



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Allograft Transplant of the Knee, Anterior Cruciate, Posterior Cruciate, and Meniscal**

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Coverage Policy

CIGNA covers anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction using allograft tissue, as medically necessary when ANY of the following conditions are met:

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

CIGNA covers meniscal allograft transplant as medically necessary when ALL of the following criteria are met:

- The 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 transplant

- 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
- The knee pain is responsible for functional limitations that result in impaired, age-appropriate activities of daily living

CIGNA does not cover collagen meniscal (scaffold) implants because they are considered experimental, investigational or unproven.

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. With allograft use, there is concern for decreased tensile properties with sterilization methods and preparation, and increased risk of inflammatory reactions and disease transmission.

Allografts are preserved by deep freezing, freeze drying, or cryo-preservation methods. Studies have shown that allograft tissue incorporates more slowly into the surrounding structure than autograft tissue and is not as rapidly remodeled.

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 injuries ranges from nonoperative treatments to 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 due to 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 can be found in the published medical literature 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). Although limited to published reviews, case series and case reports, the 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).

Literature Review: In general, 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 (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). 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. 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. 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. 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 support 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), combined with publication in textbooks (Brautigan, et al., 2003) and endorsement of the orthopaedic society (AAOS, 2007), supports the use of ACL allograft transplantation as an alternative to autograft use 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).

Meniscal Allograft Transplant

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: Matava (2007) conducted a systematic review of the literature evaluating meniscal transplant as a treatment alternative for selected symptomatic patients with previous complete or near-complete meniscectomy. A total of 15 studies were reviewed (three were retrospective comparative studies, and 12 were retrospective case series). The mean follow-up of all studies was 55 months; the mean patient age was 33.4 years; and the primary indications were a complete or near-complete meniscectomy with pain in the involved compartment, before the development of moderate or severe arthrosis. Based on the data reviewed by the authors, they concluded the procedure is indicated for the following patients:

- young (i.e., < age 50) physiologically active patients
- previous complete or near-complete meniscectomy and pain in the involved compartment prior to the development of moderate to severe arthrosis
- 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)
- ligamentous instability or axial malalignment should be addressed either prior to or concurrent with the procedure

Other recommendations by the authors included that the graft be either fresh-frozen or cryopreserved, although no definitive measurement method has been accepted at this time; there is immediate or early re-establishment of knee motion and full weight-bearing by six weeks; and athletic activity be limited to light sports. Additionally, according to data in the studies evaluated, the success rate of the procedure demonstrated that 60% of the patients exhibited a successful result, although the range of success varied between 12.5% and 100%. Moreover, Matava reported that research is incomplete, and Level I and II evidence is needed before any definitive treatment recommendations can be made regarding the numerous factors involved in meniscal transplantation.

Success of meniscal allograft transplant is usually defined as pain relief, improved function, lack of meniscal symptoms, lack of rejection, and peripheral healing of the graft. Many subjects have had concurrent ACL injuries with joint instability, with both ligament repair and meniscal allograft transplantation being performed, making it difficult to evaluate the effect of allografting alone on joint pain and stability. Study populations are small making it difficult to draw firm conclusions. Outcome measures differ widely across studies; some use structural change measures such as the Outerbridge grading system for articular wear, while others employ functional rating scales, or a combination of functional and structural measures. Despite these and other confounding variables, 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. 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). 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, meniscal prostheses and autogenous grafts have been investigated as alternative treatment approaches to meniscal allograft transplant (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 is approved for the reinforcement and repair of soft tissue injuries of the medial meniscus (FDA, 2008); the device is not currently cleared for use in lateral meniscal injuries.

Literature Review: Clinical studies evaluating these emerging technologies are few. 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, the data involves small patient populations evaluating short-term outcomes and there is no consensus opinion with regard to their widespread clinical application. As a result, no strong conclusions can be made regarding safety and efficacy.

There is a paucity of evidence evaluating the safety and efficacy of collagen meniscal implants; these studies 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. 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). 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). According to the best practice guidelines, "Allograft tissue is most commonly used in revision or complex surgery, and that there are sterility, storage, and cross infection issues which should be understood by the surgeon and discussed with the patient."

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: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction

ICD-9-CM Diagnosis Codes	Description
715.90	Osteoarthritis, unspecified whether generalized or localized, unspecified site
717.0-717.49	Tear/Derangement Meniscus
717.7	Chondromalacia patellae
717.83	Old disruption of anterior cruciate ligament
717.84	Old disruption of posterior cruciate ligament
730.10	Chronic osteomyelitis, site unspecified
730.16	Chronic osteomyelitis, lower leg
732.7	Osteochondritis dissecans
836.0-836.2	Tear cartilage or meniscus - Knee
844.2	Sprain and strain of cruciate ligament

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
L8699 [†]	Prosthetic implant, not otherwise specified

[†] **Note:** Experimental, investigational, unproven and not covered when used to report collagen meniscal (scaffold) implants.

*Current Procedural Terminology (CPT[®]) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0071	Allograft Transplant of the Knee, Anterior Cruciate and Meniscal
Great-West Healthcare	7/12/2006	06.343.01	Meniscal Allograft Transplantation

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.