



UM-CDG-024 Amniotic and Placental Derived Product
Injections and/or Applications

Approved By:
Director, Health Services

Effective Date:
10/22/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address all amniotic membrane, amniotic fluid or other placental derived product injections and/or applications as a means of managing musculoskeletal injuries, joint conditions, and all other conditions not stated as considered not medically necessary by SECUR Health Plan. This coverage determination guideline does not address burns, wounds, or ophthalmic conditions.

Amniotic and placental derived products are reported to possess certain beneficial characteristics and have been identified as a source of stem cells. Stem cells, by definition, can differentiate into any cell of an organism as well as the ability for self-renewal. They are thought to promote healing with a lower risk of low immunologic reaction.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

Musculoskeletal: connective tissues including bones, muscles, and associated tissues

Placenta: multilayered circulatory temporary organ that supplies food and oxygen to the fetus during pregnancy with layers including the amnion, the innermost membrane and the chorion, the outermost membrane.

Amniotic fluid: the fluid surrounding the fetus and amnion

Umbilical cord: vascular conduit connecting the fetus to the placenta comprised of the umbilical vein, allantois, and yolk sac embedded in Wharton's jelly

Wharton's jelly: gelatinous soft connective tissue derived from extra-embryonic mesoderm within the umbilical cord

Amniotic membrane: is divided into three distinct layers: a single epithelial layer, a thick basement membrane, and an avascular stromal (mesenchymal) layer. The avascular stromal layer is further divided into three layers, the compact, middle fibroblast, and spongy layer.

Spongy layer: loosely connected to the chorionic membrane, highly concentrated with proteoglycans and glycoproteins including hyaluronic acid as well as type I, III, and IV collagen

Middle fibroblast layer: made up of type I, III, and IV collagen

Compact layer: sits adjacent to the basement membrane and is composed of type I, III, and IV collagen and fibronectin

Basement layer: anchors the epithelial layer and contains collagen types IV, V, and VII, fibronectin, laminin, and hyaluronic acid

Amniotic epithelial cells: produce type III and IV collage, glycoproteins such as laminin and fibronectin, which

become the basement membrane

POLICY

The US Food and Drug Administration (FDA), under Sect. 361 of the Public Health Service Act (regulated by the Centers for Biologics Evaluation and Research CBER, an arm of the FDA) oversees the therapeutic use of “human cells or tissue products” or “HCT/Ps”. Once these types of products are harvested, their processing and handling will determine whether the products fall under Section 361 guidance or default to the more regulated section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act. The regulatory pathway for pre-market FDA approval of new drugs, devices and/or biological products, requires registration as a New Drug application (NDA), a Premarket Approval (PMA) or other appropriate device premarket clearance such as 510(k), or a (BLA) Biologics License Approval.

If a human cells or tissue product meets Section 361 FDA requirements, the product will not require FDA pre-market review and approval. To meet “Section 361” FDA regulatory requirements, the placental/amniotic-based tissue product must meet the following four criteria:

1. Minimally Manipulated
2. Intended for Homologous Use (as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent)
3. The manufacture of the HCT/P does not involve the combination of the cells or tissues with another agent, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P
4. Either:
 - i. The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
 - ii. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
 - a. Is for autologous use.
 - b. Is for allogeneic use in a first-degree or second-degree blood relative.
 - c. Is for reproductive use.

Due to the ongoing development of new products and clinical trials, the field of FDA regulatory requirements is evolving. SECUR Health Plan will continue to follow any guidance as it is issued by the FDA.

Lack of standard formulation, dose, frequency of administration, and standard of care in treatment with these products further complicates regulation and guidance determinations. Despite this lack of standardization, numerous amniotic and placental-derived products have been released for use in treatment of musculoskeletal conditions. These conditions include, but are not limited to tendon/ligament injuries, musculoskeletal injuries, cartilage damage, osteoarthritis, or pain related to these conditions as well as adjunctive orthopedic surgical treatments. Due to the lack of component standardization, the remainder of this coverage determination guideline will use the term amniotic and placental-derived products to mean ANY product derived from ANY combination of amniotic membrane/chorion/placenta/Wharton’s jelly/umbilical cord/amniotic fluid/umbilical cord blood.

Although amniotic and placental-derived products are marketed to treat certain musculoskeletal conditions, there is limited available support for safety and efficacy from human clinical trials. There is insufficient evidence-based literature to support coverage of amniotic and non-amniotic placental-derived products injected or applied, both

non-operatively and intra-operatively, as treatment of musculoskeletal conditions or pain related to conditions as not associated with thermal burn, wound, or ophthalmologic treatment.

Based on the available human clinical trials reviewed, there is no consistent formulation, method of delivery, or administration studied to allow for a determination of a standard dosing schedule nor frequency, nor efficacy that can translate across different products. This applies to both non-operative and operative injections/applications used for the treatment of musculoskeletal conditions. For a treatment to be considered medically reasonable and necessary per 1862(a)(1)(A) of The Act, the treatment must be appropriate, including duration and frequency furnished in accordance with accepted standards of medical practice for the condition. The existing evidence and lack of standardization of preparation, content, administration safety and effectiveness, precludes standards of medical practice for amniotic and placental-derived product injections and/or applications and, for reasons do not meet the requirement of Reasonable and Necessary based on Statute 1862 A(1)(a) requirement of Not Experimental or Investigational.

Based on this, SECUR Health Plan will consider injections and/or applications associated with amniotic and placental derived product injections and/or applications for musculoskeletal indications for non-wounds, discussed within this coverage determination guideline as not medically necessary, for any member, for any condition.

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