8.01.18 Lysis of Epidural Adhesions

Policy Statement

Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, are considered investigational. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

Policy Guidelines

Coding

The following CPT codes specifically identify the injection of hypertonic saline, which may be performed over the course of multiple or single days.

- **62263**: Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
- **62264**: Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day

As noted here, the protocols for lysis of epidural adhesions vary. Some institutions may perform lysis of epidural adhesions as an inpatient procedure, performed in multiple sessions over the course of several days through an indwelling catheter. In the descriptor of the CPT book, it is noted that CPT code 62263 describes the percutaneous insertion and removal of an epidural catheter and that code 62263 is not reported for each adhesiolysis treatment, but it should be reported once to describe the entire series of injection/infusion spanning 2 or more treatment days.

In 2008, CPT code 0027T (Endoscopic lysis of epidural adhesions with direct visualization using mechanical means [e.g., spinal endoscopic catheter system) or solution injection (e.g., normal saline]) was deleted. Endoscopic lysis of epidural adhesions should now be coded using miscellaneous code 64999.

There is instruction following CPT code 77003 in the CPT book that states 62263 and 62264 include fluoroscopic guidance and localization.

Description

Lysis of epidural adhesions involves passing a catheter, either endoscopically or percutaneously, under fluoroscopic guidance into the epidural space to break up adhesions and reduce pain and inflammation.

Related Policies

- N/A

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

Lysis of epidural adhesions is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

### Rationale

#### Background

**Epidural Fibrosis and Adhesive Arachnoiditis**

Epidural fibrosis with or without adhesive arachnoiditis most commonly occurs as a complication of spinal surgery and may be included under the diagnosis of “failed back surgery syndrome”. Both conditions result from the manipulation of the supporting structures of the spine. Epidural fibrosis can occur in isolation, but adhesive arachnoiditis is rarely present without associated epidural fibrosis. Arachnoiditis is most frequently seen in patients who have undergone multiple surgical procedures.

Epidural fibrosis and adhesive arachnoiditis are related to inflammatory reactions that result in the entrapment of nerves within dense scar tissue, increasing the susceptibility of the nerve root to compression or tension. The condition most frequently involves the nerves within the lumbar spine and cauda equina. Signs and symptoms indicate the involvement of multiple nerve roots and include low back pain, radicular pain, tenderness, sphincter disturbances, limited trunk mobility, muscular spasm or contracture, and motor-sensory and reflex changes. Typically, pain is characterized as constant and burning. In some cases, pain and disability are severe, leading to analgesic dependence and chronic invalidism.

#### Treatment

Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option. The Racz procedure involves the passage of a fluoroscopically guided catheter (the Racz catheter), inserted either endoscopically or percutaneously, and the use of epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics. Theoretically, the use of hypertonic saline results in mechanical disruption of the adhesions. The saline may also function to reduce edema within previously scarred and/or inflamed nerves. Finally, manipulating the catheter at the time of the injection may disrupt adhesions. Spinal endoscopy has been used to guide the lysis procedure, but the procedure is more commonly performed percutaneously using epidurography to guide catheter placement and identify nonfilling adhesions that indicate epidural scarring. Using endoscopy guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-dimensional visualization to steer the catheter toward the adhesions. With the increased visualization, the catheter is more apt to precisely place the injectate in the epidural space and onto the nerve root. Various protocols for lysis have been described; in some situations, the catheter may remain in place for several days for serial treatment sessions.

Endoscopic epidurolysis is also being investigated to treat degenerative chronic low back pain, including spondylolisthesis, stenosis, and hemia associated with radiculopathy. Along with mechanical adhesiolysis, hyaluronidase, ciprofloxacin, and ozone have been applied.
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Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one 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. RCTs 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.

Lysis
The evidence for lysis of epidural adhesions consists of single-center trials, most of them from a single U.S. pain management group.

Clinical Context and Therapy Purpose
The purpose of lysis in patients who have epidural adhesions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of lysis improve the net health outcome in patients with epidural adhesions?

The following PICOs were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with epidural adhesions.

Interventions
The therapy being considered is lysis.

Lysis is a surgical procedure generally administered in an inpatient hospital setting under conscious sedation using imaging guidance.

Comparators
The following practice is currently being used to treat lysis: medical management.

