OSTEOCHONDRAL ALLOGRAFTS AND AUTOGRAFTS

Medical Policy: 07.01.65

Original Effective Date: May 2014

Reviewed: August 2018

Revised: August 2018

BENEFIT APPLICATION:

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available.

DESCRIPTION:

Cartilage injuries are described and classified based on the location of injury, size of the injury, and the depth of the injury. The type of surgery necessary largely depends on the aforementioned factors. The procedure is generally an outpatient surgical procedure performed under general anesthesia. Generally performed through arthroscopy (when using an autograft, which is your own body's tissue) or performed as an open surgery for larger lesions requiring an allograft (cartilage taken from a cadaver).

Classification of Articular Cartilage Lesions by Severity

GRADE	OUTERBRIDGE
0	Normal cartilage
I	Softening and swelling
II	Fragmentation and fissures in area less than 0.5 inch in diameter
III	Fragmentation and fissures in area larger than 0.5 inch in diameter
IV	Exposed subchondral bone

Source: Campbell's Operative Orthopaedics, 2007

ALLOGRAFTING

Osteochondral allografting, also called OATS, osteochondral transfer, or mosaicplasty, 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. The use of donor bone is necessary due to the size of lesion, Osteochondral allografting is recommended for lesions 4cm2-10cm2. The goal of this procedure is to provide viable chondrocytes and supporting bone that will be sufficient to maintain the cartilage matrix and thereby relieve pain and reduce further damage. The procedure is performed through an open approach to the knee.The exact area of cartilage that is missing on the patient's femur is mapped out and harvested as a cylinder of cartilage and bone. This cylinder of donor cartilage is then press fit into the patient's femur, completing the cartilage transplant.

AUTOGRAFTING

Osteochondral autograft transfer, also called OATS or mosaicplasty, involves harvesting cylinders of cartilage and bone from areas of the knee, from the patient, that do not bear much weight. These cylinders are then press fit into the cartilage lesion on the weightbearing surface of the knee. The donor sites are then backfilled with synthetic plugs or left to heal on their own. During the OATS procedure a single plug is taken from the patient versus several

plugs being removed during the mosaicplasty. All plugs will be removed from non-weight bearing areas. Osteochondral autograft transfer is indicated for cartilage lesions from 1.5 cm2 to 4 cm2 that have failed microfracture surgery or abrasive arthroplasty.

These techniques are limited by the amount of donor tissue available in the joint. Donor site morbidity increases as more tissue is harvested. Treatment of small lesions may be performed arthroscopically, while treatment of larger lesions is typically performed through an open arthrotomy.

MINCED CARTILAGE REPAIR

Minced cartilage repair is considered a second generation technique that does not require in vitro cell expansion and is described as a single-staged minimally invasive procedure. The procedure uses minced pieces of cartilage seeded over a scaffold which allows for even distribution of the chondrocytes to expand within the defect providing structural and mechanical protection. The first clinical application of the minced cartilage technique was the cartilage autograft implantation system (CAIS) developed by DePuy Mitek. A second technology, DeNOVO NT Graft ("Natural Tissue Graft"; Zimmer Inc, Warsaw, is another application for cartilage regeneration using minced donated juvenile cartilage.

Note: The DeNovo® NT Natural Tissue Graft is a tissue based articular cartilage graft that is processed from healthy donors less than 13 years of age and greater than 6 lbs. in weight. Donors are sourced through appropriate Organ and Tissue Procurement Organizations (OTPOs). BioCartilage® (Arthrex)/ArthrexOATS consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture.

ALLOGRAFT DISCS

ProChondrix® (AlloSource) and Cartiform® (Arthrex) are wafer-thin allografts where the bony portion of the allograft is reduced. The discs contain hyaline cartilage with chondrocytes, growth factors, and extracellular matrix proteins. ProChondrix® is available in dimensions from 7 to 20 mm and is stored fresh for a maximum of 28 days. Cartiform® is cut to the desired size and shape and is stored frozen for a maximum of 2 years. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

ANKLE LESIONS

For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 cm2 who receive a fresh osteochondral allograft, there is little evidence. For individuals who have large (area >1.5 cm2) or cystic (volume >3.0 cm3) cartilage lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes a small number of patients in an RCT, case series, and a systematic review of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found a significant failure rate with osteochondral allografts for talar lesions. Although there is a potential to delay or avoid arthrodesis or total ankle arthroplasty in younger patients, use of an allograft may be detrimental to future treatments. Additional study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

