Sentara Health Plans

Medicaid

Tissue Transplantation of the Knee, Ankle and Talus

Table of Content

Purpose
Description & Definitions
Criteria
Coding
Document History
References
Special Notes
Keywords

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Coverage Policy	Surgical 39
Version	4

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses the surgical procedure for Tissue Transplantation of the Knee, Ankle and Talus.

- Patellar tendon allograft is covered without criteria.

Description & Definitions:

Tissue transplantation by various methods (autologous chondrocyte/allograft/autograft) is used to replace or repair damaged cartilage in the knee, ankle or talus.

Criteria:

Tissue transplantation of the knee is considered medically necessary with **1 or more of the following:**

- **Autologous chondrocyte transplant** is considered medically necessary for individuals with **All of the following:**
  - Disabling pain related to a full thickness focal chondral defect
  - Physician letter listing any prior surgery for treatment of femoral condyle defect
  - Arthroscopic evidence of significant cartilaginous defect of the femoral condyle by photography or operative report or MRI
  - Age 15 – 60 years
  - Body mass index 35 or less
  - Presence debilitating pain and/or knee locking for at least one year
  - Single focal articular cartilage defect down to but not through the subchondral bone on a load bearing surface
  - Total size of defect measures 2 – 10 centimeters
  - Knee is stable with intact meniscus and normal joint space on x-ray

- No active inflammation or other arthritis clinically or by x-ray
- Failure of conservative therapy including minimum of 2 months physical therapy and traditional surgical interventions
- Individual will cooperate with post operative weight bearing and activity restrictions
- Individual has the potential to complete post operative rehabilitation
- No active infection present
- No history of cancer in affected limb
- No known history of allergy to the antibiotic Gentamicin
- No known sensitivities to bovine cultures

- **Allograft transplantations of the Anterior/Posterior Cruciate Ligament or the Medial/Lateral Collateral Ligament** are considered medically necessary for individuals with **1 or more of the following:**
  - Ligament deficiency who are not candidates for autogenous transplantation
  - Pathology such as chronic patellar tendonitis and hamstring injury
  - Any other contraindications to using their own tissue such as collagen disease or generalized ligamentous laxity
- **Matrix-induced autologous chondrocyte implantation (MACI)** is considered medically necessary for individuals with **ALL of the** following:
  - FDA-approved matrix-induced chondrocyte implantation (e.g., MACI (Vericel) autologous cultured chondrocytes on porcine collagen membrane)
  - Symptomatic
  - Pain that interferes with ADLs or employment
  - Failed to respond to conservative treatment after 6 months
  - As an alternative to autologous cultured chondrocytes (e.g., Carticel) for knee joint only
  - Full-thickness cartilage defects of the knee (articular cartilage defect)
  - Adult patients
  - (grade III or IV) isolated defect of the knee
  - Does not involve defects of the subchondral bone
  - There has been an inadequate response to prior surgical therapy to correct the defect
  - No allergies to bovine material/cultures or gentamicin
- **Meniscal allograft transplantation** is considered medically necessary for individuals with **All of the following:**
  - More than 50% or complete loss of meniscus
  - Degenerative changes are absent or minimal
  - Knee is stable (intact or reconstructed ACL)
  - Individual is under age 55
  - Pre-operative studies (MRI or previous arthroscopy) show absence of near absence of the meniscus
- **Osteochondral Autograft Transplantation or Autologous Mosaicplasty** is considered medically necessary for individuals with **All of the following:**
  - MRI or arthroscopic examination results provided which detail the size, location, and type of the defect
  - Size of the cartilage defect is between 1.0 to 2.5 centimeters squared in total area
  - Condition of the knee includes 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
  - Age 15-50 years
  - Persistent symptoms of disabling localized knee pain for at least 6 months, which have failed to respond to conservative treatment
  - An intact meniscus is present
  - The lesion is largely contained with near normal surrounding articular cartilage and articulating cartilage, (grades 0, 1, 2)
  - Normal joint space is present
  - No active infection is present
  - No inflammation or osteoarthritis is present in the joint

