I. Policy: Artificial Intervertebral Disc

II. Purpose/Objective:
To provide a policy of coverage regarding Artificial Intervertebral Disc

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Artificial intervertebral discs have been proposed as a treatment for patients with degenerative disc disease that is unresponsive to conservative therapies. Total disc replacement using an artificial intervertebral disc implant replaces the functions of the nucleus and annulus. Various designs of artificial intervertebral discs are undergoing evaluation in clinical trials.

INDICATIONS:

A Artificial Lumbar Discs
The use of an artificial intervertebral disc is limited to skeletally mature members with single-level degenerative disc disease from L3-S1, and who have had no relief from low back pain after a minimum of 6 months of failed conservative therapy (e.g., physical therapy, bracing, injections), and no other complicating conditions such as multi-level disease, non-contained disc, previous spinal fusion, osteoporosis, mid-sagittal stenosis less than 8mm, positive straight leg raise radiculopathy, other surgery at the affected level, significant facet arthritis, spinal tumor, morbid obesity, metal allergy, scoliosis, or more than 3 mm of spondylolisthesis at the involved level. The device must be approved by the FDA for its intended use in the lumbar spine. ProDisc® is currently the only lumbar artificial disc that is FDA-approved in the U.S. The FDA approval letter states, “This device is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L3-S1.

B Artificial Cervical Discs
The Plan considers the use of artificial cervical discs medically necessary in members when ALL the following criteria are met:

1. Disc has the approval of the U.S. Food and Drug Administration (FDA);
2. Member is between 18-60 years of age;
3. Replacement on a single or multiple levels* level between C3 and C7
4. Documented evidence of symptomatic cervical degenerative disc disease (Intractable radiculopathy and/or myelopathy) with at least one of the following items producing nerve root and/or spinal cord compression:
   a. Herniated disc
   b. Osteophyte formation
5. Documented evidence of least 6 weeks of unsuccessful conservative treatment, signs of progression or spinal cord/nerve compression with continued non-operative procedure;
6. Documented evidence of a Neck Disability Index** Score greater than or equal to 30;
7. Documented evidence of a Neck Pain Score of greater than or equal to 20.

* Note: not all cervical artificial discs have FDA labeling for contiguous two level degenerative disc disease.

**The Neck Disability Index (NDI) was developed as a modification of the Oswestry Low Back Pain Disability Index. Each of the ten sections is scored from 0 – 5. The maximum score is therefore 50. The NDI can be found at: http://www.maic.qld.gov.au/forms-publications-stats/pdfs/NDI.pdf

EXCLUSIONS:
The Plan does NOT provide coverage for the use of artificial intervertebral disc for any indication other than listed above because it is considered experimental, investigational or unproven.

The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.
The Plan does NOT provide coverage for the use of artificial intervertebral cervical disc for ANY of the following:

- Evidence of marked cervical instability
- Member has a fused adjacent level
- Radiographic confirmation of severe facet joint disease or degeneration
- Member has had prior surgery at the treated level
- Member has clinically compromised vertebral bodies
- Evidence of severe spondylosis at the level to be treated
- Member has an osteoporosis score of less than or equal to -2.5

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental, Investigational or Unproven Services or Treatment.

For the Medicare Business Segment: According to the current CMS National coverage determination, Lumbar Artificial Intervertebral Disc replacement is not covered for Medicare beneficiaries over 60 years of age.

CODING ASSOCIATED WITH Artificial Intervertebral Disc:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.

- 22899 Unlisted procedure; spine
- 64999 Unlisted procedure; nervous system
- 0095T Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
- 0098T Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
- 0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than 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
- 0195T Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace; lumbar; single interspace.
- 0196T Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace; lumbar; each additional interspace.
- 0375T Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels.
- 22856 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyectomy for nerve root or spinal cord decompression and microdecompression), single interspace, cervical
- 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); lumbar, single interspace
22858  Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure)

22861  Revision including replacement of total disc arthroplasty (artificial disc). Anterior approach, single interspace; cervical

22862  Revision of total disc arthroplasty, anterior approach, lumbar, single interspace

22864  Revision including replacement of total disc arthroplasty (artificial disc). Anterior approach, single interspace; cervical

22865  Removal of total disc arthroplasty, anterior approach; lumbar, single interspace


LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written

REFERENCES:


Lemaire JP. Long Term Results with the SB Charité Artificial Disc. International Symposium - Swiss Spine Institute Program Study, June 22, 2002, 09.45h


FDA Approves First of a Kind Medical Device to Treat Cervical Degenerative Disc Disease. July 17, 2007


This policy will be revised as necessary and reviewed no less than annually.

Devised: 3/05

Revised: 7/05 (approval, criteria); 8/06; 8/07 (updated exclusions and coding); 12/08 (exclusion and coding); 10/09 (indications for cervical), 9/10, 9/11, 9/14 (added multi-level indication to cervical discs), 1/16 (added Indication)

Reviewed: 9/12, 9/13; 1/17