



Ocular Remodeling

LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare	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"/> Medicaid	<input checked="" type="checkbox"/> Oregon

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

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

Amniotic Membrane Transplantation Grafts

Amniotic membrane grafting is clinically appropriate for the treatment of moderate to severe ocular surface disease when there is active corneal or conjunctival epithelial compromise. In this setting, amniotic membrane grafts act as a biologic dressing that promotes epithelial healing, reduces inflammation, and stabilizes the ocular surface in individuals who have failed, are intolerant of, or have contraindications to standard medical management.

Note: Amniotic membrane grafting is not indicated for early or mild sensory-deficient corneal disease without epithelial compromise.

Corneal Cross-linking (CXL) Epithelium-off

Corneal cross-linking (CXL) is a procedure designed to stabilize progressive keratoconus and corneal ectasia by strengthening corneal collagen through riboflavin activation with ultraviolet-A light. The standard method, epithelium-off CXL, removes the corneal epithelium for better riboflavin absorption, while epithelium-on CXL remains investigational due to insufficient evidence of efficacy.

Hydrophilic Contact Lens for Corneal Bandage

Hydrophilic bandage contact lenses provide a protective, fluid-ventilated barrier over the cornea to support healing, reduce irritation, and improve visual function in severe ocular surface disease. They are used when significant epithelial compromise is present and when standard medical treatments and procedures have been ineffective or are not appropriate.

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.

Criteria

Commercial

Prior authorization is required.

I. Amniotic Membrane Grafts for Ocular Surface Disease

PacificSource considers Amniotic Membrane grafts for ocular surface reconstruction (corneal or conjunctiva) medically necessary when **ALL** of the following criteria is met:

- A.** Confirmed diagnosis of Ocular Surface Disease (OSD), with **ONE** or more of the following diagnoses listed below:
1. Persistent or recurrent epithelial breakdown (e.g., exposure-related keratitis, Persistent epithelial defect (PED), Recurrent corneal erosions, Non-healing corneal abrasions, ulcers or wounds, Post-infectious keratitis with persistent epithelial defect (active infection must be adequately treated prior to amniotic membrane grafting), Severe exposure-related keratitis associated with epithelial compromise)
 2. Neurotrophic corneal disease (e.g., Neurotrophic keratitis or keratopathy, Neurotrophic corneal ulcers (e.g., herpetic, diabetic, post-surgical, or post-surgical))
 3. Autoimmune, Inflammatory, or Cicatrizing Ocular Surface Disease (e.g., Autoimmune-related keratitis (e.g., rheumatoid arthritis–associated keratitis, vasculitic keratitis), Stevens–Johnson syndrome, Toxic epidermal necrolysis (TEN), Cicatrizing conjunctivitis (including ocular mucous membrane pemphigoid), Ocular graft-versus-host disease (GVHD))
 4. Acute Ocular Surface Injury (e.g., Acute chemical or thermal burns of the ocular surface, Ocular surface trauma resulting in epithelial compromise)
 5. Corneal Structural Compromise (e.g., Stromal thinning or corneal melt, Descemetocoele, Small corneal perforation associated with ocular surface disease)
 6. Limbal Stem Cell Deficiency (e.g., Partial or complete limbal stem cell deficiency, Limbal stem cell deficiency secondary to due to chemical, thermal, radiation, inflammatory, or cicatrizing disease)

7. Severe Refractory Dry Eye Disease when epithelial breakdown is present (e.g., Sjögren's syndrome, keratoconjunctivitis sicca refractory to treatment)

B. Documented failure of, intolerance to, or contraindication to standard medical management (e.g., ocular lubricants, antimicrobial therapy, punctual occlusions, corneal bandages) or other alternative reconstructive therapies

II. 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 Corneal Cross-Linking MCG A-1040 (AC) criteria is met.

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

III. Hydrophilic Contact Lens for Corneal Bandage (e.g., PVR Prosthetic Replacement of Ocular Surface Ecosystem (PROSE) Scleral Lens or Boston Scleral Lens)

PacificSource may consider a therapeutic hydrophilic contact lenses (corneal bandage) medically necessary when **ALL** of the following conditions are met:

A. Diagnosis of **ONE** of the following severe ocular surface diseases:

1. Severe Dry Eye Disease with Epithelial Breakdown (examples include but are not limited to: Sjogren's syndrome, Chronic Ocular Graft-versus-Host disease, keratoconjunctivitis sicca refractory to treatment, radiation-induced or surgery-induced severe eye disease, Filamentary keratitis)
2. Limbal (corneal) stem cell deficiency (examples include but are not limited to: Partial, complete, or idiopathic limbal (corneal) stem cell deficiency; limbal stem cell deficiency secondary to chemical, thermal, or radiation injury, inflammatory or cicatrizing ocular surface disease, or surgical procedure;; Toxic epidermal necrolysis (TEN); Aniridia; Ocular mucous membrane pemphigoid)
3. Autoimmune-Associated Corneal Disorders (examples include but are not limited to: Rheumatoid arthritis-associated keratitis, Vasculitic keratitis, Epidermal dysplasia, Stevens-Johnson syndrome)
4. Dermatologic autoimmune disorders with corneal involvement (examples include but are not limited to: Atopy, ectodermal dysplasia, epidermolysis bullosa)
5. Neurotrophic Keratopathy (Acquired or Congenital) (examples include but are not limited to: Herpetic keratitis, Neurotrophic keratitis or keratopathy, Neurotrophic keratoconjunctivitis, Diabetes-related neurotrophic keratopathy, post-surgical trigeminal injury, congenital corneal anesthesia, Familial dysautonomia, Seckel syndrome)
6. Corneal Exposure Disorders (examples include but are not limited to: Exposure keratopathy, Paralytic or Anatomic corneal exposure, Persistent corneal erosions, Corneal ulcers)
7. Other Severe Ocular Surface Disorders (examples include but are not limited to: Descemetocele, Corneal ectasia, Bullous keratopathy with associated corneal edema)

