

<b>Policy Name</b>	Clinical Policy - Keratoconus and Related Corneal Ectasias
<b>Policy Number</b>	1328.00
<b>Department</b>	Clinical Product & Development
<b>Subcategory</b>	Medical Management
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<b>Company Entities Supported (Select All that Apply)</b> <input checked="" type="checkbox"/> Superior Vision Benefit Management <input checked="" type="checkbox"/> Superior Vision Services <input checked="" type="checkbox"/> Superior Vision of New Jersey, Inc. <input checked="" type="checkbox"/> Block Vision of Texas, Inc. d/b/a Superior Vision of Texas <input checked="" type="checkbox"/> Davis Vision (Collectively referred to as 'Versant Health' or 'the Company')
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<b>Acronyms</b>	
CXL	Corneal Cross Linking
DALK	Deep Anterior Lamellar Keratoplasty
PROSE	Prosthetic Replacement of Ocular Surface Ecosystem
PK	Penetrating Keratoplasty
RGP	Rigid Gas Permeable Lenses

<b>PURPOSE</b>
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To provide the medical criteria to support the indication(s) for treatment of keratoconus and related corneal ectasias. Applicable procedure codes are also defined.

<b>POLICY</b>
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## A. BACKGROUND

Keratoconus is an ectatic disorder of the cornea characterized by thinning and protrusion; it causes irregular astigmatism which is not correctable with spectacles. It can be either an

iatrogenic or an inheritable disease, with numerous risk factors and potential causes. It is typically bilateral, but the two eyes may progress at different rates and not all patients progress at the same rate. If left unmanaged, keratoconus may change the shape of the cornea and be visually disabling. It tends to afflict younger patients and is documented to significantly impair their quality of life.

Other ectatic conditions, including pellucid marginal corneal degeneration (PMD) and ectasia secondary to corneal refractive surgery, also require similar medically necessary treatment.

## **B. Medically Necessary**

Contact Lenses are the initial therapy for the treatment of keratoconus and related corneal ectasias. There are many options of contact lenses that can be used. The choice of which contact lens is appropriate is based on the results of the contact lens evaluation. See Clinical Policy 1309.00 Medically Necessary Contact Lenses.

For cases of keratoconus and related ectasias that progress with further visual function loss, despite contact lens therapy, the following interventions may be medically indicated, as stipulated:

1. Corneal Cross Linking (CXL)<sup>1 2 3</sup>
  - a. An increase of at least 1 diopter, within 24 months in the steepest keratometry meridian; or,
  - b. An increase of at least 1 diopter within 24 months, in astigmatism as measured by manifest refraction; or,
  - c. A reduction in best corrected visual acuity of one line within 24 months, due to keratoconus or related corneal ectasias; and,
  - d. Corneal thickness greater than 300 microns; and,
  - e. Clear central cornea; and,
  - f. Non pregnant status
2. Implantation of corneal ring segments (e.g., Intacs®)
  - a. Contact lens therapy has failed to achieve or stabilize functional vision; or,
  - b. Contact lens therapy is intolerable regardless of achieving functional vision; and,
  - c. The central cornea is clear; and,
  - d. The corneal thickness is 400 microns or greater; and,
  - e. The patient is 21 years or older.
  - f. The only remaining alternative therapy is penetrating keratoplasty.<sup>2</sup>
3. Lamellar Keratoplasty/Deep Anterior Lamellar Keratoplasty (DALK) and Penetrating Keratoplasty (PK) are medically necessary when the following occurs:

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<sup>1</sup> Cankaya, 2024 and Polido, 2022.

<sup>2</sup> Vinciguerra, 2012

<sup>3</sup> Blackburn, 2019.

- a. Contact lens therapy is not tolerated or has failed to achieve or stabilize functional vision; and,
- b. For DALK procedure, the patient has no prior history of hydrops.

### C. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale as in requirements above. All medical record items must be available upon request. For any retrospective review, a full operative report and/or the clinical care plan is needed.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

### D. Procedural Detail

<b>CPT / HCPCS CODES</b>	
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (Report medication separately)
65710	Keratoplasty (corneal transplant); anterior lamellar
65730	Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)
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 separately in addition to code for primary procedure)
65785	Implantation of intrastromal corneal ring segments
92072	Fitting of contact lens for management of keratoconus, initial fitting
92310	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia
92313	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneoscleral lens
J2787	Riboflavin 5'-phosphate, ophthalmic solution, up to 3 ml
S0515	Scleral lens cover
V2510	Contact lens, gas permeable, spherical, per lens
V2511	Contact lens, gas permeable, toric, prism ballast, per lens

V2513	Contact lens, gas permeable, extended wear, per lens
V2520	Contact lens, hydrophilic, spherical, per lens (piggyback lens: hard+soft)
V2521	Contact lens, hydrophilic, toric, or prism ballast, per lens (piggyback lens: hard+soft)
V2523	Contact lens, hydrophilic, extended wear, per lens; piggyback lens, hard + soft.
V2531	Contact lens, scleral, gas permeable, per lens (for contact lens modification, see 92325)
V2599	Contact lens, other types
V2627	Scleral cover shell (PROSE)
<b>REQUIRED MODIFIERS</b>	
50	Bilateral procedure
RT	Right side
LT	Left side
<b>INVALID MODIFIERS</b>	
22	Increased Procedural Service

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<b>RELATED POLICIES</b>	
1309	Medically Necessary Contact Lenses
1315	Keratoplasty and Keratectomy (corneal transplantation)

<b>DOCUMENT HISTORY</b>		
<b><i>Approval Date</i></b>	<b><i>Revisions</i></b>	<b><i>Effective Date</i></b>
06/20/2018	Initial policy	06/20/2018
07/25/2019	Annual review; no criteria changes	08/01/2019
06/03/2020	Annual review; additional CPT codes	11/01/2020
04/07/2021	Annual review; no criteria changes	09/01/2021
04/06/2022	Annual review; no criteria changes	07/01/2022
04/12/2023	Removed time measurement criteria for keratoconus progression and treatment; added time periods to vision change measurements. Removed diopter change criteria for Intacs; Combined DALK and PK criteria; removed requirement for DALK/PK clear central cornea; removed CXL as a contraindication for PK.	10/01/2023
04/03/2024	Removed age limitations for corneal cross linking; removed visual acuity loss requirement for lamellar keratoplasty (DALK).	07/01/2024

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