Select Health Medical Policies

Ophthalmology Policies

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Select Health

MEDICAL POLICY

AUTOLOGOUS SERUM EYE DROPS

Policy # 597
Implementation Date:11/30/16
Review Dates: 12/21/17, 12/1/18, 12/12/19, 12/6/20, 10/26/21, 1/13/23, 12/5/23, 12/1/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Dry eye is a common disorder of the tear film, which is a layer of tears covering the surface of the eye. Dry eye affects many adults older than 40 years of age. One common treatment for dry eye is artificial tears, which provide lubrication to the surface of the eye. However, artificial tears lack the biologically active components found in natural tears that are critical to the maintenance of the tear film. Another therapy commonly used when artificial tears are ineffective or as an adjunct therapy is immunotherapy with agents such as (Restasis) or the LFA-1 agonist lifitegrast (Xiidra). These agents act by reducing the inflammatory process, thus, allowing for normal tear development.

Alternatively, eye drops made by separating the liquid and cellular components of the patient's blood, known as autologous serum eye drops, have also been used in the treatment of dry eyes since the 1970s. These drops possess many of the same biological nutrients found in natural tears, some of the associated growth factors and TGF beta which may impact the inflammatory process on the eye. Because of this, autologous serum eye drops are believed to be a better tear substitute and have become a common treatment for dry eye. These drops, however, lack standardization with concentrations ranging from 20% to 100% and some preparations including topical antibiotics.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover autologous serum eye drops as it is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Four RCTs were found in which Autologous serum (AS) was compared with artificial tear treatment or saline in individuals (n = 72 participants) with dry eye of various etiologies (Sjögren's syndrome-related dry eye, non-Sjögren's syndrome dry eye and postoperative dry eye induced by laser-assisted in situ keratomileusis (LASIK)). The quality of the evidence provided by these trials was variable. Most of the risk of bias domains were judged to have an unclear risk of bias in two trials owing to insufficient reporting of trial characteristics. One trial was considered to have a low risk of bias for most domains while another was considered to have a high risk of bias for most domains. Incomplete outcome reporting and heterogeneity in the participant populations and follow-up periods prevented the inclusion of these trials in a summary meta-analysis. For the primary outcome, improvement in participant-reported symptoms at one month, one trial (12 participants) showed no difference in participant-reported symptoms between 20% AS and artificial tears. Based on the results of two trials in 32 participants, 20% AS may provide some improvement in participant-reported symptoms compared to traditional artificial tears after two weeks of treatment. One trial also showed positive results with a mean difference in tear breakup time (TBUT) of 2.00 seconds (95% CI 0.99 to 3.01 seconds) between 20% AS and artificial tears after two weeks, which were not similar to findings from the other trials. Based on all other objective clinical assessments, AS was not associated with improvements in aqueous tear production measured by Schirmer's test (two trials, 33 participants), ocular surface condition with fluorescein (four trials, 72 participants) or Rose Bengal staining (three trials, 60 participants), and epithelial metaplasia by impression cytology compared to artificial tears (one trial, 12 participants). Data on adverse effects were not reported by three of the included studies. In one study, there were no serious adverse events reported with the collection of and treatment with AS.

Overall, there was inconsistency in the possible benefits of AS in improving participant-reported symptoms and TBUT and lack of effect based on other objective clinical measures. Well-planned, large, high-quality RCTs are warranted, in different severities of dry eye and using standardized questionnaires to measure participant-reported outcomes and objective clinical tests as well as objective biomarkers to assess the benefit of AS therapy for dry eye.

A prospective open-label single-armed study (Semeraro et al., 2014) of 50% autologous serum eye drops for acute (chemical burns) and chronic (recurrent corneal erosions, neurotrophic keratitis, and keratoconjunctivitis sicca) unresponsive to conventional lubricating therapy. The study suggested resolution of epithelial defects. However, the study was limited by a small sample size (n=15 group 1 and n=11 group 2) and by the lack of a control group.

In a single-center interventional (Lekhanont et al., 2016) of n=109 eyes with persistent corneal epithelial defects treated with 100% undiluted autologous serum tears and suggested safety and efficacy. Treatment group compared with historical control group (n=79) at same institution. Two adverse events were reported, including 1 patient with eyelid swelling that resolved with stopping the serum eye drop.

This study suggests more complete and more rapid epithelialization in the serum eye drop group. Epithelialization occurred in 87.16% serum and 69.62% control groups ($P = 0.001$). The median time to complete epithelialization was 14 days (95% CI 12–21) in the treatment group and 28 days (95% CI 21–59) in the control group ($P = 0.001$). However, the study design could have been improved with a true randomized control design.

In conclusion, a literature search conducted between 2014 and 2017, found that, although there may be possible benefits of autologous serum tears, any potential benefit remains inconsistent. Additionally, the optimal concentration (20%–100%) of autologous serum tears has not been established; further investigation and high-quality randomized controlled studies are required.

