



AUTOMATED PERCUTANEOUS LUMBAR DISCECTOMY

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I. DESCRIPTION

Automated percutaneous lumbar discectomy (APLD) is a minimally invasive surgical technique for treatment of herniated lumbar intervertebral discs. For this procedure, a thin, blunt-tipped suction and cutting probe is inserted through the skin, and the end of the probe is placed into the middle of the herniated disc under fluoroscopic guidance. This device is then used to remove some or all of the degenerated portion of the center of the disc. The goal of this procedure is to relieve pressure on nerve roots without damaging surrounding tissues, thereby minimizing postoperative complications and morbidity. APLD is intended as an alternative to chemonucleolysis, open discectomy, or other types of percutaneous discectomy for individuals who have a relatively small degree of lumbar disc protrusion without fragmentation or complete extrusion of disc material and who have failed conservative therapy.

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.”

II. POLICY/CRITERIA

Automated percutaneous lumbar discectomy (APLD) is considered investigational and is not a covered benefit.

Percutaneous discectomies at levels other than lumbar (i.e. cervical or thoracic), and done manually or with a laser, are also considered investigational and not covered.

The following procedures (coded the same as APLD) are also not covered:

- DISC Nucleoplasty
- Intradiscal Thermal Annuloplasty
- Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)



- Percutaneous endoscopic discectomy with or without laser (PELD) (also known as arthroscopic microdiscectomy or Yeung Endoscopic Spinal Surgery System (Y.E.S.S.))
- Percutaneous lumbar discectomy or laser-assisted disc decompression (LADD)
- Microendoscopic discectomy (MED) procedure for decompression of lumbar spine stenosis, lumbar disc herniation, or other indications

APLD was reviewed by Priority Health’s Technology Assessment Committee (TAC) in September 2006 and is based on the recommendations of the TAC review.

III. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule, the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html will govern.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

V. BACKGROUND

Among the studies of APLD identified in the literature search were two randomized trials in which APLD was compared with either chemonucleolysis or microdiscectomy (Revel et al., 1993; Chatterjee et al., 1995). Revel et al. compared APLD with chemonucleolysis in 141 patients with lumbar disc herniation. Treatment was considered successful in 61% patients in the chemonucleolysis group compared with 44% in the APLD group ($P<0.05$). The



complication rate was low in both groups, although 42% patients in the chemonucleolysis group reported back pain. Chatterjee et al. compared APLD with microdiscectomy in 71 patients with contained lumbar disc herniation. Only 29% patients had satisfactory outcome in the APLD group compared with 80% in the microdiscectomy group ($P<0.001$). Although the study was originally designed for 160 patients, recruitment was halted due to the inferior results in the APLD group. The authors concluded that APLD is ineffective for the treatment of small, contained lumbar disc herniation.

Results from a meta-analysis by Gibson et al. (2006) came to similar findings. These authors analyzed 27 randomized controlled trials of surgery for lumbar disc prolapse that were published up to December 1999 and indexed in the MEDLINE database, including 3 trials that evaluated the effect of APLD for lumbar herniation. Analysis of the pooled data from these trials indicated that there is moderate evidence that APLD results in poorer clinical outcomes than standard discectomy or chymopapain treatment.

In addition, there were two randomized trials that were too small to warrant detailed analysis. Haines et al. (2002) compared APLD with conventional open discectomy in patients with lumbar disc herniation. Although designed to enroll 330 patients, there were significant difficulties with recruitment, and only 34 patients were actually enrolled and randomized to percutaneous discectomy ($n=21$) or to conventional open discectomy ($n=13$). Fifteen of the 21 patients in the percutaneous treatment group underwent APLD with the Nucleotome. Of the 27 patients evaluable at 6 months, 41% of the APLD patients and 40% of the conventional discectomy patients were assessed as having successful outcomes, which as defined as an excellent or good rating, based on ability to return to work and daily activities, absence of pain, and no need for analgesic medication. Due to small sample size, the results of this study are inconclusive. In another small, randomized trial, Krugluger and Knahr (2000) evaluated 22 patients assigned to treatment with APLD or chemonucleolysis. Based on severity of neurological deficit and Oswestry scores, neither treatment provided significant improvement.

