MEDICAL POLICY

POLICY TITLE	AMNIOTIC MEMBRANE AND AMNIOTIC FLUID INJECTIONS
POLICY NUMBER	MP-4.042

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I. POLICY

Treatment of nonhealing diabetic lower-extremity ulcers using the following human amniotic membrane products (AmnioBand® Membrane, Q4151, Q4168, Biovance®, Q4151, EpiCord®, Q4187, Epifix®, Q4186, Grafix™, Q4132, Q4133) may be considered **medically necessary.**

Human amniotic membrane grafts with or without suture (Prokera®, AmbioDisk™) (65778, 65779, 65780, Q4100) may be considered **medically necessary** for the treatment of the following ophthalmic indications:

- Neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy (see Policy Guidelines);
- Corneal ulcers and melts that do not respond to initial conservative therapy (see Policy Guidelines);
- Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment;
- Bullous keratopathy as a palliative measure in patients 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;
- Moderate or severe Stevens-Johnson syndrome;
- Persistent epithelial defects that do not respond to conservative therapy (See Policy Guidelines);
- Severe dry eye (DEWS 3 or 4) with ocular surface damage and inflammation that remains symptomatic after Steps 1, 2, and 3 of the dry eye disease management algorithm (see Policy Guidelines); or
- Moderate or severe acute ocular chemical burn.

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Human amniotic membrane grafts with suture or glue (65779) may be considered medically necessary for the treatment of the following ophthalmic indications:

- Corneal perforation when corneal tissue is not immediately available; or
- Pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft.

Human amniotic membrane grafts with or without suture are considered investigational for all ophthalmic indications not outlined above. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Injection of micronized or particulated human amniotic membrane is considered **investigational** for all indications as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures. (Q4100, Q4139, Q4145, Q4155, Q4162, Q4171, Q4174, Q4177)

Injection of human amniotic fluid is considered **investigational** for all indications as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure. (Q4137, Q4138, Q4140, Q4148, Q4150, Q4153, Q4156, Q4157, Q4159, Q4160, Q4163, Q4169, Q4170, Q4173, Q4176, Q4178, Q4180, Q4181, Q4183, Q4184, Q4185, Q4188, Q4189, Q4190, Q4191, Q4192, Q4194, Q4198, Q4201, Q4204, Q4227, Q4229,Q4230, Q4231)

POLICY GUIDELINES

Nonhealing of diabetic wounds is defined as less than a 20% decrease in wound area with standard wound care for at least 2 weeks, based on the entry criteria for clinical trials (e.g., Zelen et al, 2015).

Conservative therapy for neurotrophic keratitis may include 5 days of pressure patching, therapeutic contact lens, topical lubricants, and topical antibiotics.

Conservative therapy for corneal ulcers and melts may include 2 days of patching, therapeutic contact lens, and topical antimicrobial agents.

A persistent epithelial defect is one 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 of a persistent epithelial defect may include 5 days of the following: topical lubricants, topical antibiotics, therapeutic contact lens, or patching.

Tear Film and Ocular Surface Society staged management for dry eye disease (Jones et al, 2017)

Step 1:

- Education regarding the condition, its management, treatment and prognosis
- Modification of local environment
- Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification/elimination of offending systemic and topical medications
- Ocular lubricants of various types (if meibomian gland dysfunction is present, then consider lipid containing supplements)
- Lid hygiene and warm compresses of various types

Step 2:

If above options are inadequate consider:

- Non-preserved ocular lubricants to minimize preservative-induced toxicity
- Tea tree oil treatment for Demodex (if present)
- Tear conservation
- Punctal occlusion
- Moisture chamber spectacles/goggles
- Overnight treatments (such as ointment or moisture chamber devices)
- In-office, physical heating and expression of the meibomian glands
- In-office intense pulsed light therapy for meibomian gland dysfunction
- Prescription drugs to manage dry eye disease
- Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
- Topical corticosteroid (limited-duration)
- Topical secretagogues
- Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine)
- Topical LFA-1 antagonist drugs (such as lifitegrast)
- Oral macrolide or tetracycline antibiotics

Step 3:

If above options are inadequate consider:

- Oral secretagogues
- Autologous/allogeneic serum eye drops

- Therapeutic contact lens options
- Soft bandage lenses
- Rigid scleral lenses

Step 4:

If above options are inadequate consider:

- Topical corticosteroid for longer duration
- Amniotic membrane grafts
- Surgical punctal occlusion
- Other surgical approaches (e.g. tarsorrhaphy, salivary gland transplantation)

