



# Cigna Medical Coverage Policy

**Subject** Allograft Transplantation of the Knee

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## Coverage Policy

### Allograft Knee Ligament Reconstruction

Cigna covers knee ligament reconstruction (i.e., anterior cruciate, posterior cruciate, medial collateral, lateral collateral) using allograft tissue as medically necessary for the treatment of ligament injury (e.g., rupture, laxity) when ANY of the following conditions is met:

- Previous reconstruction has failed and requires revision.
- Surgical reconstruction requires the use of multiple ligament transfers.
- Individual has a medical condition (e.g., anatomic anomaly, prior knee injury or prior knee surgery) that precludes the use of autograft tissue.

Cigna does not cover knee ligament reconstruction (i.e., anterior cruciate, posterior cruciate, medial collateral, lateral collateral) using allograft tissue for ANY other indication because it is considered not medically necessary.

### Meniscal Allograft Transplantation

Cigna covers meniscal allograft transplantation as medically necessary for the treatment of meniscal injury (e.g., tears, derangement) when ALL of the following criteria are met:

- Individual is skeletally mature and not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., age less than 55)

- Preoperative imaging studies (or prior surgery) confirm absent or near absent meniscus
- Minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less)
- Normal knee alignment and stability (i.e., intact or reconstructed ACL) or stability will be achieved concurrently with meniscal transplantation
- Presence of severe, disabling knee pain unresponsive to standard medical management (e.g., nonsteroidal anti-inflammatory agents [NSAID's], analgesics, intra-articular injections, exercise, assistive device, bracing) for at least six months
- Knee pain is responsible for functional limitations that result in impaired, age-appropriate activities of daily living

**Cigna does not cover meniscal allograft transplantation for ANY other indication because it is considered not medically necessary.**

#### **Other Procedures**

**Cigna does not cover ANY of the following when used alone or as part of a ligament or meniscus reconstruction, regeneration, or transplantation, because each is considered experimental, investigational or unproven (This list may not be all inclusive):**

- autologous platelet-derived growth factors (e.g., platelet rich plasma)
- bioactive scaffolds (e.g., collagen meniscal implants)
- bioresorbable porous polyurethane
- Healing Response Technique
- meniscal prosthesis
- tissue-engineered menisci
- xenografts

## **General Background**

Allografts are grafts of tissues made available from a cadaver and are alternatives to autografts. Allografts spare autogenous tissue-harvesting and morbidity, decrease the required surgical time, and are available in a large choice of tissue size and type.

Allografts are preserved by deep freezing, freeze drying, or cryopreservation methods. Studies have shown that allograft tissue incorporates more slowly into the surrounding structure than autograft tissue and is not as rapidly remodeled. Additionally with allograft use, there is concern for decreased tensile properties with sterilization methods and preparation, and increased risk of inflammatory reactions and disease transmission.

Musculoskeletal allograft use is supported by the American Academy of Orthopaedic Surgeons (AAOS) as a therapeutic alternative to autograft use (AAOS, 2001). Since allograft transplant is a surgical procedure it is not subject to regulation by the FDA. However, the FDA does regulate certain aspects of tissue banking, and tissues are subject to FDA requirements for good tissue practices, infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices.

### **Anterior Cruciate Ligament (ACL) Allograft Transplantation**

The treatment of ACL injury includes but is not limited to nonoperative treatment, extra-capsular augmentation, and primary ligament repair to the anterior cruciate ligament with reconstruction. The current standard of care for patients with an ACL injury requiring reconstruction is autograft replacement with use of bone-patellar tendon-bone (BPTB) grafts, quadruple semitendinosus/gracilis tendon grafts, hamstring tendon grafts, or the quadriceps tendon grafts.

Individuals who may be considered candidates for allograft use include those where the nature and severity of the injury render patients unsuitable as candidates for autologous replacement, when there is failure of ACL reconstruction surgery and when multiligament reconstruction is necessary (Strickland, et al., 2003). Failed ACL reconstruction may result from recurrent instability, infection or arthrofibrosis. Recurrent instability may result

from technical failure, biologic failure, trauma, or from laxity in secondary ligamentous restraints (Wolf and Lemak, 2002).

