Introduction

The amniotic membrane and amniotic fluid are structures that surround the fetus in the uterus (womb). The fluid protects the fetus from injury. The membrane is a thin mesh of protein and contains growth factors, stem cells, and other items crucial to a developing fetus. Processing and then using the amniotic membrane and/or fluid (after delivery), has been proposed to treat a number of conditions in adults. High quality medical studies show that using specific amniotic membrane products may be useful for treating diabetic ulcers in some cases, for specific eye conditions, and for a disorder known as Stevens-Johnson syndrome. This policy describes when these products may be considered medically necessary. Using amniotic membrane for other conditions or using amniotic fluid products is considered unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Treatment of nonhealing diabetic lower-extremity ulcers | Treatment of nonhealing* diabetic lower-extremity ulcers using the following human amniotic membrane products may be considered medically necessary:  
  - AmnioBand® Membrane  
  - Biovance®  
  - Epifix®  
  - Grafix™  
  
  *Note: Nonhealing is defined as less than a 20% decrease in wound area with standard wound care for at least 2 weeks. |
| Sutured human amniotic membrane grafts       | Sutured human amniotic membrane grafts may be considered medically necessary for the treatment of the following ophthalmic indications:  
  - acute ocular Stevens-Johnson syndrome  
  - corneal ulcers and melts  
  - neurotrophic keratitis  
  - persistent epithelial defects (defined as):  
    - failed to respond to 2 days of any: topical lubricants or antibiotics, therapeutic contact lens, or patching (see Related Information for more details)  
  - pterygium repair |

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| Sutured human amniotic membrane grafts       | Sutured human amniotic membrane grafts are considered investigational for the treatment of all other ophthalmic conditions including but not limited to:  
  - dry eye syndrome  
  - burns  
  - corneal perforation  
  - bullous keratopathy  
  - limbus stem cell deficiency  
  - after photorefractive keratectomy |
| Human amniotic membrane without suture       | Human amniotic membrane without suture (eg, Prokera®, AmbioDisk™) for ophthalmic indications is investigational. |
Injection of micronized or particulated human amniotic membrane is considered investigational for all indications including but not limited to treatment of:
- osteoarthritis
- plantar fasciitis

Injection of human amniotic fluid is considered investigational for all indications.

All other human amniotic membrane products and indications not listed above are considered investigational, including but not limited to treatment of lower-extremity ulcers due to venous insufficiency.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
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<tr>
<td>Q4131</td>
<td>EpiFix or Epicord, per sq cm</td>
</tr>
<tr>
<td>Q4132</td>
<td>Grafix Core, per sq cm</td>
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<tr>
<td>Q4133</td>
<td>Grafix Prime, per sq cm</td>
</tr>
<tr>
<td>Q4137</td>
<td>AmnioExcel or BioDExCel, per sq cm</td>
</tr>
<tr>
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<td>AmnioMatrix or BioDMatrix, injectable, 1 cc.</td>
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<td>Q4145</td>
<td>EpiFix, injectable, 1 mg</td>
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<td>Q4148</td>
<td>Neox 1k, per sq cm</td>
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<td>Q4151</td>
<td>AmnioBand or Guardian, per sq cm</td>
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<td>Q4154</td>
<td>Biovance, per sq cm</td>
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<td>Q4155</td>
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<td>Q4156</td>
<td>Neox 100, per sq cm</td>
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<tr>
<td>Q4168</td>
<td>AmnioBand, 1 mg</td>
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</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### Related Information

#### Definition of Terms

**Persistent epithelial defect:** A defect that failed to close completely after 5 days of conservative treatment or has failed to demonstrate a decrease in size after 2 days of conservative treatment.

**Conservative treatment:** The use of topical lubricants and/or topical antibiotics and/or therapeutic contact lens and/or patching. Failure of multiple modalities should not be required prior to moving to human amniotic membrane grafts. An amniotic membrane graft requires less effort on the part of the patient to adhere to a treatment regimen and has a significant advantage in regarding treatments requiring multiple drops per day.

