



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 07/10/13
LAST REVIEW DATE: 07/22/14
LAST CRITERIA REVISION DATE: 07/22/14
ARCHIVE DATE:

AUTOGRAFTS AND ALLOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Chondral and osteochondral grafts replace damaged or destroyed articular cartilage with healthy articular cartilage from the individual (autograft) or from a cadaver (allograft). A plug of bone with healthy cartilage attached is harvested from a non-weight-bearing area of the individual's own femoral condyles and inserted into tunnels that have been prepared in the area of the damaged or destroyed cartilage. If the defect is large, an osteochondral allograft is performed using a suitable cadaver donor.

Autologous and allogeneic minced cartilage has been investigated for repair of damaged articular cartilage.

PolyGraft™ TruFit® Plug Bone Graft Substitute (BGS) is a resorbable synthetic bone filler that has been investigated for the repair of osteochondral defects.

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Criteria:

All requests will be reviewed by the medical director(s) and/or clinical advisor(s).

- Osteochondral autografting or allografting is considered **medically necessary** with documentation of **ALL** of the following:
 1. Cartilage defect measures 1.0 cm squared or greater in total area
 2. Grade III or IV full thickness isolated defect of the weight-bearing surfaces of the medial or lateral femoral condyles, trochlear region or patella
 3. Defect is contained with normal surrounding articular and articulating cartilage (Defined as grade II degeneration or less)
 4. Defect is unipolar (involving only one side of the joint), discrete and single (i.e., no kissing lesions)
 5. Disabling localized knee pain for at least 6 months duration and failure of conservative treatment (e.g., rest, analgesics) unless otherwise contraindicated
 6. Individual is not a candidate for total knee replacement
 7. Knee is stable with normal alignment
 8. No inflammation or osteoarthritis present in the knee
 9. Age 15 to 55 years
- Osteochondral autografting or allografting of the ankle is considered **medically necessary** with documentation of **ALL** of the following:
 1. Cartilage defect measures 1.0 to 3.0 cm squared in total area
 2. Defect is contained with normal surrounding articular and articulating cartilage (Defined as grade II degeneration or less)
 3. Defect is unipolar (involving only one side of the joint), discrete and single (i.e., no kissing lesions)
 4. No active infection is present
 5. No history of cancer in the bones, cartilage, fat or muscle of the affected limb
- Osteochondral autografting or allografting for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

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Criteria: (cont.)

All requests will be reviewed by the medical director(s) and/or clinical advisor(s).

- Autologous and allogeneic minced cartilage for the treatment of focal articular cartilage lesions is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.
- PolyGraft Trufit Plug BGS for all indications is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Resources prior to 07/10/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.78 BCBS Association Medical Policy Reference Manual. Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions. Re-issue date 06/12/2014, issue date 08/15/2001.
2. Clinical Trials.Gov. Smith & Nephew's European Trufit Study. Accessed 06/18/2013.
3. Dholander AA, Liekens K, Almqvist KF, et al. A pilot study of the use of an osteochondral scaffold plug for cartilage repair in the knee and how to deal with early clinical failures. *Arthroscopy*. Feb 2012;28(2):225-233.



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Resources: (cont.)

4. Hindle P, Hendry JL, Keating JF, Biant LC. Autologous osteochondral mosaicplasty or TruFit plugs for cartilage repair. *Knee Surg Sports Traumatol Arthrosc.* Apr 16 2013.
5. Joshi N, Reverte-Vinaixa M, Diaz-Ferreiro EW, Dominguez-Oronoz R. Synthetic resorbable scaffolds for the treatment of isolated patellofemoral cartilage defects in young patients: magnetic resonance imaging and clinical evaluation. *Am J Sports Med.* Jun 2012;40(6):1289-1295.