The traditional, gold standard approach to ACL reconstruction with allograft focuses on the anteromedial bundle (i.e., single bundle) although another approach referenced in the medical literature is the double-bundle approach. Evidence in the published medical literature indicates that the single-bundle technique may lead to persistent anteroposterior laxity and a persistent pivot shift, contributing to residual instability (Zelle, et al., 2007; Tejwani, et al., 2007). Authors contend the double-bundle technique is more technically challenging and focuses on reconstruction of both the AM and PM bundles and may improve knee biomechanics and functional outcomes. Evidence indicates that short-term results for double-bundle reconstruction of the ACL are at least comparable to single-bundle in gaining stability. However, there are concerns with potential osteonecrosis of the femoral condyle, condyle fracture, graft impingement, and potential difficulty if revision is necessary (Zelle, et al. 2007). Some scientific evidence suggests the double-bundle approach improves stability and short-term functional outcomes (Shen, et al., 2007; Tejwani, et al., 2007; Seon, et al., 2008; Fu, et al., 2008, Sun, et al., 2014).

**Literature Review:** Outcome measures differ widely across studies with regard to surgical technique, tissue processing, patient populations and reported clinical outcomes for ACL reconstruction. Short-term improvements in pain and activity have been reported, and despite few studies supporting long-term results, many patients have done well clinically. Evidence in the published, peer-reviewed scientific literature for primary ACL reconstruction using allografts is mixed and primarily in the form of small case studies, without control groups, and retrospective clinical reviews lacking long-term outcomes and graft survivability. Some studies do support the use of allograft as an alternative for primary ACL reconstruction (Almqvist, et al., 2009; Sun, et al, 2009; Poehling, et al., 2005; Kleipool, et al., 1998; Harner, et al., 1996). Authors who prefer autogenous grafts for primary ACL reconstruction cite the risk of infection, the potential for immune response, and a potentially higher failure rate as reasons not to use allografts. Authors who prefer allografts cite less donor site morbidity, less postoperative pain, smaller incisions, less operative time and comparable results in terms of knee stability as reasons for preference of allograft use (Brautigan, et al., 2003). Barrett et al. (2005) reported an advantage of allograft for primary ACL reconstruction was a quicker return to sports; however, the disadvantages were increased laxity and higher incidence of failure in patients over age 40 years. The authors did not find allograft to be a superior graft compared to autograft. The results of a meta-analysis by Prodromos and colleagues (2007) confirmed a lower stability rate and higher failure rate when allograft was compared to autograft for primary ACL reconstruction. In addition, Krych et al. (2008) conducted a meta-analysis comparing results of BPTB autograft with BPTB allograft. Using the single-leg hop test, graft failure and functional outcome favored the autograft for ACL reconstruction. When the authors excluded grafts that were irradiated and chemically processed, there were no statistically significant differences in clinical outcomes among the studies reviewed. Two published systematic reviews found no statistically significant difference with allograft use compared to autograft use for primary ACL reconstruction (Foster, et al., 2010; Carey, et al., 2009). Foster and colleagues (2010) concluded that graft source has a minimal effect on the outcome of patients undergoing ACL reconstruction. Greenberg et al. (2010) reported the results of a combined prospective and retrospective study comparing allograft with autograft infection rates in primary ACL reconstruction and noted that there was no increase in clinical risk of infection with the use of allograft. In 2013, Hu et al. published the results of a meta-analysis comparing allografts to autografts for primary ACL reconstruction and reported that there were no significant differences in outcomes in terms of laxity, Lachman test, Pivot Shift, IKDC Scores, Lysholm Scores, Tegner Scores and clinical failures. Subgroup analysis provided some support that autograft allowed patients to return to higher levels of activity compared to allograft (Hu, et al, 2013). In general, the published results in the scientific literature regarding improved clinical outcomes are mixed. The routine use of allografts for primary ACL reconstruction is not supported by robust data and seems to offer few advantages; further investigation is needed to demonstrate long-term graft viability and improved health outcomes.

