*SPINE PROCEDURES*

**Effective Date:** August 4, 2016  
**Review Dates:** 2/11, 4/11, 4/12, 4/13, 8/13, 5/14, 2/15, 5/15, 5/16  
**Date Of Origin:** February 9, 2011  
**Status:** Current

*Note: For Lumbar Fusion (including Sacroiliac Joint Fusion), see policy #91590, and for Lumbar Laminectomy, see policy #91591.*

**Summary of Changes**

Clarifications:

- •

Deletions:

- •

Additions:

- Pg. 4, VII, Concentrated bone marrow aspirate for spinal surgery is not a covered benefit. There is insufficient evidence to determine safety and efficacy of this treatment.

**POLICY/CRITERIA**

**Covered Procedures**

I. **Artificial Intervertebral Discs**
   A. **Artificial Cervical Discs:**
      Artificial intervertebral cervical discs are a covered benefit when **all** of the following are met:
      1. Disc is FDA approved and used in accordance with approved indications
      2. Single level reconstruction (C3-C7) following discectomy, or 2-level contiguous reconstruction (C3-C7) following discectomy
      3. Intractable radiculopathy and/or myelopathy due to herniated disc or osteophyte formation.
      4. Symptomatic nerve root and/or spinal cord compression documented by all of the following:
         i. neck and/or arm pain
         ii. functional deficit and/or neurological deficit
         iii. radiographic studies (e.g. CT, MRI, x-rays)

   B. Hybrid artificial cervical disc and fusion procedure: hybrid surgery of artificial cervical disc done with anterior cervical fusion is considered experimental and investigational and not a covered benefit due to lack of evidence to support safety and efficacy.
C. Artificial Lumbar Discs: Artificial intervertebral lumbar discs are not a covered benefit because there is insufficient evidence on their long-term safety and effectiveness, including impact on other discs and bony structures of the back.

II. Radiofrequency Ablation for Back Pain
A. Coverage is provided for radiofrequency ablation (RFA) targeting pain originating in the cervical, thoracic, or lumbar spinal regions under the following conditions:
   1. Patient’s symptoms are not consistent with identifiable pathology including disc herniation, spondylolisthesis, spinal stenosis
   2. Absence of any neurologic deficit
   3. Back or neck pain predominates over leg pain or arm pain, respectively
   4. Two diagnostic medial branch nerve blocks, provided under a standard protocol that alternates long- and short-acting anesthetic blocks, produce symptom relief physiologically consistent with medial nerve branch pathology. (Dreyfuss, P, Spine 2000)

B. Limitations
   1. For the purposes of this policy, an RFA procedure consists of one or more ablations during a single visit.
   2. RFA procedures are limited to two per year.
   3. RFA procedures beyond two per year require medical review.
   4. RFA of the SI (sacroiliac) joint is not a covered benefit.

III. Kyphoplasty or Vertebroplasty
A. Percutaneous Vertebroplasty and Kyphoplasty may be a covered benefit for patients with vertebral lesions resulting from osteolytic vertebral metastasis or multiple myeloma; vertebral hemangiomas; steroid- induced vertebral body fractures; painful vertebral eosinophilic granuloma with spinal instability; or osteoporotic spinal compression fractures if all of the following are met:
   1. Pain is severe and debilitating, and cannot be relieved by optimal medical and pain management therapy.
   2. Non-surgical therapy for at least 90 days following discovery of the compression fracture. Exceptions may be made if non-surgical therapy is not indicated or tolerated (e.g. pain management in frail elderly).
   3. The affected vertebra has not been extensively destroyed and is at least one third and no more than two thirds of its original anterior height.

B. Coverage is not provided for kyphoplasty or vertebroplasty when any of the following conditions are present:
   1. Patients with young, healthy bones or those who sustained a vertebral body fracture or collapse in a major accident.
2. Patients with spinal curvature such as scoliosis or kyphosis that is due to causes other than osteoporosis.

3. Patients who suffer from spinal stenosis or herniated discs with nerve or spinal cord compression and loss of neurological function not associated with a vertebral compression fracture.

4. Patients with infection in the affected area.

5. Patients with coagulation disorders.


7. Acute burst fractures or high energy fractures (Hayes).

8. Non-painful, stable VCFs

9. Chronic back pain of long-standing duration, even if associated with old compression fractures, unless pain is localized to a specific chronic fracture and medical therapy has failed.

