



## Ocular Remodeling

LOB(s): <input checked="" type="checkbox"/> Commercial  <input checked="" type="checkbox"/> Medicare  <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:  <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington
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## Enterprise Policy

*Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member’s policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member’s policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member’s policy, the Member’s policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.*

## Background

The surface layers of the eye consist of the conjunctiva, the sclera, and the cornea. Both the conjunctiva and cornea are covered by a layer called the epithelium, which completely regenerates every three to 10 days, requiring constant renewal of cells in order to remain healthy. In eyes with ocular surface disease, the epithelium is damaged, and treatment depends on the underlying causes.

Limbal stem cells are the main source of regeneration for corneal cells that affect the ocular surface. Due to trauma or a variety of diseases, limbal stem cell deficiency (LSCD) can develop which can cause changes to the cornea and or the conjunctiva. Symptoms of limbal stem cell deficiency may include photophobia, blurred, or decreased vision, tearing, pain, chronic inflammation, and redness.

Amniotic Membrane Transplantation (AMT) with or without limbal stem cell transplantation is a surgical treatment option to address limbal stem cell deficiency. The purpose is to reconstruct damaged ocular surfaces and promote healing of corneal, conjunctival, and eyelid tissues. The amniotic membrane tissue may be autologous or allogeneic.

Amniotic membrane products have also been used for the management of select ophthalmologic wounds and reconstruction where there is limited access to autologous tissue for transplant, or when allogeneic transplant is not appropriate. These products (e.g., Ambio2, Ambio5, AmnioDisk, AmnioGraft, ProKera, Prokera Slim) come in a wide array of forms and most are obtained directly from tissue banks.

### **Corneal Cross-linking (CXL) Epithelium-off**

Corneal cross-linking (CXL) is an outpatient procedure designed to treat progressive

keratoconus and corneal ectasia. Keratoconus is a progressive eye disease characterized by deformation (becomes cone shaped) of the cornea. Corneal ectasia is a form of keratoconus that occurs after refractive surgery. The goal of CXL is to stop the cornea from getting thinner, weaker, and more irregular in shape.

The CXL procedure strengthens and stabilizes the cornea by creating new links between collagen fibers within the cornea. The two-step procedure applies liquid riboflavin (vitamin B2) to the surface of the eye immediately followed by a controlled exposure of ultraviolet light.

There are two basic types of corneal cross-linking:

Epithelium-off CXL and Epithelium-on CXL. Epithelium-off CXL removes the thin outer layer (epithelium) of the cornea to allow the liquid riboflavin to penetrate the corneal tissue more easily.

Epithelium-on (transepithelial) corneal collagen cross-linkage (CXL) is considered experimental, investigational, or unproven.

### **Prosthetic Replacement of Ocular Surface Ecosystem (PROSE)**

The prosthetic replacement of the ocular surface ecosystem (PROSE) is a type of fully customized gas permeable rigid scleral contact lens for use in individuals with ocular surface disease. PROSE devices are removable transparent domes that vault over the cornea to create a smooth surface over the distorted, damaged, or diseased ocular surface.

### **Intrastromal corneal ring segments**

Intrastromal corneal ring segments (e.g., Intacs™) are removable corneal inserts designed to reshape the anterior surface of the cornea. The rings consist of two plastic arc-shaped segments which are surgically implanted into the perimeter of the cornea.

If approved, coverage of intrastromal corneal ring segments for keratoconus will be covered under the medical plan benefit, not the vision endorsement.