Evidence in the published, peer-reviewed scientific literature (Avery, 2004; Strickland, et al., 2003; Seibold, et al., 2003), along with support in medical textbooks (Brautigan, et al., 2003) and endorsement of the orthopaedic society (AAOS, 2007), indicates that ACL allograft transplantation is a safe and effective alternative to autograft for ACL revision, multiple ligament reconstruction or when autogenous tissue cannot be used.

### **Posterior Cruciate Ligament (PCL) Allograft Transplantation**

The posterior cruciate ligament is located in the back of the knee and connects the tibia to the femur. Although not as common as ACL injuries, injuries to the posterior cruciate ligament do occur and often result from falls or

automobile accidents—isolated tears are rare. Injuries may result in a partial or complete tear of the ligament and if left untreated may result in chronic patello-femoral and/or medial compartment arthrosis. Partial tears often heal with conservative measures and do not require surgery. Conservative treatment involves immobilization and physical therapy. If pain and instability develop despite treatment, surgery is recommended. Surgical reconstruction is also indicated for more severe injuries involving multiple ligaments and/or complete tears. Although repairs have been successful, due to poor healing properties of the PCL, reconstruction is often performed. Both autograft and allograft may be considered for reconstruction; advantages, disadvantages, and indications for graft type are similar to ACL reconstruction. Autologous graft options include BPTB, quadriceps and hamstring. Allograft options include Achilles tendon, BPTB, quadriceps and soft tissue grafts such as hamstring and tibialis or posterior tendons.

**Literature Review:** The use of PCL allograft transplantation is well-accepted in the published medical literature as an alternative to autograft when used for the treatment of multiple ligament reconstruction of the knee and/or when autogenous tissue cannot be used (AAOS, 2009; Heinzelmann and Barrett, 2009; Phillips, 2007).

### **Collateral Ligament Allograft Transplantation (Medial and Lateral)**

The collateral ligaments are located on the side of the knee and include a medial collateral ligament (MCL) and a lateral collateral ligament (LCL). The MCL connects the femur to the tibia and the LCL connects the femur to the fibula. Together these ligaments control the sideways motion of the knee. Injury typically results from forces that push the knee sideways or inwards. If untreated, injuries to the collateral ligaments can result in functional instability of the knee adversely affecting activities of daily living, work, and participation in sports.

**Medial Collateral Ligament (MCL):** MCL tears are more common than LCL tears, although LCL tears are more likely to result in instability. Isolated tears to the MCL generally do not require surgery, regardless of the degree of tear (Shelton, 2009, Nogalski, 2009). Even when associated with ACL injury, MCL tears are often treated conservatively. Surgical repair may be considered for severe injury or for multiligament reconstruction, however the optimal treatment recommendations for multiligamentous knee injuries involving the MCL are not clearly defined (Miyamoto, et al, 2009; Shelton, 2009). Open repair may be performed at the time of ACL reconstruction with repair and/or reconstruction of both ligaments, the ACL may be reconstructed with conservative treatment of the MCL injury or there may be operative management of the MCL and nonoperative management of the ACL..

**Lateral Collateral Ligament (LCL):** Isolated LCL injuries are rare (Nogalski, 2009). In all LCL injuries with instability however, primary repair should be considered (Shelton, 2009), particularly when combined with other ligament injuries. Unlike MCL tears, when associated with tears of the PCL or ACL, conservative treatment of LCL is not usually successful and reconstructive surgery of both injuries is required.

Conservative treatment of collateral ligament injury generally involves immobilization, protected weight-bearing with crutches, physical therapy and exercise, and nonsteroidal anti-inflammatory agents. Autograft and allograft tissues may be considered for reconstruction; surgery is performed through an open procedure, advantages, disadvantages, and indications for graft type are similar to ACL reconstruction. Autograft tissue commonly used for reconstruction of collateral ligaments includes the biceps femoris tendon, iliotibial band or for isolated LCL, semitendinosus tendon (i.e., hamstring tendon). Soft tissue allografts include semitendinosis, anterior tibialis, or posterior tibialis. When reconstruction is indicated, depending on the degree of injury, multiple autografts and/or allografts may be necessary for complex reconstructions.