10. Use as a prophylactic procedure for osteoporosis

11. Kyphosis (as a treatment for secondary complications related to kyphosis)

12. As a prophylaxis in osteopenia (no evidence of fracture or planned surgical procedure)

13. Vertebroplasty/Kyphoplasty utilizing bone cement/fillers that are not FDA approved for this procedure

14. Extensive vertebral destruction

15. Significant vertebral collapse, in which the vertebra is less than one third of its original height

16. Neurologic symptoms related to spinal cord and nerve root compression

17. Cervical vertebroplasty (Note: May be performed only in rare instances by physicians highly skilled in this procedure.)

18. Retropulsed fracture fragment or tumor mass causing significant spinal canal compromise

19. Allergy to PMMA or other bone cement to be used

Non-Covered Procedures

IV. Automated Percutaneous Lumbar Discectomy (APLD)
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
• Percutaneous HydroDiscectomy Surgical Technique /HydroCision/SpineJet HydroSurgery System

V. AxiaLIF® Axial Lumbar Interbody Fusion
The AxiaLIF® axial lumbar interbody fusion system may be covered as an adjunct to lumbar spinal fusion when the criteria of the “lumbar fusion” medical policy are met. See Priority Health’s Lumbar Fusion medical policy #91590.

VI. IDET and Other Thermal Intradiscal Procedures (TIPs)
Review of the evidence for the use of IDET and other TIPs for low back pain does not demonstrate improved health outcomes. Lacking evidence of clinical improvement, the following procedures are considered experimental and investigational and are not a covered benefit:
   a. Intradiscal electrothermal therapy (IDET)
   b. Intradiscal electrothermal annuloplasty (IEA)
   c. Intradiscal thermal annuloplasty (IDTA)
   d. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
   e. Percutaneous radiofrequency thermomodulation
   f. Coblation percutaneous disc decompression
   g. Nucleoplasty
   h. Radiofrequency annuloplasty (RA)
   i. Intradiscal biacuplasty (IDB)
   j. Percutaneous (or plasma) disc decompression (PDD)
   k. Targeted disc decompression (TDD)

TIPs may also be identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, Accuthem, or TransDiscal electrodes).

VII. Concentrated Bone Marrow Aspirate for Spinal Surgery
Concentrated bone marrow aspirate for spinal surgery is not a covered benefit. There is insufficient evidence to determine safety and efficacy of this treatment.
MEDICAL NECESSITY REVIEW

Covered Procedures
Artificial Cervical Discs
☒ Required
AxiaLIF™ Axial Lumbar Interbody Fusion
☒ Required (please see Lumbar Fusion medical policy #91590)
Radiofrequency Ablation for Back Pain
☒ Required after two (2) radiofrequency ablation procedures per plan year
Kyphoplasty/Vertebroplasty
☒ Required (except for Medicare)

Non-Covered Procedures
Artificial Lumbar Discs
☒ Not Covered
Automated Percutaneous Lumbar Discectomy (APLD)
☒ Not Covered
IDET and Other Thermal Intradiscal Procedures (TIPs)
☒ Not Covered
Hybrid Artificial Cervical Disc and Fusion Procedure
☒ Not Covered
Concentrated Bone Marrow Aspirate for Spinal Surgery
☒ Not Covered

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. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **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); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--.00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--.00.html). If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--.00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--.00.html), the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.
DESCRIPTION/BACKGROUND

Back Pain

Back pain affects 80% of Americans at some time in their lives. According to an article by Diwan and Khan, published in Orthopedic Clinics of North America in 2003, over $80 billion is spent annually in American to treat chronic back pain. Progressive back pain is more likely to occur when the person is in their most productive period in life, between the years of 30 and 50. In a study conducted by the U.S. Dept of Health and Human Services in 2003, the total age-adjusted percentages per 100,000 people who reported severe (pain that lasted a whole day or more) low back pain in the prior three (3) months were: 27.4% and neck pain 14.7%. Uncontrolled pain remains one of the greatest healthcare crises affecting Americans to date. Pain is the major cause of disability, a leading reason for physician office visits, and the most frequent indication for diagnostic studies, including MRIs and X-rays and is purported to cost Americans upwards of $100 billion annually in direct health care costs.