Outcomes
The general outcomes of interest are reductions in symptoms (e.g., pain severity) and medication use, improvement in functional improvement, and treatment-related adverse events (e.g., neurologic deficits).

Postsurgical follow-up can range from six to eight weeks.

Systematic Reviews
A systematic review on endoscopic adhesiolysis by Helm et al (2013) included an RCT and 3 observational studies and noted there was a limited amount of literature on endoscopic
adhesiolysis. Despite limitations in available evidence, using U.S. Preventive Services Task Force quality of evidence criteria, reviewers concluded there was fair evidence that spinal endoscopic adhesiolysis is effective in reducing chronic low back and/or leg pain in post lumbar surgery syndrome in both the short- and long-term (>12 months).

Hayek et al (2009) concluded that, based on level II-1 or II-2 evidence (1 randomized trial, 5 observational studies), endoscopic adhesiolysis provides short- and long-term relief of pain based on the U.S. Preventive Services Task Force criteria. Epter et al (2009) with Hayek et al (2009) and others concluded that there was level I or II evidence (3 randomized trials, 4 observational studies) for percutaneous adhesiolysis.

In a review, Racz et al (2008) concluded, based on the literature (randomized trials and case series) and expert opinion, that evidence was strong for short-term (3 months) efficacy and moderate for long-term (>3 months) efficacy.

A review by Chopra et al (2005) focused on 3 randomized studies by Heavner and Manchikanti and concluded that there was moderate-to-strong evidence of the effectiveness of percutaneous adhesiolysis. A 2007 update of that review also concluded that there was strong evidence for short-term and moderate evidence of long-term effectiveness of percutaneous adhesiolysis and spinal endoscopy. Applying the U.S. Preventive Services Task Force criteria, a 2012 update of the review found fair evidence that percutaneous adhesiolysis is effective in relieving low back and/or leg pain caused by post lumbar surgery syndrome or spinal stenosis. Complications were considered to be minimal.

The primary studies cited in these reviews were assessed individually for this evidence review (see the following sections).

**Percutaneous Lysis of Adhesions Without Spinal Endoscopy**

**Randomized Controlled Trials**

Gerdesmeyer et al (2013) reported on a randomized, double-blind, placebo-controlled trial assessing percutaneous epidural lysis of adhesions for chronic lumbar radicular pain at 4 participating treatment centers. Of 381 patients screened, 90 patients were randomized in permuted blocks of 4 to 8 to adhesiolysis or placebo. Eligible patients had chronic lumbosacral radicular pain after disc protrusion or after failed back surgery and had completed at least four months of unsuccessful conservative treatment. Patients in both groups (adhesiolysis and placebo) received injections on each of three days and physical therapy after the series of injections. In the adhesiolysis group, the day 1 injection consisted of 10 mL saline with 150 U/mL hyaluronidase, plus 10 mL saline with 40 mg triamcinolone and 2 mL of 0.25% bupivacaine; this initial injection was followed by day 2 and 3 injections of saline with an anesthetic. The placebo group received saline injections each of the three days through a catheter placed over the affected area but not into the spinal canal. After 3 months, the Oswestry Disability Index (ODI) score significantly improved in the adhesiolysis group (55.3 to 26.4) compared with the placebo group (55.4 to 41.8; p<0.01). After three months, the visual analog scale (VAS) score was also significantly improved in the adhesiolysis group (6.7 to 2.9) compared with the placebo group (6.7 to 4.8; p<0.01). ODI and VAS scores remained significantly more improved in the adhesiolysis group than the control group at 6 and 12 months. In the adhesiolysis group, more patients experienced pain during the intervention and transient neurologic deficits (numbness, paralysis, motor weakness) after the intervention than in the control group (34 vs 20 and 42 vs 6, respectively). All neurologic deficits resolved during hospitalization. Limitations of this trial included failure to place the catheter near the anterolateral epidural space of the targeted pathology, and the unknown effect of each component of treatment. The large effect seen in the placebo group also brings into question whether the placement of the catheter in the subcutaneous tissue produces a beneficial effect.