Billing/Coding Information

CPT CODES

68899	Unlisted procedure, lacrimal system

HCPCS CODES

No specific codes identified

Key References

1. Albegger KW, Tilz GP. Sjogren's syndrome and its therapy. A therapeutic attempt using antilymphocyte serum [Zum Sjogren–syndrom und seiner behandlung. Ein therapieversuch mit antilymphozytenglobulin] Zeitschrift Fur Laryngologie, Rhinologie, Otologie Und Ihre Grenzgebiete.1972;51(7):429–437.
2. Alvarado Valero MC, Martinez Toldos JJ, Borras Blasco J, Alminana Alminana A, Perez Ramos JM. Treatment of persistent epithelial defects using autologous serum application [Tratamiento de defectos epiteliales persistentes mediante suero autologo] Archivos De La Sociedad Espanola De Oftalmologia.2004;79(11):537–542.
3. Anderson NG, Regillo C. Ocular manifestations of graft versus host disease. Current Opinion in Ophthalmology. 2004;15(6):503–507.
4. Badami K, McKellar M. Allogeneic serum eye drops-a useful alternative for those unable to be autologous donors. Transfusion; Proceedings of the AABB Annual Meeting and TXPO; New Orleans (LA). 2009 Oct 24–27.2009.
5. Bradley JC, Bradley RH, Mccartney DL, Mannis MJ. Serum growth factor analysis in dry eye syndrome. Clinical and Experimental Ophthalmology. 2008;36(8):717–720.
6. Brown SM, Bradley JC. The effect of autologous serum eye drops in the treatment of severe dry eye disease: a prospective randomized case-control study. American Journal of Ophthalmology.2005;140(3):565.
7. Caceres V. Review of autologous serum for dry eye finds more research needed. EyeWorld (March 2014).
8. Chiang CC, Lin JM, Chen WL, Tsai YY. Allogeneic serum eye drops for the treatment of severe dry eye in patients with chronic graft-versus-host disease. Cornea. 2007;26(7):861–863.
9. Craig JP. A natural solution to dry eye? Clinical and Experimental Ophthalmology. 2008;36(2):109–110.
10. Fuchsluger TA, Steuhl KP, Meller D. Neurotrophic keratopathy-a post-LASIK case report. Klinische Monatsblatter fur Augenheilkunde. 2005;222(11):901–904.
11. Geerling G, Hartwig D. Autologous serum-eye-drops for ocular surface disorders. A literature review and recommendations for their application [Autologe serum–augentropfen zur therapie der augenoberflache eine ubersicht zur wirksamkeit und empfehlungen zur anwendung] Ophthalmologe.2002;99(12):949–959.
12. Geerling G, Maclennan S, Hartwig D. Autologous serum eye drops for ocular surface disorders.British Journal of Ophthalmology. 2004;88(11):1467–1474.
13. Geerling G, Unterlauft JD, Kasper K, Schrader S, Opitz A, Hartwig D. Autologous serum and alternative blood products for the treatment of ocular surface disorders [Eigenserum und alternative Blutprodukte zur Behandlung von Augenoberflachenerkrankungen] Ophthalmologe.2008;105(7):623–631.
14. Harritshoj LH, Hansen MB, Julian HO. Ready-made allogenic serum eye drops for severe dry eye disease. Vox Sanguinis; Proceedings of the 21st Regional Congress of the International Society of Blood Transfusion; Lisbon, Portugal. 2011 Jun 18–22.2011.
15. Hyon JY, Lee YJ, Yun PY. Management of ocular surface inflammation in Sjogren syndrome. Cornea.2007;26(9) Suppl 1: S13–S15.
16. Jaksche A, Sbeity Z, Domeier E, Fimmers R, Holz F, Loeffler KU. Undiluted versus diluted Autologous Serum Eye Drops (ASED): A prospective, randomized, double-blind study in patients with refractory dry eye-syndrome. Investigative Ophthalmology and Visual Science. 2005;46 ARVO E-abstract 2045.
17. Koffler BH. Autologous serum therapy of the ocular surface with novel delivery by platelet concentrate gel. Ocular Surface. 2006;4(4):188–195.
18. Kojima T, Dogru M, Matsumoto Y, Goto E, Tsubota K. Tear film and ocular surface abnormalities after eyelid tattooing. Ophthalmic Plastic and Reconstructive Surgery. 2005;21(1):69–71.
19. Kojima T, Higuchi A, Goto E, Matsumoto Y, Dogru M, Tsubota K. Autologous serum eye drops for the treatment of dry eye diseases. Cornea. 2008;27(Suppl 1):25–30.
20. Lekhanont, K., P. Jongkhajornpong, T. Anothaisintawee and V. Chuckpaiwong (2016). "Undiluted Serum Eye Drops for the Treatment of Persistent Corneal Epitheilal Defects." Sci Rep 6: 38143.
21. Messmer EM. Management of keratoconjunctivitis sicca in Sjogren's syndrome. Aktuelle Rheumatologie. 2005;30(1):59–65.
22. Moon, J., Ko, J. H., Yoon, C. H., Kim M. K., & Oh, J. Y. (2018). Effects of 20% Human Serum on Corneal Epithelial Toxicity Induced by Benzalkonium Chloride: In Vitro and Clinical Studies. *Cornea*, *37*(5):617–623. doi: 10.1097/ICO.0000000000001475
23. Movahedan H, Ghassemifar V. Treatment of persistent corneal epithelial defect with autologous serum. *Asian Journal of Ophthalmology*. 2006;8(6):236–241.
24. Noble BA, Loh RS, MacLennan S, Pesudovs K, Reynolds A, Bridges LR, et al. Comparison of autologous serum eye drops with conventional therapy in a randomised controlled crossover trial for ocular surface disease. British Journal of Ophthalmology. 2004;88(5):647–652.
25. Ogawa Y, Okamoto S, Mori T, Yamada M, Mashima Y, Watanabe R, et al. Autologous serum eye drops for the treatment of severe dry eye in patients with chronic graft-versus-host disease. Bone Marrow Transplantation. 2003;31(7):579–583.
26. Pan Q, et al. Autologous Serum as a treatment for dry eye. Cochrane Database of Systemic Reviews. 2013; 8 Art. No CD009327.
27. Poon AC, Geerling G, Dart JK, Fraenkel GE, Daniels JT. Autologous serum eyedrops for dry eyes and epithelial defects: clinical and in vitro toxicity studies. British Journal of Ophthalmology.2001;85(10):1188–1197.
28. Semeraro, F., E. Forbice, O. Braga, A. Bova, A. Di Salvatore and C. Azzolini. (2014). "Evaluation of the efficacy of 50% autologous serum eye drops in different ocular surface pathologies." Biomed Res Int 2014: 826970.
29. Sul, S., Korkmaz, S., Alcamli, G., Ozyol, P., & Ozyol, E. (2018). Application of autologous serum eye drops after pterygium surgery: a prospective study. *Graefes Arch Clin Exp Ophthalmol*, *256*(10):1939–1943. doi: 10.1007/s00417-018-4068-8
30. Watson SL, Daniels JT, Geerling G, Dart JK. Clinical trials of therapeutic ocular surface medium for moderate to severe dry eye. Cornea. 2010;29(11):1241–1246.
31. Yoon KC, Heo H, Im SK, You IC, Kim YH, Park YG. (2007) Comparison of autologous serum and umbilical cord serum eye drops for dry eye syndrome. American Journal of Ophthalmology. 144(1):86–92.
32. Young, AL, et al. The use if Autologous Serum Tears in persistent corneal epithelial defects. *Eye*. (2004); 18: 609.