There were also a number of prospective and retrospective uncontrolled studies of APLD that met the criteria for detailed review (≥ 100 patients); success rates in these studies were variable. Two of the studies (Teng et al., 1997; Bonaldi, 2003) were quite large ($n=1525$ and $n=1047$, respectively), while the others ranged in size from 137 to 518 patients. In the two larger studies, results were judged to be excellent in 54% to 58% of patients several months after APLD; however, since these studies lacked control or comparison groups and outcome measures were primarily subjective, the true treatment effect of APLD cannot be determined.

Quality of Evidence: The overall quality of evidence regarding the efficacy of APLD is relatively poor, consisting primarily of uncontrolled studies, retrospective studies, and case series reports, with only two randomized trials comparing APLD with other treatment methods. It is likely that the variation in



reported success rates is largely due to subjective outcome measures and differences in method of evaluation and criteria used to define a successful outcome. While most of the studies included some measures of pain, function, ability to work, and patient satisfaction, they may have differed in the method in which these measures were applied and in how the patient's answers were interpreted by the investigators. The majority of studies did not include concurrent control groups. In addition, bias in favor of the treatment on the part of some investigators may have influenced interpretation of the results, leading to a more favorable report. This assumption is supported by the relatively low success rates seen in the trials in which an independent assessor examined the patients and in the randomized trials that compared APLD with either chemonucleolysis or microdiscectomy. In addition, there could have been differences in APLD technique that resulted in a true difference in patient outcomes, as suggested by Gibson et al. (2006) who performed a meta-analysis study of three APLD studies. The authors concluded that the trials were not comparable due to differences in APLD procedure.

Efficacy: Some of the uncontrolled prospective studies and large case series reports describe a relatively high initial success rate for APLD in patients with herniated lumbar discs and no free disc fragments. However, other studies report much lower success rates in similar patient groups. Moreover, results with APLD were clearly inferior when directly compared with results obtained with chemonucleolysis or microdiscectomy. In addition, several studies with periodic scheduled follow-up documented a decline in treatment effect over the first year, suggesting that the benefits of APLD may not be long lasting. The immediate benefits described after APLD may result from a reduction in inflammatory substances at the herniation site after the saline lavage that occurs during the procedure. This hypothesis is supported by reports that there is an immunocompetent cellular response at the epidural interface of lumbar herniations and the identification of high levels of phospholipase A₂, an inflammatory enzyme, in herniated and degenerative discs (Saal, 1995). Therefore, the action of APLD may be to remove inflammatory mediators, at least temporarily, and thereby reduce the symptoms associated with the herniated disc rather than to reduce significantly the bulk of the herniated disc material. Further studies of APLD, with appropriate controls and length of follow-up, are needed before conclusions regarding efficacy can be made.

Medical Treatment of Lumbar Disc Herniation: An important issue that was not addressed in any of the reviewed studies is the outcome of lumbar disc herniation in patients who are treated with medical therapy alone. Since the studies evaluating APLD did not include a control group of medically treated patients, and, in some cases, patients had received only 6 to 8 weeks of some kind of conservative therapy, it is not known if APLD improved the outcome or enhanced the speed of recovery compared with medical treatment alone. This issue is relevant in evaluation of all surgical treatments for disc herniation and will only be resolved by randomized trials that include a medical treatment control group.



VI. CODING INFORMATION

CPT/HCPCS code:

Not Covered

62287 Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous diskectomy, percutaneous laser diskectomy)

S2348 Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

S2350 Diskectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; lumbar, single interspace

S2351 Diskectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

C2614 Probe, percutaneous lumbar discectomy

22899 Unlisted procedure of the spine

64999 Unlisted procedure, nervous system

(Explanatory notes must accompany unlisted codes.)

VII. REFERENCES

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