Two comparative effectiveness RCTs by Manchikanti et al (2009) reported on 1-year outcomes. Patients in 1 trial had failed back surgery syndrome (planned enrollment, 200
patients), and patients in the other had chronic low back pain (planned enrollment, 120 patients). The comparator in both trials was epidural corticosteroid injection. In both trials, the procedure in the intervention group included epidurography, the introduction of the Racz catheter to the level of defect, adhesiolysis and/or targeted catheter positioning, repeat epidurography with confirmation of ventral and lateral filling, and injection of lidocaine. After all the procedures were performed, patients received an injection of 10% sodium chloride solution and an injection of betamethasone. The control group received epidurography, the introduction of the catheter up to S3 or S2, repeat epidurography, injection of lidocaine, and injection of normal saline and betamethasone. For the patients with failed back surgery, significant pain relief (defined as >50% reduction in VAS score) was achieved by 73% of patients in the lysis group compared with 12% in the control group (p<0.001). For patients with spinal stenosis, there were no outcomes reported at the time of publication. In the 2-year follow-up report on the study with 120 patients treated for chronic low back pain, Manchikanti et al (2012) reported 82% of patients receiving adhesiolysis had significant improvement in functional status and relief of pain of at least 50% compared with only 5% improvement in the epidural corticosteroid injection group.11 If patients had improved functioning and reduced pain by at least 50% for at least 3 months following adhesiolysis, repeat adhesiolysis was permitted. Patients in the adhesiolysis group received an average of 6.4 adhesiolysis procedures while patients in the epidural corticosteroid injection group averaged 2.4 procedures over the two-year period.

A number of limitations are apparent in these trials. Losses to follow-up in the control groups were large in both studies (10/60 at 6 months, 43/60 at 12 months, 52/60 at 2 years in the failed back surgery study; 10/25 at 6 months, 18/25 at 12 months in the spinal stenosis study). There were few dropouts in the intervention groups. Thus, differential loss in follow-up is a major concern. Patients received additional treatments if needed (criteria for repeat treatment not given), and the type of treatment was based on the response to the previous injections, either after unblinding or without unblinding. Physicians performing procedures could not be blinded to the treatment group, but they did not know which patients were participating in the studies.

Several earlier, smaller, randomized trials were reported by Manchikanti and colleagues. Manchikanti et al (2004) published the results of a trial that randomized 75 patients to 1 of 3 groups, either a control group consisting of catheterization without adhesiolysis or to adhesiolysis with or without additional hypertonic saline.12 All patients received epidural injections of local anesthetic and corticosteroids. Significant differences in pain relief, ODI scores, and range of motion were noted between the two treatment groups and the control group. In another trial, Manchikanti et al (2001) randomized 45 patients to a 1- or a 3-day course of lysis of epidural adhesions.13 A total of 97% of the treatment group with 1 to 3 injections reported at least 50% pain relief at 3 months, which fell to 93% at 6 months, and to 47% at 1 year. There were no significant improvements in the control group.

**Prospective Studies**

Serious adverse events from epidural lysis have been reported.14 Manchikanti et al (2012) reported on a prospective observational study of complications in 10000 fluoroscopically directed epidural injections, including more than 800 cases treated by percutaneous adhesiolysis at their institution.15 Measured outcomes included intravascular entry of the needle, profuse bleeding, local bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation, infection, numbness, postoperative soreness, and increased pain. There was an intravascular entry in 11.6% of adhesiolysis cases, return of blood in 3.6% transient nerve root irritation in 1.9%, and dural puncture in 1.8% of cases. Other complications occurred in less than 1% of cases. There were no major complications in this cohort.

**Section Summary: Percutaneous Lysis of Adhesions Without Spinal Endoscopy**

Several RCTs have reported benefits for epidural lysis of adhesions compared with placebo treatment. The interpretation of these trials is limited by differences in patients, populations, and treatment protocols. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There was also
a large effect seen in the placebo group, raising questions whether some components of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would be helpful in determining whether specific treatment protocols have beneficial effects in specific patient populations.

**Percutaneous Lysis of Adhesions With Spinal Endoscopy Randomized Controlled Trials**

One small RCT was identified by Manchikanti et al (2003).\(^\text{16}\) Twenty-three patients with back pain of greater than six months in duration were randomized to spinal endoscopy followed by injection of local anesthetic or corticosteroid (control group) or the above procedure plus lysis of adhesions with normal saline and mechanical disruption with the fiberoptic endoscope. The trial was double-blinded. Patient selection criteria included failure of conservative management, including failure of prior attempts at lysis of adhesions using hypertonic saline. The principal outcomes included changes in VAS and ODI scores at six months. In the control group, the mean VAS score dropped from 8.7 at baseline to 7.6 at 6 months, while the scores in the intervention group dropped from 9.2 at baseline to 5.7 at six months. The difference between groups was statistically significant. There was also a significant difference between groups in the percentage of patients experiencing at least a 50% reduction in pain. Blinding appeared to be successful because 6 of the 16 patients in the control group believed they were in the intervention group, and 8 of 23 patients in the intervention group believed they were in the control group. While this trial reported promising results, its small size limits interpretation.

