Policy Statement

Injection of allograft into the intervertebral disc for the treatment of degenerative disc disease is considered investigational.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
The following CPT codes may be billed for this procedure:

- **0627T**: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
- **0628T**: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
- **0629T**: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
- **0630T**: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)

Description

Degeneration of the intervertebral discs is commonly observed in imaging and has been proposed to be a source of back pain. In order to treat the observed changes in the discs, cellular therapies such as mesenchymal stem cells are being studied. One of these cellular therapies involves the intradiscal injection of a mixture of nucleus pulposus allograft and viable cells into the degenerated disc.

Related Policies

- Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used With Autologous Bone Marrow)

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
Regulatory Status

VIA Disc Matrix (Vivex Biomedical) is composed of human disc tissue donated from cadavers with viable cells. It consists of a nucleus pulposus allograft suspension that is mixed with a minimum of 6 X10^6 cryopreserved cells. The cell source and method of processing has not been disclosed, and it is not clear if VIA Disc Matrix meets the U.S. Food and Drug Administration (FDA) criteria for what is considered minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based products (HCT/Ps).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, Title 21, parts 1270 and 1271. In 2017, the FDA published clarification of HCT/Ps. An HCT/P is defined as human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. If a HCT/P does not meet the criteria below and does not qualify for any of the stated exceptions, the HCT/P will be regulated as a drug, device, and/or biological product and applicable regulations and premarket review will be required. A HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria:

1. The HCT/P is minimally manipulated;
2. The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent;
3. The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
4. Either:
   1. The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
   2. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
      1. Is for autologous use;
      2. Is for allogeneic use in a first-degree or second-degree blood relative; or
      3. Is for reproductive use

An investigational device trial of rexlemestrocel-L (Mesoblast) has been completed is currently under FDA review.

Rationale

Background
Degenerative Disc Disease

Back pain is a common condition in adults. Most episodes of back pain are self-limited and will resolve within 1 month, but a small percentage will persist and become chronic. Chronic back pain can arise from a variety of etiologies including musculoskeletal pain, vertebral compression fractures, spinal stenosis, disc hemiation, or other degenerative changes to the disc that compress the nerve roots and lead to radiculopathy. Age-related degeneration of the intervertebral discs is common and includes numerous biochemical and morphologic changes; the most common of which is loss of glycosaminoglycan and associated loss in water content. Pro-inflammatory molecules increase, while endplate calcification impairs nutrient flow.

Together, these lead to an increase in cell death in the nucleus pulposus. Although degenerative changes to the disc are frequently observed on imaging, their contribution to back pain in the absence of radiculopathy is uncertain. Spine imaging, such as magnetic resonance imaging, computed tomography, or plain radiography, shows that lumbar disc degeneration is widespread, but for most people does not cause symptoms. Because many
degenerative changes of the disc that are seen on imaging are asymptomatic, identifying the source of the back pain is challenging.

**Treatment**

Conservative management of back pain is the first-line treatment for most patients. Nonsteroidal anti-inflammatory drugs or other analgesics are used for symptom relief. Duloxetine or tramadol are recommended second-line pharmacologic therapies by the American College of Physicians. Additionally, modification of activity in conjunction with some form of exercise therapy is frequently prescribed early in the course of symptoms. For patients with persistent nonradicular back pain, guidelines recommend interdisciplinary rehabilitation, which is defined as an integrated approach using physical rehabilitation in conjunction with a psychological or psychosocial intervention. Opioids may also be prescribed. Although spinal fusion surgery is frequently performed for non-specific back pain with degenerative changes to the disc, surgery has not been shown to be more effective than comprehensive conservative treatment. Cell therapy is being explored as a method to regenerate the intervertebral disc by rehydration, height restoration, and repopulating native cells.

**Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens, and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Clinical Context and Therapy Purpose**

The purpose of a viable allograft injection for degenerative disc disease is to provide a treatment option that improves outcomes in patients who have failed conservative therapy. Conservative treatment of degenerative disc disease includes rest, analgesics, physical therapy, bracing, and if lower back pain persists, repeated corticosteroid injections. Opioids may be prescribed, but alternative treatments for chronic back pain are needed due to the potential for addiction. Despite high utilization, many patients with chronic back pain do not improve with available treatments. When combined with large increases in the number of patients who present with low back pain, there is a high unmet need for alternative treatments and a need to determine which patient populations may benefit from specific interventions. A variety of autologous and allogenic cellular therapies, including disc cells, chondrocytes, notochordal cells and mesenchymal stem cells, have been evaluated. One technology that is being investigated is injection of a viable disc allograft into the degenerated disc in an attempt to reverse the morphological changes and slow further degeneration.
The question addressed in this evidence review is: Does the injection of a viable disc allograft injection into the lumbar disc improve the net health outcome in patients with degenerative disc disease?

The following PICO was used to select literature to inform this review.

**Populations**
The relevant population of interest is patients with chronic back pain attributed to 1 or 2 level degenerative disc disease and lack of improvement with conservative treatment. There is no gold standard for the diagnosis of symptomatic degenerative discs, and identification of symptom-causing degeneration is controversial. Contraindications for the procedure include other sources of chronic back pain, including radicular pain, symptomatic spinal stenosis, disc protrusion >5 mm, or spondylolisthesis >5 mm.

**Interventions**
The therapy being considered is an injection of allograft taken from the intervertebral disc of donor cadavers. The manufacturer states that the nucleus pulposus allograft suspension is mixed with a minimum of 6 X10⁶ viable cryopreserved cells. The method of processing has not been disclosed. Nucleus pulposus allograft tissue and a vial of cells (VIA Disc Matrix) are mixed and injected into 1 or 2 degenerated intervertebral discs under imaging guidance. The injections are done under moderate conscious sedation and can be conducted as an outpatient procedure.

**Comparators**
Conservative treatment may include oral pain medication, physical therapy, and epidural steroid injections. The terms “nonsurgical” and “nonoperative” have also been used to describe conservative treatment.

**Outcomes**
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Outcome measures for back surgery are relatively well-established (Table 1). Visual analog scores (VAS) can be used to assess pain and the Oswestry Disability Index (ODI) assesses functional limitations related to back pain. Studies may also use a broader functional status index such as the SF-12 or SF-36, particularly the physical function subscale of SF-36. Determining the minimal clinically important difference (MCID) for these measures is complex. The MCID for a given measure can depend on the baseline score or severity of illness, the method used to calculate MCID, and the times at which the scores are measured. For these reasons, some investigators prefer to calculate a minimum detectable difference (MDD). Both short-term and long-term outcomes are important in evaluating back treatments. For intradiscal allograft injection, net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, or VAS measures; and 5-year surgery or re-intervention rates, which reflect longer-term complications, recurrences, and treatment failures.

Group means are commonly designated as primary outcome measures in spine studies. Variation in the calculation and definition of MCIDs makes it difficult to compare response rates across studies. Nevertheless, clinical trials should prespecify a MCID for ODI and, when used, the other measures in the table and report response rates in addition to group means.

Objective measures such as the Pfirrmann grade with magnetic resonance imaging (MRI) and disc height might provide supportive evidence, but are not the clinical outcomes of interest.
### Table 1. Patient-reported Outcome Measures for Back Pain

<table>
<thead>
<tr>
<th>Measure</th>
<th>Outcome Evaluated</th>
<th>Description</th>
<th>MDD and MCID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry Disability Score (ODI)</td>
<td>Functional disability and pain related to back conditions.</td>
<td>Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0-100% of maximum score</td>
<td>MDD: 8-10 points MCID varies; often 15 points (30 percentage points)</td>
</tr>
<tr>
<td>RMDQ</td>
<td>Disability from back problems.</td>
<td>Twenty-four items; scored 0-24 (higher scores are worse).</td>
<td>MCID: 30% reduction</td>
</tr>
<tr>
<td>Visual analog scale for back pain</td>
<td>Degree of back pain.</td>
<td>Patients indicate the degree of pain on a 0-100 scale.</td>
<td>MDD: 2 points</td>
</tr>
</tbody>
</table>

MCID: minimal clinically important difference; MDD: minimal detectable difference; RMDQ: Roland and Morris Disability Questionnaire.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

#### Randomized Controlled Trials

Study characteristics and results are shown in Tables 2 and 3. Limitations of the studies are described in Tables 4 and 5.