Definition of Chronic Pain:

1. Pain, which persists beyond the usual course of an acute disease, or a reasonable time for any injury to heal that is associated with chronic pathological processes that cause continuous pain or pain at intervals for months or years.
2. Persistent pain that is not amenable to routine pain control methods.
3. Pain that exists beyond an expected time frame for healing.
4. Pain, where healing may never occur.

Back Pain Procedures

Artificial Intervertebral Discs

When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion; over 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining whether a patient's back pain is related to degenerative disc disease, and in part due to the success of the procedure itself. Additionally, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. As an alternative, a variety of artificial intervertebral discs have been investigated over the past thirty years. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed, and to maintain the normal biomechanics of the adjacent vertebrae.

The major potential advantage of a prosthetic intervertebral disc over current therapies for degenerated disks (such as spinal fusion or diskectomy) is that the prosthetic intervertebral disk is intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels. Investigators
have found, however, that creation of an intervertebral disc prosthesis poses significant challenges with respect to prosthetic design and materials:

- The biomechanics of the intervertebral segment are difficult to replicate
- It is a challenge to find materials that are both biocompatible and effective
- The prosthetic disc should achieve long-term mechanical fixation.

Several moderate-size randomized controlled trials (RCTs) comparing different types of artificial cervical discs with anterior cervical discectomy and fusion (ACDF) have been published. Evidence to date demonstrates that total disc replacement (TDR) is at least as effective as ACDF in improving signs and symptoms associated with degenerative disease and improving quality of life (QOL) for up to 2 years. The evidence also shows that total disc replacement (TDR) reduces the need for reoperation. Low-quality evidence suggests that TDR reduces the risk of new adjacent segment disease (ASD) but may have higher rates of intraoperative and perioperative complications. Reliable follow-up data for more than 3 years are lacking, which is an especially serious limitation regarding the evidence for the intended advantage of TDR (reduction in long-term ASD).

The best available evidence for 2-level TDR is limited to the pivotal trial (NCT00389597; Davis et al., 2013). The Mobi-C pivotal trial was conducted at 24 U.S. centers and randomized 330 patients with cervical DDD at 2 contiguous levels to receive TDR with the Mobi-C (n=225) or ACDF with allograft bone and anterior plating n=105). Primary outcome measure was overall success rate at 24-month follow-up. While both groups significantly improved in Neck Disability Index (NDI) score, visual analog scale (VAS) neck pain score, and VAS arm pain score, the group receiving the Mobi-C showed significantly greater improvements in NDI score (37±20 versus 30±19 mean change from baseline; \( P<0.05 \)), and VAS neck pain score at 6 weeks and at 3, 6, and 12 months after surgery. ASD was significantly lower at 24 months in the group receiving TDR with the Mobi-C; 13.1% and 2.9% of TDR patients had ASD at the superior and inferior segments, compared with 33.3% and 18.1% of ACDF patients (\( P<0.03 \)). Reoperation rates were significantly lower in the Mobi-C group (3.1% versus 11.4%); ACDF and TDR had similar mean hospitalization time and perioperative blood loss; procedural time was significantly longer for TDR (2.2 hours versus 1.8 hours; \( P=0.0002 \)) (Davis et al., 2013).

**Radiofrequency Ablation for Back Pain**

Radiofrequency ablation, or rhizotomy, is a therapeutic procedure designed to decrease or eliminate pain symptoms within the spinal facets. Facet joints are located in the posterior compartment of the spinal column, innervated by nerve endings from the medial branches of the posterior rami. The primary function of the facet joints is stabilization of movement between vertebrae, and assisting in axial weight-bearing.

Fluoroscopy-guided injections with local anesthetics, corticosteroids, or phenol into or around the facet joints have been used to treat facet joint pain. The facet joints are considered to be the source of pain if diagnostic blocks of the medial branch of the
posterior primary ramus significantly reduce or eliminate pain and if the individual has no definite localizing clinical or imaging findings.

Radiofrequency ablation utilizes radiowave-induced heat to create a lesion in a sensory nerve, which then interrupts the nerve impulse to the involved facet joints for up to six months or longer.