**Literature Review:** There is a paucity of published data evaluating allograft as an alternative to autograft for reconstruction of the MCL or LCL. Evidence is primarily in the form of published reviews and textbook sources with few clinical trials (Shelton, 2009; Brinker, et al., 2009). The evidence indicates allograft tissues for both MCL and LCL reconstruction are commonly used as an alternative to autograft with successful surgical outcomes (Shelton, 2009; Brinker, et al., 2009). Medial collateral ligament allografts may remodel more rapidly and achieve greater average strength relative to control ligaments than ACL allografts (Brinker, et al., 2009). The indications for MCL and LCL allograft are similar to those for ACL and PCL reconstruction and include the treatment of multiligament knee injuries and/or when autogenous tissue cannot be used.

### **Meniscal Allograft Transplantation**

Meniscal allograft transplantation is a surgical procedure that has been proposed as treatment for a subset of patients with irreparable meniscal tears, or who have undergone previous total meniscectomy. The procedure

can be performed either arthroscopically or by open technique and involves grafting a donor meniscus into the knee of the patient. Graft types include fresh, fresh-frozen, deep-frozen, lyophilized (freeze-dried), and cryopreserved. Each of these methods has advantages and drawbacks. There is no consensus on the optimal donor menisci preservation method, and the application of different techniques in studies evaluating the efficacy of meniscal transplant precludes the ability to draw conclusions on which technique offers the best outcomes.

The goal of meniscal allograft transplantation is to restore knee function and prevent further joint degeneration by replacing the damaged or destroyed meniscus with allograft tissue having similar properties. Newer techniques employ a bone bridge or bone plugs attached to the allograft, which are implanted in the tibia and held in place by sutures to form a secure attachment for the donor meniscus. Other reconstructive procedures, such as anterior cruciate ligament (ACL) repair, are often performed at the same time as the meniscal transplant.

Patient selection criteria for meniscal allograft transplantation are not well-defined and vary across studies. However, candidates are generally young, with minimal degenerative changes, have a stable knee and normal axial alignment, and have failed to respond to conservative care.

Proposed indications for meniscal allograft transplant include one of the following:

- patients who have had total meniscectomy with early arthritis, to slow progression of degenerative changes
- patients with loss of anterior cruciate ligament, to stabilize the ACL
- patients undergoing osteotomy, to improve high tibial osteotomy and delay recurrent deformity
- prophylactic transplantation in asymptomatic patients, to prevent osteoarthritis that occurs with meniscectomy

Contraindications to meniscal allograft transplant include advanced articular degeneration, axial malalignment, flattening of the femoral condyle, and history of prior knee infection.

**Literature Review:** The general consensus in the published literature is that meniscal allograft transplantation may be indicated in a specifically defined subset of patients considered too young or active for arthroplasty. Based on the results of a systematic review, Matava (2007) concluded the procedure is indicated for young, physiologically active individuals (i.e., age < 50), with a previous complete or near complete meniscectomy, pain in the involved compartment prior to the development of moderate to severe arthrosis, and ideally less than 2–3 mm of joint space narrowing on weight-bearing anterior posterior (AP) or flexion AP, and/or limited chondral wear on arthroscopic visualization (Outerbridge Grade I or II). The authors noted ligamentous instability or axial malalignment should be addressed either prior to or concurrent with the procedure.

Data from short-term, mid-term term and a few long-term studies, primarily in the form of case reports, case series and retrospective reviews, have demonstrated the effectiveness of this procedure in alleviating pain and swelling and in improving knee function using various clinical outcome measures (Chang, et al, 2008; Sekyia, et al., 2007; Stone, et al., 2006; Rueff, et al., 2006; Cole, et al., 2006; Verdonk, et al., 2005; Noyes, et al., 2004). Elattar et al. (2011) reported the results of a meta-analysis of 44 published clinical trials evaluating meniscal allograft transplantation and concluded that despite the poor quality of data, meniscal allograft transplantation is a safe, reliable procedure for select individuals and it should not be considered experimental. Nevertheless, the evidence does not yet clearly support whether or not meniscal allografting can prevent or slow degenerative changes in the joint. The AAOS indicates for 80 to 90 percent of cases the transplants are effective in relieving activity-related pain and swelling, although long-term results are not yet available and it is not known whether the transplant will delay or slow the development of arthritis or other degenerative changes in the knee. Further studies are required to confirm whether or not meniscal transplant can prevent articular degeneration.