## **Criteria**

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### **Commercial**

**Prior authorization is required.**

#### **I. Amniotic Membrane Transplantation (AMT)**

PacificSource considers Autologous or Allogeneic Amniotic Membrane Transplantation (AMT) with or without limbal stem cell transplantation for ocular surface reconstruction medically necessary when **ONE** or more of the criteria is met:

- A.** For reconstruction of **Corneal Surface**, as indicated for **ONE** or more of the following conditions:
1. Acute thermal/chemical burns
  2. Band Keratopathy
  3. Corneal ulceration (central or peripheral)
  4. Descemetocoele or Perforation of corneal surface
  5. Neurotropic Keratitis

6. Bullous keratopathy
7. Partial or complete limbal stem cell deficiency (with stem cell grafting)
8. Persistent epithelial defect that failed conservative treatment

**B.** For reconstruction of the **Surface of the Conjunctiva**, as indicated for **ONE** or more of the following conditions:

1. Acute Stevens-Johnson syndrome
2. Acute thermal/chemical burns
3. Covering defects after removal of conjunctival lesions (conjunctival intraepithelial neoplasia, tumors, scars, or folds parallel to the edges of the eyelids)
4. Bleb revisions
5. Pterygium if there was insufficient conjunctiva for an autograft
6. Scleral thinning
7. Superior Limbic Keratoconjunctivitis that failed conjunctival resection
8. Symblepharon, fornix reconstruction

## **II. Amniotic Membrane Products**

PacificSource may consider the use of amniotic membrane products with or without suture(s) (e.g., Ambio2, Ambio5, AmnioDisk, AmnioGraft, ProKera, ProKera Slim) to be medically necessary for the treatment of severe ocular surface disease when the **BOTH** of the following criteria is met:

**A.** Documented failure of, intolerance to, or contraindication to Autologous or Allogeneic ~~treatment~~ using conventional medical management

**B.** Treatment is for **ONE** or more of the following conditions:

1. Bullous keratopathy
2. Chemical or thermal burns to cornea
3. Pterygium
4. Recurrent corneal abrasions, erosions, ulcers, wounds
5. Recurrent severe keratitis (e.g., autoimmune, bacterial, exposure, neurotrophic, viral, etc.)
6. Stevens-Johnson syndrome
7. Trauma

## **III. Corneal Cross-linking (CXL) Epithelium-off**

PacificSource considers corneal collagen cross-linking (CXL) epithelium-off which uses riboflavin and ultraviolet light as a medically necessary treatment when **ALL** of MCG (A-1040 AC) criteria is met.

**NOTE:** Riboflavin (Photrexa) is considered part of the cost of the corneal collagen cross-linking (CXL) procedure and is not separately reimbursable.

## **IV. Prosthetic Replacement of Ocular Surface Ecosystem (PROSE)**

PacificSource may consider Prosthetic Replacement of Ocular Surface Ecosystem (PROSE) to be medically necessary when **ALL** of the following conditions are met:

- A. Adult **OR** pediatric members are diagnosed with **ONE** of the following ocular surface diseases including but not limited to:
  - 1. Keratoconus
  - 2. Sjogren's syndrome, ocular Graft-versus-Host disease, severe dry eye syndrome, Filamentary Keratitis
  - 3. Limbal stem cell deficiency (e.g., Stevens-Johnson syndrome, chemical radiation, and thermal burns)
  - 4. Disorders of the skin (e.g., atopy, ectodermal dysplasia, epidermolysis bullosa)
  - 5. Neurotrophic keratitis (e.g., Herpes simples, herpes zoster, Familial Dysautonomia)
  - 6. Exposure keratopathy
- B. Standard appropriate treatments have been exhausted (e.g., include but not limited to)
  - 1. Pharmacologic treatment is not effective (e.g., ocular lubricants, tear stimulating drugs, topical ophthalmologic steroids. oral steroids, antimicrobial therapy)
  - 2. Eye inserts (e.g., Lacrisert)
  - 3. Therapeutic contact lens treatments have been tried and failed or are not an option
  - 4. Procedures (e.g., closing tear ducts, ectropion repair) are not effective

#### V. **Intrastromal Corneal Ring Segments**

PacificSource may consider intrastromal corneal ring segments to be medically necessary when **ALL** of the following criteria is met:

- A. Diagnosis of Keratoconus;
- B. The member has experienced a progressive deterioration in their vision such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles;
- C. The member is age 21 or older;
- D. The member has clear central corneas;
- E. The corneal thickness at the proposed incision site is 450 microns or greater; **and**
- F. The members only remaining option to improve their functional vision is corneal transplantation

#### **Medicaid**

PacificSource Community Solutions follows Oregon Health Plan (OHP) Oregon Administrative Rules (OARs) 410-141-3820 to 3830 & 410-120-1200 for coverage of Amniotic Membrane Transplantation (AMT).

PacificSource Community Solutions follows Guideline Note 9 of the OHP Prioritized List of Health Services for coverage of Collagen cross-linking of cornea.

PacificSource Community Solutions follows OAR 410-140-0160 and considers Prosthetic Replacement of Ocular Surface Ecosystem (PROSE) not covered.

PacificSource Community Solutions follows Guideline Note 168 of the OHP Prioritized List of Health Services for coverage of Intrastromal Corneal Ring Segments.

PacificSource Community Solutions follows New and Emerging Technology Policy for code 92499 Unlisted Ophthalmological Service/Procedure as experimental, investigational, unproven (E/I/U).

## Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

PacificSource Medicare uses National Coverage Determination 80.5 for Scleral Shell.

## Experimental/Investigational/Unproven

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PacificSource considers amniotic membrane transplantation and limbal stem cell transplantation experimental, investigational, or unproven for all other indications (e.g., gelatinous drop-like ulcer, restrictive strabismus, use of trabeculectomy for primary open-angle glaucoma).

Epithelium-on (transepithelial) corneal collagen cross-linkage (CXL) is considered experimental, investigational, or unproven.

PacificSource considers the implantation of intrastromal corneal ring segments to be experimental, investigational and/or unproven for all other indications.

## Coding Information

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The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- 0402T Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)
- 65778 Placement of amniotic membrane on the ocular surface for wound healing; self-retaining
- 65779 Single layer, sutured
- 65780 Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
- 65785 Implantation of intrastromal corneal ring segments
- 66999 Unlisted procedure, anterior segment of eye
- 92071 Fitting Of Contact Lens for Treatment of Ocular Surface Disease
- 92072 Fitting Of Contact Lens for Management of Keratoconus, Initial Fitting
- 92499 Unlisted Ophthalmological Service/Procedure

- J2787 Riboflavin 5'-phosphate, ophthalmic solution, up to 3 mL
- S0515 Scleral lens, liquid bandage device, per lens
- V2530 Contact Lens Gas Impermeable
- V2531 Contact lens, scleral, gas permeable, per lens
- V2627 Scleral Cover shell
- V2790 Amniotic membrane for surgical reconstruction, per procedure (bundled payment)

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## Definitions

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**Acute thermal/chemical burns** - consist of burns to the sclera, conjunctiva, cornea, and eyelid and are associated with significant limbal ischemia and lack healthy limbal stem cells for epithelialization; classified by etiologic agents as either chemical injuries (e.g., those caused by acid or alkali) or radiant energy injuries (e.g., those caused by heat or ultraviolet [UV] radiation).

**Atopic keratoconjunctivitis** - a chronic, allergic ocular disease that occurs most often in adults with a history of atopic dermatitis.

**Band keratopathy** - a corneal disease derived from the appearance of calcium on the central cornea; causes include trauma, eye drops PV Carpine (aka Pilocarpine), and hypercalcemia due to renal failure, sarcoidosis, hyperparathyroidism, and certain malignancies.

**Bleb revisions** - excision of avascular bleb tissue, dissection posteriorly between conjunctiva and tenon's capsule, and advancement and suturing of the conjunctiva at the limbus.

**Bullous keratopathy** - a disorder caused by corneal endothelial decompensation due to degeneration (Fuch's endothelial dystrophy), surgical trauma, intractable glaucoma, or previous corneal graft failure.

