MEDICAL POLICY

DENovo NT (NATURAL TISSUE)/DENovo ET (ENGINEEREDE TISSUE) JUVENILE CARTILAGE GRAFT

Established:  5/4/12  
Reviewed:     6/10/13  
By: Roger Hinkson, M.D., MPH  
Consulting Medical Director

POLICY

- Not recommended due to insufficient evidence of safety and efficacy
- Searches of the medical literature yielded no prospective randomized controlled studies to refine indications and contraindications (Farr et al.).

SUPPORTING DOCUMENTATION

ODG:

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, nor could other sources. (Cigna, 2010) 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:

CIGNA does not cover juvenile cartilage allograft tissue implantation (e.g., DeNovo® NT Natural Tissue Graft, DeNovo® ET™ Engineered Tissue Graft [ISTO Technologies, Inc., St. Louis, MO / Zimmer, Inc., Warsaw IN]) for the treatment of articular cartilage lesions because it is considered experimental, investigational, or unproven.

DeNovo® NT Natural Tissue Graft (ISTO Technologies, Inc., St. Louis, MO, Zimmer, Inc., Warsaw IN) DeNovo® NT Natural Tissue Graft 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. There are no studies evaluating the DeNovo NT Natural Tissue Graft in the published medical literature. DeNovo® ET™ Engineered Tissue Graft (ISTO Technologies, Inc. St. Louis, MO, Zimmer, Inc., Warsaw IN) 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 evaluating the DeNovo ET tissue graft in the published medical literature.

REFERENCES

Cigna Medical Policy Coverage: Chondrocyte Implantation of the Knee, Number 0105, June 15, 2012.


Official Disability Guidelines, Knee Chapter, 2013