The Viable Allograft Supplemented Disc Degeneration in the Treatment of Patients with Low Back Pain (VAST) trial (NCT03709901) is a multicenter RCT that has enrolled 220 patients. Patients who have failed conservative management for 6 months will be treated with the VIA Disc Matrix, placebo injection, or continued non-surgical management in a 3.5:1:1 ratio and followed for up to 36 months. Inclusion criteria are clinical disc degeneration at 1 or 2 levels from L1 to S1 with moderate to severe disability (low back pain >6 mos, ODI >40, VAS >40 mm), and moderate Pfirrmann grading (levels 3 to 6) on MRI. Exclusion criteria are disc protrusion >5 mm, spondylolisthesis >5 mm at any level, and body mass index >35.

Results for the first 24 patients were evaluated for safety at 1 month, with 12 month VAS and ODI of these first participants reported by Beall et al (2020). The report included 16 patients treated with the VIA Disc Matrix, 4 patients who received a placebo injection into the intervertebral disc, and 4 individuals who continued with non-surgical management. Cross-over of the non-surgical management group to allograft injection was allowed at 3 months.

No major safety concerns were identified. Adverse events were reported in 6 of 16 (37.5%) participants in the experimental group and 1 of 4 (25%) participants in the placebo injection group. None of the adverse events were considered related to the allograft. It is notable that at 1 month, both injection groups showed similar improvement in ODI and VAS. The conservative management arm did not improve, and all 4 patients in this group crossed over to VIA Disc Matrix at 3 months. At the planned 6 month follow-up, VAS for the 2 injection groups began to diverge, and 1 patient in the placebo control group did not continue in the study and subsequently received the injection of VIA Disc Matrix. Power for the VAST trial is based on 220 patients in the full study and no statistical analysis was performed for these initial safety results. Notably, however, scores on the ODI improved to some extent for both injection groups, suggesting a strong placebo or non-specific effect for this procedure.
A review of clinicaltrials.gov indicates that recruitment of the 218 participants in the VAST trial has been completed and follow-up is continuing. Trial completion is expected in January 2022.

### Table 2. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions Active</th>
<th>Comparator</th>
<th>Comparator Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beall et al (2020)</td>
<td>US</td>
<td>15</td>
<td>2017-2022</td>
<td>220 patients with disc degeneration at 1 or 2 levels from L1 to S1 with ODI ≥40, VAS ≥40 mm, and Pfirrmann level 3 to 6 on MRI</td>
<td>VIA Disc Matrix injection (1.25 to 1.75 cm³ allograft and 6 x 10⁶ cells) under fluoroscopic guidance</td>
<td>Intradiscal saline placebo injection (1.75 cm³ per level)</td>
<td>Conservative management</td>
</tr>
</tbody>
</table>

MRI: magnetic resonance imaging; ODI: Oswestry Disability Index; RCT: randomized controlled trial; US: United States; VAS: visual analog scale.

### Table 3. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Oswestry Disability Index</th>
<th>Visual Analog Score</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beall et al (2020)</td>
<td>N</td>
<td>23</td>
<td>24</td>
</tr>
<tr>
<td>VIA Disc Matrix</td>
<td>15.67</td>
<td>12.27</td>
<td>6/16 (37.5%)</td>
</tr>
<tr>
<td>Placebo injection</td>
<td>9.33</td>
<td>19.67</td>
<td>1/4 (25%)</td>
</tr>
<tr>
<td>Conservative management</td>
<td>62.75 (before crossover)</td>
<td>54.0 (before crossover)</td>
<td>0</td>
</tr>
</tbody>
</table>

NR: not reported; RCT: randomized controlled trial.