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Autologous Serum Eye Drops, continued

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MEDICAL POLICY

BLEPHAROPLASTY, BROW PTOSIS REPAIR, AND RECONSTRUCTIVE EYELID SURGERY

Policy # 567

Implementation Date:7/15/15
Review Dates: 2/18/19, 11/20/19, 1/20/21, 5/30/21, 5/8/22, 5/31/23, 6/4/24, 6/1/25
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Description

The ocular region is the most important site of expression of human emotions and is the first part of the face to show signs of aging. Aging usually shows first at the periorbital and palpebral regions. Local, systemic, and endocrine disorders as well as adverse life conditions may alter the appearance of the ocular region. Many times, the surgical procedures to correct the signs of aging are performed for cosmetic purposes and may be accompanied by other plastic surgery procedures of the face.

Visual acuity, intraocular pressure, and the function of the intrinsic muscles must be assessed as part of the pre-operative evaluation to detect cases of unilateral blindness or other sight impairments.

Blepharoplasty, the correction of drooping upper or lower eyelids, is performed to counteract the effects of sun damage, heredity, and gravity. Ptosis repairs (of the lids or brow) may be performed for folding and wrinkling of the skin due to a decrease in thickness and to a distention of the elastic fibers.

Patients experiencing a descent of the eyebrow and hooding of the upper part of the superior palpebral region may require a brow lift. Brow lifts may be performed via incisions possibly from ear to ear or via endoscope. Many patients with significant functional dermatochalasis associated with brow ptosis are candidates for brow elevation procedures.

Floppy eyelid syndrome (FES) is a chronic papillary conjunctivitis characterized by a loose upper lid that readily everts on elevation and a soft rubbery tarsus. These patients are commonly misdiagnosed and treated unsuccessfully for a period. Appropriate treatment consists of stopping all medication to treat associated conditions. A shield is placed over the eyes at night or tape is put over the eyelids to keep them shut. If palliative treatment fails, a horizontal shortening procedure or eyelid wedge resection may be indicated.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers blepharoplasty and reconstructive eyelid surgery, including brow ptosis, when the following criteria are met.

The following information must be available from the requesting provider for ALL reviews:

A. Results of complete (taped and untaped) bilateral visual field examinations, including visual points seen and not seen. (except for ectropion, entropion, anophthalmic socket and trichiasis repairs where visual fields are not necessary)

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B. Clinical documentation supporting the impact of visual field defects have on ADL.

C. Lateral and full-face photographs with corneal light reflex apparent in full face view.

Coverage Criteria

I. **Upper Lid Blepharoplasty/Blepharoptosis repair (CPT 15822,15823, and 67901–67909)** may be considered medically necessary for the affected eye when ANY of the following conditions are met:

A. Presence of one of the following conditions as identified by photos without meeting visual loss criteria:

a. Trichiasis

b. Ectropion

c. Entropion

B. In the absence of one of the conditions listed above, unilateral or bilateral upper lid blepharoplasty or blepharoptosis repair may be considered medically necessary for reconstructive purposes when the affected eye meets ALL the following criteria:

a. The patient must have a Functional/Physical Impairment complaint directly related to the position of the eyelid(s).

b. Automated peripheral or superior visual field testing, with the eyelids taped and untaped, showing improvement of 30% or 12 degrees in the number of points seen on the tape testing.