### Evidence Review

#### Description

Several commercially available forms of human amniotic membrane (HAM) and amniotic fluid can be administered by patches, topical application, or injection. Amniotic membrane and amniotic fluid are being evaluated for the treatment of a variety of conditions, including chronic full-thickness diabetic lower extremity ulcers, venous ulcers, knee osteoarthritis, plantar fasciitis, and ophthalmic conditions.
Background

Human Amniotic Membrane

Human amniotic membrane (HAM) consists of 2 conjoined layers (the amnion and chorion) and forms the innermost lining of the amniotic sac and placenta. When prepared for use as an allograft, the membrane is harvested immediately after birth, cleaned, sterilized, and either cryopreserved or dehydrated. Many products available using amnion, chorion, amniotic fluid, and umbilical cord 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 conditions. The products are formulated either as patches, which can be applied as wound covers, or as suspensions or particulates, or connective tissue extractions, which can be injected or applied topically (see Table 1).

Fresh amniotic membrane contains collagen, fibronectin, and hyaluronic acid, along with a combination of growth factors, cytokines, and anti-inflammatory proteins such as interleukin-1 receptor antagonist. There is evidence that the tissue has anti-inflammatory, antifibroblastic, and antimicrobial properties. HAM is considered to be non-immunogenic and has not been observed to cause substantial immune response. It is believed that these properties are retained in cryopreserved HAM (C-HAM) and dehydrated HAM (D-HAM) products, resulting in a readily available tissue with regenerative potential. In support, one D-HAM product has been shown to elute growth factors into saline and stimulate the migration of mesenchymal stem cells both in vitro and in vivo.

Use of a HAM graft, which is fixated by sutures, is an established treatment for disorders of the corneal surface, including neurotrophic keratitis, corneal ulcers and melts, following pterygium repair, Stevens-Johnson syndrome, and persistent epithelial defects. Amniotic membrane products that are inserted like a contact lens have more recently been investigated for the treatment of corneal and ocular surface disorders. Amniotic membrane patches are also being evaluated for the treatment of various other conditions, including skin wounds, burns, leg ulcers, and prevention of tissue adhesion in surgical procedures (see Related Medical Policies). Additional indications studied in pre-clinical models include tendonitis, tendon repair, and nerve repair. The availability of HAM opens the possibility of regenerative medicine for an array of conditions.
**Amniotic Fluid**

Amniotic fluid surrounds the fetus during pregnancy and provides protection and nourishment. In the second half of gestation, most of the fluid is a result of micturition and secretion from the respiratory tract and gastrointestinal tract of the fetus, along with urea. The fluid contains carbohydrates, proteins and peptides, amino acids, fats, enzymes, hormones, pigments, and fetal cells. Use of human and bovine amniotic fluid for orthopedic conditions was first reported in 1927. Amniotic fluid has been compared with synovial fluid, containing hyaluronan, lubricant, cholesterol, and cytokines. Injection of amniotic fluid or amniotic fluid–derived cells is currently being evaluated for the treatment of osteoarthritis and plantar fasciitis.

Amniotic membrane and amniotic fluid are also being investigated as sources of pluripotent stem cells. Pluripotent stem cells can be cultured and are capable of differentiation toward any cell type. The use of stem cells in orthopedic applications is addressed in a separate policy (see [Related Medical Policies](#)).

### Table 1. Amniotic Membrane and Amniotic Fluid Preparations: Preparation and Components

<table>
<thead>
<tr>
<th>Product (Supplier)</th>
<th>Preparation</th>
<th>Amnion</th>
<th>Chorion</th>
<th>Amniotic Fluid</th>
<th>Umbilical Cord</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Cryopreserved, Dehydrated, or Extracted</td>
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</tr>
<tr>
<td>Patch</td>
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<tr>
<td>Affinity™ (NuTech Medical)</td>
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<tr>
<td>AlloWrap™ (AlloSource)</td>
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<td>AmbioDisk® (IOP Ophthalmics)</td>
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<td>AmbioDryS® (IOP Ophthalmics)</td>
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<td>AmnioBand® Membrane (MTF Wound Care)</td>
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<tr>
<td></td>
<td>Cryopreserved, Dehydrated, or Extracted</td>
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<td>Cygnus (Vivex Biomedical)</td>
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<td>PalinGen® Membrane (Amnio ReGen Solutions)</td>
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<td>Plurivest™ (Aedicell)*</td>
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<td>Prokera® (Bio-Tissue)</td>
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<td>Revitalon™ (Medline Industries)</td>
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<tr>
<td>WoundEx® (45 microns, Skye Biologics)*</td>
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<tr>
<td>WoundEx® (200 microns, Skye Biologics)*</td>
<td>D</td>
<td></td>
<td>X</td>
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</tr>
</tbody>
</table>

