Corneal Remodeling

DESCRIPTION

Refractive surgery refers to surgical procedures designed to correct refractive errors by reshaping the corneal surface, and to improve the focusing power of the eye, thus reducing or eliminating the need for corrective lenses. For many individuals with refractive errors, spectacles or contact lenses have been shown to provide more accurate corrections than refractive surgery. According to the AAO Preferred Practice Pattern on refractive surgery "eyeglasses are the simplest and safest means of correcting a refractive error, therefore eyeglasses should be considered before contact lenses or refractive surgery" (AAO, 2013). This policy is meant to guide coverage for Members with specific conditions for whom eyeglasses are inadequate.

Keratoconus: a degenerative non-inflammatory disorder of the cornea that results in a progressive thinning and abnormal protrusion of the cornea. This distortion of the cornea results in decreased visual acuity (such as astigmatism or myopia) which are then considered "refractive" disorders.

Keratoplasty: Corneal transplant, typically utilizing cadaver corneal tissue.
Penetrating keratoplasty: aka penetrating keratoplasty: full thickness corneal transplant
Non-penetrating Keratoplasty or deep anterior lamallar keratoplasty: replaces specific layers of the cornea.
Endothelial keratoplasty: partial thickness corneal transplant, replaces diseased portion of the cornea, specific variations address corneal disorders (such as Fuch's dystrophy, Descemet membrane, bullous keratopathy)

Phototherapeutic Keratectomy (PTK): Procedure for the correction of corneal disease.
Note: Phototherapeutic keratectomy (PTK) should not be confused with photorefractive keratectomy (PRK). Although technically the same procedure, PRK involves use of the excimer laser for correction of refractive errors (e.g., myopia, hyperopia, astigmatism, and presbyopia) in persons with otherwise non-diseased corneas.

Corneal Collagen Cross-linking: CXL is a procedure used to treat progressive keratoconus. Ultraviolet (UV) light is combined with riboflavin eye drops to create new collagen crosslinks in the cornea, strengthening and stabilizing the cornea and delaying the progression of deformation associated with keratoconus. The viscous riboflavin solution is applied to the eye topically before and during UV irradiation.

Lasik surgery [aka Laser in situ keratomileusis]: LASIK is a refractive surgery procedure that reshapes the surface of the cornea to focus visual images directly onto the retina and improve visual acuity.
The LASIK technique is designed to correct certain refractive errors and eliminate or reduce the need for corrective lenses.

COVERED HCPCS CODES

C1818	Integrated keratoprosthesis
L8609	Artificial cornea [Boston Keratoprosthesis/Boston KPro]
S0810	Photorefractive Keratectomy (PRK)
S0812	Phototheraputic keratectomy (PTK)
V2785	Corneal Tissue Processing

COVERED CODES - ONLY FOR MEMBERS WITH THE LASIK SURGERY RIDER

S0800	Laser In Situ Keratomileusis (LASIK)

COVERED CPT® CODES

0290T	Corneal incisions in the recipient cornea created using a laser, in preparation for penetrating or lamellar keratoplasty
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)
65710	Keratoplasty (Corneal Transplant); Lamellar
65730	Keratoplasty (Corneal Transplant); Penetrating (Except In Aphakia)
65750	Keratoplasty (Corneal Transplant); Penetrating (In Aphakia)
65755	Keratoplasty (Corneal Transplant); Penetrating (In Pseudophakia)
65756	Keratoplasty (Corneal Transplant); Endothelial
65757	Backbench Preparation of Corneal Endothelial Allograft Prior To Transplantation (List Sep)
65760	Keratomileusis
65767	Epikeratoplasty
65770	Keratoprosthesis

65772	Corneal Relaxing Incision, Correction, Surgically Induced Astigmatism
65775	Corneal Wedge Resection, Correction, Surgically Induced Astigmatism
65785	Implantation of intrastromal corneal ring segments

NON-COVERED HCPCS CODES - for the Treatment of Refractive Conditions

C1780	Lens, intraocular (new technology)
Q1004	Ntiol Category 4
Q1005	Ntiol Category 5
S0596	Phakic iol refractive error
V2630	Anter Chamber Intraocul Lens
V2631	Iris Support Intraoclr Lens
V2632	Post Chmbr Intraocular Lens
V2788	Presbyopia-correct function