Dry eye severity level DEWS 3 to 4

Discomfort, severity, and frequency - Severe frequent or constant
Visual symptoms - chronic and/or constant, limiting to disabling
Conjunctival Injection - +/- or +/+
Conjunctive Staining - moderate to marked
Corneal Staining - marked central or severe punctate erosions
Corneal/tear signs - Filamentary keratitis, mucus clumping, increase in tear debris
Lid/meibomian glands - Frequent
Tear film breakup time - < 5
Schirmer score (mm/5 min) - < 5

Cross-reference:

MP 2.033 Recombinant and Autologous Platelet Derived Growth Factors as Treatment of Wound Healing and Other Non-Orthopedic Conditions
MP 1.017 Bio-Engineered Skin and Soft Tissue Substitutes
MP 4.039 Orthopedic Applications of Platelet Rich Plasma
MP 2.028 Eye Care
MP 4.033 Diagnosis and Treatment of Dry Eye Syndrome

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual MP-7.01.149 Amniotic Membrane and Amniotic Fluid Injections. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

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.

Human Amniotic Membrane (HAM)

HAM consists of two conjoined layers, the amnion, and chorion, and forms the innermost lining of the amniotic sac or 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).

The 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.[1,] There is evidence the tissue has anti-inflammatory, antifibroblastic, and antimicrobial properties. HAM is considered nonimmunogenic and has not been observed to cause a substantial immune response. It is believed these properties are retained in cryopreserved HAM and dehydrated HAM products, resulting in a readily available tissue with regenerative potential. In support, one dehydrated 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.[2,]

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.[1,] Additional indications studied in preclinical 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 proteins, carbohydrates, peptides, fats, amino acids, 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 evidence review 8.01.52.

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

Product (Supplier)	**Preparation**	**Components**			
	Cryopreserved, Dehydrated, or Extracted	Amnion	Chorion	Amniotic Fluid	Umbilical Cord
Patch					
Affinity™ (NuTech Medical)	C	X			
AlloWrap™ (AlloSource)	NS	X			
AmbioDisk® (IOP Ophthalmics)	D				
AmbioDry5® (IOP Ophthalmics)	D				
AmnioBand® Membrane (MTF Wound Care)	D	X	X		
AmnioClear™ (Liventa Bioscience)	NS	X	X		
AmnioExcel® (Derma Sciences)	D	X			
AmnioFix® (MiMedx)	D	X			
AmnioGraft® (Bio-Tissue)	C	X			
Artacent® Wound (Tides Medical)	D	X			
BioDDryFlex® (BioD)	D	X			
BioDfence™ (BioD)	D	X	X		
BioSkin (HRT)[a]	D	X	X		
Biovance® (Alliqua Biomedical)	D	X			
Clarix® (Amniox Medical)	C	X			X
Cygnus (Vivex Biomedical)	D	X			

Cygnus Max (Vivex Biomedical)	D				X
EpiCord™ (MiMedx)	D				X
EpiFix® (MiMedx)	D	X	X		
Dermavest™ (Aedicell)[a]	C	X	X		X
Grafix® (Osiris)	C	X	X		
Guardian/AmnioBand® (MTF Wound Care)	D	X	X		
Neox® 100 (Amniox Medical)	C	X			X
Neox® Cord (Amniox Medical)	C	X			X
Neox® Wound Allograft (Amniox Medical)	C	X			X
NuShield™ (NuTech Medical)	D	X	X		
PalinGen® Membrane (Amnio ReGen Solutions)	C	X			
Plurivest™ (Aedicell)[a]	C	X	X		X
Prokera® (Bio-Tissue)	C				
Revitalon™ (Medline Industries)	D	X	X		
WoundEx® (Skye Biologics)[a]	D	X	X		
Suspension, particulate, or extraction					
AmnioBand® Particulate (MTF Wound Care)	D	X	X		
AmnioMatrix® (Derma Sciences)	D	X		X	
AmnioVisc™ (Lattice Biologics)	NS			X	
BioSkin® Flow (HRT)[b]	E	X	X	X	X
Clarix® Flo (Amniox Medical)	C	X			X
Interfyl™ (Alliqua Biomedical)	NS	X	X		
Neox® Flo (Amniox Medical)	C	X			X
OrthoFlo™ (MiMedx)	D			X	
PalinGen® Flow (Amnio ReGen Solutions)	C	X		X	
PalinGen® SportFlow (Amnio ReGen Solutions)	C	X		X	

ProMatrX™ ACF (Amnio ReGen Solutions)	C	X		X	
ReNu™ (NuTech Medical)	D	X		X	
WoundEx® Flow (Skye Biologics)[b]	E	X	X	X	X

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

[a,b] Processed by HRT and marketed by under different tradenames.

