The Real Life Problem:

Getting Your Cartilage Procedure Approved- Dealing with Insurers

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Current state of insurance industry

The economy has severely impacted the financial reserves of insurance companies. As a result, they have reinstated all utilization review programs. In addition, there is a massive consolidation in the industry and we will eventually be left with 5 major insurers/ claims administrators (Highmark, Wellpoint, Humana, United and Cigna). What is currently essentially state run franchises (Blues) will, by 2011, become essentially national in scope and therefore use the same criteria for determination of benefits. Is this good or bad?

What can the Physician do?

1. Get to know the local insurance company medical director
2. Become an advisor or Orthopaedic consultant to the company
3. Request a face to face meeting with the medical director
4. Write letters
5. Use evidence based medicine (evidence is important but cost is still more important)
6. Understand that CPT codes have a long vetting process and AMA considers an established CPT code adequate evidence for insurance coverage. However, insurers do not feel the same way!
7. CPT codes useful in cartilage repair:
    a. 27412: ACI
    b. 27415: Open OCA
    c. 29886: OAT
    d. 29879: microfracture
    e. 29868: meniscal transplant
    f. 27457: HTO
    g. 27450: DFO

Review the coverage policies for cartilage repair (available online) and use the correct descriptive terminology in your clinical data

1. Age 15-50
2. At least 6 months of symptoms
3. Normal joint space
4. No inflammation or osteoarthritis
5. BMI < 30
6. Stable ligaments
7. Adequate meniscus

8. No malalignment
9. No “kissing lesions”
10. Grade 3-4 lesion of “appropriate size”
    a. <1.5 cm for autograft
    b. >1.5 cm for ACI
    c. >2 cm for allograft
    d. Grade 1-2 for meniscus transplant

The following is an typical example of current medical policy for treatment of cartilage defects:

Anthem

Medical Policy

Subject: Treatment of Osteochondral Defects of the Knee and Ankle
Policy #: SURG.00093 **Current Effective Date:** 01/14/2009
Status: Reviewed **Last Review Date:** 11/20/2008

Description/Scope

This document addresses indications for autologous chondrocyte transplant (ACT), osteochondral allograft, osteochondral autograft (OATS/mosaicplasty) and the use of resorbable synthetic bone filler materials for the treatment of cartilaginous defects of the knee and ankle.

NOTE: This document does not apply to allogeneic meniscal implantation. (See TRANS.00015 *Meniscal Allograft Transplantation of the Knee*.)

Position Statement

Medically Necessary:

Note: *Members must meet the disease specific criteria as well as the general patient selection criteria as set forth in this document for the specific procedure to be considered medically necessary.*

- Autologous chondrocyte transplantation (ACT), also known as autologous chondrocyte implantation (ACI), to treat cartilaginous defects of the knee is considered **medically necessary** when **all** of the following criteria are met:
    1. Inadequate response to prior surgical therapy to correct the defect;
    2. Size of the cartilage defect is between 1.5 and 10 cm squared in total area;

3. The defect involves only the cartilage and not the subchondral bone, unless ACT is being used to treat osteochondritis dissecans associated with a bony defect of less than 7 mm in depth which has failed prior conservative treatment. (Lesions due to osteochondritis dissecans associated with a bony lesion greater than 7 mm in depth must first undergo corrective bone grafting followed by a 6 month postoperative period to allow for healing of the cone underlying the defect).
4. No known history of allergy to the antibiotic Gentamicin;
5. No known sensitivities to bovine cultures;
6. Condition involves a focal, full thickness, (grade III or IV) isolated defect of the knee involving the weight bearing surface of the medial or lateral femoral condyles or trochlear region caused by acute or repetitive trauma.
7. All criteria listed in the "General Patient Selection Criteria" section below are met.