### Table 4. Study Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Duration of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beall et al (2020)</td>
<td>1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.</td>
<td>1. The conservative management protocol was not described.</td>
<td>1. 12 month follow-up is reported in this preliminary publication. Follow-up to 36 months is planned.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

### Table 5. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beall et al (2020)</td>
<td>3. The randomization process was not described.</td>
<td>1, 2, 3 The placebo-controlled group was blinded but</td>
<td>3. All of the patients in the conservative management and 1 of 4 in</td>
<td>1, 2. Power analysis was conducted for the full</td>
<td>4. Statistical analysis will be conducted</td>
<td></td>
</tr>
</tbody>
</table>
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- **Allocation key:** 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
- **Blinding key:** 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
- **Selective Reporting key:** 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- **Data Completeness key:** 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
- **Power key:** 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
- **Statistical key:** 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**Summary of Evidence**

For individuals with degenerative disc disease who receive a viable allograft injection, the evidence includes preliminary results from a RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Results from the first 24 patients of a trial on VIA Disc Matrix have been reported. The trial has completed recruitment of 218 of the 220 planned participants, and follow-up will continue for 36 months, with expected completion in January 2022. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

**Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**American College of Physicians**

In 2017, the American College of Physicians recommended that “for patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation. (Grade: strong recommendation, low-quality evidence).

In patients with chronic low back pain who have had an inadequate response to nonpharmacologic therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for
individual patients and after a discussion of known risks and realistic benefits with patients. (Grade: weak recommendation, moderate-quality evidence).1

North American Spine Society et al
In 2020, the North American Spine Society, along with 9 other societies, published multidisciplinary evidence-based guidelines on the diagnosis and treatment of low back pain.5 There were 82 clinical questions that were addressed in the comprehensive evidence review. Regarding degenerative disc disease, the guideline gave a grade A recommendation that provocative discography without manometric measurements correlates with both pain reproduction in the presence of moderate to severe disc degeneration on MRI/CT[magnetic resonance imaging/computed tomography] discography and with the presence of endplate abnormalities on MRI imaging. There was insufficient evidence to make a recommendation for or against the use of intradiscal bone marrow concentrate in patients with discogenic low back pain, and no review of intradiscal allograft injection.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Ongoing NCT02412735a A Prospective, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of a Single Injection of Rexlemestrocel-L Alone or Combined With Hyaluronic Acid (HA) in Subjects With Chronic Low Back Pain</td>
<td>404</td>
<td>Mar 2021</td>
</tr>
<tr>
<td></td>
<td>Ongoing NCT03709901a Viable Allograft Supplemented Disc Regeneration in the Treatment of Patients With Low Back Pain With or Without Intervertebral Disc Herniation - VAST Trial</td>
<td>218</td>
<td>Jan 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

References

4. Parker SL, Mendenhall SK, Shau DN, et al. Minimum clinically important difference in pain, disability, and quality of life after neural decompression and fusion for same-level

Documentation for Clinical Review

- No Records Required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>0627T</td>
<td>Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level</td>
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<td>0628T</td>
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<td>0629T</td>
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</tr>
<tr>
<td></td>
<td>0630T</td>
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</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
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</tr>
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</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/2021</td>
<td>New policy.</td>
</tr>
</tbody>
</table>
Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.
## Appendix A

### POLICY STATEMENT

<table>
<thead>
<tr>
<th>BEFORE</th>
<th>AFTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
<td>Allograft Injection for Degenerative Disc Disease 7.01.166</td>
</tr>
<tr>
<td>Policy Statement: N/A</td>
<td>Policy Statement: Injection of allograft into the intervertebral disc for the treatment of degenerative disc disease is considered <strong>investigational.</strong></td>
</tr>
</tbody>
</table>