**Cornea** - clear covering over the iris and pupil.

**Corneal epithelium** - outer layer of the cornea, slightly less than 10 percent of the thickness of the entire cornea.

**Corneal stroma** - middle layer of the cornea about 90 percent of the thickness of the overall composed of strands of connective tissue called collagen fibrils.

**Dry Eye Syndrome** - a disorder of the tear film due to tear deficiency or excessive evaporation, which causes damage to the ocular surface and is associated with symptoms of ocular discomfort.

**Deep corneal ulcer** - can be caused by trauma, chemical injury, contact lens and infections or other eye conditions such as entropion, distichiasis, corneal dystrophy, and keratoconjunctivitis sicca.

**Descemetocele** - protrusion of Descemet's membrane through the cornea.

**Ectasia or Keratectasia** - is a serious long-term complication of laser in situ keratomileusis (LASIK) surgery and photorefractive keratectomy; occurs postoperatively and primarily affects older

populations. Characterized by progressive thinning and steepening of the cornea, resulting in corneal optical irregularities and loss of visual acuity.

**Ectodermal Dysplasia** - a group of conditions in which there is abnormal development of the skin, hair, nails, teeth, or sweat glands.

**Familial Dysautonomia** - an inherited disorder of the nervous system that affects the development and survival of certain nerve cells.

**Filamentary Keratitis** - a condition in which strands composed of degenerated epithelial cells and mucus develops and adheres to the corneal surface causing pain and foreign body sensation.

**Graft-versus-Host disease** - A condition that occurs when donated stem cells or bone marrow (the graft) see the healthy tissues in the patient's body (the host) as foreign and attack them.

**Keratoconus** - a degeneration of the structure of the cornea in which the corneal surface thins and begins to bulge into a cone shape, which is usually a myopic shift often associated with irregular astigmatism, leading to visual impairment.

**Limbal stem cell deficiency** - characterized by a loss or deficiency of the stem cells in the limbus that are vital for re-population of the corneal epithelium and to the barrier function of the limbus.

**Neurotrophic keratitis** - a degenerative corneal disease characterized by decreased or absent corneal sensation, leading to epithelial breakdown, impaired healing, and ultimately corneal ulceration.

**Persistent epithelial defect** - is often caused by microtrauma, neurotrophic keratopathy and exposure. Etiologies for PED include dry eye, exposure keratopathy, limbal stem cell deficiency, diabetic keratopathy, neurotrophic keratopathy following corneal transplant surgery (involving the anterior portion of the cornea), and herpetic infections.

**Pterygium** - is a wing-shaped, vascular, fleshy growth that originates on the conjunctiva and that can spread to the corneal limbus and beyond.

**Sclera** - clear covering over the white of the eye.

**Scleral shell** - a comprehensive term for different types of hard scleral contact lenses used as an artificial support and protective covering of a shrunken, sightless, or damaged eye.

**Scleral thinning** - can occur in various conditions, including myopic degeneration, chronic scleritis, local scleral pathologies and scleral injury. Autoimmune conditions or collagen vascular diseases often present with scleral pathologies, which can also lead to scleral thinning.

**Sjogren's syndrome** - a chronic autoimmune condition characterized by degeneration of the salivary and lachrymal glands, causing dryness of the mouth and eyes.

**Stevens - Johnson syndrome** - begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters. Stevens-Johnson syndrome is an immune-complex-mediated hypersensitivity complex that typically involves the skin and the mucous membranes.

**Symblepharon** - partial or complete adhesion of the palpebral conjunctiva of the eyelid to the bulbar conjunctiva of the eyeball; can be caused by any conjunctival infection (bacterial or viral conjunctivitis) or allergic conjunctivitis (vernal or atopic conjunctivitis) with secondary scarring.

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## Appendix

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**Policy Number:**

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