- Osteochondral **allograft** transplantation to treat cartilaginous defects of the knee is considered **medically necessary** when **all** of the following criteria are met:
    1. Arthroscopic examination results which detail the size, location and type of the defect;
    2. Size of the cartilage defect is greater than or equal to 2 cm squared in total area;
    3. Condition involves a focal, full thickness, (grade III or IV) isolated defect of the weight bearing surface of the medial or lateral femoral condyles or trochlear region caused by acute or repetitive trauma;
    4. All criteria listed in the "General Patient Selection Criteria" section below are met.
- Osteochondral **autograft** transplantation, either osteochondral autograft transplant (OATS) or autologous mosaicplasty to treat cartilaginous defects of the knee is considered **medically necessary** when **all** of the following criteria are met:
    1. Arthroscopic examination results which detail the size, location and type of the defect;
    2. Size of the cartilage defect is between 1.0 to 2.5 cm squared in total area;
    3. Condition involves a focal, full thickness, (grade III or IV) isolated defect of the knee involving the weight bearing surface of the medial or lateral femoral condyles or trochlear region caused by acute or repetitive trauma;
    4. All criteria listed in the "General Patient Selection Criteria" section below are met.

General Selection Patient Criteria

For **all** procedures listed above, **all** of the General Patient Selection Criteria listed below must be met:

1. Age 15-50 years;
2. Persistent symptoms of disabling localized knee pain for at least 6 months, which have failed to respond to conservative treatment;
3. An intact meniscus is present;
4. The lesion must be discrete, single and unipolar (involving only one side of the joint. "Kissing lesions" are an exclusion);

5. The lesion is largely contained with near normal surrounding articular cartilage and articulating cartilage, (grades 0, 1, 2);
6. A normal joint space is present;
7. No active infection is present;
8. No inflammation or osteoarthritis is present in the joint;
9. The knee is stable, with normal alignment (corrective procedure may be performed in combination with or prior to transplantation);
10. Patient is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation;
11. No history of cancer in the bones, cartilage, fat or muscle of the affected limb;
12. Body Mass Index (BMI) less than or equal to 30.

Attachments to this document are provided for each procedure listed above. All information identified on the appropriate sheet must be provided with requests for determination of medical appropriateness. The attachments themselves are provided for reference/guidance purposes.

- Attachment A – "*Autologous Chondrocyte Transplantation of the Knee - Medical Review Sheet*"
- Attachment B – "*Osteochondral Allograft Transplantation of the Knee - Medical Review Sheet*"
- Attachment C – "*Osteochondral Autograft Transplantation of the Knee - Medical Review Sheet*"

Investigational and Not Medically Necessary:

Use of autologous chondrocyte transplantation, osteochondral allograft transplantation, or osteochondral autograft transplantation (OATS/mosaicplasty) for joints other than the knee is considered **investigational and not medically necessary,** including but not limited to the ankle (talus).

Use of autologous chondrocyte transplantation, osteochondral allograft transplantation, and osteochondral autograft transplantation (OATS/mosaicplasty) are considered **investigational and not medically necessary** when the criteria cited above are not met.

Non-autologous mosaicplasty using resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the knee or ankle is considered **investigational and not medically necessary.**

Rationale

Autologous Chondrocyte Transplantation (ACT)
The majority of the literature concerning autologous chondrocyte transplantation (ACT) for the knee consists mostly of small uncontrolled case series with patients whose lesions varied greatly in size, type and location. Recently, as part of a post-approval commitment required by the Food and Drug Administration (FDA), Genzyme conducted a prospective, longitudinal, multi-center Study of the Treatment of Articular Repair (STAR). This study assessed the effectiveness of

