

<b>Place name of Medical Policy:</b> Denovo NT (Natural Tissue)/Denovo ET (Engineered Tissue) Juvenile Cartilage Graft			
<b>Prepared by:</b>	Leela Rangaswamy M.D.	<b>Established Date:</b>	TBD
<b>Specialty:</b>	Orthopedic Surgery	<b>Reviewed Date:</b>	07/06/17
<b>Referral Number:</b>	847171		

**POLICY**

- Not recommended due to insufficient evidence of safety and efficacy.
- Searches of medical literature yielded no studies of these juvenile cartilage grafts

**SUPPORTING DOCUMENTATION**

ODG Knee and Leg (updated 06/27/17) - Online Version

Juvenile cartilage allograft tissue implant

Not recommended. The DeNovo NT Natural Tissue Graft (ISTO Technologies, Inc.; Zimmer, Inc.), a minced juvenile cartilage allograft, and the DeNovo ET Engineered Tissue Graft, a tissue-engineered juvenile cartilage graft, have been proposed for the treatment of articular cartilage lesions.

There is insufficient evidence to determine the safety and efficacy of these procedures in the treatment of articular cartilage defects of the knee. ODG could not find any studies evaluating the DeNovo tissue graft in the published medical literature, and other sources found that evidence in the literature was insufficient. (Cigna, 2011)

DeNovoNT is a juvenile cartilage allograft tissue intended for the repair of articular cartilage defects (e.g., knee, ankle, hip, shoulder, elbow, great toe). The DeNovo NT Graft consists of particulated natural articular cartilage with living cells. Tissues are recovered from juvenile donor joints. The cartilage is manually minced to help with cell migration from the extracellular matrix and facilitate fixation. During implantation, the minced cartilage is mixed in a fibrin glue adhesive. DeNovo NT is classified as minimally manipulated allograft tissue and is therefore not subject to the FDA premarket approval process. A case series evaluating this product for the treatment of articular cartilage defects of the knee began in 2006 and is expected to be completed in 2013. DeNovo ET is a scaffold-free hyaline cartilage implant designed for the repair and regeneration of knee cartilage. The DeNovo ET graft uses tissue-engineered juvenile cartilage cells applied to defects of the joint surface using a protein-based adhesive. There are no studies of either graft in the published medical literature.

Cigna Medical Policy Coverage: Chondrocyte Implantation of the Knee, Number 0105, June 15, 2011. The

DeNovo<sup>®</sup> NT Natural Tissue Graft, a minced juvenile cartilage allograft, and the DeNovo<sup>®</sup> ET<sup>™</sup> Engineered Tissue Graft, a tissue-engineered juvenile cartilage graft, have been proposed for the treatment of articular cartilage lesions. There are no studies evaluating these products in the published medical literature. There is insufficient evidence to determine the safety and efficacy of these procedures in the treatment of articular cartilage defects of the knee.

**REFERENCE(S)**

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