NON-COVERED CPT® CODES for the Treatment of Refractive Conditions

65765	Keratophakia
65771	Radial Keratotomy
66840	Removal, Lens Material; Aspiration Technique, 1+ Stages
66850	Removal, Lens Material; Phacofragmentation, W/Aspiration
66920	Removal, Lens Material; Intracapsular
66930	Removal, Lens Material; Intracapsular, Dislocated Lens
66940	Removal, Lens Material; Extracapsular (Other Than 66840, 66850, 66852)
66983	Intracapsular Cataract Extraction W/Insertion, Lens Prosthesis (1 Stage)
66985	Insertion, Intraocular Lens Prosthesis (Secondary Implant) (No Concurrent Cataract Removal)

COVERAGE CRITERIA

Post-Cataract Post-Transplant Corneal Surgery [65772, 65775]

1. Correction of surgically induced astigmatism with astigmatic keratotomy (AK) [corneal relaxing incision, limbal relaxing incisions) or corneal wedge resection is covered for HAP/AHL Members when ALL the following are met:
    a. Member has had ONE of the following:
        i. Previous penetrating keratoplasty (corneal transplant) within the past 60 months
        ii. Cataract surgery within the last 36 months
    b. Member meets BOTH of the following criteria:
        i. The degree of astigmatism must be 3.00 diopters or greater
        ii. Member is intolerant of glasses or contact lenses.
2. Covered under Member's medical benefit, a vision rider is not required.

Phototherapeutic Keratectomy (PTK) [65760; S0812]

1. Phototherapeutic keratectomy (PTK) is covered for HAP/AHL Members with ANY of the following corneal conditions:
    a. Superficial corneal dystrophy (including granular, lattice and Reis-Buckler's dystrophy)
    b. Epithelial membrane dystrophy
    c. Irregular corneal surfaces due to Salzmann's nodular degeneration or keratoconus nodule
    d. Corneal scars and opacities, including post-traumatic, postinfectious, postsurgical and secondary to pathology
    e. Recurrent corneal erosions when more conservative measures (e.g., lubricants, hypertonic saline, patching, bandage contact lenses, gentle debridement of severely aberrant epithelium) have failed to halt the erosions
2. Note: Phototherapeutic keratectomy (PTK) should not be confused with photorefractive keratectomy (PRK). Although technically the same procedure, PTK is used for the correction of particular corneal diseases, whereas PRK involves use of the excimer laser for correction of refractive errors (e.g., myopia, hyperopia, astigmatism, and presbyopia) in persons with otherwise non-diseased corneas. PRK is considered not medically necessary.

Endothelial Keratoplasty: [65756; 65757]

1. Endothelial keratoplasty (Descemet's stripping endothelial keratoplasty (DSEK), Descemet's stripping automated endothelial keratoplasty (DSAEK), and Descemet's membrane endothelial keratoplasty (DMEK) are covered for HAP/AHL Members with endothelial failure and otherwise healthy corneas for ANY of the following indications:
    a. Bullous keratopathy
    b. Corneal edema
    c. Endothelial corneal dystrophy and other posterior corneal dystrophies
    d. Mechanical complications due to corneal graft or ocular lens prostheses
    e. Rupture of Descemet's membrane.

Collagen Cross-Linking for Keratoconus: [0402T]

1. Epithelium-off photochemical collagen cross-linkage using riboflavin and ultraviolet A is covered for HAP/AHL Members for keratoconus and keratectasia.

Keratoprosthesis (Artificial Cornea): [65770; C1818; L8609]

1. An artificial cornea (such as Boston Keratoprosthesis or Boston KPro) is covered for HAP/AHL Members for corneal blindness when ALL the following are met:
    a. Member has a severely opaque and vascularized cornea with vision that is less than 20/400 in the affected eye and less than optimal vision in the opposite eye
    b. Member has had 2 or more failed penetrating keratoplasties (corneal transplants) and has a poor prognosis for further grafting
    c. Member has no evidence of end-stage glaucoma nor retinal detachment.