autologous chondrocyte implantations in patients who had failed prior treatments for articular cartilage defects of the knee. (Zaslav 2008). One hundred fifty-four patients who had failed previous treatment for articular cartilage defects of the knee (medial condyle, lateral condyle, or trochlea) received autologous chondrocyte transplantation. Failed prior surgical procedures included debridement, subchondral drilling, osteochondral autograft, microfracture and abrasion arthroplasty. Follow-up period was 48 months. Outcome measures included change in baseline knee function, knee pain, quality of life and general patient health using standardized measurement tools (Modified Cincinnati Overall Knee Score, VAS, KOOS, SF36). The duration of the benefit of the autologous chondrocyte transplantation was compared with the benefit duration of the prior failed non-autologous chondrocyte transplantation procedure using an independent observer and objective criteria for treatment failure. The mean age for the cohort was 34.5 (± 8.1 years) and mean BMI was 27.9 ± (4.6). The chondral defect(s) size in this cohort was moderate to large. Only 12% had defects <2cm² while 51% were ≥ 4cm² with a mean lesion size at implant of 4.6 cm². One limitation of this study is its lack of a concurrent, randomized controlled comparison with other therapies.

One hundred twenty-six patients (82%) completed the protocol and 28 patients (18%) discontinued the study prior to completion. The majority of patients (76%) reported significant improvements in knee function and symptoms, including activities of daily living and recreational activities. Seventy-six percent of the study participants were deemed a treatment success, while 24% were considered treatment failures. Mean improvements for all outcome measures were observed from baseline to all time points ($P < .001$). No significant difference was noticed between patients whose primary surgery had been a marrow-stimulating procedure and those whose primary procedure had been a debridement alone. The median difference in the duration of benefit between the failed prior non-autologous chondrocyte transplantation treatment and the autologous chondrocyte transplantation was 31 months ($P < .001$). Seventy-six patients (49%) had subsequent surgical procedures(s), most were arthroscopic. Researchers concluded that individuals with moderate to large chondral lesions with failed prior cartilage treatments can expect sustained and clinically significant improvement in pain and function after autologous chondrocyte transplantation. A subset analysis of the outcome of those patients with BMI >30 and/or older than 50 years of age is not provided.

Researchers have also been investigating the use of ACT for osteochondral defects of the ankle. A review of the peer-reviewed scientific literature did not reveal any published controlled trials that compared the efficacy and safety of ACT for the repair of osteochondral defects of the ankle with standard therapies including subchondral drilling or microfracture. Schafer (2003) reviewed the literature and identified four case series reports which totaled 40 patients treated for cartilage lesions of the ankle joint with chondrocyte transplant. Results of these case series were promising although follow-up was limited (18 to 33 months) and outcome measures were varied. It was concluded that given the limited number of patients studied, it was not possible to define indications for ACT of the talus and no conclusions could be made with regard to which specific type and size of defect would be appropriate for cartilage repair of the ankle with chondrocyte transfer.

Giannini and colleagues (2008) conducted a single-center case series study in Italy of 46 patients who underwent autologous chondrocyte implantation for repair of type II or IIA post-traumatic

talar dome lesions from 2001 – 2004. Researchers investigated the outcome of autologous chondrocyte implantation using laboratory expanded autologous chondrocytes grown on a hyaluronan-based scaffold (Hyalograft C®, Fidia Advanced Biopolymers, Abano Terme, Italy). During the first phase of the surgery, ankle arthroscopy was performed and cartilage was harvested from the detached osteochondral fragment or from the margins of the lesion. Lesions deeper than 5 mm were first filled with autologous cancellous bone. Chondrocytes were then cultured using the Hyalograft C® scaffold. In a second surgical procedure, the lesion was arthroscopically implanted with the Hyalograft C® –cultured chondrocyte patch. The American Orthopaedic Foot and Ankle Society (AOFAS) score was used to clinically evaluate the patients preoperatively and at 12 and 36 months after surgery. At a mean time interval of 18 months, the first 3 patients underwent a second-look arthroscopy with cartilage harvested from the implant and histological examination.

Preoperatively, the mean AOFAS rating was 57.2 +/- 14.3. At the 12-month follow-up, the mean AOFAS rating was 86.8 +/- 13.4 ($P < .0005$), compared to 89.5 +/- 13.4 ($P < .0005$) at 36 months after surgery. Clinical results varied based on the age of patients and previous operations for cartilage repair. Histological examination in the first three patients implanted revealed the regeneration of hyaline-like cartilage. At the time of this review, the Hyalograft C® implant has not been approved by the U.S. Food and Drug Administration (FDA) for marketing the United States.

