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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit 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

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 contact lenses and 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.

**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 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
  - 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.

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)
65760  keratomileusis
65765  epikeratophakia
Keratoprosthesis
radial keratotomy
corneal relaxing incision for correction of surgically induced astigmatism
corneal wedge resection for correction of surgically induced astigmatism
Phototherapy Keratectomy (PTK)
Unlisted corneal procedure (keratoplasty to treat specific lesions of the cornea, i.e., phototherapeutic keratectomy to remove scar tissue from the visual field)

Astigmatism correcting function of intraocular lens
Presbyopia correcting function of intraocular lens
Ocular Implant
Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)

Riboflavin 5'-phosphate ophthalmic solution up to 3 mL

**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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.

**REFERENCES:**
HGSA Medical Policy S-41 Corneal surgery to Correct Refractive Errors.
Merck Manual of Diagnosis and Therapy, Section 8, Chapter 96 Corneal Disorders.
Crystalens™ Model AT-45 Accommodating Posterior Chamber Intraocular Lens (IOL) - P030002
HTAIS Custom Hotline Response. Intrastromal corneal ring segments (Intacs prescription inserts) for Keratoconus.

(online) ECRI: Lansdale, PA


Novitas Solutions, Inc. Local Carrier Determination (LCD) for Cataract Extraction (L34344). Accessed 2/12/14.


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


Hersh, PS, Stulting, RD, Muller, D, Durrie, DS, Rajpal, RK. United States Multicenter Clinical Trial of Corneal Collagen Crosslinking for Keratoconus Treatment. Ophthalmology. 2017 Sep;124(9):1259-70.


Hayes Inc. Corneal Cross-Linking for Treatment of Keratoconus. Comparative Effectiveness Review. Feb 15, 2018


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)

**Reviewed:** 10/08, 10/09, 3/11, 3/12, 3/13, 3/15