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Medical Coverage Policy

Effective Date: 6/26/2018 Revision Date: 6/26/2018 Review Date: 6/26/2018 Policy Number: HCS-0494-010

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Change Summary: Updated Description, Coverage Limitations, Background, Provider Claims Codes, Medical Terms, References, Title

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Disclaimer	Medical Alternatives
Description	Provider Claims Codes
Coverage Determination	Medical Terms
Background	References

Disclaimer

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Description Osteochondral Defect

An osteochondral defect is any type of damage to articular cartilage and underlying subchondral bone due to traumatic injury or degenerative changes (eg, osteochondritis dissecans (OCD), osteonecrosis or osteoarthritis). Due to the inability of the articular cartilage to heal itself efficiently, surgical procedures have been developed to stimulate new cartilage growth.

Autologous chondrocyte transplantation (ACT) or autologous chondrocyte implantation (ACI) is a two-step procedure utilized to repair traumatic-cartilage defects of the knee joint. First, autologous chondrocytes are collected during a cartilage biopsy performed as an arthroscopic procedure. The chondrocytes are then

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replicated in a cell culture and seeded on a porcine cellular membrane (eg, MACI) at a cell processing facility. After approximately six weeks, an arthrotomy is performed to debride the defect, trim the membrane to the size of the defect for complete coverage and then secure the membrane over the damaged area using a fibrin sealant.

Osteochondral allograft transplant refers to the replacement of damaged articular cartilage and bone with tissue from a cadaveric donor. These allografts can either be fresh or frozen. Osteochondral allograft transplantation is used predominantly in the treatment of large and deep osteochondral lesions resulting from conditions such as osteochondritis dissecans (OCD), osteonecrosis or traumatic osteochondral fractures.

Osteochondral autograft transplant (OAT) involves the transplantation of small plugs of healthy bone and hyaline cartilage from joint areas with less weight bearing. The most common donor sites are the areas of the knee or ankle (on the same side). Small holes are drilled through the lesion and the newly harvested plugs are inserted into the holes. The two most commonly performed types of OAT procedures are:

- **Mosaicplasty** A technique that consists of removing small osteochondral cylinders from low weight bearing surfaces of the affected joint or another joint in the same individual and transplanting them in a mosaic-like formation into focal chondral or osteochondral defects in the knee. It is usually utilized to treat larger defects.
- Osteochondral Autograft Transfer System (OATS) procedure This procedure is similar to mosaicplasty; however, it involves the use of a larger, single plug that usually fills an entire defect (eg, those associated with anterior cruciate ligament [ACL] tears).

Cryopreserved viable osteochondral allograft product (eg, Cartiform) is made of fullthickness articular cartilage and a thin layer of subchondral bone, harvested from a human cadaver, which maintains intact native cartilage architecture with viable chondrocytes, growth factors and extracellular matrix proteins to promote articular cartilage repair. The wafer thin, disc shaped graft is often used in conjunction with marrow stimulation (eg, microfracture) purportedly allowing the host mesenchymal stem cells to infiltrate the graft from the underlying bone marrow after stimulation to provide dense extracellular matrix intended to enhance biomechanical stability and promote chondrogenesis.^{9,12} (Refer to Coverage Limitations section)

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Juvenile cartilage allograft tissue implantation (eg, DeNovo NT natural tissue graft, DeNovo ET engineered tissue graft) was developed to repair damaged articular cartilage. The living articular cartilage is obtained from juvenile donors and minced into small particles. The particles are then surgically placed into the damaged cartilage defect and secured using a fibrin adhesive. Processing the cartilage into small particles purportedly allows the chondrocytes to escape their surrounding extracellular matrix to the surrounding tissues and form new articular like cartilage tissue matrix.⁸ (Refer to Coverage Limitations section)

Manipulated (decellularized) human tissue graft products (eg, Chondrofix osteochondral allograft) are made of bone and cartilage tissue that is harvested from a cadaveric donor that has been processed to remove blood, cells and fat from the tissue. It is sterilized to kill bacteria and other microorganisms while purportedly promoting bone integration and remodeling to reduce the risk of inflammation in repair of Grade III and Grade IV osteochondral lesions. (Refer to Coverage Limitations section)

Minced cartilage or biopaste extracellular matrix products (eg, BioCartilage) are made of allograft cartilage that when injected into an osteochondral defect, during a microfracture surgical procedure repair, provides a scaffold over the defect. The scaffold purportedly provides a tissue network that signals autologous cellular interactions and improves the quality of tissue healing within the articular cartilage defect.¹⁹ (Refer to Coverage Limitations section)