While autologous chondrocyte transplantation is a promising technology, due to the limited scientific evidence available, conclusions regarding the efficacy, safety and durability of ACT as a treatment for osteochondral defects of the ankle cannot be made at this time.

Osteochondral Allograft
The current medical literature regarding osteochondral allografting of the knee shows that this procedure has demonstrated acceptable long-term results measured by reduction in pain, improved physical function, and sustained osteochondral graft viability. Several long-term studies have demonstrated long-term donor osteochondral grafts viability up to 10 years and one as long as 14 years with a success rate reported at 63%. Shorter term studies have reported success rates of between 75-80%. The evidence indicated that osteochondral allografting has been highly successful in patients with chondral defects resulting from trauma or osteochondritis dissecans, but less so in patients with osteonecrosis or steroid induced lesions. Finally, the literature is unanimous in emphasizing the importance of proper patient selection including adequate joint stability and alignment.

Experience with osteochondral allografts for talar cartilage defects is limited to a small number of case series (Gross, 2001, Kim, 2002, and Tontz 2003) totaling 28 patients. The results reported from these small case series using varied outcome measures have been mixed and do not permit conclusions with respect to the efficacy, durability and safety of osteochondral allografts in the treatment of osteochondral defects of the ankle.

Osteochondral Autograft Transplantation (OATS/Mosaicplasty)
The medical literature regarding osteochondral autograft transplant (OATS) and mosaicplasty of the knee consists mostly of single-institution case series focusing on chondral lesions of the

knee. These studies include heterogeneous populations of patients, some of whom are undergoing treatment for additional abnormalities such as ligament or meniscal repair. Therefore, it is not known whether improvement in symptoms can be attributed to the osteochondral autografting or other components of the surgery. In addition, there are very few studies currently available comparing the results of osteochondral autografting with other established therapies. However, there is a large collection of small studies demonstrating that osteochondral autografting procedures, including mosaicplasty, confer significant benefit in terms of both functional improvement and pain relief in a population where alternative therapies are limited. Several studies have evaluated the long term viability of osteochondral autografts with histological examinations at up to three years post-transplant. The vast majority of these studies report finding stable hyaline cartilage at the operative site. In almost all articles published, patients with misalignment, arthritis, unstable knees, and missing or compromised meniscus, were excluded from the studies due to concerns regarding suitability for the procedures. Finally, there is little agreement on any limitations regarding the size of chondral defects that are appropriate for these procedures. The medical literature suggests that mosaicplasty might be appropriate for lesions ranging from as little as 1.5 cm^2 to as large as 16 cm^2. Most recent evidence supports the position that the larger the chondral defect, the higher the complication rate and rates of donor site morbidity. Thus, at this time it may be appropriate to limit these procedures to small to moderate lesions, between 1.1 and 2.5 cm^2, until further evidence is available to fully evaluate this issue.

Studies of the use of autografts in the treatment of osteochondral lesions of the ankle talus are largely case series in design. Hangody et al (2001) reported the clinical outcome of 36 consecutive patients followed for two to seven years after autologous transplantation mosaicplasty from a non-weight bearing portion of the knee to the ipsilateral ankle talus. The average size of the defects treated was one centimeter. Patients with osteoarthritis were excluded from the study. Most patients (29 of the 34) had previous surgical intervention(s) including arthroscopic debridement, loose body removal, drilling, curettage and/or microfracture. All patients achieved full range of motion within eight weeks following surgery. Average follow-up for the entire series was 4.2 years (2-7 years). Five patients were followed to seven years. No patients at the end of follow-up showed loosening of the graft. Using a standardized scoring tool (Hannover), results of 28 cases were rated "excellent", six were rated "good", and two "moderate". There were no cases with long term donor site morbidity.