**Prospective and Retrospective Studies**

Donato et al (2011) reported a 48-month follow-up from a prospective case series of 234 patients with chronic low back pain due to failed back surgery syndrome, spondylolisthesis, stenosis, or hernia.\(^\text{17}\) In addition to the mechanical removal of adherences, targeted ozone, hyaluronidase, and ciprofloxacin were applied. Efficacy was prospectively evaluated by an independent investigator at 1 week and 3, 6, 12, 24, 36, and 48 months. Significant improvements in VAS and ODI scores were reported throughout the 48-month follow-up. Adverse events included 32 (13.7%) patients who had sacral pain lasting at least 2 weeks and 13 (5.5%) patients who experienced nonpainful paresthesia and subsequently underwent surgical intervention. This study has a number of limitations, including the lack of information on the number of patients available for long-term follow-up and the lack of a control group.

Two other retrospective studies by Manchikanti et al (1999, 2000) have examined outcomes for patients who underwent lysis with (n=120) or without (n=60) adjunctive endoscopy.\(^\text{18,19}\) Because these articles were coauthored by the same investigator, it is likely that they included overlapping patients. These studies also did not include a control group, and thus clinical conclusions regarding the contribution of endoscopy are not possible.

**Summary of Evidence**

For individuals who have epidural adhesions who receive lysis, the evidence includes RCTs. The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several RCTs have reported benefits for epidural lysis of adhesions compared with placebo treatment. Many of these trials were conducted at the same center. The interpretation of these trials is limited by differences in patients, populations, and treatment protocols. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There was also a large effect in the placebo group, raising questions whether some components of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would help determine whether specific treatment protocols have beneficial effects in specific patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.
Supplemental Information
Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians
The American Society of Interventional Pain Physicians (2013) updated its practice guidelines on the management of chronic spinal pain.20 The guidelines stated that “for lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to postsurgery syndrome and spinal stenosis.” Percutaneous adhesiolysis was recommended, “after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections.” The guidelines also indicated that spinal epidural endoscopic adhesiolysis was not discussed because there is limited evidence; moreover, the procedure is rarely used. The studies cited in the guidelines were evaluated for this evidence review.

American Pain Society
The American Pain Society’s (2009) clinical practice guidelines on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain did not discuss or draw conclusions on adhesiolysis.21 The guidelines stated that “for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms.”

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 unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<td>NCT01053572*</td>
<td>Evaluation of the Role of Steroids and 10% Hypertonic Sodium Chloride in Adhesiolysis in Post Lumbar Surgery Syndrome Patients: A Prospective, Randomized, Double-Blind, Equivalence, Controlled Trial of Percutaneous Lumbar Adhesiolysis</td>
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<td>Jan 2014 (completed)</td>
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<td>NCT01053273*</td>
<td>Comparative Effectiveness of Percutaneous Adhesiolysis and Caudal Epidural Steroid Injections in Low Back and/or Lower Extremity Pain: A Randomized, Equivalence Trial</td>
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<td>Jan 2014 (completed)</td>
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NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

References


**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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

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<th>Type</th>
<th>Code</th>
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<td>CPT®</td>
<td>62263</td>
<td>Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days</td>
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<td>62281</td>
<td>Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic</td>
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<td>62282</td>
<td>Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, lumbar, sacral (caudal)</td>
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<td>J7131</td>
<td>Unlisted procedure, nervous system</td>
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**Policy History**

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

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<td>10/07/2011</td>
<td>Policy revision without position change</td>
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<tr>
<td>08/06/2013</td>
<td>Policy revision without position change. Policy placed on No Further Routine Literature Review status</td>
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<td>01/30/2015</td>
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<td>01/01/2019</td>
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<td>01/01/2020</td>
<td>Annual review. No change to policy statement. Literature review updated.</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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.