Synthetic resorbable polymers (eg, PolyGraft, TruGraft granules, and TruFit plugs) are polymer scaffolds that are being proposed for the repair of osteochondral articular cartilage defects. The implant functions as a scaffold for chondral and osteogenic cells with the synthetic polymer being resorbed as the cells produce their normal matrices. ¹¹ (Refer to Coverage Limitations section)

Subchondral Defect

Subchondroplasty is a minimally invasive procedure developed to treat chronic, nonhealing subchondral defects known as bone marrow lesions (BMLs) or bone marrow edema (BMEs). The procedure involves percutaneously injecting a flowable

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calcium phosphate bone substitute into the region of the bone marrow lesion under fluoroscopic guidance. Subchondral bone refers to the epiphyseal bone directly underneath the area of articular cartilage.^{6,20} (Refer to Coverage Limitations section)

CoverageAutologous Chondrocyte TransplantationDetermination

Humana members may be eligible under the Plan for **ACT of the knee** when **ALL** of the following criteria are met:

- Absence of any contraindication listed in the Coverage Limitations section; AND
- Documentation including radiological interpretation and report for soft tissue pathology (eg, MRI) or arthroscopy of a focal chondral defect size of 1 to 10 cm²; AND
- Failure of at least six weeks of conservative treatment (eg, medication, physical therapy); **AND**
- Full-thickness (grade III or IV) isolated cartilaginous defect of the knee involving the lateral or medial femoral condyle or trochlear groove of the femur caused by acute or repetitive trauma; **AND**
- Individual is expected to comply with prescribed postoperative rehabilitation program; **AND**
- Knee must be stable and aligned (a corrective procedure in combination with, or prior to, chondrocyte implantation may be necessary to ensure stability, alignment and normal weight distribution within the joint); **AND**
- Previous arthroscopic or surgical repair greater than six months prior to transplantation; **AND**
- Skeletally mature adolescent with documented closure of growth plates to 55 years of age; **AND**
- Symptoms such as lesion related pain, swelling or catching/locking which limits

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activities of daily living

Osteochondral Allograft/Autograft Transplantation

Humana members may be eligible under the Plan for an **osteochondral allograft OR osteochondral autograft transplant** of the knee when **ALL** of the following criteria are met:

- Disabling localized knee pain that is unresponsive to at least six weeks of conservative treatment (eg, medication, physical therapy); **AND**
- Focal, full thickness (grade III or IV) articular cartilage defects; AND
- Documentation including radiological interpretation and report for soft tissue pathology (eg, MRI) or arthroscopy of a chondral defect on the weight bearing portion of the lateral or medial femoral condyle, or trochlear region of the knee that is between 1-2.5 cm in diameter or less than 2.5 cm² total for autograft transplants, or greater than 2 cm² total for allograft transplants; AND
- No evidence of arthritis on the corresponding tibial surface; AND
- Normal appearing hyaline cartilage surrounds the borders of the defect; AND
- Normal knee alignment; AND
- Skeletally mature adolescent with documented closure of growth plates to 55 years of age

CoverageHumana members may NOT be eligible under the Plan for ACT for any indication notLimitationslisted above including, but not limited to, the following:

- Cartilage defects in joints other than the knee (patella is considered separate from the knee joint); OR
- Individuals who have had a previous total meniscectomy; OR

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- Individuals with osteochondritis dissecans (OCD) lesions; OR
- Initial or first line of surgical therapy

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Contraindications to ACT with MACI implant include, but may not be limited to:

- Individuals with inflammatory arthritis or joint disease (eg, rheumatoid arthritis);
 OR
- Individuals with known history of hypersensitivity to gentamicin, other aminoglycosides or products of bovine or porcine origin; **OR**
- Individuals with uncorrected congenital blood coagulation disorders; OR
- Prior knee surgery (preceding six months) excluding surgery to procure biopsy or accompanying procedure to prepare the knee for MACI implant; **OR**
- Severe osteoarthritis of the knee

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **osteochondral allograft OR osteochondral autograft transplant** for any indications other than those listed above including, but not limited to, the following joints:

- Ankle; OR
- Elbow; OR
- Hip; **OR**
- Patella; OR

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• Shoulder

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **articular cartilage repair using the following products:**