Scranton (2006) published a retrospective case series study of the outcomes of 53 consecutive patients with Type-V talar osteochrondral defects treated with autograft plugs harvested arthroscopically from the ipsilateral knee. The type V lesions treated were confined to those with a diameter of 8 mm to 20 mm confirmed by CT or MRI. The majority of patients (32 or 64%) had previously undergone one or more prior ankle surgical procedures including debridement, curettage, drilling, internal fixation or grafting. A total of 40 patients had symptoms for more than one year. The majority of patients had also received at least six months of prior conservative treatment which included rest, immobilization and physiotherapy without improvement. Two patients were lost to follow-up and one patient died of unrelated cause one year following the procedure. Of the 50 patients evaluated at a mean follow-up of 36 months (24-83), 45 (90%) achieved "good" to "excellent" score in the Karlsson-Peterson Ankle questionnaire and were satisfied with the outcome. The outcome questionnaire used was a

standardized assessment of eight functional outcome measures of ankle stability, pain, swelling, stiffness, activities of daily living (ADL), stair climbing, running and use of ankle supports (Karlsson J. 1991). Although each patient had presented with what were described as disabling symptoms of swelling, catching or pain with activity refractory to conservative therapies, baseline Karlsson-Peterson Ankle scores were not measured.

Kreuz et al (2006) recently reported a prospective case series of 35 patients with Stage III or IV (cystic) (Loomer 1993) osteochondral talar lesions treated with mosaicplasty using autologous grafts harvested from a low weight bearing area of the ipsilateral talar articular facet. All patients had previously failed surgery on the same ankle which included drilling, removal of loose body, or abrasion arthroplasty. Mean lesion size was 6.3 mm in diameter (4 mm-10 mm). Twenty patients required either a malleolar or tibial wedge osteotomy to access the lesion, while 15 had either an anterior or postero-lateral approach without osteotomy. The American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot survey was administered before the procedure and at the end of follow-up. Mean follow-up period was 49 months. The AOFAS Ankle-Hindfoot survey is a recognized method of reporting the clinical status of the ankle and foot. This tool incorporates both subjective and objective clinical measures of pain, function, range of motion, and alignment. In this case series, the mean preoperative AOFAS score was 54.5 of 100 points (47-60). Overall improvement between pre-operative and follow-up (mean 49 months) AOFAS scores was 35.4 points (26-48) with a mean follow-up score of 89.9 ($P \leq 0.017$). AOFAS score in patients not requiring osteotomy rose by 39 points ($P=0.0001$), with malleolar osteotomy by 30.1 points ($P=0.017$), with tibial wedge osteotomy by 34.9 points ($P=0.0002$), and with postero-lateral approach by 32 points (P not reported).

A recent randomized controlled trial comparing the outcomes of chondroplasty, microfracture, and osteochrondral autograft transplantation (OAT) in 32 patients with osteochondral lesions of the talus was reported (Gobbi 2006). Patients with Ferkel class 2b, 3, and 4 osteochondral lesions of the talus were randomized to one of the three treatments and outcomes measured with the AOFAS scale and a subjective assessment numeric evaluation tool (SANE) rating. Eleven patients had chondroplasty, 9 patients had microfracture, and 12 patients had OAT. Mean time to follow-up was 53 months (24-119). There were no differences at 12 and 24 months in AOFAS scores or in SANE ratings at the end of follow-up between the three groups of patients studied. This recent study is limited by size, but is one of the few which used a randomized, prospective design with comparison of the varied treatment options available for the treatment of osteochondral lesions of the talus. The study did not include a non-surgical control group.

More recently, there has been interest in the use of the PolyGraft® material (polylactide-co-glycolide (PLG) copolymer, calcium sulfate, polyglycolide (PGA) fibers and surfactant) to repair osteochondral defects. The only published, peer-reviewed-scientific literature found on PolyGraft® consisted of seven small studies carried out on animals. There were no published peer-reviewed clinical trials on humans. Therefore, there is insufficient scientific evidence to allow conclusions regarding the safety and efficacy of the use of this technology in humans at this time.

