantages of the anterior endoscopic approach were discussed, including a difficult learning curve.

Another study compared full endoscopic interlaminar or transforaminal lumbar discectomy versus conventional microdiscectomy for clinically symptomatic lumbar disc herniation in 200 patients. The duration of pain ranged from 1 day to 16 months (mean, 82 days), and all forms of disc herniations were included in the study (random assignment to the treatment group). The particular endoscopic approach (interlaminar or transforaminal) was determined by the location of the herniation. The mean operating time for endoscopic discectomy was approximately half that of conventional microdiscectomy (22 vs 43 minutes). Access-related osseous resection was required in 91 cases (91%) of the microdiscectomy group and 13 cases (13%) of the endoscopic group. The complication rate was significantly greater in the microdiscectomy group, with 1 delayed wound healing, 1 soft tissue infection, and 3 cases of transient urinary retention. Postoperative pain and pain medication were significantly reduced in the endoscopic group (data not reported), and the postoperative work disability was shorter (25 vs 49 days). At 24 months after surgery, 178 patients (89%) were available for follow-up. The 2 groups had similar improvement in leg pain; 79% of microdiscectomy and 85% of endoscopic discectomy patients reported being pain-free. More patients in the microdiscectomy group (5% vs 1%) underwent revision spinal canal expansion and fusion.

A fourth study by Ruetten et al compared revision endoscopic interlaminar or transforaminal lumbar discectomy versus conventional microdiscectomy in 100 patients who had recurrent lumbar disc herniation after conventional discectomy. Patients were enrolled who had undergone previous conventional discectomy, presented with acute occurrence of radicular leg symptoms on the same side after a pain-free interval, and who showed a recurrent disc herniation in the same level by magnetic resonance imaging. The duration of pain ranged from 1 day to 13 months. Seventy-nine patients (79%) had received a mean of 9 weeks of conservative treatment. Due to limited
technical mobility, criteria for the endoscopic transforaminal approach included sequestering of material between the cranial and caudal pedicle. Operating time was significantly shorter with the endoscopic approach (24 vs 58 minutes), and access-related osseous resection was required in 3 cases (6%) of the endoscopic group compared with 47 cases (94%) of the microdiscectomy group. There were 4 cases of dura injury (3 microdiscectomy and 1 endoscopic discectomy) and an overall serious complication rate that was significantly greater (21% vs 6%) for the microdiscectomy group. Postoperative pain and pain medication were significantly reduced in the endoscopic group, as was postoperative work disability (28 vs 52 days). At 24 months, 87 patients (87%) were available for follow-up. Seventy-nine percent had no leg pain at follow-up; there was no significant difference between the groups for any of the clinical outcomes (VAS, NASS, ODI).

In 2010, Teli et al reported an RCT of microendoscopic interlaminar lumbar discectomy compared with microdiscectomy or open discectomy in 240 patients with posterior lumbar disc herniation.(19) Most hemiations (60%) were extrusions. Group assignment was randomized but was revealed to the patients before the surgery due to a requirement of the local ethics committee. Laminotomy, medial facetectomy when needed, and nerve root retraction followed by discectomy were performed identically in the 3 groups. Surgeons had at least 5 years' experience in all of the operative techniques. The average surgical time was longer in the endoscopic group (56 minutes) compared with micro or open discectomy (43 and 36 minutes, respectively). Follow-up assessments were performed at 6, 12, and 24 months by an independent investigator; 212 patients (91%) completed the 24-month evaluation. Intention-to-treat analysis showed no significant difference in the outcome variables (VAS, ODI, SF-36). The endoscopic procedure resulted in an increase in dural tears (8.7% vs 2.7% or 3%), root injuries (3% vs 0% or 0%), and recurrent hemiations (11.4% vs 4.2% or 3%) compared with the microdiscectomy or open approach, although these were not statistically different.

Garg et al reported a randomized trial of microendoscopic lumbar discectomy versus open discectomy in 112 patients with a single-level disc herniation.(20) The report did not describe the method of randomization or whether patients or assessors were blinded. Surgical time was significantly greater in the endoscopic group (84 vs 56 minutes) while blood loss (41 vs 306 mL) and hospital stay (3 vs 12 days) were reduced. Outcomes on the ODI were similar at baseline (25.78 endoscopic and 21.02 open discectomy) and all follow-up visits through 1 year postoperatively (1.75 endoscopic and 2.14 open discectomy).

Preliminary results have been reported from an RCT from Scotland that compares transforaminal endoscopic discectomy with microdiscectomy.(26)

Observational Studies

The learning curve for an interlaminar approach to endoscopic lumbar discectomy was reported by Wang et al in 2011.(27) Thirty patients were divided into 3 groups of 10 (first, middle, and last 10 cases). There was a significant difference in operative time when comparing the first (107.9 minutes) and middle cases (68.5 minutes) and the last cases (43.2 minutes). The complication rate was 12.5% for the first 10 cases, 10% for the middle 10 cases, and 0% for the last 10 cases. The need for conversion to an open procedure was 20% for the first 10 cases and 0% for the middle and last. At a mean 1.6-year follow-up (range, 1.2-2.0 years), there were no symptomatic recurrences.

