Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOLS

Artificial Intervertebral Disc: Cervical Spine

Lumbar Spinal Fusion

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With degenerative disc disease</td>
<td>• Lumber artificial intervertebral disc</td>
<td>• Conservative therapy</td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lumbar spinal fusion</td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
</tbody>
</table>

DESCRIPTION

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to spinal fusion in patients with degenerative disc disease leading to disabling symptoms.

SUMMARY OF EVIDENCE

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) of artificial discs versus fusion with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement compared to spinal fusion. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (e.g., faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes that would make noninferiority sufficient to demonstrate
the clinical benefit of the artificial lumbar disc have not been established. No RCTs compared activL® to spinal fusion or conservative care. In general, RCTs were limited by a lack of blinding, insufficient follow-up to evaluate potential harms, and lack of comparison to the criterion standard for treatment of degenerative disc disease. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

Artificial intervertebral discs of the lumbar spine are considered investigational.

BACKGROUND

Degenerative disc disease, the most frequent cause of back pain requiring surgery, is common with age or trauma. Spine imaging, such as magnetic resonance imaging (MRI), computed tomography, or plain radiography, shows that lumbar disc degeneration is widespread, but for most people it does not cause symptoms. Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with nonoperative treatment, and no contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. Patients who require procedures in addition to fusion (e.g., laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion. More than 200,000 spinal fusions are performed each year. However, outcomes with spinal fusion have been controversial, in part due to the difficulty in determining if a patient’s back pain is related to degenerative disc disease and in part due to the success of the procedure itself. Also, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain normal biomechanics of the adjacent vertebrae and motion at the operative level once the damaged disc has been removed.

Use of a motion-preserving artificial disc increases the potential for various types of implant failure. They include device failure (e.g., device fracture, dislocation, or wear), bone-implant interface failure (e.g., subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (e.g., osteolysis, heterotopic ossification, pseudotumor formation).

REGULATORY STATUS

Three artificial lumbar disc devices (activL®, Charite®, ProDisc®-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (Table 1). Production under the name Charite® was stopped in 2010 and the device was withdrawn in 2012.

Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of postmarketing studies. The activL® (Aesculap Implant Systems), Charite® (DePuy), and ProDisc®-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease at 1 level. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. The activL device is approved for use at 1 level. Initial approval for ProDiscL was also limited to patients with disease at 1 level. In April 2020, the ProDiscL indication was expanded to include patients with disease at up to 2 consecutive levels.1
### Table 1. U.S. Food and Drug Administration-Approved Lumbar Artificial Disc Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Indication</th>
<th>PMA Number</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>activL</td>
<td>Aesculap Implant Systems, LLC</td>
<td>The activL® Artificial Disc (activL) is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL® Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL® Artificial Disc should have failed at least six months of nonoperative treatment prior to implantation of the device.</td>
<td>P120024</td>
<td>06/11/2015</td>
</tr>
<tr>
<td>ProDisc-L</td>
<td>Synthes Spine</td>
<td>The PRODISC®-L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level. Patients receiving the PRODISC®-L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the PRODISC®-L Total Disc Replacement.</td>
<td>P050010</td>
<td>8/25/2006</td>
</tr>
<tr>
<td>Charite</td>
<td>Depuy Spine, Inc</td>
<td>The CHARITE Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than 3mm of spondylolisthesis at the involved level. Patients receiving the CHARITE Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the CHARITE Artificial Disc.</td>
<td>P040006</td>
<td>10/26/2004 Withdrawn 1/5/2012</td>
</tr>
</tbody>
</table>

PMA: premarket approval

A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. The INMOTION® is not currently marketed in the United States.
- The Maverick™ artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation.
- The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access.
- Kineflex-L™ (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L, scheduled in 2013, but was canceled without explanation.
- FDA product code: MJO.
Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.