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, title 21, parts 1270 and 1271. HAM products and amniotic fluid products are included in these regulations.

In 2003, Prokera™ was cleared for marketing by the Food and Drug Administration through the 510(k) process for the ophthalmic conformer that incorporates amniotic membrane (K032104). The Food and Drug Administration 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." The development of Prokera, a commercially available product, was supported in part by the National Institute of Health and the National Eye Institute.

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.

IV. RATIONALE

TOP

SUMMARY OF EVIDENCE

Diabetic Lower-Extremity Ulcers

For individuals who have non-healing diabetic lower-extremity ulcers who receive a patch or flowable formulation of HAM (i.e., AmnioBand Membrane, Biovance, EpiFix, Grafix), the evidence includes RCTs. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. The RCTs evaluating amniotic and placental membrane products for the treatment of non-healing (<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 ITT analysis. For the HAM products that have been sufficiently evaluated (i.e., AmnioBand Membrane, Biovance, EpiCord, 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 two RCTs. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. The evidence on HAM for the treatment of lower-extremity venous ulcers includes two multicenter RCTs with EpiFix. One RCT reported larger percent wound closure at four weeks but the percentage of patients with complete wound closure did not differ between EpiFix and the SOC. 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 SOC 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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 HAM or amniotic fluid, the evidence includes two small RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Research on HAM injections for plantar fasciitis is at an early stage. The 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

Neurotrophic Keratitis with Ocular Surface Damage and Inflammation that does not Respond to Conservative Therapy

For individuals who have neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy who receive HAM, the evidence includes an RCT.
The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. An RCT of 30 patients showed no benefit of sutured HAM graft compared to tarsorrhaphy or bandage contact lens. Based on clinical input, HAM might be considered for patients who did not respond to conservative therapy. Clinical input indicated that non-sutured HAM in an office setting would be preferred to avoid a delay in treatment associated with scheduling a surgical treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Corneal Ulcers and Melts that does not Respond to Initial Medical Therapy

For individuals who have corneal ulcers and melts that does not respond to initial medical therapy who receive HAM, the evidence is limited. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. Corneal ulcers and melts are uncommon and variable and RCTs are not expected. Based on clinical input, HAM might be considered for patients who did not respond to conservative therapy. Clinical input indicated that non-sutured HAM in an office setting would be preferred to avoid a delay in treatment associated with scheduling a surgical treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Corneal Perforation When There is Active Inflammation After Corneal Transplant Requiring Adjunctive Treatment

For individuals who have corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment who receive HAM, the evidence is limited.
The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. No comparative evidence was identified for this indication. Clinical input supported the use of HAM to reduce inflammation and promote epithelial healing with active inflammation following corneal transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Bullous Keratopathy as a Palliative Measure in Patients Who are not Candidates for a Curative Treatment (e.g., endothelial or penetrating keratoplasty)

For individuals who have bullous keratopathy and who are not candidates for curative treatment (e.g., endothelial or penetrating keratoplasty) who receive HAM, the evidence includes an RCT. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. An RCT found no advantage of sutured HAM over the simpler stromal puncture procedure for the treatment of pain from bullous keratopathy. Based on clinical input, non-sutured HAM could be

used as an alternative to stromal puncture. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Partial LSCD with Extensive Diseased Tissue Where Selective Removal Alone is not Sufficient

For individuals who have partial LSCD with extensive diseased tissue where selective removal alone is not sufficient who receive HAM, the evidence is limited. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. No RCTs were identified on HAM for LSCD. Improvement in visual acuity has been reported for some patients who have received HAM in conjunction with removal of the diseased limbus. Clinical input noted the limitations of performing an RCT and supported the use of HAM for this indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Moderate or Severe Stevens-Johnson Syndrome

For individuals who have moderate or severe Stevens-Johnson syndrome who receive HAM, the evidence includes an RCT. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. The evidence on HAM for the treatment of Stevens-Johnson includes one RCT with 25 patients (50 eyes) that found improved symptoms and function with HAM compared to medical therapy alone. Clinical input indicated that large RCTs are unlikely due to the severity and rarity of the disease, supported the use of HAM for moderate or severe Stevens-Johnson. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Persistent Epithelial Defects and Ulceration That does not Respond to Conservative Therapy

For individuals who have persistent epithelial defects that does not respond to conservative therapy who receive HAM, the evidence is limited. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. No RCTs were identified on persistent epithelial defects and ulceration. Clinical input noted the difficulty in conducting RCTs for this indication and supported the use of amniotic membrane for persistent epithelial defects and ulcerations that does not respond to conservative therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Severe Dry Eye with Ocular Surface Damage and Inflammation That does not Respond to Conservative Therapy