- Cryopreserved viable osteochondral allograft product (eg, Cartiform); OR
- Juvenile cartilage allograft tissue implantation (eg, DeNovo NT natural tissue graft, DeNovo ET engineered tissue graft; **OR**
- Manipulated (decellularized) human tissue graft products (eg, Chondrofix osteochondral allograft; **OR**
- Minced cartilage/biopaste (eg, BioCartilage); OR
- Synthetic resorbable polymers (eg, PolyGraft, TruFit plugs)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **subchondroplasty** for any indication. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Background Additional information about articular cartridge defects, bone marrow lesions, osteoarthritis, osteochondritis dissecans or osteonecrosis may be found from the following websites:

<u>American Academy of Orthopaedic Surgeons</u>

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- National Institutes of Arthritis and Musculoskeletal and Skin Diseases
- <u>National Library of Medicine</u>

MedicalAlternatives to ACT, osteochondral allograft or autograft of the knee and boneAlternativesmarrow lesions include, but may not be limited to, the following:

- Braces and/or orthotics (Please refer to Orthotics Medical Coverage Policy)
- Intra-articular injections
- Physical therapy (Please refer to <u>Physical Therapy and Occupational Therapy</u> Medical Coverage Policy)
- Prescription drug therapy
- Surgical interventions

Physician consultation is advised to make an informed decision based on an individual's health needs.

Provider ClaimsAny CPT, HCPCS or ICD codes listed on this medical coverage policy are for
informational purposes only. Do not rely on the accuracy and inclusion of specific
codes. Inclusion of a code does not guarantee coverage and or reimbursement for a
service or procedure.

CPT® Code(s)	Description	Comments
23929	Unlisted procedure, shoulder	Not Covered if used to report any procedure outlined in Coverage Limitations section

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24999	Unlisted procedure, humerus or elbow	Not Covered if used to report any procedure outlined in Coverage Limitations section
25999	Unlisted procedure, forearm or wrist	Not Covered if used to report any procedure outlined in Coverage Limitations section
26989	Unlisted procedure, hands or fingers	Not Covered if used to report any procedure outlined in Coverage Limitations section
27299	Unlisted procedure, pelvis or hip joint	Not Covered if used to report any procedure outlined in Coverage Limitations section
27412	Autologous chondrocyte implantation, knee	
27415	Osteochondral allograft, knee, open	Not Covered if used to report any procedure outlined in Coverage Limitations section
27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])	
27599	Unlisted procedure, femur or knee	Not Covered if used to report any procedure outlined in Coverage Limitations section
27899	Unlisted procedure, leg or ankle	Not Covered if used to report any procedure outlined in Coverage Limitations section
28446	Open osteochondral autograft, talus (includes obtaining graft[s])	Not Covered

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28899	Unlisted procedure, foot or toes	Not Covered if used to report any procedure outlined in Coverage Limitations section		
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])			
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)	Not Covered if used to report any procedure outlined in Coverage Limitations section		
CPT [®] Category III Code(s)	Description	Comments		
No code(s) i	No code(s) identified			
HCPCS Code(s)	Description	Comments		
C1763	Connective tissue, nonhuman (includes synthetic)	Not Covered if used to report any product outlined in Coverage Limitations section		
C1889	Implantable/insertable device for device intensive procedure, not otherwise classified	Not Covered if used to report any product outlined in Coverage Limitations section		
J7330	Autologous cultured chondrocytes, implant			
L8699	Prosthetic implant, not otherwise specified	Not Covered if used to report any product outlined in Coverage Limitations section		
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)			

Click here to view ICD-10-CM code(s) associated with this medical coverage policy.

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Medical Terms Acute – Sharp or severe in effect; intense.

Allograft – A graft transplanted from a donor who is of the same species as the recipient but who is genetically distinct.

Anterior Cruciate Ligament (ACL) – One of the four main stabilizing ligaments of the knee. It attaches to the knee end of the femur, at the back of the joint and passes down through the knee joint to the front of the flat upper surface of the tibia.

Arthritis – Inflammation of a joint usually accompanied by pain, swelling and sometimes changes in structure.

Arthroscopy – Minimally invasive surgery that involves the introduction of a thin fiberoptic scope into a joint to allow direct visualization of internal structures.

Articular – Pertaining to the joints.

Autograft – A tissue or organ that is grafted into a new position on the body of the individual from which it was removed.

Autologous – To be derived or transferred from the same individual's body.

Arthrotomy – Surgical incision into a joint.

Biomechanical – The mechanics of biological and especially muscular activity as in exercise or locomotion.

Bone Marrow – A soft gelatin like tissue inside some bones.

Bovine – Relating to, affecting, resembling or derived from a cow or bull.