According to the American Society of Interventional Pain Physicians in their Practice Guide of 2005, “the lifetime prevalence of spinal pain has been reported as 54% to 80%, with as many as 60% of patients continuing to have chronic pain five (5) years or longer after the initial episode. Spinal pain is associated with significant economic, societal, and health impact.”

There is not a universally agreed upon method of identifying those most likely to benefit from the procedure. Patients must not have identifiable pathology including disc herniation, spondylolisthesis, spinal stenosis; should be absent of any neurologic deficit; and have back or neck pain predominating over leg pain or arm pain, respectively. Facet joint blocks are limited because capsular rupture can result in anesthetic leakage into the extracapsular space with non-discriminant anesthetization and pain relief. The medial branch double block paradigm alternates long and short acting anesthetic blocks of the medial branch nerve and may be the optimal technique available. This reduces the false positive response rate from 30% to 10% when using less than 1 cc of anesthetic.

In a prospective Canadian trial (Gofeld, 2007), patients with an appropriate response to comparative double diagnostic blocks underwent standardized radiofrequency denervation of the lumbar zygapophysial joints. Of the 209 patients, 174 completed the study, and 35 were lost to follow-up or did not provide complete data for assessment. Of the 174 patients with complete data, 55 (31.6%) experienced no benefit from the procedure. One hundred and nineteen patients (68.4%) had good (> 50%) to excellent (> 80%) pain relief lasting from 6 to 24 months. The authors conclude that proper patient selection and anatomically correct radiofrequency denervation of the lumbar zygapophysial joints provide long-term pain relief in a routine clinical setting.

The optimal technique for the procedure appears to be placement of the electrode parallel to the medial branch nerve. If electrodes are placed parallel to the target nerve, the lesions made can be expected to encompass the target nerves. If electrodes are placed perpendicular to the nerve, the nerve may escape coagulation, or be only partially coagulated parallel to the nerve (Lau, 2004).

The expected duration of effect in an appropriately performed radiofrequency ablation of a medial branch nerve when using the appropriate technique is at least six months. The average duration is expected to be ten (10) months for both cervical (Schofferman, 2004; McDonald, 1999, Lord 1996) and lumbar rhizotomy (Dreyfuss, 2000).
Vertebroplasty/Kyphoplasty

Percutaneous vertebroplasty is an interventional radiologic procedure that involves injection of bone cement into an osteolytic or osteoporotic vertebral body compression fracture with the goal of relieving pain, improving mobility, and preventing further collapse of the bone.

Kyphoplasty is a modification of the vertebroplasty procedure that involves use of an inflatable bone tamp to reduce the fracture prior to injection of the bone cement. The goal of this additional step is to restore height to the bone, thus reducing deformity of the spine.

Two published RCTs published in the *New England Journal of Medicine* have found no significant benefit with vertebroplasty. In the Investigational Vertebroplasty Safety and Efficacy Trial (INVEST), Kallmes et al (2009) reported that pain and disability outcomes at 1 month in a group of patients who underwent vertebroplasty were similar to those in a control group that underwent a sham procedure. In the other trial, Buchbinder et al (2009) measured pain, quality of life, and functional status at 1 week and at 1, 3, and 6 months after sham and active vertebroplasty and found there were no significant between-group differences at any time point. As in INVEST, patients in the 2 study groups had improvement in pain.

In Lancet (2010) VERTOSS 2 trial found vertebroplasty resulted in greater pain relief than did conservative treatment with a difference in mean VAS score between baseline and 1 month was -5.2 (95% CI -5.88 to -4.72) after vertebroplasty and -2.7 (-3.22 to -1.98) after conservative treatment, and between baseline and 1 year was -5.7 (-6.22 to -4.89) after vertebroplasty and -3.7 (-4.35 to -3.05) after conservative treatment. The difference between groups in reduction of mean VAS score from baseline was 2.6 (95% CI 1.74-3.37, p<0.00001) at 1 month and 2.0 (1.13-2.80, p<0.00001) at 1 year. No serious complications or adverse events were reported. Researchers conclude pain relief after vertebroplasty is immediate, sustained, and greater than achieved with conservative treatment.

Automated Percutaneous Lumbar Discectomy (APLD)

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.”

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.

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. 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.

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.