GUIDELINES AND POSITION STATEMENTS

AMERICAN COLLEGE OF RHEUMATOLOGY

Guidelines from the American College of Rheumatology on management of osteoarthritis (OA) of the hip and knee state that autologous osteochondral plugs (mosaicplasty) is being investigated for repair of focal chondral defects, but that this procedure is “not currently indicated in the treatment of patients with OA” (Altman et al, 2000).

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

An assessment of mosaicplasty for knee cartilage defects from the National Institute for Health and Clinical Excellence (NICE, 2006) concluded: "Current evidence suggests that there are no major safety concerns associated with mosaicplasty for knee cartilage defects. There is some evidence of short-term efficacy, but data on long-term efficacy are inadequate. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and audit or research."

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS (AAOS)

In 2010 and 2012 clinical practice guidelines on the diagnosis and treatment of osteochondritis dissecans (OCD), the American Academy of Orthopaedic Surgeons (AAOS) was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable OCD lesion.

According to the American Academy of Orthopaedic Surgeons (AAOS), most candidates eligible for articular cartilage restoration are young adults with a single injury or lesion. Older individuals, or those with many lesions in one joint, are less likely to benefit from osteochondral autograft transplantation.

In a Clinical Practice Guideline for the diagnosis and treatment of osteochondritis dissecans, the AAOS states that they unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature patients with unsalvageable fragment (AAOS 2010).

An AAOS advisory statement for use of musculoskeletal tissue allografts indicates that the AAOS believes that for appropriate patients musculoskeletal allografts represent a therapeutic alternative. These tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology and follow Food and Drug Administration (FDA) Good Tissue Practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards and recommends the use of tissue from banks that are accredited by the American Association of Tissue Banks (AAOS 2006).

There is also sufficient evidence to support the use of osteochondral allograft of the knee in patients who are physically active, have failed standard medical and surgical treatments, and are considered too young for total knee arthroplasty.

The American Orthopaedic Foot and Ankle Society

The American Orthopaedic Foot and Ankle Society supports the use of osteochondral transplantation for the treatment of OLTs that have failed other management, especially for large diameter lesions and cystic lesions. To this end, the AOFAS considers osteochondral transplantation to be a treatment option with demonstrated improved outcomes. This position is based on multiple reports from the peer-reviewed scientific literature.

PRIOR APPROVAL:

Not applicable.

POLICY:

All of the following criteria must be found in the pre-op notes to determine medical necessity of the procedure.

- Inadequate response to a prior surgical procedure (microfracture or abrasive arthroplasty) before osteochondral allografting.

FOR BOTH KNEE PROCEDURES ALL OF THE FOLLOWING CRITERIA ARE MET:

- Skeletally mature adult between 18 and 55 years of age on the date of service. If an adolescent member is evaluated, s/he should be skeletally mature with documented closure of growth plates; AND
- Inadequate response to a prior surgical procedure (microfracture or abrasive arthroplasty) The success rate and surgical ease of microfracture and abrasive arthroplasty are such that they should be used as first line therapy AND
- Persistent symptoms of disabling, localized knee pain have been present for at least six (6) months limiting ambulation; AND
- Body mass index (BMI) is less than or equal to 35 kg/m2 (for improved surgical outcomes by decreasing stress from weight-bearing on the joint); AND
- Condition consists of a full-thickness cartilaginous defect (Grade III-IV) of the femoral condyle (medial, lateral or trochlea) or patella caused by acute or repetitive trauma; (acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse); AND
- Absence of knee osteoarthritis; AND
- Absence of active infection; AND
- No history of cancer in the bone, cartilage, fat or muscle of the treated limb; AND
- Stable knee with intact, fully functional menisci and ligaments and normal knee alignment (or achieved concurrently with osteochondral grafting),.AND
- Normal joint space

ADDITIONALLY: ALL OF THE SPECIFIC PROCEDURE CRITERIA MUST ALSO BE MET:

OSTEOCHONDRAL AUTOGRAFT TRANSPLANTATION OF THE KNEE:

- Cartilage defect size is between 1.0^2 to 2.5cm^2 in total area

OSTEOCHONDRAL ALLOGRAFT (OATS/MOSAICPLASTY) TRANSPLANTATION OF THE KNEE:

- Cartilage defect measuring 2.5cm^2 to 10cm^2

Osteochondral autografting/allografting for the knee is considered **investigational** when the above criteria is not met.