Cadaver – A dead body, especially a human body to be dissected.

Cartilage – Tough, elastic, fibrous connective tissue found in various parts of the body.

Cartilaginous – Composed of cartilage.

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Chondral – Relating to cartilage.

Chondral Defect – Defect of the articular cartilage. Chondral injuries may accompany an injury to a ligament.

Chondrocyte – Connective tissue cell that is responsible for secretion of extracellular matrix of cartilage.

Chondrogenesis – Forming of cartilage.

Condyle – Rounded articular surface at the extremity of a bone.

Cryopreserved – To maintain the viability of (cells, tissue, organs, etc.) by storing them at very low temperatures.

Cultured – Artificially nurtured or grown.

Degenerative – Marked by gradual deterioration and loss of function.

Epiphyseal – The end of a long bone, usually wider than the shaft

Extracellular – Located or occurring outside a cell.

Femur – Large bone in the thigh that articulates with the pelvis above and the knee below.

Fibrin – An insoluble protein that is produced in response to bleeding and is the major component of the blood clot. Fibrin is a tough protein substance that is arranged in long fibrous chains; it is formed from fibrinogen, a soluble protein that is produced by the liver and found in blood plasma.

Fluoroscopic – By means of fluoroscopy or fluoroscope which is a type of medical imaging that shows a continuous X-ray image on a monitor.

Focal – Limited to one specific area.

Gentamicin – Broad spectrum antibiotic used in the treatment of various infections.

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Graft – To transport or surgically implant living tissue into a body part to replace a damaged part or compensate for a defect.

Hyaline Cartilage – Cartilage which covers surface of bones forming synovial joint; also called articular cartilage.

In Vitro – Made to occur in a laboratory vessel or other controlled experimental environment rather than within a living organism or natural setting.

Juvenile – Pertaining to, characteristic of, or intended for young persons.

Lateral – Position further from the midline of the body or structure.

Magnetic Resonance Imaging (MRI) – A machine that uses a large circular magnet and radio waves to generate signals from atoms in the body. These signals are used to construct images of internal structures.

Matrices – Pleural of matrix.

Matrix – Something that constitutes the place or point, from which something else originates, takes form or develops.

Meniscectomy – Excision of the meniscus, as of the knee joint.

Mesenchymal Stem Cells – Adult specialized cells capable of renewing themselves through cell division and can differentiate into different types of stem cells such as adipocytes (fat tissue), chondrocytes (cartilage) or osteocytes (bone).

Microfracture – A laparoscopic surgical procedure performed to promote new articular cartilage while repairing a cartilage defect. A sharp tool (awl) is used to make holes in the subchondral bone of a cleaned cartilage defect to create a new blood supply to bring new cells to form new cartilage.

Mosaic – A pattern made of numerous small pieces fitted together.

Orthotics - Refers to braces, splints, casts, supports and other devices used to

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support, align, prevent or correct deformities, or to improve the function of movable parts of the body.

Osteoarthritis – Form of arthritis. It usually occurs in older people and is characterized by chronic degeneration of the cartilage of the joints.

Osteochondral – Pertains to bone and cartilage.

Osteochondritis Dissecans (OCD) – Type of osteochondritis in which articular cartilage and associated bone becomes partially to totally detached to form joint loose bodies. It affects mainly the knee, ankle and elbow joints.

Osteogenic – Derived from or made up of bone forming tissue.

Osteonecrosis – A disease resulting from the temporary or permanent loss of the blood supply to the bones, which results in bone tissue death and bone collapse. If the process involves the bones near a joint, it often leads to collapse of the joint surface.

Patella – Kneecap.

Percutaneous – Through the skin.

Periosteal – Situated around a bone.

Physical Therapy – Treatment of physical dysfunction or injury by the therapeutic exercise and the application of modalities, intended to restore or facilitate normal function or development.

Polymer – A compound of high molecular weight derived by either the addition of many smaller molecules, as polyethylene or by the condensation of many smaller molecules with the elimination of water, alcohol or the like, as nylon.

Scaffold – Implanted cells that serve to allow cell attachment and migration.

Subchondral – Below or under a cartilage.

Synthetic - Noting or pertaining to compounds formed through a chemical process by

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human agency, as opposed to those of natural origin.

Tibia – Large bone between the knee and foot that supports 5/6 of the body weight.

Traumatic – A serious injury or shock to the body, as from violence or an accident.

Trochlear – Place on the femur between two bony ridges which holds the kneecap in place.

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