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

**AxiaLIF™ Axial Lumbar Interbody Fusion**

The AxiaLIF™ axial lumbar interbody fusion system is manufactured by TranS1® Inc. of Wilmington, NC. The system consists of instruments designed to allow minimally invasive presacral access to the lumbar spine. The AxiaLIF™ System enables surgeons to access the surgical area via small incisions, decreasing the degree of soft-tissue injury and trauma to the patient. The system includes stainless steel and titanium surgical
instruments, titanium alloy implantable devices, and a proprietary anterior fixation rod (3D Axial Rod™). AxiaLIF™ is used for decompression, distraction and spinal fusion at the L5-S1 junction in conjunction with facet and pedicle screw systems. It is used to treat a variety of disorders including pseudoarthrosis, spinal stenosis, Grade 1 or 2 spondylolisthesis, unsuccessful previous fusion, or degenerative disc disease.

The FDA issued 510(k) approval (K050965) for the TranS1® AxiaLIF™ System on June 14, 2005. It is listed as substantially equivalent to another product developed by TranS1, the TranS1 Axial Fixation System (K040426), which was approved on December 17, 2004. According to the FDA approval summary, the AxiaLIF™ system is an anterior spinal fixation device intended for patients requiring spinal fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 in conjunction with legally marketed facet and pedicle screw systems.

**IDET and Other Thermal Intradiscal Procedures (TIPs)**

Intradiscal electrothermal annuloplasty (IDET) is a minimally invasive surgical procedure developed for the treatment of chronic discogenic low back pain. Thermocoagulation of one or more defective intervertebral discs is accomplished using a percutaneously inserted catheter with a heating element enclosed in the tip. IDET is an outpatient procedure done under local anesthetic. The goal of the procedure is shrinkage of the disc material and destruction of the annular nerve receptors with the desired result of decreasing nerve root compression and pain from the degenerative discs.

In addition to IDET, other thermal intradiscal procedures (TIPs) are available including PIRFT (percutaneous intradiscal radiofrequency thermocoagulation), annuloplasty (electrothermal or thermal), nucleoplasty, and disc biacuplasty. These various TIPs techniques use heat and/or disruption, seeking the same desired outcome of pain relief. Numerous catheters have FDA approval for use in intradiscal thermal procedures. The devices for discogenic back pain in the TIPs’ category utilize the transfer of energy to heat and/or disruption in the cartilaginous disc to treat back pain. All of these devices passed through the FDA under 510(K), meaning that they were found to be substantially equivalent to previous devices without the requirement of clinical trials.

CODING INFORMATION

I. **Artificial Intervertebral Discs**

**ICD-10 Codes**

- G54.2   Cervical root disorders, not elsewhere classified
- G54.9   Nerve root and plexus disorder, unspecified
- M46.41 – M46.43   Discitis, unspecified
- M47.011 – M47.029   Anterior spinal artery compression syndromes
- M47.11 – M47.13   Other spondylosis with myelopathy, head and neck
- M48.01 – M48.03   Spinal stenosis, head and neck
- M50.00 – M50.93   Cervical disc
- M99.20   Subluxation stenosis of neural canal of head region
- M99.21   Subluxation stenosis of neural canal of cervical region
- M99.30   Osseous stenosis of neural canal of head region
- M99.31   Osseous stenosis of neural canal of cervical region
- M99.40   Connective tissue stenosis of neural canal of head region
- M99.41   Connective tissue stenosis of neural canal of cervical region
- M99.50   Intervertebral disc stenosis of neural canal of head region
- M99.51   Intervertebral disc stenosis of neural canal of cervical region
- M99.60   Osseous and subluxation stenosis of intervertebral foramina of head region
- M99.61   Osseous and subluxation stenosis of intervertebral foramina of cervical region
- M99.70   Connective tissue and disc stenosis of intervertebral foramina of head region
- M99.71   Connective tissue and disc stenosis of intervertebral foramina of cervical region

**CPT/HCPCS Codes**

- 22856   Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preservation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
- 22858   Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preservation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)

*No auth required for revision or removal*

- 22861   Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
- 0098T   Revision including replacement of total disc arthroplasty, anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)   *(Not covered for Priority Medicare or Medicaid)*
- 22864   Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
0095T  Removal of total disc arthroplasty, anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)  
(Not covered for Priority Medicare or Medicaid)