For individuals who have severe dry eye with ocular surface damage and inflammation that does not respond to conservative therapy, who receive HAM, the evidence includes an RCT and a large case series. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. The evidence on HAM for severe dry eye with ocular surface damage and

inflammation includes an RCT with 20 patients and a retrospective series of 84 patients (97 eyes). Placement of self-retained HAM for 2 to 11 days reduced symptoms and restored a smooth corneal surface and corneal nerve density for as long as 3 months. Clinical input supported HAM in cases of severe dry eye with ocular surface damage and inflammation that does not respond to conservative therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Moderate or Severe Acute Ocular Chemical Burns

For individuals who have moderate or severe acute ocular chemical burn who receive HAM, the evidence includes an RCT. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. Evidence includes an RCT of 100 patients with acute ocular chemical burns who were treated with HAM transplantation plus medical therapy or medical therapy alone. Patients in the HAM group had a faster rate of epithelial healing, without a significant benefit for other outcomes. Clinical input was in support of HAM for acute ocular chemical burn. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Corneal Perforation When Corneal Tissue is not Immediately Available

For individuals who have corneal perforation when corneal tissue is not immediately available who receive sutured HAM, the evidence is limited. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. The standard treatment for corneal perforation is corneal transplantation. Based on clinical input, sutured HAM may be used as a temporary measure when corneal tissue is not immediately available. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Pterygium Repair When There is Insufficient Healthy Tissue to Create a Conjunctival Autograft

For individuals who have pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft who receive HAM, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. Systematic reviews of RCTs have been published that found that conjunctival or limbal autograft is more effective than HAM graft in reducing the rate of pterygium recurrence. Based on clinical input, sutured or glued HAM may be considered when there is insufficient healthy tissue to create a conjunctival autograft (e.g., extensive, double, or recurrent pterygium). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change.Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

The following human amniotic membrane products are considered investigational for all indications; therefore, not covered:

HCPCS Codes	Description
Q4137	Amnioexcel, amnioexcel plus or per square centimeter
Q4138	BioDFence DryFlex, per sq. cm
Q4140	BioDFence, per sq. cm

Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter
Q4150	AlloWrap DS or dry, per sq. cm
Q4153	Dermavest and Plurivest, per sq. cm
Q4156	Neox 100 or clarix 100, per square centimeter
Q4157	Revitalon, per sq. cm
Q4159	Affinity, per sq. cm
Q4160	Nushield, per sq. cm
Q4163	AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-200, per sq. cm
Q4169	Artacent wound, per sq. cm
Q4170	Cygnus, per sq. cm
Q4173	PalinGen or PalinGen XPlus, per sq. cm
Q4176	Neopatch, per square centimeter
Q4178	Floweramniopatch, per square centimeter
Q4180	Revita, per square centimeter
Q4181	Amnio wound, per square centimeter
Q4183	Surgigraft, per square centimeter
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc
Q4188	Amnioarmor, per square centimeter
Q4189	Artacent ac, 1 mg
Q4190	Artacent ac, per square centimeter
Q4191	Restorigin, per square centimeter
Q4192	Restorigin, 1 cc
Q4194	Novachor, per square centimeter
Q4198	Genesis amniotic membrane, per square centimeter
Q4201	Matrion, per square centimeter
Q4202	Xwrap, per square centimeter
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	AlloGen, per cc
Q4213	Ascent, 0.5 mg
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4218	SurgiCORD, per sq cm
Q4219	SurgiGRAFT-DUAL, per sq cm

Q4220	BellaCell HD or Surederm, per sq cm
Q4232	Corplex, per square centimeter
Q4221	Amnio Wrap2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4247	Amniotext patch, per square centimeter
Q4249	Amniply, for topical use only, per square centimeter
Q4255	Reguard, for topical use only, per square centimeter

Injection of micronized or particulated human amniotic membrane or injection of human amniotic fluid for all indications, are considered investigational; therefore, not covered:

HCPCS Codes	Description
Q4100	Skin substitute, not otherwise specified (when used for Amino Fix and Ortho Flo)
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4145	EpiFix, injectable, 1 mg
Q4155	Neox Flo or Clarix Flo 1 mg
Q4162	AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 cc
Q4171	Interfyl, 1 mg
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4177	Floweramnioflo, 0.1 cc
Q4227	Amniocore, per square centimeter
Q4229	Cogenex amniotic membrane, per square centimeter
Q4230	Cogenex flowable amnion, per 0.5 cc
Q4231	Corplex p, per cc
Q4233	Surfactor or nudyn, per 0.5 cc
Q4240	Corecyte, for topical use only, per 0.5 cc
Q4242	Amniocyte plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc

Covered when medically necessary, for treatment of non-healing diabetic lower-extremity ulcers:

HCPCS Codes	Description
Q4132	Grafix core and grafixpl core, per square centimeter
Q4133	Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter
Q4151	AmnioBand or Guardian, per sq. cm

Q4154	Biovance, per sq. cm
Q4168	AmnioBand, 1 mg
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter

ICD-10-CM Diagnosis Codes	Description
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer

Amniotic membrane grafts that are with or without sutures, glue may be considered medically necessary, therefore covered for the following ophthalmic indications:

CPT Codes ®							
65778	65779	65780					

HCPCS Codes	Description
Q4100	Skin substitute, not otherwise specified (when used to bill for Prokera®, or AmbioDisk™)
V2790	Amniotic membrane for surgical reconstruction, per procedure

ICD-10-CM Diagnosis Codes	Description
H11.001	Unspecified pterygium of right eye
H11.002	Unspecified pterygium of left eye
H11.003	Unspecified pterygium of eye, bilateral
H11.011	Amyloid pterygium of right eye
H11.012	Amyloid pterygium of left eye
H11.013	Amyloid pterygium of eye, bilateral

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ICD-10-CM Diagnosis Codes	Description
H11.021	Central pterygium of right eye
H11.022	Central pterygium of left eye
H11.023	Central pterygium of eye, bilateral
H11.031	Double pterygium of right eye
H11.032	Double pterygium of left eye
H11.033	Double pterygium of eye, bilateral
H11.041	Peripheral pterygium, stationary, right eye
H11.042	Peripheral pterygium, stationary, left eye
H11.043	Peripheral pterygium, stationary, bilateral
H11.051	Peripheral pterygium, progressive, right eye
H11.052	Peripheral pterygium, progressive, left eye
H11.053	Peripheral pterygium, progressive, bilateral
H11.061	Recurrent pterygium of right eye
H11.062	Recurrent pterygium of left eye
H11.063	Recurrent pterygium of eye, bilateral
H11.069	Recurrent pterygium of unspecified eye
H16.001	Unspecified corneal ulcer, right eye
H16.002	Unspecified corneal ulcer, left eye
H16.003	Unspecified corneal ulcer, bilateral
H16.011	Central corneal ulcer, right eye
H16.012	Central corneal ulcer, left eye
H16.013	Central corneal ulcer, bilateral
H16.021	Ring corneal ulcer, right eye
H16.022	Ring corneal ulcer, left eye
H16.023	Ring corneal ulcer, bilateral
H16.031	Corneal ulcer with hypopyon, right eye
H16.032	Corneal ulcer with hypopyon, left eye
H16.033	Corneal ulcer with hypopyon, bilateral
H16.041	Marginal corneal ulcer, right eye
H16.042	Marginal corneal ulcer, left eye
H16.043	Marginal corneal ulcer, bilateral
H16.051	Mooren's corneal ulcer, right eye
H16.052	Mooren's corneal ulcer, left eye
H16.053	Mooren's corneal ulcer, bilateral
H16.061	Mycotic corneal ulcer, right eye
H16.062	Mycotic corneal ulcer, left eye
H16.063	Mycotic corneal ulcer, bilateral
H16.071	Perforated corneal ulcer, right eye
H16.072	Perforated corneal ulcer, left eye
H16.073	Perforated corneal ulcer, bilateral
H16.079	Perforated corneal ulcer, unspecified eye

POLICY TITLE	AMNIOTIC MEMBRANE AND AMNIOTIC FLUID INJECTIONS
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ICD-10-CM Diagnosis Codes	Description
H16.231	Neurotrophic keratoconjunctivitis, right eye
H16.232	Neurotrophic keratoconjunctivitis, left eye
H16.233	Neurotrophic keratoconjunctivitis, bilateral
H16.239	Neurotrophic keratoconjunctivitis, unspecified eye
H18.10	Bullous keratopathy, unspecified eye
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral
H18.831	Recurrent erosion of cornea, right eye
H18.832	Recurrent erosion of cornea, left eye
H18.833	Recurrent erosion of cornea, bilateral
H18.839	Recurrent erosion of cornea, unspecified eye
H18.891	Other specified disorders of cornea, right eye
H18.892	Other specified disorders of cornea, left eye
H18.893	Other specified disorders of cornea, bilateral
L51.1	Stevens-Johnson syndrome