### **Emerging Technologies**

The use of adjunctive treatments such as autologous platelet-derived growth factors (e.g., centrifuged platelet aggregates) and other methods of promoting vascularization (e.g., Healing Response Technique [stimulates blood clot and subsequent scar formation]) have been utilized to assist in healing of tissues, however, there is insufficient evidence in the medical literature at this time, in particular with ACL/PCL reconstruction using allograft tissue or meniscal transplant, to support any improvement in health outcomes with the use of these adjunctive treatments.

Other options under investigation for meniscal regeneration and/or transplantation include tissue-engineered menisci, bioactive scaffolds (collagen meniscal implants, bioresorbable porous polyurethane), and synthetic devices (e.g., hydrogel) (Packer and Rodeo, 2009). Collagen meniscal implants have been proposed by some authors for filling defects of partial meniscectomy with functional repair tissue. Authors hypothesize the collagen meniscal implant may help prevent or delay the progression of osteoarthritis, protecting from degenerative joint disease. In addition, xenografts and meniscal prostheses are under investigation for use as an alternative approach to meniscal allograft transplantation (Verdonk, et al., 2007).

**U.S. Food and Drug Administration:** Menaflex™ (ReGen Biologics, Inc., Hackensack, NJ), was granted a 510(k) approval from the FDA in December 2008. Menaflex is a resorbable collagen matrix regulated by the FDA as a Class II device. The collagen scaffold is used to reinforce weakened soft tissue and provides a resorbable scaffold that is replaced by the patient's own tissue. According to the FDA, the scaffold was approved for the reinforcement and repair of soft tissue injuries of the medial meniscus (FDA, 2008); the device was not cleared for use in lateral meniscal injuries. However, in 2010 the FDA announced that the Menaflex device should not have been cleared for marketing in the U.S. and implemented a rescission. A rescission is an action by the FDA to revoke a marketing clearance later determined to be erroneous. The FDA concluded that the Menaflex device is intended to be used for different purposes and is technologically different from predicate devices (i.e., devices already on the market); these differences can affect the safety and effectiveness of the device.

**Literature Review:** Clinical studies evaluating these emerging technologies are few and safety and efficacy have not been proven. Alternatives being considered for cruciate ligament and/or meniscal regeneration and/or transplantation are in the early stages of development and consist of preliminary nonhuman trials and feasibility studies. While there is some evidence in the form of case series and case reports evaluating newer technologies, the data involves small patient populations evaluating short-term outcomes and there is no consensus opinion with regard to their widespread clinical application.

The use of platelet rich plasma to enhance soft tissue healing such as with tendon and ligament repair continues to be investigated, however controlled clinical trials are lacking and its use is not supported in the peer-reviewed published scientific literature (Hall, et al., 2013). Regarding anterior cruciate ligament reconstruction in particular, Nin et al.(2009) reported the results of a randomized trial (n=100) evaluating the effect of platelet-enriched gel on the inflammatory process following primary ACL reconstruction with BPTB allograft at two year follow-up. The authors acknowledged the therapeutic role of platelet derived growth factor currently remains unclear.

Evidence evaluating the safety and efficacy of collagen meniscal implants generally involve small patient populations. Some of the preliminary results are encouraging, suggesting meniscus regeneration occurs with an associated reduction in patient symptoms (Zaffagnini, et al., 2007). One prospective randomized trial (n=311) conducted by Rodkey et al. (2008) demonstrated the use of a collagen meniscus implant appeared safe, supported new tissue ingrowth and improved clinical outcomes (e.g., pain scores, Lysholm scores and patient assessment scores) in patients with chronic meniscal injury at an average follow-up of 59 months. The authors noted that patients who received the implant regained significantly more of their lost activity when compared to a group of patients who underwent repeat partial meniscectomy. A technology assessment conducted by the California Technology Assessment Forum (2010) concluded that the collagen meniscal implant for irreparable medial meniscus injury did not meet CTAF technology assessment criterion. The published evidence did not support improvement in health outcomes or that clinical improvement was attainable outside of the investigational setting. Although promising, long-term data supporting safety, efficacy and improved clinical outcomes, including prevention of osteoarthritis, are not yet available to support widespread use of this bioactive scaffold for meniscal regeneration.

