



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Percutaneous Discectomy

**Policy #** 00208

**Original Effective Date:** 07/24/2006

**Current Effective Date:** 04/23/2014

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

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

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

### **Background/Overview**

Percutaneous lumbar discectomy (PLD) is a technique by which disc decompression is accomplished by the physical removal of disc material rather than its ablation. Originally, PLD was performed manually. This technique has been replaced with automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device.

Back pain related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain will resolve with conservative care, a surgical decompression is often considered when the pain is unimproved after a month and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of some sort of discectomy, where the extruding disc material is excised.

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. 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.

This policy addresses PLD, in which the disc decompression is accomplished by the physical removal of disc material rather than its ablation. Originally, PLD was performed manually, using cutting forceps to remove nuclear material from within the disc annulus. This technique has been replaced with automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

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. 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."

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Percutaneous Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 04/23/2014

### **Rationale/Source**

This policy was originally based on a 1990 TEC Evaluation, which concluded that percutaneous discectomy met the TEC criteria. Since the 1990 TEC Evaluation, the methodology of evidence-based medicine in general has grown in sophistication. Specifically, it is recognized that randomized clinical trials are extremely important to assess treatments of painful conditions and low back pain in particular, due both to the expected placebo effect, the subjective nature of pain assessment in general, and also the variable natural history of low back pain that often responds to conservative care. Based on a standard of controlled clinical trials to evaluate the safety and effectiveness of percutaneous discectomy, the policy statement is considered to be investigational.

Following is a summary of the key literature to date.

### **Automated Percutaneous Discectomy**

A literature search for the period of 1990 to February 2005 focused on controlled clinical trials comparing percutaneous discectomy to either open discectomy or conservative therapy. The literature search identified a large number of case series but only five controlled trials, four 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 Mehdiian assessed the current evidence for three minimally invasive techniques used to treat discogenic low back pain and radicular pain: electrothermal therapy (IDET), percutaneous discectomy, and nucleoplasty in a 2008 paper. They reported that trials of automated percutaneous discectomy suggest that clinical outcomes are at best fair and often worse when compared with microdiscectomy.

Two systematic reviews published in 2009 analyzed the literature for different devices. Singh et al. performed a systematic analysis of studies in which the Dekompressor device was used; no randomized controlled trials (RCTs) were identified. Hirsch and colleagues reviewed four RCTs and 76 observational studies in their analysis of studies in which the Nucleotome was used. One of those RCTs is described below. The other three RCTs failed to meet study quality criteria.

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

Revel and colleagues compared the outcomes of percutaneous discectomy to chymopapain injection in 141 patients with disk herniation and sciatica in a randomized study from 1993. Treatment was considered successful in 61% of patients in the chymopapain group compared to 44% in the percutaneous discectomy



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Percutaneous Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 04/23/2014

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 to 80% in the microdiscectomy group. The trial was halted early due to this inferior outcome.

The LAPDOG study was the only randomized controlled study 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 six 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 clinical trials of percutaneous discectomy of cervical or thoracic disc herniation.

### 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 to evaluate the impact of automated percutaneous discectomy on net health outcome. In addition, evidence from small randomized controlled trials does not support the use of these procedures; therefore, automated percutaneous discectomy is considered investigational.

### References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Percutaneous Discectomy", 7.01.18, 4:2013.
2. Gibson JNA, Grant IC, Waddell G. Surgery for lumbar disc prolapse. (Cochrane Review). In: The Cochrane Library, Issue 2, 2003. Oxford: Update Software.
3. Chatterjee S, Foy PM, Findlay GF. Report of a controlled clinical trial comparing automated percutaneous lumbar discectomy and microdiscectomy in the treatment of contained lumbar disc herniation. *Spine* 1995; 20(6):734-8.
4. Revel M, Payan C, Vallee C et al. Automated percutaneous lumbar discectomy versus chemonucleolysis in the treatment of sciatica. *Spine* 1993; 18(1):1-7.
5. Mayer HM, Brock M. Percutaneous endoscopic discectomy: surgical technique and preliminary results compared to microsurgical discectomy. *J Neurosurg* 1993; 78(2):216-25.
6. Hermantin FU, Peters T, Quartararo L et al. A prospective, randomized study comparing the results of open discectomy with those of video-assisted arthroscopic discectomy. *J Bone Joint Surg Am* 1999; 81(7):958-65.
7. Haines SJ, Jordan N, Boen JR et al. Discectomy strategies for lumbar disc herniation: results of the LAPDOG trial. *J Clin Neurosci* 2002; 9(4):411-7.
8. Gibson JN, Waddell G. Surgical interventions for lumbar disc prolapse. *Cochrane Database Syst Rev* 2007; (2):CD001350.
9. Boswell MV, Trescot AM, Datta S et al; American Society of Interventional Pain Physicians. Interventional techniques: evidence-based practice guidelines in the management of chronic+ spinal pain. *Pain Physician* 2007; 10(1):7-111.
10. Freeman BJ and Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: what is the current evidence? *Curr Pain Headache Rep* 2008; 12(1):14-21.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Percutaneous Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 04/23/2014

11. Hirsch JA, Singh V, Falco FJ et al. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: a systematic assessment of evidence. *Pain Physician* 2009; 12(3):601-20.
12. Singh V, Benyamin RM, Datta S et al. Systematic review of percutaneous lumbar mechanical disc decompression utilizing Dekompressor. *Pain Physician* 2009; 12(3):589-99.
13. National Institute for Health and Clinical Excellence. Automated percutaneous mechanical lumbar discectomy-guidance. November 2005. Accessible at <http://guidance.nice.org.uk/IPG141/Guidance/pdf/English>

### 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 2013 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of 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.

CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	62287
HCPCS	C2614, S2348
ICD-9 Diagnosis	722.52, 722.73
ICD-9 Procedure	80.59

### Policy History

Original Effective Date: 07/24/2006

Current Effective Date: 04/23/2014

- 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.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Percutaneous Discectomy

Policy # 00208

Original Effective Date: 07/24/2006

Current Effective Date: 04/23/2014

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.
Next Scheduled Review Date:	04/2015

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

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.