Background/Overview

Autologous Chondrocyte Transplantation (ACT)
Autologous chondrocyte transplantation (ACT) has been studied as a possible method of repairing symptomatic defects of the articular cartilage of the knee. Healthy cartilage cells (chondrocytes) are obtained from the patient via arthroscopy. These cells are then isolated and cultured in a laboratory for four to five weeks. Surgery is performed to remove the chondral defect. This area is then covered with a small bone flap, taken from the tibia (shin bone), and the cultured chondrocytes are injected under the flap.

Genzyme Tissue Repair markets its autologous chondrocyte product under the name Carticel™. Carticel™ is currently approved by the Food and Drug Administration (FDA) for the "repair of symptomatic, cartilaginous defects of the femoral condyle (medial, lateral or trochlear), caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure".

Osteochondral Allograft
Osteochondral allografting involves transplantation of a piece of articular cartilage and attached subchondral bone from a cadaver donor to a damaged region of the articular surface of a joint. This procedure is considered one of the alternatives for repairing articular cartilage defects. The donor grafts consist of the articular surface with an underlying segment of bone that helps to secure the graft to the underlying host bone.

Osteochondral Autograft Transplantation (OATS/Mosaicplasty)
In osteochondral autograft mosaicplasty, a series of small bone and cartilage grafts are harvested from a non-weight-bearing region of the joint during an arthroscopic procedure and then transplanted into the cartilage defect where they contribute to regeneration and repair of the articular surface while the bone remains undisturbed. The bone base of the transplant acts as an anchor and enables secure fixation and integration with surrounding bone. In mosaicplasty, this is done in a mosaic pattern. The OATS procedure is similar to mosaicplasty, involving the use of a larger, single plug that generally fills the entire osteochondral defect.

Non-autologous mosaicplasty has been proposed as an alternative to conventional mosaicplasty. In non-autologous mosaicplasty a series of small holes are drilled into the area of the osteochondral defect. The holes are then gently packed with a synthetic polymer. The synthetic material provides a bone void filler and provides a scaffold for the growth of new bone. The synthetic graft is gradually resorbed by the body and replaced with bone. The proposed advantage of this procedure over conventional osteochondral autograft transplantation is the elimination of the need for harvesting bone and cartilage from a donor graft site

Smith & Nephew, Inc., (formerly OsteoBiologics, Inc. [ODI]), markets non-autologous bone filler product under the name of PolyGraft® which consists of polylactide-co-glycolide (PLG) copolymer, calcium sulfate, polyglycolide (PGA) fibers and surfactant. According to the FDA label indications, PolyGraft® can be used "to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure" and may be "combined with autogenous blood products, such as platelet rich plasma, and/or sterile fluids, such as saline or Ringer's solution". Smith & Nephew Inc. manufactures several products which contain the

PolyGraft® material including, but not necessarily limited to, TruFit® BGS Plugs and the TruFit® granules.

As mentioned above, research on the use of non-autologous bone filler materials has been limited to small studies on animals, and there is insufficient scientific evidence to allow conclusions regarding the safety and efficacy of the use of this technology in humans at this time.

Definitions

Arthroscopic surgical repair: a surgical procedure using specialized video-guidance and instruments to operate on a joint without opening the surgical area in the traditional manner

Articulating cartilage: a tough, spongy material that covers the ends of bones and may be present in the areas between bones (joints) to protect the bones and act as a shock absorber

Autologous chondrocyte transplantation (ACT): also known as autologous chondrocyte implantation (ACI); this is a surgical procedure where cartilage cells are removed from a patient and grown in a lab to create more cells; these cells are then implanted into the knee at areas where there are cartilage defects, in the hope that the transplanted cells take hold and heal the defects

BMI (body mass index): the weight in kilograms, divided by height in meters squared *Note: to convert pounds to kilograms, multiply pounds by 0.455, to convert inches to meters, multiply inches by 0.0254.