1. In situations where computerized visual field testing is not available, we will accept manual visual field testing.

2. In situations where visual field testing is not possible, see section below, “When Patient is Not Capable of Visual Field Testing”.

c. Frontal or lateral photographs demonstrate visual field limitation consistent with the visual field examination.

d. Any related disease process, such as myasthenia gravis or a thyroid condition is documented as stable.

II. **Brow ptosis repair (CPT 67900)** may be considered medically necessary for reconstructive purposes when the following criteria are present in the affected eye:

A. The patient must have a Functional/Physical Impairment complaint directly related to the position of the eyelid(s).

B. Photographs demonstrate the eyebrow is below the supraorbital rim.

C. Automated peripheral or superior visual field testing, with the eyelids taped and untaped, showing improvement of 30% or 12 degrees in the number of points seen on the tape testing.

a. In situations where computerized visual field testing is not available, we will accept manual visual field testing.

b. In situations where visual field testing is not possible, see section below, “When Patient is Not Capable of Visual Field Testing”.

D. Frontal or lateral photographs demonstrate visual field limitation consistent with the visual field examination.

E. Any related disease process such as myasthenia gravis or a thyroid condition is documented as stable.

III. **Eyelid surgery in patients with an anophthalmic socket** (has no eyeball) is considered reconstructive and medically necessary when BOTH of the following criteria are present:

A. Patient has an anophthalmic condition.

B. Patient is experiencing difficulties fitting or wearing an ocular prosthesis.

IV. **Lower Lid Blepharoplasty (CPT 15820 and 15821)** is usually cosmetic, however, is considered reconstructive and medically necessary only when the following criteria are present:

A. Color photograph documents the pathology, AND

B. One of the following is present:

a. There is documentation of facial nerve damage

b. Patient is unable to close the eye due to the lower lid dysfunction

c. Functional impairment, including BOTH of the following:

i. Documented uncontrolled tearing or irritation

ii. Conservative treatments tried and failed

V. Canthoplasty/Canthopexy (CPT 21280, 21282, 67950) is considered reconstructive and medically necessary when **ALL** the following criteria are present:

A. Functional impairment;

B. Conservative treatments have been tried and failed;

C. Color photograph documents the pathology;

D. Simple repair of ectropion or entropion will not correct condition; and

E. At least one of the following patient complaints is present:

a. Epiphora (excess tearing) not resolved by conservative measures;

b. Corneal dryness unresponsive to lubricants;

c. Corneal ulcer.

VIII. Lid Retraction Surgery (CPT 67911) is considered reconstructive and medically necessary when ALL the following criteria are present:

A. Other causes have been eliminated as the reason for the lid retraction such as use of dilating eye drops and glaucoma medications;

B. Color photograph documents the pathology;

C. There is functional impairment (such as ‘dry eyes’, pain/discomfort, tearing, blurred vision);

D. Tried and failed conservative treatments;

E. In cases of thyroid eye disease, two or more Hertel measurements at least 6 months apart with the same base measurements are unchanged.

***Exceptions to requirement for visual field testing:**

Visual field testing is not required when the patient is not capable of performing a visual field test such as:

- The patient is a child 12 years of age or under.
- The patient has an intellectual disability or some other severe neurologic disease.

SELECT HEALTH MEDICARE (CMS)

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Summary of Medical Information

Blepharoplasty is generally performed for dermatochalasis (i.e., excess of eyelid skin) and corrects bagginess, fatty protrusions, and lax hanging skin around the eyes. If the eyelid itself is drooping, this is termed blepharoptosis and is corrected with a different procedure, a ptosis repair. A blepharoplasty may be performed for functional or cosmetic reasons. Cosmetic surgery is an attempt to improve the appearance of structures or tissues that are functionally and histologically normal. The goal of functional or reconstructive surgery is to restore to normal a structure that has been altered by infection, trauma, degeneration, inflammation, developmental errors, or neoplasia. Blepharoplasty is often done in combination with other functional or cosmetic procedures (e.g., brow lift) to restore more complete function or facial expression.

Prior to blepharoplasty, reconstructive eyelid surgery and/or brow lift, a preoperative evaluation, which includes a detailed medical and ocular history along with a thorough ophthalmologic examination, is generally performed. Generally, individuals are treated by ophthalmic plastic and reconstructive surgeons who specialize in diseases and problems of the eyelids, tear drain and orbit. It is recommended that patients be examined for active eye disease, dry eyes and thyroid disease, which are contraindications to eyelid surgery. Fine examination of the lid margin for chronic blepharitis, evidence of lid retraction or laxity, and signs of associated systemic disease such as thyroid disease or other problems should be assessed prior to surgery. The excessive eye bulk that may result from these conditions will typically resolve after adequate medical treatment, obviating the need for surgical intervention. The physical examination may include a Schirmer test, tear film break-up time, visual acuity with and without correction, and visual fields testing. It is recommended that preoperative photographs be taken with the eyes in primary position.