IX. REFERENCES

TOP

1. *Parolini O, Soncini M, Evangelista M, et al. Amniotic membrane and amniotic fluid-derived cells: potential tools for regenerative medicine? Regen Med. Mar 2009;4(2):275-291. PMID 19317646*
2. *Koob TJ, Rennert R, Zabek N, et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. Int Wound J. Oct 2013;10(5):493-500. PMID 23902526*
3. *Shimberg M, Wadsworth K. The use of amniotic-fluid concentrate in orthopaedic conditions. J Bone Joint Surg. 1938;20(I):167-177.*
4. *U.S. Food and Drug Administration. Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use Guidance for Industry and Food and Drug Administration Staff. 2017 https://www.regulations.gov/document?D=FDA-2017-D-6146-0003 Accessed January 13, 2020*
5. *Food and Drug Administration. 510(k) Summary: ProKeraTM Bio-Tissue Inc. (K032104). 2003; https://www.accessdata.fda.gov/cdrh_docs/pdf3/K032104.pdf. Accessed January 26, 2018.*
6. *Ananian, CC, Dhillon, YY, Van Gils, CC, Lindsey, DD, Otto, RR, Dove, CC, Pierce, JJ, Saunders, MM. A multicenter, randomized, single-blind trial comparing the efficacy of viable cryopreserved placental membrane to human fibroblast-derived dermal substitute for the treatment of chronic diabetic foot ulcers. Wound Repair Regen, 2018 Aug 12;26(3). PMID 30098272*

7. *Tettelbach, WW, Cazzell, SS, Sigal, FF, Caporusso, JJ, Agnew, PP, Hanft, JJ, Dove, CC. A multicentre prospective randomised controlled comparative parallel study of dehydrated human umbilical cord (EpiCord) allograft for the treatment of diabetic foot ulcers. 2019 Feb; 16(1): 122 -130. PMID 30246926*
8. *DiDomenico LA, Orgill DP, Galiano RD, et al. Use of an aseptically processed, dehydrated human amnion and chorion membrane improves likelihood and rate of healing in chronic diabetic foot ulcers: A prospective, randomised, multi-centre clinical trial in 80 patients. Int Wound J, 2018 Jul 19;15(6). PMID 30019528*
9. *Snyder RJ, Shimozaki K, Tallis A, et al. A prospective, randomized, multicenter, controlled evaluation of the use of dehydrated amniotic membrane allograft compared to standard of care for the closure of chronic diabetic foot ulcer. Wounds. Mar 2016;28(3):70-77. PMID 26978860*
10. *Zelen CM, Gould L, Serena TE, et al. A prospective, randomised, controlled, multi-centre comparative effectiveness study of healing using dehydrated human amnion/chorion membrane allograft, bioengineered skin substitute or standard of care for treatment of chronic lower extremity diabetic ulcers. Int Wound J. Dec 2015;12(6):724-732. PMID 25424146*
11. *Zelen CM, Serena TE, Gould L, et al. Treatment of chronic diabetic lower extremity ulcers with advanced therapies: a prospective, randomised, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J. Apr 2016;13(2):272-282. PMID 26695998*
12. *Tettelbach W, Cazzell S, Reyzelman AM et al. A confirmatory study on the efficacy of dehydrated human amnion/chorion membrane dHACM allograft in the management of diabetic foot ulcers: A prospective, multicentre, randomised, controlled study of 110 patients from 14 wound clinics.. Int Wound J, 2018 Aug 24;16(1). PMID 30136445*
13. *Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix((R)) for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. Int Wound J. Oct 2014;11(5):554-560. PMID 25048468*
14. *Smiell JM, Treadwell T, Hahn HD, et al. Real-world experience with a decellularized dehydrated human amniotic membrane allograft. Wounds. Jun 2015;27(6):158-169. PMID 26061491*
15. *Frykberg, RR, Gibbons, GG, Walters, JJ, Wukich, DD, Milstein, FF. A prospective, multicentre, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved human placental membrane.. Int Wound J, 2016 Aug 5;14(3). PMID 27489115*
16. *Serena TE, Carter MJ, Le LT, et al. A multicenter, randomized, controlled clinical trial evaluating the use of dehydrated human amnion/chorion membrane allografts and multilayer compression therapy vs. multilayer compression therapy alone in the treatment of venous leg ulcers. Wound Repair and Regeneration. Nov-Dec 2014;22(6):688-693. PMID 25224019*
17. *Bianchi C, Cazzell S, Vayser D, et al. A multicentre randomised controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix(R)) allograft for the treatment of venous leg ulcers. Int Wound J. Oct 11 2017. PMID 29024419*