In 2011, Tenenbaum et al reported the outcome of 124 endoscopic lumbar discectomies using the transfemoral approach.(28) Dividing the study group into thirds, the revision rate was 30.2% for the first group, 17.5% for the second group, and 14.6% for the third
group. This learning curve is confounded by the use of different devices in the 3 groups of patients. There were no significant differences between the groups for VAS improvement, ODI improvement, patient satisfaction, or operation time.

Lee and Lee described the learning curve for transforaminal endoscopic discectomy in 51 patients in 2008.(29) Divided into groups of 17 (first, middle, and last), mean operating time decreased from 62.1 minutes to 47.6 minutes and then to 37.9 minutes. There was no significant difference in complication or failure rates between the 3 groups at 1 year after surgery. The clinical success rate was 82.4% for the first 17 cases, 92.9% for the middle cases, and 93.8% for the last 17 cases; these were not significantly different. Learning the transforaminal approach has been reported to be easier than learning the interlaminar approach.(30)

Five-year follow-up of 120 consecutive patients treated with microendoscopic discectomy was reported by Casal-Moro et al in 2011.(31) The authors analyzed data from a prospectively maintained database that included standardized follow-up at 2 months, 1 year, and 5 years after surgery. Good to excellent results were obtained in 74.2% of patients, with fair results obtained in 18.3% and poor results in 7.5%. The mean ODI decreased from 69.6 before surgery to 16.6 after 5 years. The VAS for leg pain decreased from a mean of 7.9 before surgery to 1.7 at follow-up and the VAS for back pain decreased from 4.6 to 2.6. Nine patients (7.5%) underwent subsequent lumbar surgery during the follow-up period.

Eight to 10-year follow-up from 151 consecutive patients treated with microendoscopic discectomy was reported by Wang et al in 2012.(32) All patients were followed via telephone or office visits. At follow-up, 79% of patients were classified as excellent, 12.9% as good, 4.6% as fair, and 3.5% as poor. Five patients (3.3%) had revision surgery at a mean of 3.7 years due to recurring herniation at the same level.

**Summary**

Automated percutaneous discectomy involves placement of a probe within the intervertebral disc under image guidance with aspiration of disc material using a suction cutting device. There is insufficient evidence obtained from well-designed and executed randomized controlled trials (RCTs) to evaluate the impact of automated percutaneous discectomy on net health outcome. In addition, evidence from small RCTs does not support the use of these procedures; therefore, automated percutaneous discectomy is considered investigational.

Endoscopic discectomy involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an endoscope. The evidence consists of a number of RCTs. Most of these trials were conducted at a single center in Germany, and the comparison groups were not the same. The trials in the lumbar spine compared endoscopic discectomy with conventional microdiscectomy, and trials in the cervical spine compared procedures with anterior cervical discectomy and fusion. While the trials from Germany report outcomes that are at least as good as traditional approaches using either a laparoscopic transforaminal or interlaminar approach to the lumbar spine, a large RCT from Italy reports a trend toward increased complications and reherniations with an interlaminar approach. There are few reports from the United States. The trials by Ruetten et al are the only reports identified of endoscopic discectomy in the cervical spine. At this time, evidence is considered insufficient to evaluate health outcomes from endoscopic discectomy in U.S. centers. Therefore, it is considered investigational.
Practice Guidelines and Position Statements

The National Institute for Health and Clinical Excellence published guidance in 2005 on automated percutaneous mechanical lumbar discectomy, indicating that there is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small RCTs shows conflicting results.(33) The guidance states that in view of uncertainty about the efficacy of the procedure, it should not be done without special arrangements for consent and for audit or research.

2007 guidelines from the American Society of Interventional Pain Physicians stated that percutaneous disc decompression remains controversial; although all observational studies were positive, the evidence from 4 of 4 randomized published studies was negative.(7)

2009 clinical practice guidelines from the American Pain Society found insufficient evidence to evaluate alternative surgical methods to standard open discectomy and microdiscectomy, including laser or endoscopic-assisted techniques, various percutaneous techniques, coblation nucleoplasty, or the Disc Dekompressor.(34)

References


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services are considered investigational and therefore not covered for any indication.

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<thead>
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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td><strong>CPT®</strong></td>
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<td>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 the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar</td>
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<td>Probe, percutaneous lumbar discectomy</td>
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<td>Other destruction of intervertebral disc</td>
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**ICD-9 Diagnosis**

- All Diagnoses

**ICD-10 Diagnosis**

- For dates of service on or after 10/01/2015
  - All Diagnoses

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tr>
<td>10/31/2014</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
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**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.
Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.