Visual Field Testing

Visual field testing is used to measure the severity of eyelid and brow defects. The most significant visual field measurement associated with determining the need for blepharoplasty, blepharoptosis repair and/or brow lift is the superior visual field. The normal extent of the superior visual field is approximately 55–60 degrees at the 90-degree meridian. Impairment of the superior visual field can range from 20%, considered mild ptosis, to 64% in more severe cases where the eyelid crosses the middle of the pupil. In general, mild to moderate impairment of the visual field is of no clinical significance and requires no intervention. When obstruction of the visual field becomes severe or significant enough to interfere with the patient's ability to perform activities of daily living, surgical intervention may be warranted. In a study by Riemann et al. (2000), Goldmann manual kinetic and Humphrey automated static visual field testing were both effective in documenting ptosis-associated visual field loss. It is recommended that visual field testing demonstrates a minimum of at least 20 degrees or 30% loss of upper field vision with upper lid skin and/or upper lid margin in repose and elevated (by taping of the lid) to demonstrate potential

correction by the proposed procedure or procedures). Visual field testing is generally not performed in infants and children less than or equal to seven years of age.

Conditions Associated with Blepharoplasty, Reconstructive Eyelid Surgery, and Brow Lift

Blepharochalasis: Blepharochalasis is a rare condition that afflicts young people, usually in their teens. Redundant skin of the upper eyelid hangs down and may conceal the tarsal margin when the eye is open, impairing the visual field. It may be associated with the disease process of chronic blepharoedema and can lead to thinning of the eyelid skin and prolapse of orbital fat. Blepharoplasty, usually in combination with advancement of the levator aponeurosis (major elevator of the upper eyelid), may be indicated.

Blepharospasm: Blepharospasm is a condition in which the muscles in the eyelids and around the eyes twitch uncontrollably. There is no cure for this condition, and effective treatments are limited. Uncontrolled blepharospasm can become debilitating. Treatment can include artificial tear drops or lubricating ointment, or both. The treatment of choice for blepharospasm is an injection of botulinum toxin in the eyelids and around the eyes to paralyze them. This is a temporary treatment lasting about three to four months. If botulinum toxin is not effective, surgery can be considered. Blepharoplasty surgery involves removing the surrounding eye muscles (complete or partial myectomy) to control the blepharospasm permanently.

Brow Ptosis (Brow Lift): Brow ptosis refers to sagging tissue of the eyebrows and/or forehead. Brow ptosis may accentuate upper eyelid skin redundancy. As the brow descends below the supraorbital rim, it pushes additional skin over the upper eyelid, thereby aggravating the functional deficits in the peripheral visual fields. Upper eyelid blepharoplasty alone may worsen the degree of brow ptosis by fixing the brow in an inferior position. Therefore, it is recommended that repositioning of the brow should be considered before the blepharoplasty is performed. An adjunct procedure, such as a lateral brow lift, may need to be added to the planned reconstructive blepharoplasty. Brow ptosis repair for laxity of the forehead muscles causing functional visual impairment is indicated when photographs show the eyebrow below the supraorbital rim, and there is documentation that visual field impairment cannot be corrected by reconstructive upper lid blepharoplasty alone, as shown by taped and standardized methods of visual field testing. Photographs are taken from front, side, and oblique views. It is recommended that the patient's brow be relaxed when assessing the eyebrow position. Complications of eyebrow lifts are rare, but may include nerve damage, scarring, hematoma, or alopecia.

Dermatochalasis: Dermatochalasis refers to an excess of eyelid skin. The underlying muscle, connective tissue, and fat can also be excessive. Although dermatochalasis is most often a result of the natural aging process, the excess eyelid skin may result from specific disorders, such as thyroid eye disease, floppy eyelid syndrome, blepharochalasis syndrome, trauma, or any condition that causes stretching of the upper eyelid skin. Sometimes these changes are so severe in the upper lid that it obtrudes on the vision by hanging down over the lid margin, pushing down on the lashes against the cornea.

Ectropion: Ectropion is a turning out or sagging of the upper or lower eyelid. The condition mainly affects the lower eyelid. The sagging lower eyelid leaves the eye exposed and dry. As a result, excessive tearing is common. If the condition is not treated, crusting of the eyelid, mucous discharge and irritation of the eye may occur. A serious inflammation may result and damage the eye. Corneal dryness and irritation may lead to eye infections, corneal abrasions, or corneal ulcers.

Ectropion can be diagnosed with a routine eye exam. Special tests are usually not necessary. No completely satisfactory nonsurgical approaches exist in the management of symptomatic ectropion. When the condition is mild, the patient may experience only mild irritation from conjunctival exposure, usually associated with epiphora and perhaps a foreign body sensation from corneal drying. Artificial tears during the day and ointments at night usually improve the symptoms. Taping the lid into position, a frost suture, or a temporary tarsorrhaphy with sutures or glue may be useful. Nighttime eye shields which seal in moisture may be helpful. Some cases of ectropion caused by nerve problems can be treated temporarily if the eyelid nerves are expected to recover.

Medical management may not be adequate when the lid malposition is so severe that corneal breakdown occurs. Surgical treatment depends on the underlying cause. There are six pathological elements that may be present in an ectropic eyelid including: horizontal lid laxity, medial canthal tendon laxity, punctual malposition, vertical tightness of the skin, orbicularis paresis secondary to seventh nerve palsy, and lower eyelid retractors disinsertion. One or more of these components may be present in an ectropic eyelid.

Proper recognition of the underlying anatomic defect enables the surgeon to select the appropriate surgical procedure for correction. Scars can occur following trauma or the surgical removal of skin cancers. A skin graft taken from the upper eyelid, or from behind the ear, can be used to repair the ectropion.