Not Covered:
22551  Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2  
(NC if billed with arthroplasty)
22552  Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)  
(NC if billed with arthroplasty)
22857  Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace
22862  Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, lumbar, single interspace
22865  Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
0163T  Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace
0164T  Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace
0165T  Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace
0274T  Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T  Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar
0375T  Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels

II.  Radiofrequency Ablation for Back Pain
ICD-10 Codes that may apply:
G89.21 – G89.29  Chronic pain due to trauma
R52  Pain, unspecified
G89.3  Neoplasm related pain (acute) (chronic)
G89.4  Chronic pain syndrome
M54.03 - M54.09   Panniculitis affecting regions of neck and back
M62.830   Muscle spasm of back
M54.5 – M54.9   Other back pain

**CPT/HCPCS Codes:**

64633   Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634   Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635   Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636   Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)

### III. Kyphoplasty/Vertebroplasty

**ICD-10 Codes** that may apply:

C79.52   Secondary malignant neoplasm of bone marrow
D18.09   Hemangioma of other sites
D47.29   Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
C88.8   Other malignant immunoproliferative diseases
C94.40   Acute panmyelosis with myelofibrosis not having achieved remission   Acute myelofibrosis NOS
C94.41   Acute panmyelosis with myelofibrosis, in remission
C94.42   Acute panmyelosis with myelofibrosis, in relapse
C94.6   Myelodysplastic disease, not classified
D47.1   Chronic myeloproliferative disease
D47.9   Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D47.29   Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
M48.50xA – M48.58   Collapsed vertebra
M80.08xA – M80.08xS   Age-related osteoporosis with current pathological fracture, vertebra(e)
M80.88xA – M80.88xS   Other osteoporosis with current pathological fracture, vertebra(e)
M81.0 – M81.8   Age-related osteoporosis without current pathological fracture
M84.48xA – M84.48xS   Pathological fracture, other site
M84.58xA - M84.58xS   Pathological fracture in neoplastic disease
M84.68xA - M84.68xS   Pathological fracture in other disease
S22.000A – S22.089S   Fracture of vertebrae, thoracic
S23.100A - S23.100A   Subluxation and dislocation, thoracic vertebrae
S32.000A – SA32.059S   Fracture of vertebrae, lumbar
T50.905   Adverse effect of unspecified drugs, medicaments and biological substances
CPT/HCPCS Codes:

Vertebroplasty:

22510  Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic

22511  Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral

22512  Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)

Kyphoplasty:

22513  Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic

22514  Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar

22515  Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

Not Covered

0200T  Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles includes imaging guidance and bone biopsy, when performed

0201T  Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

S2360  Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical

S2361  Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; each additional cervical vertebral body

IV.  Automated Percutaneous Lumbar Discectomy (APLD)

CPT/HCPCS Codes:

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 discectomy, percutaneous laser discectomy)

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 osteophytectomy; lumbar, single interspace
S2351  Diskectomy, anterior, with decompression of spinal cord and/or nerve root(s),
including osteophytectomy; 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.)

V.  **AxiaLIF™ Axial Lumbar Interbody Fusion**
See [Lumbar Fusion medical policy #91590](#)

**CPT/HCPCS Codes:**
0195T  Arthrodesis, pre-sacral interbody technique, disc space preparation,
discectomy, without instrumentation, with image guidance, includes bone graft
when performed; L5-S1 interspace
22586  Arthrodesis, pre-sacral interbody technique, including disc space preparation,
discectomy, with posterior instrumentation, with image guidance, includes
bone graft when performed, L5-S1 interspace

0196T  Arthrodesis, pre-sacral interbody technique, disc space preparation,
discectomy, without instrumentation, with image guidance, includes bone graft
when performed; L4-L5 (List separately in addition to code for primary
procedure)
0309T  Arthrodesis, pre-sacral interbody technique, including disc space preparation,
discectomy, with posterior instrumentation, with image guidance, includes
bone graft, when performed, lumbar, L4-L5 interspace (List separately in
addition to code for primary procedure)  *(Not covered for Priority
Medicaid)*

**Not Covered**
0171T  Insertion of posterior spinous process distraction device (including necessary
removal of bone or ligament for insertion and imaging guidance), lumbar;
single level
0172T  Insertion of posterior spinous process distraction device (including necessary
removal of bone or ligament for insertion and imaging guidance), lumbar; each
additional level (List separately in addition to code for primary procedure)