**Suspension, particulate, or extraction**

<p>| AmnioBand® Particulate (MTF Wound Care) | D | X | X |  |  |</p>
<table>
<thead>
<tr>
<th>Product (Supplier)</th>
<th>Preparation</th>
<th>Components</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Cryopreserved, Dehydrated, or Extracted</td>
<td>Amnion</td>
<td>Chorion</td>
<td>Amniotic Fluid</td>
<td>Umbilical Cord</td>
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<tr>
<td>AmnioMatrix® (Derma Sciences)</td>
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<tr>
<td>AmnioVisc™ (Lattice Biologics)</td>
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</tr>
<tr>
<td>BioSkin® Flow (HRT)b</td>
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<td>E</td>
<td>X</td>
<td>X</td>
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<td>X</td>
</tr>
</tbody>
</table>

C: cryopreserved; D: dehydrated; E: extracted connective tissue; HRT: Human Regenerative Technologies; MTF: Musculoskeletal Transplant Foundation; NS: not specified.

* Processed by HRT and marketed under different tradenames.

AmnioClip (FORTECH GmbH) is a ring designed to hold the amniotic membrane in the eye without sutures or glue fixation. A mounting device is used to secure the amniotic membrane within the AmnioClip. The AmnioClip currently has CE approval in Europe.

**Summary of Evidence**

**Diabetic Lower-Extremity Ulcers**

For individuals who have nonhealing diabetic lower-extremity ulcers who receive a patch or flowable formulation of HAM (ie, AmnioBand Membrane, Biovance, Epifix, Grafix), the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The RCTs evaluating amniotic and placental membrane
products for the treatment of nonhealing (<20% healing with ≥2 weeks of standard care) diabetic lower-extremity ulcers have compared HAM with standard care or with an established advanced wound care product. These trials used wound closure as the primary outcome measure, and some used power analysis, blinded assessment of wound healing, and intention-to-treat analysis. For the HAM products that have been sufficiently evaluated (ie, AmnioBand Membrane, Biovance, Epifix, Grafix), results have shown improved outcomes compared with standard care, and outcomes that are at least as good as an established advanced wound care product. Improved health outcomes in the RCTs are supported by multicenter registries. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Lower-Extremity Ulcers due to Venous Insufficiency**

For individuals who have lower-extremity ulcers due to venous insufficiency who receive a patch or flowable formulation of HAM, the evidence includes 2 RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The evidence on HAM for the treatment of lower-extremity venous ulcers includes 2 multicenter RCTs with EpiFix. One RCT reported larger percent wound closure at 4 weeks, but the percentage of patients with complete wound closure did not differ between EpiFix and standard of care. A second multicenter RCT reported a significant difference in complete healing at 12 weeks, but the interpretation is limited by methodologic concerns. Well-designed and well-conducted RCTs that compare HAM with the standard of care for venous insufficiency ulcers are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Osteoarthritis**

For individuals who have knee osteoarthritis who receive an injection of suspension or particulate formulation of HAM or amniotic fluid, the evidence includes a feasibility study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pilot study assessed the feasibility of a larger RCT evaluating HAM injection. Additional trials, which will have a larger sample size and longer follow-up, are needed to permit conclusions on the effect of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.
**Plantar Fasciitis**

For individuals who have plantar fasciitis who receive an injection of suspension or particulate formulation of human amniotic membrane or amniotic fluid, the evidence includes 2 small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Research on HAM injections for plantar fasciitis is at an early stage. Evidence includes a small (N=23) double-blind comparison with corticosteroid and a patient-blinded (N=45) comparison of 2 different doses of dehydrated HAM with saline. Additional controlled trials with larger sample sizes and longer follow-up are needed to permit conclusions on the effect of HAM and amniotic fluid injections on plantar fasciitis pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ophthalmic Conditions**