B. Standard treatments have been exhausted including **ALL** of the following:

1. Pharmacologic management has not been effective (e.g., ocular lubricants, tear stimulating drugs, topical ophthalmologic steroids, oral steroids, antimicrobial therapy, eye inserts (e.g., Lacrisert))
2. Alternative procedures such as: AMT, closing tear ducts, ectropion repair have not been effective in managing condition or are not indicated
3. 12 week trial of a standard scleral contact lens has been attempted and failed or are not appropriate

IV. Intrastromal Corneal Ring Segments

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

- A. Diagnosis of Keratoconus
- B. The member has experienced a progressive deterioration in vision such that adequate functional vision cannot be achieved with contact lenses or spectacles, and corneal transplantation is the only remaining option to improve functional vision
- C. The member is aged 21 or older
- D. The member has clear central corneas
- E. The corneal thickness at the proposed incision site is 450 microns or greater

Medicaid

PacificSource Community Solutions (PCS) follows to the general coverage, limitations, and exclusions outlined in OARs 410-141-3820, 410-141-3825, and 410-120-1200, and relevant coverage guidance, including but not limited to Guideline Notes 9 and 168 of the Health Evidence Review Commission (HERC) Prioritized List of Health Services; or OARs 410-140-0010 through 410-140-0430 for coverage of ocular remodeling for non-EPSTD beneficiaries.

PacificSource Community Solutions (PCS) follows the Early and Periodic Screening, Diagnostic, and Treatment (EPSTD) coverage requirements in OAR 410-151-0002 through 410-151-0003 for EPSTD beneficiaries. Relevant coverage guidance, including but not limited to Guideline Notes 9 and 168, may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review. A case-by-case review for EPSTD Medical Necessity and EPSTD Medical Appropriateness as defined in OAR 410-151-0001 is required prior to denying. Refer to the Early and Periodic Screening, Diagnostic, and Treatment (EPSTD) policy for details.

Medicare

PacificSource Medicare uses the following National and Local Coverage Determination when applicable:

- NCD 80.5 for Scleral Shell
- NCD 80.1 for Hydrophilic Contact Lens for Corneal Bandage
- LCD L33793 for Refractive Lenses
- LCD L33737 for Eye prostheses.

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow the PacificSource Commercial clinical criteria above for determination of coverage and medical necessity of Ocular Remodeling.

Experimental/Investigational/Unproven

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.

PacificSource considers Mitomycin Intravascular Chemoembolization (MICE) to be experimental, investigational, or unproven.*

Note: * indicates the item remains E//U but will not be reviewed annually by the NTOC Committee, unless requested.

Note: PacificSource Community Solutions (PCS) and PacificSource Medicare require items listed on this policy's E//U list, to be reviewed by medical necessity review guidelines. Please see related policy, "Clinical Criteria Used in UM Decisions" to review criteria hierarchy and "Medical Necessity Reviews" for determination of coverage and medical necessity guidelines.

Coding Information

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
- 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

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

Definitions

Acute thermal/chemical burns - A burn 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 (i.e., 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 Cross-Linking (CXL) - A procedure that strengthens corneal collagen fibers using riboflavin and ultraviolet light to halt progression of keratoconus or ectasia.

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 - Caused by trauma, chemical injury, contact lens and infections or other eye conditions such as entropion, distichiasis, corneal dystrophy, and keratoconjunctivitis sicca.

Descemetocoele - Protrusion of Descemet's membrane through the cornea.

Ectasia or Keratectasia - 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.

Intrastromal Corneal Ring Segments - Small arc-shaped plastic inserts placed within the corneal stroma to flatten and reshape the cornea, improving vision in keratoconus.

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 - A loss or deficiency of the stem cells in the limbus that are vital for repopulation 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 corneal ulceration.

Persistent epithelial defect - 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 - A wing-shaped, vascular, fleshy growth that originates on the conjunctiva and that can spread to the corneal limbus and beyond.

Sclera - A 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 - Occurs 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.

Severe Ocular Surface Disease - A clinical condition characterized by significant damage or dysfunction of the corneal and/or conjunctival surfaces resulting in persistent epithelial defects, recurrent keratitis, or ocular surface instability. Common etiologies include autoimmune disorders (e.g., Sjögren's syndrome), Stevens–Johnson syndrome, ocular graft-versus-host disease, neurotrophic keratitis, chemical or thermal burns, and severe dry eye disease refractory to conventional therapy.

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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Next review: 3/1/2027

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): OARs 410-120-1200, 410-140-0010 through 410-140-0430, 410-141-3820, 410-141-3825, 410-151-0001, 410-151-0002, 410-151-0003

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