Osteochondral autografting for **all other joints, including but not limited to: shoulder, elbow, and talar joints**, and any indications other than those listed above, is considered **investigational**. The success rate and longevity in other joints have not been proven at this time. There is limited evidence in the form of randomized control studies to demonstrate the benefit for treating any other joint problems except those of the articular surfaces of the knee.

MINCED OR PARTICULATED CARTILAGE

Treatment of focal articular cartilage lesions with autologous **minced cartilage** is considered **investigational** (for example CAIS).

Treatment of focal articular cartilage lesions with allogeneic **minced cartilage**/biopaste is considered **investigational** (for example DeNOVO NT, BioCartilage® (Arthrex)/Arthrex OATS).

Use of minced articular cartilage (whether synthetic, allograft or autograft) to repair osteochondral defects is considered **investigational**. Randomized trials that compare the outcomes of minced articular cartilage repair with standard methods have not been published. Clinical studies are needed to establish the safety and outcome benefit of this technique over standard methods of cartilage repair.

OSTEOCHONDRAL DISCS

Treatment of cartilage lisions using reduced allograft osteochondral disc (e.g., Prochondrix, Cartiform) is considered **investigational**.

SYNTHETIC BONE FILLERS

Treatment of cartialage lesions 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**. (for example PolyGraft, TruFit BGS Plugs or granules)

HYBRID REPAIR

Hybrid technique of autologous chondrocyte implantation/osteochondral autograft transfer system (OATS) technique for the treatment of osteochondral defects is considered **investigational**.

PROCEDURE CODES AND BILLING GUIDELINES:

To report provider services, use appropriate CPT* codes, Modifiers, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or diagnosis codes.

- 24999 Unlisted procedure, humerus or elbow
- 27415 Osteochondral allograft, knee, open
- 27416 Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
- 27599 Unlisted procedure, femur or knee
- 27899 Unlisted procedure, leg or ankle
- 28446 Open osteochondral autograft, talus (includes obtaining graft[s])
- 29866 Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])
- 29867 Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)
- 29885 Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
- 29892 Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)
- 29999 Unlisted procedure, arthroscopy
- L8699 Prosthetic implant, not otherwise specified

SELECTED REFERENCES:

- Altman RD, Hochberg MC, Moskowics, RW, et al.; subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee. American College of Rheumatology Subcommittee on Osteoarthritis Guideline. Arthritis Rheum. 2000;43(9):1905-1915
- Pichon-Riviere Am, Augustovski F, Garcia Marti S, et al. Mosaicplasty for the treatment of intra-articular cartilage lesions of the knee [summary]. Report IRR No. 180. Buenos Aires, Argentina: Institute for Clinical Effectiveness and Health Policy (IECS); 2009.
- Hindle P, Hendry JL, Keating JF, Biant LC. Autologous osteochondral mosaicplasty or TruFit plugs for cartilage repair. Knee Surg Sports Traumatol Arthrosc. 2013 Apr 16. [Epub ahead of print].
- National Institute for Health and Clinical Excellence (NICE). Mosaicplaasty for knee cartilage defects. Interventional Procedure Guidance 162. London, UK: NICE; March 2006.
- ECRI. Osteochondral Autograft Transplantation in the Knee. Plymouth Meeting (PA):ECRI Health Technology Information Service; 2008 October 23. 8. (ECRI Hotline Response).

