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 are being investigated for ophthalmic use.

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 patients with osteoarthritis.

Note: This policy addresses human amniotic/chorionic membrane products and amniotic fluid products.

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.)

- Fixated human amniotic membrane grafts (e.g. AmnioGraft®) for the treatment of ophthalmic indications are considered medically necessary if the medical appropriateness criteria are met (See Medical Appropriateness below.)

- Unfixated or self-contained human amniotic membrane products or devices (e.g. ProKera®, AmbioDisk™) for ophthalmic indications are considered investigational.

- Human amniotic membrane grafts, fixated or unfixated, for the treatment of all other ophthalmic conditions/diseases is considered investigational, including but not limited to:
  - corneal perforation
  - bullous keratopathy
  - following photorefractive keratectomy [a type of refractive surgery to correct myopia (nearsightedness), hyperopia (farsightedness) and astigmatism; precursor to LASIK]

- Injection of micronized or particulated human amniotic membrane fluid and/or amniotic fluid for the treatment of all conditions/diseases is considered investigational.

See also: Bio-Engineered Skin and Soft Tissue Substitutes

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MEDICAL APPROPRIATENESS

- Human amniotic membrane grafts are considered medically appropriateness if **ANY ONE** of the following criteria is met:
  
  o For the treatment of chronic, non-infected, full-thickness lower-extremity diabetic skin ulcers if **ALL** of the following are met:
    
    ▪ **ANY ONE** of the following human amniotic membrane products are used:
      
      - AmnioBand® Membrane
      - Biouvance®
      - Epifix®
      - GrafixCore™
      - GrafixPrime™
  
  o For the treatment of surface ophthalmic conditions if **ALL** of the following are met:
    
    ▪ Amniotic membrane grafts are fixated with **ANY ONE** of the following methods:
      
      - Sutures
      - Glue fixation
      - Secured under a bandage contact lens
    
    ▪ Ophthalmic condition is **ANY ONE** of the following:
      
      - Neurotrophic keratitis (degenerative disease of the cornea caused by damage of the trigeminal nerve)
      - Corneal ulcers (open sore on the cornea, usually as the result of an infection)
      - Keratolysis or corneal melts (sterile melting of the cornea, may occur following cataract extraction)
      - Pterygium (i.e., ‘surfers eye’ is a pinkish, triangular tissue growth on the cornea) repair
      - Stevens-Johnson syndrome (severe skin reaction to certain medications)
      - Corneal epithelial defects (e.g. mechanical trauma, ultraviolet burns, systemic disorders leading to corneal dryness, Limbal stem cell deficiency, neurotrophic diseases causing incomplete lid closure) that have **ANY ONE** of the following:
        
        o Failed to decrease in size after two (2) days of conservative treatment
        o 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)

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, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

Literature on human amniotic membrane injection 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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