REFRACTIVE SURGERIES:

1. Intrastromal corneal ring segments (INTACS): [65785]
    a. Intrastromal corneal ring segments when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food & Drug Administration (FDA) are covered for HAP/AHL Members for the treatment of myopia and astigmatism in Members with:
        i. Keratoconus or pellicud marginal degeneration who meet ALL the following:
            A. Progressive deterioration in vision, such that adequate functional vision on a daily basis with contact lenses or spectacles can no longer be achieved
            B. Age 21 years of age or older
            C. Clear central corneas
            D. Corneal thickness of 450 microns or greater at the proposed incision site
            E. Corneal transplantation is the only other remaining option for improving functional vision
2. Epikeratoplasty (epikeratophakia): [65767]
    a. Epikeratoplasty is covered for HAP/AHL Members for ANY of the following indications:
        i. Childhood or congenital aphakia
        ii. Aphakia following cataract surgery in adult Members unable to receive intraocular lens
        iii. Members with scarred corneas and corneas affected with endothelial dystrophy
3. Lamellar keratoplasty (non-penetrating keratoplasty): [65710; 0290T; V2785]
    a. Lamellar keratoplasty is covered or HAP/AHL Members for the treatment of corneal diseases, including scarring, edema, thinning, distortion, dystrophies, degenerations, and keratoconus
4. Penetrating keratoplasty (PK) (corneal transplantation, perforating keratoplasty): [65750; 65755; 65730; 0290T; V2785]
    a. Penetrating keratoplasty (PK) is covered for HAP/AHL Members for treatment of corneal diseases, including:
        i. When used for the improvement of poor visual acuity caused by an opaque cornea
        ii. When used to remove active corneal disease, such as persistent severe bacterial, fungal, or amebic inflammation of the cornea (keratitis) after appropriate antibiotic therapy;
        iii. When used to restore altered corneal structure or to prevent loss of the globe that has been punctured
        iv. When used to treat corneal diseases, including bullous keratopathy, keratoconus, corneal scar with opacity, keratitis, corneal transplant rejection, Fuch's dystrophy, corneal degeneration, other corneal dystrophies, corneal edema, and herpes simplex keratitis.
5. Laser-assisted in-situ keratomileusis (LASIK): [S0800]
    a. LASIK surgery for refractive conditions which are correctable with glasses and/or contact lenses is covered for HAP/AHL Members whose Subscriber Contract includes the LASIK Surgery Rider.

For ALL of the above:

1. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies.
2. Some services require pre-authorization by a HAP Medical Director or designee, please refer to the Procedure reference list for specific code information.
3. Medicaid Providers should refer to the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html

LIMITATIONS

1. Please refer to the Member's LASIK Surgery Rider for specific contractual limitations.

EXCLUSIONS

1. Phototherapeutic Keratectomy (PTK):
    a. PTK is not covered for the treatment of infectious keratitis and all other indications because it has not been shown to be safe and effective for these indications.
2. Endothelial Keratoplasty:
    a. Endothelial keratoplasty procedures are not covered for conditions with concurrent endothelial disease and anterior corneal disease, including anterior corneal dystrophies, anterior corneal scars from trauma or prior infection, ectatic conditions of the cornea such as keratoconus, pellucid marginal degeneration and ectasia after previous laser vision correction surgery, and for all other indications (e.g., iris atrophy) because their effectiveness for these indications has not been established.