For individuals who have neurotrophic keratitis, corneal ulcers and melts, pterygium repair, Stevens-Johnson syndrome, or persistent epithelial defects who receive sutured HAM graft, the evidence includes several RCTs and a technology assessment. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The most widely studied condition with a technology assessment of RCT evidence is the use of HAM following pterygium repair. The technology assessment concluded, based on 4 RCTs, that conjunctival or limbal autograft was more effective than HAM. An RCT evaluating HAM for refractory neurotrophic corneal ulcers found that outcomes following HAM graft were similar to conventional therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have ophthalmic disorders other than neurotrophic keratitis, corneal ulcers and melts, pterygium repair, Stevens-Johnson syndrome, or persistent epithelial defects who receive sutured HAM graft, the evidence includes a systemic review article and RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. A 2012 Cochrane review found a single RCT on HAM graft for acute ocular burns. The trial suggested a benefit in the healing rate for ocular burns, but it was considered at high or uncertain risk of bias due to unequal baseline scores and the lack of masking of the treatment condition. A trial assessing HAM for the treatment of bullous keratopathy reported no difference in clinical outcomes between HAM and stromal puncture. RCTs are needed to evaluate the benefit of HAM for these indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have ophthalmic conditions who receive HAM without suture, the evidence includes an RCT (N=20), a within-subject comparative study, and case series. Relevant outcomes
are symptoms, morbid events, functional outcomes, and quality of life. Traditionally, amniotic membrane has been sutured onto the eye for a variety of severe ocular surface disorders. The Prokera device is novel because it has a ring around the cryopreserved HAM allograft that permits it to be inserted under topical anesthesia, similar to insertion of a contact lens, allowing for more widespread use. Use of Prokera has been reported for refractory dry eye syndrome, ulcerative keratitis, neurotrophic keratitis, recurrent epithelial erosion, high-risk corneal grafts, acute chemical and thermal burns, acute Stevens-Johnson syndrome, necrotizing scleritis, and limbal stem cell deficiency. Current evidence on its use is limited. While the small RCT and case series reported generally positive effects, the prospective comparative trial found no benefit of HAM compared to a bandage contact lens for healing a wound after photorefractive keratectomy. RCTs are needed to determine whether sutureless HAM improves healing for the various ophthalmic disorders. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
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<tr>
<td>NCT02318511a</td>
<td>An Investigation of ReNu™ Knee Injection: Monitoring the Response of Knee Function and Pain in Patients With Osteoarthritis</td>
<td>200</td>
<td>Mar 2018</td>
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<tr>
<td>NCT02609594a</td>
<td>A Multi-center Randomized Controlled Clinical Trial Evaluating Two Application Regimens of Amnioband Dehydrated Human Amniotic Membrane and Standard of Care vs. Standard of Care Alone in the Treatment of Venous Leg Ulcers</td>
<td>240</td>
<td>Nov 2018</td>
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<tr>
<td>NCT02880592a</td>
<td>A Multi-center, Randomized Controlled Clinical Trial Evaluating the Effect of Fresh Amniotic Membrane in the Treatment of Diabetic Foot Ulcers</td>
<td>100</td>
<td>Nov 2018</td>
</tr>
<tr>
<td>NCT02427191a</td>
<td>A Prospective, Single-Blinded, Randomized Controlled Trial of the Micronized dHACM Injection as Compared to the Saline Placebo Injection in the Treatment of Plantar</td>
<td>146</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
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<td>---------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>NCT02838784*</td>
<td>The Efficacy and Safety of Artacents™ for Treatment Resistant Lower Extremity Venous and Diabetic Ulcers: A Prospective Randomized Study</td>
<td>134</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT03379324*</td>
<td>A Prospective, Randomized Study Comparing Outcomes Following Arthroscopic Double-row Rotator Cuff Repair With and Without the Addition of a Cryopreserved, Liquid, Injectable Amnion Allograft</td>
<td>260</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>NCT02322554</td>
<td>The Registry of Cellular and Tissue Based Therapies for Chronic Wounds and Ulcers</td>
<td>50,000</td>
<td>Jan 2020</td>
</tr>
<tr>
<td>NCT03390920</td>
<td>Evaluation of Outcomes With Amniotic Fluid for Musculoskeletal Conditions Musculoskeletal Conditions</td>
<td>200</td>
<td>Jun 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2017 Input**

In response to requests, clinical input on use of human amniotic membrane for ophthalmic disorders was received from 1 specialty society while this policy was under review in 2017.

Based on the evidence and independent clinical input, the clinical input supports that the following indications provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice:

- Use of sutured human amniotic membrane (also described as amniotic membrane graft [AMG]) for individuals with:
Neurotrophic keratitis
- Corneal ulcers and melts
- Following pterygium repair
- Stevens-Johnson syndrome, and
- Persistent epithelial defects.

Based on the evidence and independent clinical input, the clinical input does not support whether the following indications provide a clinically meaningful improvement in the net health outcome or are consistent with generally accepted medical practice:

- Use of sutured AMG for individuals with
- Corneal perforation
- Bullous keratopathy
- Limbus stem cell deficiency, and
- Severe dry eye.