- ECRI Institute. Ostgeochondral Autograft Transplantation for the Ankle. Plymouth Meeting (PA): ECRI Institute; 2009 October 27. 8p. [ECRI hotline response].
- Ebert JR, Robertson WB, Woodhouse J, Fallon M, Zheng MH, Ackland T, Wood DJ. Clinical and magnetic resonance imaging-based outcomes to 5 years after matrix-induced autologous chondrocyte implantation to address articular cartilage defects in teh knee. Am J Sports Med. 2011 Apr;39(4):753-63.
- Jones DG, Peterson, L. Autoloous Chondrocyte Implantaion. American Academy of Orthopaedic Surgeons Instructional Course Lectures 2007;56:429-445.
- Advanced Technologies and Regenerative Medicine, LLC (ATRM). Cartilage autograft implantation system (CAIS) for the repair of knee cartilage through cartilage regeneration. NLM Identifier: NCT00881023. Last updated on October 15, 2012.
- Baums MH, Heidrich G, Schultz W, et al. The surgical technique of autologous chondrocyte transplantation of the talus with use of a perosteal graft. Surgical technique. J Bone Joint Surg Am. 2007; 89 Suppl 2 Pt.2:170-182.
- Zimmer, Inc. Post Market Study of DeNovo NT, Natural Tissue Graft NLM Identified: NCT00791245. Last updated on January 25, 2012.
- Solheim E, Hegna J, Oyen J et al. Results at 10 to 14 years after osteochondral autografting (mosaicplasty) in articular cartilage defects in the knee. Knee 2013; 20(4):287-90.
- Astur DC, Arliani GG, Binz M et al. Autologous osteochondral transplantation for treating patellar chondral injuries: evaluation, treatment, and outcomes of a two-year follow-up study. J Bone Joint Surg Am 2014; 96(10):816-23.
- Tompkins M, Hamann JC, Diduch DR et al. Preliminary results of a novel single-stage cartilage restoration technique: particulated juvenile articular cartilage allograft for chondral defects of the patella. Arthroscopy 2013; 29(10):1661-70.
- Emmerson BC, Gortz S, Jamali AA et al. Fresh osteochondral allografting in the treatment of osteochondritis dissecans of the femoral condyle. Am J Sports Med 2007; 35(6):907-14.
- Gracitelli GC, Meric G, Briggs DT, et al. Fresh osteochondral allografts in the knee: comparison of primarytransplantation versus transplantation after failure of previous subchondral marrow stimulation. Am J Sports Med. Apr 2015;43(4):885-891. PMID 25817190
- De Caro F, Bisicchia S, Amendola A, et al. Large Fresh Osteochondral Allografts of the Knee: A Systematic Clinical and Basic Science Review of the Literature. Arthroscopy. Apr 2015;31(4):757-765. PMID 25660010
- Solheim E, Hegna J, Inderhaug E, et al. Results at 10-14 years after microfracture treatment of articular cartilage defects in the knee. Knee Surg Sports Traumatol Arthrosc. Nov 23 2014. PMID 25416965
- Ulstein S, Aroen A, Rotterud JH, et al. Microfracture technique versus osteochondral autologous transplantation mosaicplasty in patients with articular chondral lesions of the knee: a prospective randomized trial with long-term follow-up. Knee Surg Sports Traumatol Arthrosc. Jun 2014;22(6):1207-1215. PMID 24441734
- American Academy of Orthopaedic Surgeons. Clinical practice guideline on the diagnosis and treatment of osteochondritis dissecans 2010.
- Hayes, Winifred S. Health Technology Brief Osteochondral allograft transplantation for articular disorders of the ankle. March 30, 2015.
- Gross, C., Adams, S., Easley, M., and Nunley, J. (2016, January) Role of fresh osteochondral allografts for large talar osteochondral lesions. Journal of the American Academy of Orthopaedic Surgeons. January 2016, Vol 24, No 1, e9-e17.
- Ahmad, J., & Jones, K. (2015). Comparison of osteochondral autografts and allografts for treatment of recurrent or large talar osteochondral lesions. Foot Ankle International. Abstract retrieved September 11, 2015 from PubMed database
- Farr J, Tabet SK, Margerrison E, et al. Clinical, Radiographic, and Histological Outcomes After Cartilage Repair With Particulated Juvenile Articular Cartilage: A 2-Year Prospective Study. Am J Sports Med. Apr 9 2014;42(6):1417-1425. PMID 24718790
- Gracitelli GC, Meric G, Briggs DT, et al. Fresh osteochondral allografts in the knee: comparison of primary transplantation versus transplantation after failure of previous subchondral marrow stimulation. Am J Sports Med. Apr 2015;43(4):885-891. PMID 25817190