18. *Bianchi C, Tettelbach W, Istwan N, et al. Variations in study outcomes relative to intention-to-treat and per-protocol data analysis techniques in the evaluation of efficacy for treatment of venous leg ulcers with dehydrated human amnion/chorion membrane allograft. Int Wound J, 2019 Mar 14;16(3). PMID 30864259*
19. *Vines JB, Aliprantis AO, Gomoll AH, et al. Cryopreserved amniotic suspension for the treatment of knee osteoarthritis. J Knee Surg. Aug 2016;29(6):443-450. PMID 26683979*
20. *Tsikopoulos K, Vasiliadis HS, Mavridis D. Injection therapies for plantar fasciopathy ('plantar fasciitis'): a systematic review and network meta-analysis of 22 randomised controlled trials. Br J Sports Med. Nov 2016;50(22):1367-1375. PMID 27143138*
21. *Zelen CM, Poka A, Andrews J. Prospective, randomized, blinded, comparative study of injectable micronized dehydrated amniotic/chorionic membrane allograft for plantar fasciitis--a feasibility study. Foot Ankle Int. Oct 2013;34(10):1332-1339. PMID 23945520*
22. *Cazzell, SS, Stewart, JJ, Agnew, PP, Senatore, JJ, Walters, JJ, Murdoch, DD, Reyzelman, AA, Miller, SS. Randomized Controlled Trial of Micronized Dehydrated Human Amnion/Chorion Membrane (dHACM) Injection Compared to Placebo for the Treatment of Plantar Fasciitis.. NA. PMID 30058377*
23. *Khokhar, SS, Natung, TT, Sony, PP, Sharma, NN, Agarwal, NN, Vajpayee, RR. Amniotic membrane transplantation in refractory neurotrophic corneal ulcers: a randomized, controlled clinical trial. Cornea, 2005 Jul 15;24(6). PMID 16015082*
24. *Suri, KK, Kosker, MM, Raber, II, Hammersmith, KK, Nagra, PP, Ayres, BB, Halfpenny, CC, Rapuano, CC. Sutureless amniotic membrane ProKera for ocular surface disorders: short-term results. Eye Contact Lens, 2013 Aug 16;39(5). PMID 23945524*
25. *Liu J, Li L, Li X. Effectiveness of Cryopreserved Amniotic Membrane Transplantation in Corneal Ulceration: A Meta-Analysis. Cornea. 2019 Apr;38(4). PMID 30702468*
26. *Paris Fdos S, Goncalves ED, Campos MS, et al. Amniotic membrane transplantation versus anterior stromal puncture in bullous keratopathy: a comparative study. Br J Ophthalmol. Aug 2013;97(8):980-984. PMID 23723410*
27. *Kheirkhah, AA, Casas, VV, Raju, VV, Tseng, SS. Sutureless amniotic membrane transplantation for partial limbal stem cell deficiency.. Am. J. Ophthalmol., 2008 Mar 11;145(5). PMID 18329626*
28. *Pachigolla, GG, Prasher, PP, Di Pascuale, MM, McCulley, JJ, McHenry, JJ, Mootha, VV. Evaluation of the role of ProKera in the management of ocular surface and orbital disorders.. Eye Contact Lens, 2009 May 29;35(4). PMID 19474753*
29. *Sharma N, Thenarasun SA, Kaur M, et al. Adjuvant role of amniotic membrane transplantation in acute ocular stevens-johnson syndrome: a randomized control trial. Ophthalmology. Mar 2016;123(3):484-491. PMID 26686968*
30. *Bouchard, CC, John, TT. Amniotic membrane transplantation in the management of severe ocular surface disease: indications and outcomes.. Ocul Surf, 2007 Jan 12;2(3). PMID 17216092*
31. *John, TT, Tighe, SS, Sheha, HH, Hamrah, PP, Salem, ZZ, Cheng, AA, Wang, MM, Rock, NN. Corneal Nerve Regeneration after Self-Retained Cryopreserved Amniotic Membrane in Dry Eye Disease.. J Ophthalmol, 2017 Sep 13;2017:6404918. PMID 28894606*