### **Professional Societies/Organizations**

The American Academy of Orthopedic Surgeons published an advisory statement regarding the use of musculoskeletal tissue allografts (AAOS, 2001, [Revised 2006, 2011]). The AAOS supports the following:

- The use of musculoskeletal allograft as a therapeutic alternative to autograft use for appropriate patients. Allograft tissues should be acquired from facilities that demonstrate compliance, use well-

accepted banking methodology and good tissue practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards.

- The AAOS strongly favors on-site inspection and accreditation of tissue banks that demonstrate compliance with appropriate standards.
- The AAOS supports informed consent, for both the donor family and the recipient of human tissue, in accordance with local, state and federal laws and regulations.

The British Orthopedic Association, the British Association for Surgery of the Knee, and the British Orthopedics Sports Trauma Association published a consensus statement regarding best practice for primary isolated anterior cruciate ligament reconstruction (BOA, 2001; [Revised 2009]). According to the best practice guidelines, “Allograft tissue is most commonly used in revision or complex surgery, and that there is sterility, storage, and cross infection issues which should be understood by the surgeon and discussed with the patient.”

**Use Outside of the US:** Meniscal implant devices are available for use in countries outside the U.S. For example, Actifit™ (Orteq® LTD, United Kingdom), a biodegradable polyurethane scaffold designed to help repair meniscal tears, is currently approved for use in Europe. According to the manufacturer, NUsurface® Meniscus Implant (Active Implants® LLC, Memphis TN), a free-floating non-degradable polycarbonate-urethane device intended for total meniscal replacement, is also undergoing clinical trials in Europe, Israel, France, Germany, Belgium, the Netherlands, United Kingdom and Sweden.

### Summary

Evidence in the published, peer-reviewed scientific literature evaluating allografts for cruciate ligament (i.e., anterior [ACL], posterior [PCL]) and meniscal transplantation supports safety and efficacy in selected patients who have few other options. Further research is needed to confirm optimal allograft preservation method, long-term impact on net health outcomes, the immunological response to transplantation and whether or not these procedures prevent progression of arthritis. The published data evaluating adjunctive or alternative treatments (e.g., bioactive scaffolds, synthetics) for ACL/PCL reconstruction or meniscal transplant is insufficient to allow conclusions regarding safety, efficacy and improved health outcomes with the use of these technologies.

## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

### Knee Ligament Reconstruction

**Covered when medically necessary:**

CPT®*	Description
27405	Repair, primary, torn ligament and/or capsule, knee; collateral
27407	Repair, primary, torn ligament and/or capsule, knee; cruciate
27409	Repair, primary, torn ligament and/or capsule, knee; collateral and cruciate ligaments
27427	Ligamentous reconstruction (augmentation), knee; extra-articular
27428	Ligamentous reconstruction (augmentation), knee; intra-articular (open)
27429	Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction

HCPCS	Description
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<b>Codes</b>	
C1762	Connective tissue, human (includes fascia lata)

### **Meniscal Allograft Transplantation**

**Covered when medically necessary:**

<b>CPT<sup>®*</sup> Codes</b>	<b>Description</b>
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

**Experimental/Investigational/Unproven/Not Covered when used to report autologous platelet-derived growth factors, bioactive scaffolds (e.g., collagen meniscal implants), bioresorbable porous polyurethane, healing response technique, meniscal prosthesis, tissue engineered implants, or xenograft:**

<b>CPT<sup>®*</sup> Codes</b>	<b>Description</b>
29999	Unlisted procedure, arthroscopy
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed

<b>HCPCS Codes</b>	<b>Description</b>
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)
L8699	Prosthetic implant, not otherwise specified
P9020	Platelet rich plasma, each unit

**\*Current Procedural Terminology (CPT<sup>®</sup>) © 2013 American Medical Association: Chicago, IL.**

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