Based on the evidence and independent clinical input, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice:

- Use of sutureless AMG (eg, Prokera) instead of sutured AMG.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

Medicare National Coverage

There is no national coverage determination. In the absence of an national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
Regulatory Status

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Human amniotic membrane products and amniotic fluid products are included in these regulations.

In 2003, Prokera™ was cleared for marketing by FDA through the 510(k) process for the ophthalmic conformer that incorporates amniotic membrane (K032104). FDA determined that this device was substantially equivalent to the Symblepharon Ring. The Prokera™ device is intended “for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred.”

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/15</td>
<td>New Policy. Policy created with literature review through February 5, 2015; considered investigational.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Policy updated with literature review through December 14, 2015; reference 4 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>02/17/17</td>
<td>Coding update. Added HCPCS codes Q4137, Q4151, Q4162, Q4163, and new code Q4168 (effective 01/01/17).</td>
</tr>
<tr>
<td>04/01/17</td>
<td>Annual review, approved March 14, 2017. Amniotic membrane products and information were moved to this policy from 7.01.113. Treatment of nonhealing diabetic lower-extremity ulcers using the following (AmnioBand®, Membrane, Biovance®, Epifix®, Grafix™) human amniotic membrane products may be considered medically necessary. All other human amniotic membrane products and indications not listed above are considered investigational. Added the word human to other policy statements for clarification.</td>
</tr>
<tr>
<td>06/20/17</td>
<td>Coding update, added HCPCS codes Q4137, Q4151, Q4162, Q4163, and Q4168 back to policy as they were inadvertently left off of the policy when previous update was made on April 1, 2017. Also added HCPCS codes Q4148 and Q4156.</td>
</tr>
<tr>
<td>08/01/17</td>
<td>Interim Review, approved July 18, 2017. Policy moved into new format. Policy updated with literature review through April 27, 2017; references 7 and 21-28 added. Clinical input reviewed. Sutured amniotic membrane grafts considered medically necessary for neurotrophic keratitis, corneal ulcers and melts, following pterygium repair, Stevens-Johnson syndrome, and persistent epithelial defects. Ophthalmic products added and discontinued product names removed from Table 1. Added HCPCS codes Q4131-Q4133, Q4145, and Q4154.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; references 10, 12, 17, 24, and 29 added. Specific indications added to the investigational policy statements.</td>
</tr>
</tbody>
</table>
**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

LifeWise Health Plan of Oregon complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

LifeWise:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-6396, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through LifeWise Health Plan of Oregon. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-596-3440 (TTY: 800-842-5357).

 العربية (Amharic):

لا يجوز هذا الإشعار معلومات هامة قد يجوز هذا الإشعار معلومات مهمة بخصوص طلبك أو LifeWise Health Plan of Oregon. في حالة عدم القدرة على الوصول إلى هذا الإشعار، يمكن الحصول على ترجمته إلى اللغة العربية من خلال الاتصال بـ 800-596-3440 (TTY: 800-842-5357).

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 LifeWise Health Plan of Oregon 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費為您的母語得到本訊息和幫助。請撥電話 800-596-3440 (TTY: 800-842-5357).

Français (French):


Deutsche (German):


Hmoob (Hmong):


Ilokano (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipangggep iti aplikasyonyo wengo coverage babaen iti LifeWise Health Plan of Oregon. Daytoy ket mabalin dagiti importante a petaa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidengo nga addang sabbay dagiti partikular a naituding nga aldaw tapno mapagpalinaedyo ti coverage ti salun-atyo wengo tulong kadagit gastos. Adda karbangayo nga mangala iti daytoy nga impormasion ken tulong iti benuyo a pagasa nga awan ti bayadanyo. Tumawag iti numero nga 800-596-3440 (TTY: 800-842-5357).

Italiano (Italian):


Oromo (Cushite):

LifeWise Health Plan of Oregon

This notification contains important information about your application or coverage through LifeWise Health Plan of Oregon. To obtain more detailed information, please contact us at 800-596-3440 (TTY: 800-842-5357) or visit our website at www.lifewise.org.

(For Inquiry (Korean))

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에

이니 LifeWise Health Plan of Oregon를 통한 커버지에 관한

정보를 포함하고 있습니다. 본 통지서는 핵심이 되는 날짜들

귀하의 권리와 커버지의 계속 유지하기에 절단

이용된 것감까지 조치를 취해야 할 필요가 있을 수 있습니다.

귀하의 이러한 정보, 공고의 언어로도 이용이 불가능할 수 있

관리가 있습니다. 800-596-3440 (TTY: 800-842-5357)로 전화하시십시오.