Entropion: Entropion is an abnormal inward rotation of the eyelid. The relaxing of the eyelid tendons and eyelid muscles results in the eyelid turning inward. When the eyelid turns inward, the eyelashes and skin rub against the eye which can cause watering of the eyes (trichiasis), redness, irritation, or burning. Serious inflammation may lead to damage to the eye. Entropion occurs most commonly as a result of aging with the weakening of eyelid muscles. Entropion may occur after trauma and scar contraction or after surgery. The long-term use of medications such as some used for glaucoma may produce shrinkage and entropion. There are many subdivisions of entropion. The most common type is involutional entropion.

Patients who have entropion are typically evaluated as possible surgical candidates. Medical therapy is typically attempted prior to surgical repair. The extent of ocular findings, patient's age, and systemic comorbidities must be considered in developing a treatment plan. A slit lamp is used to examine the surface of the eyeball for tear problems or for damage from inverted eyelashes. Surgery to repair entropion is usually performed on an outpatient basis in the physician's office or in an ambulatory surgical center under local anesthesia. There are a number of surgical procedures, and each surgeon has a preferred surgical method to correct entropion.

Epiblepharon: In epiblepharon, a horizontal fold of redundant pretarsal skin and orbicularis muscle extends beyond the eyelid margin and compresses the eyelashes against the globe. Generally, the condition is bilateral, prevalent in Asian populations, and commonly involves the lower lid. Some patients always display symptoms of the clinical findings, whereas, others are symptomatic only in downgaze. Although both epiblepharon and congenital entropion result from lower eyelid retractor defects, their clinical presentation and course contrast sharply with nearly 80% of children who show epiblepharon have no ocular complaints. Frequently, the condition resolves with the normal vertical growth of the facial bones. Although the majority of patients can be managed conservatively, treatment should not be delayed in symptomatic cases. A transcutaneous reattachment of the lower lid retractor anterior fibers to the skin and orbicularis is achieved by reforming the lower eyelid crease through the removal of a horizontal skin and orbicularis muscle strip and deep fixational suture closure.

Ptosis (Blepharoptosis): Ptosis is an abnormally low position of the upper eyelid margin which is determined while the eye is looking in primary gaze. Blepharoplasty surgery and ptosis surgery are distinctly different. They are performed to correct anatomic defects in different upper eyelid lamellae. Ptosis may result from masses, trauma, and congenital or acquired deformities of the levator or Müller neuromuscular complexes. Ptosis results myogenic, involutional, neurogenic, mechanical, traumatic, or developmental causes. Ptosis may be categorized by age of onset (congenital versus acquired), severity, and physiological etiology. Patients with ptosis may present with various symptoms, including visual field obstruction, headache, and fatigue. Surgery is considered in patients who are symptomatic. The goal of ptosis repair is to elevate the eyelid without causing excessive lagophthalmos or ocular exposure.

Conditions that can mimic true ptosis but that are mechanical (pseudoptosis), and not an isolated intrinsic condition include: anophthalmic socket, hypertropia (elevation of the eyeball), blepharospasm or increased facial tone, enophthalmos (the affected eyeball is retrodisplaced with the upper eyelid draping over the anterior corneal surface), and severe dermatochalasis with or without associated brow ptosis.

The eyelid fissure is a measurement of the opening of the eyelid when the eye is in primary position looking straight ahead. It is measured in millimeters at the center of the eyelid from the bottom of the upper lid to the top of the lower lid. The normal measurement is 9–10 mm. Ptotic eyes are defined as those with eyelid fissures less than 9 mm. Quantitative data on the effect of ptosis on the superior peripheral field of vision has been studied. Margin reflex distances (MRDs) are measurements that are used. Upper eyelid MRD1 is the distance from the upper eyelid to the corneal light reflex which approximates the center of the pupil and the visual axis. Normal MRD1 is 4–5 mm. The unobstructed normal superior field measures approximately 50 degrees. Visual field impairment can occur when the MRD1 is less than 4 mm. With an MRD1 of 2 mm, the superior visual field impairment is in the range of 24–30%. This corresponds to 12–15 degrees of superior visual field loss. A MRD1 measurement of greater than 2.5 mm is considered normal. Lower eyelid MRD2 is the distance from the corneal light reflex

to the lower lid. A measurement of > 5 mm represents a lower eyelid that is too low and can be caused by entropion or ectropion. A patient can have a ptotic upper eyelid and a normal eyelid fissure if the lower eyelid position is abnormally low. Levator function is a measurement of how well the levator muscle works. Normal function is greater than 11 mm. A poor levator function is ≤ 4 mm. An upper eyelid MRD1 measurement of ≤ 2.0 mm is considered to be associated with significant visual impairment. Several studies show visual field impairment from ptosis is consistently present when the midpupil to upper eyelid distance is ≤ 2.0 mm. This is generally accepted as functional ptosis.

In a prospective study by Murchison et al. (2009), the authors reported significant differences in MRD among ethnic groups. African Americans, Latinos, and Asians were expected to have lower MRDs than are whites of the same sex and age. No significant differences in MRD were found between African Americans and Latinos or between Latinos and Asians. Sex was not found to be a predictor of MRD, although the authors reported that more than 20% of the variability in MRD can be explained by ethnicity and age.

