 Draft Revised Policy: Do Not Implement

Human Amniotic Membrane Grafts and Amniotic Fluid Injections

DESCRIPTION

Several commercially available forms of human amniotic membrane (HAM) and amniotic fluid can be administered by grafts, topical application, or injection. There are many products available using amnion, chorion, amniotic fluid, and umbilical cord that are being studied for the treatment of a variety of conditions, including chronic full thickness diabetic lower extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic surface disorders.

Human amniotic membrane (HAM) consists of 2 conjoined layers, the amnion and chorion, and forms the innermost lining of the amniotic sac or placenta. When prepared for use, the membrane is harvested immediately after birth, cleaned, sterilized, and either cryopreserved or dehydrated.

HAM grafts used for certain ocular surface disorders (e.g., AmnioGraft®) have been shown to be effective in promoting healing. Traditionally they have been fixated with sutures or glue or secured under a bandage contact lens. Self-contained or ringed devices (e.g., AmbioDisk™, ProKera®) with no sutures, glue, or bandage lens needed allow for application in an office setting rather than as an outpatient.

Amniotic fluid injections have been proposed as treatment for certain orthopedic uses (e.g., osteoarthritis, plantar fasciitis. When administered by injection. (e.g., AmnioMatrix®, Clarix® Flo) human amniotic tissue is micronized or reduced in particle size to a form that can be suspended in liquid. HAM injections are being evaluated for the treatment of a variety of conditions, including tendonitis, plantar fasciitis, cartilage damage, and for alleviation of pain and stiffness in individuals with osteoarthritis.

Note: This policy addresses human amniotic/chorionic membrane products and amniotic fluid products only, for other bioengineered skin and soft tissue products please refer to the **Bioengineered Skin and Soft Tissue Substitutes** medical policy.

The proposal is to add words or statements in red and delete words or statements with a strikethrough.

POLICY

- Human amniotic membrane grafts for the treatment of lower-extremity diabetic skin ulcers are considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Human amniotic membrane grafts (e.g., AmnioGraft®, ProKera®, AmbioDisk™) for the treatment of certain ophthalmic indications are considered ***medically necessary*** if the medical appropriateness criteria are met **(See Medical Appropriateness below.)**

- Human amniotic membrane grafts, for the treatment of all other conditions/diseases is considered ***investigational.***

- Injection of micronized or particulated human amniotic membrane fluid and/or amniotic fluid for the treatment of all conditions/diseases, including but not limited to treatment of osteoarthritis and plantar fasciitis, is considered ***investigational***.

MEDICAL APPROPRIATENESS

- Human amniotic membrane grafts are considered medically appropriate if **ANY ONE** of the following criteria is met:

  - For the treatment of non-healing (less than a 20% decrease in wound area after 2 weeks of standard care) diabetic lower-extremity skin ulcers are considered medically appropriate if **ANY ONE** of the following products are used:
    - AmnioBand® Membrane
    - Biovance®
    - Epifix®
    - EpiCord®
    - GrafixCore™ (Grafix® PL Core)
    - GrafixPrime™ (Grafix ® PL Prime)
    - Affinity®
    - AmnioExcel®
    - NuShield®

  - For the treatment of ophthalmic conditions with suture, glue, or bandage contact lens (e.g., AmnioGraft®) for **ANY ONE** of the following:
    - Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment
    - Pterygium (i.e., surfer's eye' is a pinkish, triangular tissue growth on the cornea) repair

  - For the treatment of ophthalmic conditions with or without suture or glue (e.g., ProKera®, AmbioDisk™) for **ANY ONE** of the following:
    - Neurotrophic keratitis (degenerative disease of the cornea caused by damage of the trigeminal nerve) that has not responded to conservative therapy (e.g., pressure patching, therapeutic contact lens, topical lubricants, or topical antibiotics)
    - Corneal ulcers (open sore on the cornea, usually as the result of an infection) that have not responded to conservative therapy (e.g., patching, therapeutic contact lens, or topical antimicrobial agents)
    - Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment
    - Corneal epithelial defects (e.g., mechanical trauma, ultraviolet burns, systemic disorders leading to corneal dryness, recurrent corneal erosion, superficial punctate keratitis (SPK), epithelial basement membrane dystrophy (EBMD), Limbal stem cell deficiency, neurotrophic diseases causing incomplete lid closure) that have **ANY ONE** of the following:
      - Failed to decrease in size after two (2) days of conservative treatment
      - Failed to close completely after five (5) days of conservative treatment (conservative treatment includes at least one of the following: topical lubricants, topical antibiotics, therapeutic contact lens, or patching)
    - Bullous keratopathy as a palliative measure in individuals who are not candidates for curative treatment (e.g., endothelial, or penetrating keratoplasty)
    - Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient
    - Keratolysis or corneal melts (sterile melting of the cornea, may occur following cataract extraction)
    - Stevens-Johnson syndrome (severe skin reaction to certain medications)
    - Moderate or severe acute ocular chemical burn
    - Severe dry eye with ocular surface damage and inflammation that remains symptomatic after treatment with **ONE or MORE** of the following:
      - Warm compresses on the lids

- Ocular lubricants and/or ointments
- Prescription drugs to manage dry eye disease (such as topical antibiotics, topical corticosteroids, topical secretagogues, oral secretagogues, oral macrolide or tetracycline antibiotics
- Therapeutic contact lens, either soft or rigid

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

ADDITIONAL INFORMATION

Literature on human amniotic membrane injections for regenerative medicine is at a very early stage. Additional studies with larger sample sizes and longer follow-up are needed to permit conclusions. Therefore, this technology remains investigational for applications other than lower extremity diabetic skin ulcers and certain surface ocular disorders.

SOURCES

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EFFECTIVE DATE

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