Femoral condyle: the end of the thigh bone nearest the knee

Meniscus: a piece of cartilage, a tough, spongy material, that lies in the knee joint, between the ends of the bones which acts as a shock absorber

Mosaicplasty (autologous): a surgical procedure where one or several plugs of bone, along with its articular cartilage, is taken from one area of the knee of a patient and transplanted to another part of the knee on the same patient

Mosaicplasty (non-autologous): a surgical procedure where one or several plugs of defective bone, along with its articular cartilage, is removed and replaced with synthetic material

Osteoarthritis: a degenerative condition of the cartilage in the joints resulting in loss of motion and pain

Osteochondral allograft transplantation: a surgical procedure where a portion of bone, along with its articular cartilage, is taken from another person and transplanted into the patient

Osteochondral autograft transplant (OATS): a surgical procedure where a portion of bone, along with its articular cartilage, is taken from one area of a patient and transplanted to another location on the same patient

Osteochondritis dissecans: a condition where a loss of the blood supply to an area of bone underneath a joint surface results in the affected bone and its covering of cartilage gradually loosening and causing pain

Subchondral bone: bone that lies directly underneath articulating cartilage

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage or these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

27412	Autologous chondrocyte implantation, knee
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) includes harvesting of autograft[s])
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft)
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

HCPCS

J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

ICD-9 Diagnosis

717.0-717.9	Internal derangement of knee
732.7	Osteochondritis dissecans (knee)
733.90	Disorder of bone and cartilage; unspecified

When services are Investigational and Not Medically Necessary:
For procedure codes listed above when criteria are not met, for all other diagnoses not listed, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

CPT

28446	Open osteochondral autograft, talus (includes obtaining graft[s])
29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (when code used to describe arthroscopic osteochondral talus graft)
	No specific code for autologous chondrocyte implantation or osteochondral allograft of the ankle
	No specific code for autologous chondrocyte implantation, osteochondral autograft or osteochondral allograft of other joints
	No specific code for the use of resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the knee or ankle

ICD-9 Diagnosis

All diagnoses

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/20/2008	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated review date, rationale, references and history sections.
Reviewed	11/29/2007	MPTAC. Minor revisions to language in position statement. No substantive change to patient selection criteria. Updated review date, background/overview, references and history sections. Updated coding section with 01/01/2008 CPT/HCPCS changes. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary".
Revised	12/07/2006	MPTAC. Changed title to "Treatment of Osteochondral Defects of the Knee and Ankle." Revised position statement to address the use of resorbable synthetic bone filler material. Rationale and Background/Overview sections to address repair of osteochondral defects of the ankle and the use of resorbable synthetic bone filler material. References updated.
Revised	09/14/2006	MPTAC review. Revised medically necessary criteria for ACT, OATS, Mosaicplasty and osteochondral allograft procedures. Coding updated: removed CPT 0012T, 0013T, HCPCS S2113 deleted 12/31/04 (see historical policy). Document re-numbered from TRANS.00001 to SURG.00093.
Reviewed	03/23/2006	MPTAC annual review. Updated references.
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	06/16/2003	TRANS.00001	Transplantation for Chondral Defects
WellPoint Health Networks, Inc.	06/24/2004	3.07.03	Autologous Chondrocyte Transplantation
	06/24/2004	3.07.17	Osteochondral Autografts in the Treatment of Articular Cartilage Lesions
	06/24/2004	3.07.22	Osteochondral Allografting of the Talus
	09/23/2004	Clinical Guideline	Autologous Chondrocyte Transplantation

Note: this form is provided as a guide for collection of information only **Attachment A**

Autologous Chondrocyte Transplantation of the Knee
Medical Review Sheet (use of this form is optional)