- Kosaka M, Nakase J, et al. Outcomes and failure factors in ssurgical treatment for osteochondral dissecans of the capitellum. J Pediatr Orthop. 2013; 33(7) 719-24.
- Iwasaki N. Kato H, et al. Autologous osteochondral mosiacplasty for osteochondritis dissecans of the elbow in teenage athletes. J Bone Joint Surg Am. 2010;92 208-216.
- Durur-Subasi I, Durur-Karakaya A, Yildirim OS. Osteochondral Lesions of Major Joints. Eurasian J Med. Jun 2015;47(2):138-144. PMID 26180500
- Freeland E, Dowd T. Osteochondral Lesions of the Talus. 2015
- VanTienderen RJ, Dunn JC, Kusnezov N, et al. Osteochondral allograft transfer for treatment of osteochondral lesions of the talus: a systematic review. Arthroscopy. Jan 2017;33(1):217-222. PMID 27546173
- Westermann RW, Hancock KJ, Buckwalter JA, et al. Return to sport after operative management of osteochondritis dissecans of the capitellum: a systematic review and meta-analysis. Orthop J Sports Med. Jun 2016;4(6):2325967116654651. PMID 27482526
- Dell'Osso G, et al. The biphasic bioresorbable scaffold (Trufit®) in the osteochondral knee lesions: long-term clinical and MRI assessment in 30 patients. Musculoskeletal Surg 2016 Aug;100(2):93-96.
- Gracitelli GC, et al. Surgical interventions (microfracture, drilling, mosaicplasty, and allograft transplantation) for treating isolated cartilage defects of the knee in adults. Cochrane Database Syst Rev 2016 Sept 3;9:CD016075.
- Mehta V. Clinical results of a novel fresh cartilage allograft for focal articular cartilage defects. Poster presented at: International Cartilage Repair Society 13th World Congress; 2016 Sept 24-27; Sorrento, Italy.
- Yasui, Y., Wollstein, A., Murawski, C., & Kennedy, J. (2017). Operative treatment for osteochondral lesions of the talus: biologics and scaffold-based therapy. Cartilage, 8 (1), 42-49.
- Pareek, A., Reardon, P., Maak, T., Levy, B., Stuiart, M., & Krych, A. (2016). Long-term outcomes after osteochondral autograft transfer: a systematic review at mean follow-up of 10.2 years. Arthroscopy: The journal of Arthroscopic and Related Surgery, 32 (6), 1174-1184.
- Nielsen ES, McCauley JC, Pulido PA, et al. Return to sport and recreational activity after osteochondral allograft transplantation in the knee. Am J Sports Med. Jun 2017; 45(7):1608-1614.
- Johnson CC, Johnson DJ, Garcia GH, et al. High short-term failure rate associated with decellularized osteochondral allograft for treatment of knee cartilage lesions. Arthroscopy. Dec 2017; 33(12):2219-2227
- Riboh JC, Cvetanovich GL, Cole BJ, et al. Comparative efficacy of cartilage repair procedures in the knee: a network meta-analysis. Knee Surg Sports Traumatol Arthrosc. Dec 2017;25(12):3786-3799. PMID 27605128
- Farr J, Gracitelli GC, Shah N, et al. High failure rate of a decellularized osteochondral allograft for the treatment of cartilage lesions. Am J Sports Med. Aug 2016;44(8):2015-2022. PMID 27179056
- Saltzman BM, Lin J, Lee S. Particulated juvenile articular cartilage allograft transplantation for osteochondral talar lesions. Cartilage. Jan 2017;8(1):61-72. PMID 27994721

POLICY HISTORY:

- August 2018 - Annual Review, Policy Revised
- August 2017 - Annual Review, Policy Revised
- August 2016 - Annual Review, Policy Revised
- September 2015 - Annual Review, Policy Revised
- October 2014 - Interim Review, Policy Revised

- May 2014 - New policy

Wellmark medical policies address the complex issue of technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. Wellmark medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Wellmark does not provide health care services and, therefore, cannot guarantee any results or outcomes. Participating providers are independent contractors in private practice and are neither employees nor agents of Wellmark or its affiliates. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies may be updated and therefore are subject to change without notice.

*CPT® is a registered trademark of the American Medical Association.