32. *McDonald, MM, Sheha, HH, Tighe, SS, Janik, SS, Bowden, FF, Chokshi, AA, Singer, MM, Nanda, SS, Qazi, MM, Dierker, DD, Shupe, AA, McMurren, BB. Treatment outcomes in the DRy Eye Amniotic Membrane (DREAM) study.. Clin Ophthalmol, 2018 Apr 20;12:677-681. PMID 29670328*
33. *Tandon, RR, Gupta, NN, Kalaivani, MM, Sharma, NN, Titiyal, JJ, Vajpayee, RR. Amniotic membrane transplantation as an adjunct to medical therapy in acute ocular burns.. Br J Ophthalmol, 2010 Aug 3;95(2). PMID 20675729*
34. *Eslani M, Baradaran-Rafii A, Cheung AY et al. Amniotic Membrane Transplantation in Acute Severe Ocular Chemical Injury: A Randomized Clinical Trial. Am. J. Ophthalmol. 2019 Mar;199:209-215. PMID 30419194*
35. *Tamhane A, Vajpayee RB, Biswas NR, et al. Evaluation of amniotic membrane transplantation as an adjunct to medical therapy as compared with medical therapy alone in acute ocular burns. Ophthalmology. 2005 Nov;112(11). PMID 16198422*
36. *Kheirkhah, AA, Johnson, DD, Paranjpe, DD, Raju, VV, Casas, VV, Tseng, SS. Temporary sutureless amniotic membrane patch for acute alkaline burns.. Arch. Ophthalmol., 2008 Aug 13;126(8). PMID 18695099*
37. *Kaufman SC, Jacobs DS, Lee WB, et al. Options and adjuvants in surgery for pterygium: a report by the American Academy of Ophthalmology. Ophthalmology. Jan 2013;120(1):201-208. PMID 23062647*
38. *Clearfield, EE, Muthappan, VV, Wang, XX, Kuo, II. Conjunctival autograft for pterygium. Cochrane Database Syst Rev, 2016 Feb 13;2:CD011349. PMID 26867004*
39. *Hingorani, AA, LaMuraglia, GG, Henke, PP, Meissner, MM, Loretz, LL, Zinszer, KK, Driver, VV, Frykberg, RR, Carman, TT, Marston, WW, Mills, JJ, Murad, MM. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine.. NA. PMID 26804367*
40. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.149, Amniotic Membrane and Amniotic Fluid Injections. February 2019.*

X. POLICY HISTORY

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MP-4.042	**CAC 11/28/17** New policy. BCBSA adopted**.** Treatment of non-healing diabetic lower-extremity ulcers using the following human amniotic membrane products (AmnioBand® Membrane, Biovance®, Epifix®, Grafix™) may be considered medically necessary. Fixed amniotic membrane grafts are considered medically necessary for neutropathic keratitis, corneal ulcers and melts following pterygium repair, Stevens Johnson, and persistent epithelial defects. Injection of micronized amniotic membrane and injection of amniotic fluid for all indications are considered investigational. Self-contained or unfixated amniotic membrane products (e.g., Prokera®) for ophthalmic indications are considered not medically necessary**.** Criteria for Amniotic membrane transplants was previously

	addressed in MP-2.028 Eye Care. Amniotic membrane transplants for pemphigoid and alkali burns changed to investigational. FEP variation added. AmbioDisk added as another example of a human amniotic membrane without suture for ophthalmic indications considered investigational. Coding reviewed.
	5/1/18 Admin Coding update. Added codes 65780 and V2790 as covered services.
	1/1/19 Admin Update: Updated deleted & revised codes. Added new codes Q4183- Q4192, Q4194, Q4198, Q4201 & Q4204 effective 1/1/19.
	7/11/18 Minor review. The terminology "Amniotic membrane grafts that are fixated using sutures or glue fixation or secured under a bandage contact lens" was changed to "Sutured human amniotic membrane grafts". Added investigational statement "Human amniotic membrane without suture (e.g., Prokera®, AmbioDisk™) for ophthalmic indications, previously not medically necessary. "Treatment of lower-extremity ulcers due to venous insufficiency" added as a specific indication to the all other investigational policy statement. Coding updated. Effective 3/1/19.
	4/16/19 Minor review: EpiCord added to medically necessary statement for diabetic lower extremity ulcers. Changed sutured and non-sutured amniotic membrane to medically necessary for specified ophthalmic conditions. Previously medically necessary for sutured only. Added additional ophthalmic conditions where treatment is considered medically necessary including corneal perforations, bullous keratopathy, partial limbal stem cell deficiency, severe dry eye, and moderate to severe acute ocular chemical burn when criteria is met. For neurotrophic keratitis with ocular surface damage and inflammation, corneal ulcers and melts, persistent epithelial defects – added "that does not respond to conservative therapy". For Steven's-Johnson syndrome – added moderate to severe. For human amniotic membrane grafts with suture or glue – added medically necessary criteria for corneal perforation. Pterygium repair remains indicated for human amniotic membrane graft with suture or glue with added criteria. New 2019 codes added to policy (Q4205-Q4222). Description updated on Q4184. Effective 10/1/2019
	04/20/2020 Consensus review. No changes to policy statements.
	05/29/2020 New codes added to policy, effective date of 07/01/2020
	10/01/2020 Administrative update. New code Q4249 and Q4255 added to policy. Effective 10/01/2020.

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