(For Inquiry (Lao))

ដូចមនឹងលេខទិន្នន័យដ៏សេដ្ឋកិច្ចដែលបានផ្តល់ឱ្យបរិមាណយ៉ាង

ទូទៅ LifeWise Health Plan of Oregon និងអក្សរសាច់ដ៏អស្ចារ្យ។

សូមមើលអំពីការរក្សាសិទ្ធិដ៏ល្អិតដោយការដំណើរការ

ការបញ្ជាក់ដ៏ល្អល្អ។ សូមរក្សាសិទ្ធិដ៏ល្អិតដោយការដំណើរការ

នឹងបញ្ជាក់ផ្តល់ឱ្យបរិមាណយ៉ាង។ សូមទិញអំពីវិPB ចូលថ្មី។

800-596-3440 (TTY: 800-842-5357)។

(For Inquiry (Khmer))

ខ្សែភ្លេងនេះមានគំនិតសំខាន់ដែលត្រូវបានដាក់ក្នុងវិញ្ញាបនិក

LifeWise Health Plan of Oregon។ សូមធ្វើការឱះនិយមជាងគំនិ

ភ្លេងនេះដោយការមើលអំពីការរក្សាសិទ្ធិដ៏ល្អល្អ។

សូមទិញអំពីវិPB ចូលថ្មី។

800-596-3440 (TTY: 800-842-5357)។

(For Inquiry (Punjabi))

ہمارہ نوشتوں میں اہم اطلاعات موجود ہیں۔ اہم اطلاعات

سے متعلق معلومات کے لئے LifeWise Health Plan of Oregon

کی سہولت کی ذمہ داری ہے۔

800-596-3440 (TTY: 800-842-5357)。

(For Inquiry (Farsi))

این اطلاعات حاوی اطلاعات مهم میں شامل ہیں۔ این اطلاعات

میں اہم ہے کہ یہ اطلاعات مهم ہے۔

800-596-3440 (TTY: 800-842-5357)。

(For Inquiry (Polski))

To ogłoszenie może zawierać ważne informacje. Do ogłoszenia może

zawierać ważne informacje odnośnie Państwa wniosku lub zakresu

świadectw poprzez LifeWise Health Plan of Oregon. Prosimy zwrócić

uwage na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie

przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej

lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej

informacji we własnym języku. Zadzwoń pod 800-596-3440 (TTY: 800-842-5357)

(For Inquiry (Português))

Este aviso contém informações importantes. Este aviso poderá conter

informações importantes a respeito de sua aplicação ou cobertura por meio

do LifeWise Health Plan of Oregon. Poderão existir datas importantes neste

aviso. Talvez seja necessário que você tome providências dentro de
determinados prazos para manter sua cobertura de saúde ou ajuda de
custos. Você tem o direito de obter esta informação e ajuda em seu idioma

e sem custos. Ligue para 800-596-3440 (TTY: 800-842-5357)。

(For Inquiry (Portuguese))

Este aviso contém informações importantes. Este aviso poderá conter

informações importantes a respeito de sua aplicação ou cobertura por meio

do LifeWise Health Plan of Oregon. Poderão existir datas importantes neste

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determinados prazos para manter sua cobertura de saúde ou ajuda de
custos. Você tem o direito de obter esta informação e ajuda em seu idioma

e sem custos. Ligue para 800-596-3440 (TTY: 800-842-5357)。

(Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення

може містити важливу інформацію про Ваше звернення щодо

страховального покриття через LifeWise Health Plan of Oregon. Зверніть

увагу на ключові дати, які можуть бути вказані у цьому повідомленні.

Існує імовірність того, що Вам треба будь-що зробити певні кроки у

конкретні кінцеві строки для того, щоб зберегти Ваше медичне

страхування або отримати фінансову допомогу. У Вас є право на

отримання цієї інформації та допомоги безкоштовно на Вашій рідній

мові. Дозвоніться по номеру телефону 800-596-3440 (TTY: 800-842-5357).

(Tiếng Việt (Vietnamese))


(For Inquiry (Romanian))

Prenta notificare conține informații importante. Această notificare

poate conține informații importante privind cererea sau acoperirea asigurării
dumneavoastră prin LifeWise Health Plan of Oregon. Po exista date cheie în această notificare. Este posibil să fie nevoie să acționați până

la anumite termene limite pentru a vă menține acoperirea asigurării de