

MEDICAL POLICY

Date Reviewed: 02/23/01, 09/28/01, 10/26/01, 02/22/02, 06/17/03, 01/28/05, 08/25/06, 02/15/08

Subject: Intervertebral Disc Therapy (includes Intradiscal Biaculoplasty, Intradiscal Electrothermal Therapy (IDET), Intradiscal Electrothermal Annuloplasty (IDEA), Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), Nucleoplasty, Laser Assisted Disc Decompression (LADD), Percutaneous Disc Decompression, Chemonucleolysis, Intervertebral Disc Prosthesis, Artificial Disc Replacement)

Description: Intervertebral disc therapy includes various procedures to treat vertebral disc herniations. IDET/IDEA/PIRFT uses thermal energy via a catheter to shrink the disc collagen and denervate the nerve endings in the disc in an effort to eliminate discogenic pain symptoms. Nucleoplasty is a percutaneous method of decompressing herniated vertebral discs that uses radiofrequency and thermal energy to remove part of the disc. Percutaneous disc decompression, which can be performed with a cutting device (manual or automated) or laser, is a procedure where a portion of the herniated disc is removed for decompression. During chemonucleolysis, an enzyme (chymopapain) is injected into a herniated lumbar disc to degrade the disc material which leads to decompression. The major potential advantage of a prosthetic intervertebral disc over current therapies for degenerated disks (such as spinal fusion or discectomy) 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

Indications of Coverage:

Chemonucleolysis is considered medically necessary when all of the following criteria are met:

The patient's leg pain is worse than low back pain

The lumbar radiculopathy (pain, numbness, or tingling in at least one extremity) can be reproduced with a nerve root tension test (for example, femoral stretch, straight leg raise) and there is documentation of an objective neurologic deficit (for example, diminished deep tendon reflex (DTR), weakness, or paresthesias in the dermatome affected by the disc

Only a single level herniated disc with nerve root impingement (documented by MRI, CT, or CT myelogram) is documented.

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

IDET/IDEA/PIRFT, nucleoplasty, percutaneous disc decompression, laser assisted disc decompression, and intervertebral disc replacement are all considered experimental or investigative as there is insufficient literature documenting the effectiveness of these procedures.

Injections of another substance other than chymopapain for chemonucleolysis is considered experimental or investigative.

Documentation Required:

Office notes and procedure report

Imaging (MRI, CT, CT myelogram) report

Rationale: Numerous procedures have been proposed to treat spinal pain presumed to be the result of intervertebral disc disease. To date, few of the techniques can be supported with literature from controlled clinical trials documenting the effectiveness of the varied procedures. Chemonucleolysis is one of the few procedures that have shown any benefit, and then only in selected individuals.

There are ongoing studies regarding the effectiveness of other percutaneous intervertebral disc procedures since previous studies generally included small numbers of participants, did not evaluate long-term effectiveness, and did not establish the superior effectiveness of one procedure over another.

In 2004, the Food and Drug Administration (FDA) approved artificial intervertebral discs for implantation. At the same time, the FDA required that the manufacturer complete a five-year study documenting the effectiveness of the device. Since that five year follow-up is not complete, it is not possible to establish the effectiveness of intervertebral disc prostheses. Additionally, a recent evaluation of the technology determined that there was insufficient evidence to determine the effectiveness of the devices or whether there is an improved outcome over standard treatments for discogenic pain. The FDA approved a device for the cervical spine in June 2007, and clinical trials regarding this device are ongoing. Currently, there is limited peer-reviewed literature supporting the effectiveness of intervertebral disc replacement in the cervical spine. No national professional organization has published a recommendation for intervertebral disc prostheses.

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Approved by the Medical Director