It is recommended that before ptosis surgery is considered, photographic documentation of the patient while looking in primary gaze, down-gaze, and side views be required. Visual fields may be performed on each ptotic eyelid with the eyelids in their natural position and again with the eyelids taped up to simulate postsurgical response. It is recommended that the patient be examined for pupil abnormalities and motility problems prior to surgery. The Schirmer test and slit lamp examination are performed to rule out dry eye.

The most common complications of ptosis surgery are a part of the inherent inaccuracy of the procedure which involves undercorrections and overcorrections. Depending on the case series, the rate of undercorrections and overcorrections varies from 5–35%. Massaging the eyelid downward may resolve or reduce overcorrection. It is recommended that reoperating on patients with overcorrections be completed within two weeks of the original surgery, after edema has resolved, and before scarring has taken place. True complications of ptosis surgery can include lagophthalmos, exposure keratitis, lid lag, corneal ulceration, and visual loss. Patients who have congenital ptosis, postoperative lagophthalmos, or acquired myopathies require continued evaluation after surgery to monitor for possible ocular exposure, or the development of associated ophthalmic conditions.

Thyroid Disease: Symptoms that are associated with thyroid disease may include unilateral or bilateral upper-eyelid retraction and proptosis (i.e., protruding eye). Most often, medical treatment for the thyroid pathology will resolve these deformities, but occasionally, reconstructive blepharoplasty may be necessary to prevent corneal exposure and erosion.

In December 2011, the AAO published an update to the 1995 Ophthalmic Technology Assessment (OTA) for Functional Indications for Upper and Lower Eyelid Blepharoplasty. The 2011 OTA evaluates the Functional Indications for Blepharoplasty and Blepharoptosis Repair by assessing functional preoperative impairment and surgical outcomes. Functional surgical indications currently in use include impaired visual acuity, decreased peripheral vision, a compensatory chin-up backward head tilt, difficulty reading, dermatitis, eye strain and fatigue, and difficulty wearing a prosthesis in an anophthalmic socket. The literature search included studies up to July 2008. A total of 13 case series studies reported the functional effects or treatment results of simulated ptosis; several types of blepharoptosis repair, including conjunctiva-Müller's muscle resection, frontalis suspension, and external levator resection; and upper eyelid blepharoplasty. The inclusion criteria were that the publication was an original report, that it was relevant to surgical treatment of ptosis or upper eyelid dermatochalasis, that it reported a primary outcome of functional improvement, and that it had a follow-up period of at least six weeks (if a surgical series). The AAO reported that the repair of blepharoptosis and upper eyelid dermatochalasis provides significant improvement in vision, peripheral vision, and quality of life activities. The studies used different perimetric techniques. Despite these testing variations, the results show similar relationships between ptosis and superior visual field loss. The unobstructed normal superior field measures approximately 50 degrees. Visual field impairment can occur when the MRD1 is less than 4 mm. With an MRD1 of 2 mm, the superior visual field impairment is in the range of 24–30%. This corresponds to 12–15 degrees of superior visual field loss. Preoperative indicators of improvement include margin reflex distance 1 (MRD1) of 2 mm or less, superior visual field loss of at least 12 degrees or 24%, down-gaze ptosis impairing reading and other close-work activities, a chin-up backward head tilt due to visual axis obscuration, symptoms of discomfort or eye strain due to droopy lids, central visual interference due to upper eyelid position, and patient self-reported functional impairment.

The literature supports the following guidelines for indicating when surgical intervention is expected to provide functionally significant improvement. Ptosis and upper eyelid blepharoplasty surgery were found to be functionally beneficial for each of these quantitative findings:

- MRD1 of ≤ 2 mm measured in primary gaze
- superior visual field loss of 12 degrees or 24%
- down-gaze ptosis impairing reading documented by MRD1 of ≤ 2 mm measured in down gaze

Ptosis and upper eyelid blepharoplasty were also found to be functionally beneficial for the following qualitative findings:

- self-reported functional impairment from upper eyelid droop
- chin-up backward head tilt induced by visual field impairment caused by lids
- interference with occupational duties and safety resulting from visual impairment caused by the upper lids
- symptoms of discomfort, eye strain, or visual interference due to the upper eyelid position

The reviewed literature did not provide strong data on the following functional indications for ptosis and blepharoplasty surgery:

- dermatitis
- difficulty wearing a prosthesis in an anophthalmic socket
- temporal visual field impairment preventing a driver from meeting licensing standards

Billing/Coding Information

CPT CODES

Blepharoplasty (Lower Eyelid)

15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad

Blepharoplasty (Upper Eyelid)

15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Brow Ptosis Repair

67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

Upper Eyelid Blepharoptosis Repair

67901	Repair of blepharoptosis, frontalis muscle technique with suture or other material (e.g. banked fascial)
67902	Repair of blepharoptosis, frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis, (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis, (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis, superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis, conjunctivo-tarso-Muller's muscle-levator resection (e.g., Fasanella-Servat type)
67909	Reduction of overcorrection of ptosis

Lid Retraction

67911	Correction of lid retraction

Canthus Repair and Lid Repair

21280	Medical canthopexy (separate procedure)
21282	Lateral canthopexy
67950	Canthoplasty (reconstruction of canthus)
67961	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva, canthus, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; up to one-fourth of lid margin
67966	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva canthus, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; over one-fourth of lid margin.