3. Collagen Cross-Linking:
    a. Photochemical collagen cross-linkage is not covered for all other indications because its effectiveness for other indications has not been established.
    b. Epithelium-on (transepithelial) collagen cross-linkage is not covered for keratoconus, keratectasia, and all other indications because its effectiveness for other indications has not been established.
    c. Performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) is not covered because its effectiveness for other indications has not been established.
4. Refractive Surgery:
    a. Surgery to correct refractive errors in HAP/AHL Members with otherwise non-diseased corneas is not covered for per the subscriber contract. Refractive errors include presbyopia, hyperopia, and myopia. Non-Covered surgeries include but are not limited to the following:
        i. Radial keratotomy (RK)
        ii. Minimally invasive radial keratotomy (Mini-RK)
        iii. Astigmatic keratotomy (AK) (arcuate incision, corneal wedge resection) for conditions other than those addressed under coverage criteria
        iv. Hexagonal Keratotomy (HK)
        v. Standard keratomileusis (ALK)
        vi. Keratophakia
        vii. Lamellar keratoplasty (non-penetrating keratoplasty) when performed solely to correct astigmatism and other refractive errors.
            A. Lamellar keratoplasty (non-penetrating keratoplasty) is considered investigational for the treatment of pterygium
        viii. Penetrating keratoplasty (PK) (corneal transplantation, perforating keratoplasty) when performed solely to correct astigmatism or other refractive errors
        ix. Photorefractive keratectomy (PRK) and Photoastigmatic keratectomy (PARK or PRK-A)
        x. Conductive Keratoplasty
        xi. Methods of thermokeratoplasty other than conductive keratoplasty (see coverage criteria), such as the superficial treatment of Gassett and Kaufman for keratoconus, holmium:YAG laser thermokeratoplasty (laser thermokeratoplasty or LTK), or the hot needle of Fyodorov, are not covered for the treatment of refractive errors, keratoconus, and all other indications because their effectiveness for these indications has not been established.
        xii. Orthokeratology
        xiii. Scleral Expansion Surgery is not covered for presbyopia and all other indications because its effectiveness for these indications has not been established.
        xiv. Intrastromal corneal ring segments (INTACS) for indications other than those listed in coverage criteria.
        xv. Intraocular lens implants (clear lens extraction) (aphakic intra-ocular lenses (IOLs))
            A. Note: Intra-ocular lens implants for Members persons with aphakia is addressed in the Benefit Administration Manual policy: Intraocular Lens Implant
        xvi. Implantable contact lens (without lens extraction) (Phakic IOLs) (such as but not limited to: Artisan phakic IOL; Collamer lens or Visian ICL)
    b. Lasik surgery:
        i. Members whose Subscriber Contract does not include the LASIK Surgery Rider do not have coverage for LASIK surgery for refractive conditions which are correctable with glasses and/or contact lenses according to the HAP/AHL Subscriber Contract.
5. Keratoprosthesis:
    a. The Boston KPro is not covered for other uses (including but not limited to the treatment of primary glaucoma) because the effectiveness for uses other than described under coverage criteria has not been established.
    b. The AlphaCor keratoprosthesis is not covered for HAP/AHL members as it is considered unproven due to insufficient evidence of effectiveness.
6. Excimer Laser Crescent Keratectomy for Keratoconus is not covered for HAP/AHL members because its effectiveness has not been established.

RELATED BENEFIT ADMINISTRATION MANUAL POLICIES:

1. Artificial Retina Devices
2. Contact Lens and Eyeglasses
3. Intraocular Lens Implant

MEDICARE REFERENCE:

1. National Coverage Determination (NCD) for Refractive Keratoplasty (80.7) https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=72&ver=1

MEDICAID REFERENCE:

1. Michigan Medicaid Provider Manual. http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf
    a. Billing & Reimbursement for Professionals
        i. SECTION 6 - SPECIAL BILLING
            A. 6.23 VISION

b. Early and Periodic Screening, Diagnosis and Treatment
    i. SECTION 5 – SENSORY SCREENING
c. Healthy Michigan Plan
    i. SECTION 4 – COVERAGE
d. Practitioner
    i. SECTION 11 – SURGERY – GENERAL
        A. 11.1.B. SERVICES NOT INCLUDED IN THE GLOBAL SURGERY PACKAGE
            I. 11.11 VISION PROCEDURES AND CARE
e. Children's Special Health Care Services
    i. SECTION 3 – MEDICAL ELIGIBILITY
f. Vision
    i. SECTION 1 – GENERAL GUIDELINES AND REQUIREMENTS
    ii. SECTION 2 – DIOPTER CRITERIA
    iii. SECTION 3 – SERVICES
        A. 3.1 DIAGNOSTIC SERVICES
        B. 3.4 OPHTHALMIC FRAMES AND LENSES
        C. 3.6 CONTACT LENSES
g. Forms Appendix
    i. Documentation of Medical Necessity for the Provision of Contact Lenses

This Benefit policy discusses the medical criteria for covered services. Coverage of services for Members is based on the Member's subscriber documents and are subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Advantage Members).
HAP HMO/POS and AHL EPO/PPO Members:
If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.
ASO Members:
Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.
Medicare Advantage Plan Members:
Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.
Medicaid Plan Members:
For Medicaid/Healthy Michigan Plan members coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will apply.

EFFECTIVE DATE

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