

Policy: MP023

Section: Medical Benefit Policy

Subject: Keratoplasty

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Keratoplasty

II. Purpose/Objective:

To provide a policy of coverage regarding Keratoplasty

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Keratoplasty is a surgical procedure in which all or part of the cornea is replaced by healthy corneal tissue from a donor.

INDICATIONS:

- Corneal opacification
- Keratoconus
- Corneal scarring
- Chemical injury or mechanical trauma of the cornea
- Corneal degeneration
- Corneal dystrophy

Arcuate keratotomy is covered when performed for the correction of surgically induced astigmatism following medically indicated cataract removal or corneal transplant surgery. All other applications to correct refractive error are considered

NOT COVERED.

Intrastromal corneal ring segments (INTACS) are a flexible silastic ring implanted beneath the surface of the cornea to elevate the edge the cornea. This flattens the front of the cornea, decreasing myopic refractive error. Intrastromal corneal ring segments for the treatment of keratoconus may be considered medically necessary when **All** of the following criteria apply:

1. Documented evidence of a progressive deterioration in their vision, such that member can no longer achieve adequate functional vision on a daily basis with contacts or spectacles; **AND**
2. The member is twenty-one years of age or older; **AND**
3. The member has clear central cornea; **AND**
4. The member has a corneal thickness of 450 microns or greater at the proposed incision site; **AND**
5. Corneal transplantation is the only other remaining option to improve functional vision.

Endothelial Keratoplasty (Descemet's stripping endothelial Keratoplasty (DSEK), Descemet's membrane endothelial keratoplasty (DMEK), Descemet's stripping automated endothelial keratoplasty (DSAEK) and Descemet's membrane automated endothelial keratoplasty (DMAEK) may be considered medically necessary for the treatment of endothelial dysfunction including but not limited to Fuch's endothelial dystrophy, failed previous corneal transplant, Aphakic and pseudophakic bullous keratopathy, corneal edema caused by endothelial failure, and rupture in Descemet membrane.

Keratoprosthesis

An FDA-approved corneal prosthetic may be considered medically necessary when all of the following criteria are met:

- The cornea is severely opacified; and
- Best corrected visual acuity is 20/400 or less in the affected eye, and 20/40 or worse in the opposite eye; and
- No evidence of end-stage glaucoma or limited visual potential due to current or chronic retinal detachment; and
- At least one of the following:
 - Documentation of one or more failed corneal transplant
 - Ocular condition unlikely to be resolved by corneal transplant
 - Autoimmune condition with rare ocular involvement
 - Stevens-Johnson syndrome
 - Ocular cicatricial pemphigoid
 - Ocular chemical injury

Corneal Collagen Cross-Linking (CXL) - Epithelium-off corneal collagen cross-linking (e.g., Photrexa {Riboflavin 5'-Phosphate}) is considered **medically necessary** if **ALL** of the following are met:

- Treatment is indicated for **either** of the following conditions:
 - Progressive keratoconus
 - Post keratotomy corneal ectasia

and
- Documentation of failure of conservative treatment (e.g., spectacle lens correction, rigid contact lens)

EXCLUSIONS:

Keratoplasty or corneal remodeling procedures for the sole purpose of correcting refractive error is specifically **excluded** in the applicable benefit documents for all lines of business.

Corneal collagen cross-linking for the treatment of other conditions/diseases not specifically listed is considered experimental, investigational or unproven and is **NOT COVERED** for any indication.

Epithelium-on (epi-on or transepithelial) corneal collagen crosslinking is considered experimental, investigational or unproven and is **NOT COVERED** for any indication.

Femtosecond Laser-Assisted Corneal Endothelial Keratoplasty (FLEK or FLAK) or Femtosecond and Excimer Lasers-Assisted Endothelial Keratoplasty (FELEK) is considered experimental, investigational or unproven and is **NOT COVERED** for any indication.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**

Accommodating Intraocular Lens. Presbyopic reduction surgery utilizing an accommodating intraocular lens (IOL) as an alternative to LASIK to eliminate the need for bifocal lenses or reading glasses is **NOT COVERED**. The use of an accommodating IOL (including, but not limited to Crystalens™) implant as an alternative IOL during the surgical repair of cataracts to correct refractive error and eliminate the need for spectacle lenses is covered only to the extent of the standard fixed focal length intraocular lens as outlined below:

Toric Intraocular Lens - The use of a toric intraocular lens (including but not limited to the STARR® Toric IOL) implant as an alternative IOL during the surgical repair of cataracts to correct astigmatism and eliminate the need for contact lenses or spectacle lenses is covered only to the extent of the standard fixed focal length intraocular lens as outlined below:

NOTE: To be consistent with a CMS directive, the Plan has implemented the following approach to the use of these lenses:

1. Coverage for post cataract lens implants will be limited to the standard fixed focal length IOL.
2. A member may request these accommodating focal length lenses through their Ophthalmology provider, but the member will be responsible for any cost over and above that of the standard fixed focal length IOL.
3. Providers wishing to implant the accommodating lens are advised to have the member sign a waiver prior to the surgery stating that the member understands their financial liability. The provider may then balance bill the member directly.

This approach is consistent with the current CMS policies and will apply to all lines of business unless there is specific language in the applicable benefit documents.

Intrastromal corneal ring segments as an alternative to or in conjunction with LASIK to correct refractive error, astigmatism, or to eliminate the need for bifocal lenses or reading glasses is **NOT COVERED**. The use of refractive surgery and associated implanted devices to correct refractive error and eliminate the need for spectacle lenses is an **EXCLUSION** and is **NOT COVERED** per the applicable benefit documents.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**.

CODING ASSOCIATED WITH: keratoplasty

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 65710 Keratoplasty (corneal transplant); lamellar
- 65730 penetrating (except in aphakia) to correct the condition of keratoconus (Dx code 371.60-371.62;743.41)
- 65750 penetrating (in aphakia)
- 65755 penetrating (in pseudoaphakia)
- 65756 Keratoplasty (corneal transplant); endothelial
- 65757 Backbench preparation of corneal endothelial allograft prior to transplantation
- 65760 keratomileusis
- 65765 epikeratophakia
- 65770 Keratoprosthesis
- 65771 radial keratotomy
- 65772 corneal relaxing incision for correction of surgically induced astigmatism
- 65775 corneal wedge resection for correction of surgically induced astigmatism
- S0812 Phototherapy Keratectomy (PTK)
- 66999 Unlisted corneal procedure (keratoplasty to treat specific lesions of the cornea, i.e., phototherapeutic keratectomy to remove scar tissue from the visual field)
- V2787 Astigmatism correcting function of intraocular lens
- V2788 Presbyopia correcting function of intraocular lens
- L8610 Ocular Implant
- 0402T Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed
- J2787 riboflavin 5'-phosphate ophthalmic solution up to 3 mL
- 0616T Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens
- 0617T Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens
- 0618T Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/01 (Surgical Correction of Refractive Error)

Revised: 11/02(added definition); 11/26/03(re-title policy to Keratoplasty); 2/05 (add exclusions); 10/05 (clarification for accommodating IOL use); 10/06; 10/07(wording); 3/10 (added toric lens clarification), 3/14 (added DSEK indications); 3/16 (added indications and exclusions), 11/16 (Added Keratoprosthetic); 10/17 (added CXL exclusion); 9/18 (add indication for CXL, exclusions); 9/19 (update indications)

Reviewed: 10/08, 10/09, 3/11, 3/12, 3/13, 3/15, 9/20, 9/21, 9/22, 9/23

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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