**Policy Name:** Juvenile Cartilage Allograft Tissue Implantation for Articular Cartilage Repair  

**Effective Date:** 12/1/2016

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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

Juvenile cartilage allograft tissue implantation for articular cartilage repair is investigative and therefore **NOT COVERED.**

**Note:** See also related Medica utilization management policy, **Autologous Cultured Chondrocyte (Carticel®) Transplantation for the Knee.**

**Description**

Articular cartilage is a thin layer of specialized connective tissue (hyaline cartilage) that allows for smooth movement, shock absorption, and distribution of load-bearing force in joints. Because it has limited healing capacity, cartilage is susceptible to damage from acute injuries or inflammatory conditions. Cartilage defect symptoms include pain, swelling, and functional disability in the affected joint.

Juvenile cartilage allograft tissue implantation is a proposed treatment for articular cartilage defects in the knee, hip, ankle and shoulder. DeNovo® NT Natural Tissue Graft (Zimmer, Inc.) is an off the shelf (i.e., not custom prepared) human tissue allograft, consisting of juvenile hyaline cartilage pieces with viable chondrocyte cells, intended for the repair of articular cartilage defects. This is single-stage surgery, eliminating the need for the individual to undergo a two-step surgery. Cartilage tissue is recovered from cadaveric juvenile donor joints and is purported to have a higher capacity for growth and repair of defects than autologous cartilage.

The surgery is performed by making a small incision in the patient’s joint and removing the degenerated cartilage from the defect site. The defect’s surface area is measured to estimate how many DeNovo NT graft packs will be needed, and a foil mold is made of the defect. The juvenile donor cartilage is then mixed with fibrin glue in the mold and allowed to set. The surgeon then implants the graft formed in the mold into the cartilage defect using more fibrin adhesive.
DeNovo® ET Engineered Tissue (ISTO Technologies, Inc.) is a scaffold-free living cartilage implant designed as an off the shelf product to repair and regenerate damaged knee cartilage. DeNovo ET graft uses tissue engineered juvenile cartilage cells applied to defects of the joint using an adhesive. According to ISTO’s Website, DeNovo ET is an investigational product and is currently in Phase III clinical trial. In an agreement with Zimmer, ISTO has assumed full control of DeNovo ET and has renamed the product RevaFlex™.

**FDA Approval**
Minimally manipulated allograft tissue is not subject to U.S. Food and Drug Administration (FDA) premarket approval processes. The FDA requires that the manufacturers of human allograft products be registered. Currently DeNovo NT is registered on the FDA’s Human Cell and Tissue-Based Products (HCT/P) list. No listing could be found for DeNovo ET or RevaFlex.

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s).

Original Effective Date: 12/1/2013

Re-Review Date(s): 9/1/2016