    - Knee is stable with normal alignment (corrective procedure may be performed in combination/prior to transplantation)
    - Individual is willing and able to comply with post operative weight-bearing restrictions and rehabilitation
    - No history of cancer in the bones, cartilage, fat, or muscle of the affected limb
    - Body mass index 35 or less
- **Osteochondral allograft transplantation** including DeNovo products is considered medically necessary for individuals with **1 or more of the following:**
    - Avascular necrosis lesions of the femoral condyle
    - Non repairable stage 3 or 4 osteochondritis dissecans
    - Otherwise healthy, active, non-elderly individuals with **1 of the following:**
        - Failed arthroscopic procedures
        - Not a candidate due to **1 or more of the following:**
            - Size of lesion
            - Shape of lesion
            - Location of lesion
    - Treatment is for **All of the following:**
        - Isolated traumatic injury
        - Full thickness depth lesion (grade 4 down to or including the bone)
        - Lesion is surrounded by healthy cartilage
        - Opposing articular surface is generally free of disease or injury

Autologous chondrocyte transplantation is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Autologous cellular implant derived from adipose tissue (MFAT)
- Bioactive scaffolds (e.g., collagen meniscal implants)
- Bio-Gide (resorbable bilayer membrane made of porcine collagen)
- Bioresorbable porous polyurethane
- Collagen meniscus implants
- Combined meniscal allograft and autologous chondrocyte implantation of the knee
- Decellularized osteochondral allograft plugs (e.g., Chondrofix®) or reduced osteochondral allograft discs (e.g., ProChondrix®, Cartiform®) to repair osteochondral defects of the knee or ankle
- Extracellular Matrix with BioCartilage (Arthrex) for Orthopedic Indications
- Healing Response Technique
- Hybrid autologous chondrocyte implantation performed with osteochondral autograft transfer system (OATS) technique
- Kissing lesions with Osteochondral autograft transplantation
- Lesions in other joints, including the ankle and talus
- Lesions of the tibia or patella
- Matrix-induced autologous chondrocyte implantation in joints other than the knee
- Meniscal prosthesis
- 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
- Osteochondritis dissecans
- Previous history of cancer in the bones, cartilage, fat or muscle of the treated limb
- Synthetic resorbable polymers (e.g., PolyGraft BGS, TruFit [cylindrical plug], TruGraft [granules]) for osteochondral articular cartilage defects
- Tissue-engineered menisci
- Transplantation indications for repair chondral defects of the elbow, shoulder, ankle or other joints except the knee
- Treatment of cartilage damage associated with generalized osteoarthritis
- Treatment of cartilage damage associated with osteoarthritis or degenerative joint disease
- Use of minced articular cartilage (whether synthetic, allograft or autograft) to repair osteochondral defects of the knee or ankle

- Xenografts

Matrix-induced autologous chondrocyte implantation (MACI) is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- As initial or first line of surgical therapy
- Growth plates have not closed
- elbow, shoulder, ankle or other joints except the knee
- Combination of autologous transplant and transfer for repair
- Cartilage defect associated with 1 or more of the following:
    - Osteoarthritis
    - Rheumatoid arthritis
    - Inflammatory diseases
    - Significant osteoarthritic or inflammatory process

Coding:

Medically necessary with criteria:

Coding	Description
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) (eg, mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

Considered Not Medically Necessary:

Coding	Description
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
29891	Arthroscopy, ankle, surgical, excision of osteochondral defect of talus and/or tibia, including drilling of the defect
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: July
- 2021: July
- 2020: January
- 2015: March, May
- 2013: August
- 2012: March, May, August
- 2011: May, December
- 2010: September
- 2009: December
- 2008: August
- 2001: August

Reviewed Dates:

- 2023: July
- 2020: July
- 2019: July
- 2018: June
- 2017: January, October
- 2015: August
- 2014: August
- 2011: August
- 2010: August
- 2009: August
- 2007: December
- 2005: October, December
- 2004: October
- 2003: March, October
- 2002: March
- 2001: February
- 2000: December
- 1999: November
- 1998: February

Effective Date:

- September 1997

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Tissue Transplantation of the Knee, SHP Surgical 39, knee, tissue, transplant, transplantation, meniscus, meniscal, tendon, cruciate, ligament, cartilage, autologous, allograft, chondrocyte, DeNovo, autograft, Autologous Chondrocyte Transplantation, Denovo Cartilage Implant, Mosaicplasty, Osteoarticular Transfer System, OATS, Patellar Tendon Allograft, ACT, Bio-Gide, Meniscal Allograft Transplantation, femoral condyle, medial, lateral, trochlear, cartilaginous, Anterior Cruciate Ligament, ACL, Posterior Cruciate Ligament, PCL, Medial Collateral Ligament, MCL, Lateral Collateral Ligament, LCL