Patient Name: _____

Requesting Physician_____

Subscriber No: _____

Office Telephone No:_____

1. Has patient had symptom duration > 6 months?
   Yes_____ No _____
2. Has the patient had an inadequate response to prior surgical therapy to correct the defect?
   Yes_____ No _____
   If yes, please indicate which surgical therapy was performed. _____
3. Size of cartilage defect: _____ (must be between 2 and 10 cm^2)
4. Is the lesion full thickness, grade III or IV, isolated to the femoral condyle, and discrete, single and unipolar?
   Yes_____ No _____
5. Is there bone involvement?
   Yes_____ No _____
6. Is normal joint alignment documented on x-rays?
   Yes_____ No _____
7. Is osteoarthritis present in the knee?
   Yes_____ No _____
8. Confirm the absence of the following:
   _____ "Kissing Lesions"
   _____ Total meniscectomy or abnormal meniscus in affected knee
   _____ Infection in the knee
   _____ Inflammatory or osteoarthritis of the knee
   _____ Allergy to gentamicin or bovine cultures
   _____ BMI >= 30

9. Is the patient willing to comply with post-operative weight-bearing restrictions and rehabilitation?
   Yes_____ No _____
   (Questions 10 & 11 are for informational purposes and are not a part of medical necessity determination)
10. Has the surgeon completed the Genzyme Tissue Repair Surgeons Training program?
    Yes_____ No _____
11. If the answer to #10 is no, how many surgeries has the surgeon performed/assisted in? _____

Note: this form is provided as a guide for collection of information only

Attachment B

Osteochondral *Allograft* Transplantation of the Knee
Medical Review Sheet

Patient Name: _____

Requesting Physician_____

Subscriber No: _____

Office Telephone No:_____

1. Patient Age: _____ (must be 15-50)
2. Date of the arthroscopic knee examination. _____

   Please answer questions 3 – 6 based on the findings of the arthroscopic knee examination.
   Note: It is understood that because the arthroscopic knee examination may be performed in conjunction with the osteochondral allograft transplantation procedure, there may be instances where this information is not known until after the transplantation has been completed.

3. Size of cartilage defect: _____ (must be ≥ 2 cm^2)
4. Is the lesion full thickness, grade III or IV, discrete, single and unipolar?
   Yes_____ No _____
5. Is normal joint alignment documented on x-rays?
   Yes_____ No _____
   If "No" - must be performed at the time of surgery.
6. Is osteoarthritis present in the knee?
   Yes_____ No _____
7. Is the patient willing to comply with postoperative weight-bearing restrictions and rehabilitation?
   Yes_____ No _____
8. Confirm the absence of the following:
   _____ "Kissing Lesions"
   _____ Total meniscectomy or abnormal meniscus in affected knee
   _____ Infection in the knee
   _____ Inflammatory or osteoarthritis of the knee

Note: this form is provided as a guide for collection of information only

Attachment C

Osteochondral *Autograft* Transplantation of the Knee
Medical Review Sheet

Patient Name: _____

Requesting Physician_____

Subscriber No: _____

Office Telephone No:_____

1. Patient Age: _____ (must be 15-50)

2. Date of the arthroscopic knee examination. _____

   Please answer questions 3 – 6 based on the findings of the arthroscopic knee examination.

   Note: It is understood that because the arthroscopic knee examination may be performed in conjunction with the osteochondral autograft transplantation procedure, there may be instances where this information is not known until after the transplantation has been completed.
3. Size of cartilage defect: _____ (must be between 1.0 and 2.5 cm^2)
4. Is the lesion full thickness, grade III or IV, discrete, single and unipolar?
   Yes_____ No _____
5. Is normal joint alignment documented on x-rays?
   Yes_____ No _____
   If "No" - must be performed at the time of surgery.
6. Is osteoarthritis present in the knee?
   Yes_____ No _____
7. Is the patient willing to comply with postoperative weight-bearing restrictions and rehabilitation?
   Yes_____ No _____
8. Confirm the absence of the following:
   _____ "Kissing Lesions"
   _____ Total meniscectomy or abnormal meniscus in affected knee
   _____ Infection in the knee
   _____ Inflammatory or osteoarthritis of the knee

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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 eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.