VI.  **IDET and Other Thermal Intradiscal Procedures (TIPs)**
**ICD-9 Codes that may support medical necessity**
*Not applicable*
HCPCS/CPT Codes

Not Covered

22526  Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level

22527  Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (List separately in addition to code for primary procedure)

22899  Unlisted procedure, spine  (when billed for any of the listed, not covered procedures)

64999  Unlisted procedure, nervous system

Explanatory notes must accompany claims billed with unlisted codes

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

Other Not Covered Procedures

0202T  Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine

0221T  Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine

0222T  Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), each additional vertebral segment (List separately in addition to code for primary procedure)

G0276  Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial  
(May be covered for Medicare – notification required)

VII. Concentrated Bone Marrow Aspirate

No established CPT codes for this or related procedures at this time

CPT/HCPCS Codes, including but not limited to the following, should not be submitted for this treatment:

38220  Bone marrow; aspiration only

96379  Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

REFERENCES

Artificial Intervertebral Discs


Hayes, Inc. Lumbar Total Disc Replacement for Degenerative Disc Disease April 1, 2009 Surgery with disc prosthesis versus rehabilitation in patients with low back pain and degenerative disc: two year follow-up of randomised study Hellum, C. et. al. and the Norwegian Spine Study Group BMJ 2011;342:d2786


Hayes, Inc. Artificial Disc Replacement for Cervical Degenerative Disc Disease, December 23, 2014

Special Note: This policy is based on the review and recommendations of artificial lumbar discs by the Technology Assessment Committee on June 4, 2004 and June 1, 2007.

Artificial cervical discs were reviewed by the Technology Assessment Committee on June 1, 2007.

Radiofrequency Ablation for Back Pain


**Vertebroplasty/Kyphoplasty**


LCD for Vertebroplasty (Percutaneous) and Kyphoplasty Wisconsin Physicians Service Insurance Corporation, October 2009
Local Coverage Determination (LCD):
Vertebroplasty (Percutaneous) and Vertebral Augmentation including cavity creation (L30516), WPS @http://www.ems.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=30516&ContrId=266&ver=25&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Michigan&KeyWord=vertebroplasty&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAABAAAAA %3d%3d (Retrieved May 1, 2014)

Automated Percutaneous Lumbar Discectomy (APLD)
Percutaneous Vertebroplasty and Kyphoplasty; Percutaneous Lumbar Discectomy; IDET; spinal Manipulation under anesthesia; Laser discectomy; and Disc Nucleoplasty.
Gibson, JNA, et. al. Surgery for lumbar disc prolapse, the Cochrane Database of Systematic Reviews, February 3, 2006
AxiaLIF™ Axial Lumbar Interbody Fusion

AxiaLIF™ (Axial Lumbar Interbody Fusion) System (TranS1® Inc.) for Percutaneous Minimally Invasive Anterior Lumbosacral Surgery, Hayes, Inc. April 2006


Hayes, Inc. AxiaLIF® (Axial Lumbar Interbody Fusion) System (TranS1® Inc.) for Percutaneous Minimally Invasive Anterior Lumbosacral SurgerySearch & Summary, February 2008.


IDET and Other Thermal Intradiscal Procedures (TIPs)


Saal, JA and Saal, JS. Intradiscal Electrothermal Treatment for Chronic Discogenic Low Back Pain. Spine, Vol. 27, No. 9, pp.966-974


Webster, BS, et. al. Outcomes of Workers’ Compensation Claimants with Low Back Pain Undergoing Intradiscal Electrothermal Therapy. Spine, Vol. 29, No. 4, pp. 435-441

Analysis of the Pauza Study (The Regence Group, Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation, 06/2005, Available on the World Wide Web

Summary of Davis, et.al. (HAYES Alert, Study Questions Benefits of IDET for Chronic Low Back Pain, June 2004).


Other
Hayes, Inc. Concentrated Bone Marrow Aspirate for Spinal Surgery, March 10, 2016

AMA CPT Copyright Statement:
All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member’s plan in effect as of the date services are rendered. Priority Health’s medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health’s medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan’s ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name “Priority Health” and the term “plan” mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.