Revision History

Revision Date	Summary of Changes
8/8/23	For Commercial Plan Policy, modified the following criteria in both sections I and II: "Automated peripheral or superior visual field testing, with the eyelids taped and untaped, showing improvement of 30% ***or 12 degrees*** in the number of points seen on the tape testing."

Key References

1. American Society of Plastic Surgeons (ASPS). Practice Parameter for Blepharoplasty. Approved by the Executive Committee of the American Society of Plastic Surgeons®, March 2007. Available at: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/Blepharoplasty-Practice-Parameter.pdf
2. MCG™ Care Guidelines, 19th edition, 2015. Blepharoplasty, Canthoplasty, and Related Procedures ACG: A-0195 (AC).
3. Trussler AP, Rohrich RJ. MOC-PSSM CME article: Blepharoplasty. Plast Reconstr Surg. 2008 Jan; 121 (1 Suppl): 1-10.
4. American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS). Blepharoplasty. 2012a. Accessed February 16, 2012. Available at URL address: http://www.asoprs.org
5. American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS). Patient information. Ectropion. 2012b. Accessed February 16, 2012. Available at URL address: http://www.asoprs.org
6. American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS). Patient information. Entropion 2012c. Accessed February 16, 2012. Available at URL address: http://www.asoprs.org
7. American Society of Plastic Surgeons (ASPS). Practice Parameter for Blepharoplasty. March 2007a. Accessed February 16, 2012. Available at URL address: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters.html
8. American Society of Plastic Surgeons (ASPS). ASPS recommended insurance coverage criteria for third-party payors. Blepharoplasty. March 2007b. Accessed February 16, 2012. Available at URL address: http://www.plasticsurgery.org/for-medical-professionals/legislation-and-advocacy/health-policy-resources/recommended-insurance-coverage-criteria.html
9. Anderson DR. Standard perimetry. Ophthalmol Clin North Am. 2003 Jun;16(2):205-12, vi.
10. Anderson RL, Jordan DR. Thyroid Eyelid Retraction. In: Levine MR, editor. Manual of Oculoplastic Surgery. 3rd ed. Philadelphia, PA: Butterworth Heinemann: 2003: Ch 17.
11. Brown BZ. Blepharoplasty. In: Levine MR, editor. Manual of Oculoplastic Surgery. 3rd ed. Philadelphia, PA: Butterworth Heinemann: 2003: Ch 9.
12. Cahill KV, Bradley EA, Meyer DR, Custer PL, Holck DE, et al. Functional indications for upper eyelid ptosis and blepharoplasty surgery: a report by the American Academy of Ophthalmology. Ophthalmology. 2011 Dec;118(12):2510-7. Epub 2011 Oct 22.
13. Centers for Medicaid and Medicare Services (CMS). CGS Administrators, LLC. Local coverage determination (LCD) for Blepharoplasty. LCD ID number L31828. For services performed on or after 10/17/2011. Accessed February 16, 2012. Available at URL address: http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx
14. Cohen AJ, Mercandetti M. Ptosis, Adult. Medscape reference. Updated August 5, 2011. Accessed February 16, 2012. Available at URL address: http://emedicine.medscape.com/article/1212082-overview
15. Custer PL. Blepharoptosis. In: Yanoff M, Duker JS, editors. Opthalmology. 3rd ed. St Louis, MO: Mosby: 2008: Ch 12.5.
16. Dailey RA, Saulny SM. Current treatments for brow ptosis. Curr Opin Ophthalmol. 2003 Oct;14(5):260-6.
17. Edmonson BC, Wulc AE. Ptosis evaluation and management. Otolaryngol Clin North Am. 2005 Oct;38(5):921-46.
18. Eliasoph I. Current techniques of entropion and ectropion correction. Otolaryngol Clin North Am. 2005 Oct;38(5):903-19.
19. Faucett DC. Essential blepharospasm. In: Yanoff M, Duker JS, editors. Opthalmology. 3rd ed. St Louis, MO: Mosby: 2008: Ch 12.8.
20. Federici TJ, Meyer DR, Lininger LL. Correlation of the Vision-related Functional Impairment Associated with Blepharoptosis and the Impact of Blepharoptosis Surgery. Ophthalmology 1999 Sep; 106(9):1705-12.
21. Friedman O, Zaldvar R, Wang T. Blepharoplasty. In: Flint, P, Haughey B, Lund V, editors. Flint: Cummings Otolaryngology: Head & Neck Surgery. 5th ed. St Louis, MO: Mosby: 2010: Ch 30.
22. Fung S, Malhotra R, Selva D. Thyroid orbitopathy. Aust Fam Physician. 2003 Aug;32(8):615-20.

23. Gigantelli JW. Entropion. In: Yanoff M, Duker JS, editors. Opthalmology. 3rd ed. St Louis, MO: Mosby; 2008; Ch 12.6.
24. Hoenig JA. Comprehensive management of eyebrow and forehead ptosis. Otolaryngol Clin North Am. 2005 Oct;38(5):947-84.
25. Katowitz JA, Heher KL, Hollsten DA. Involutional Entropion. In: Levine MR. Manual of Oculoplastic Surgery. 3rd ed. Philadelphia, PA: Butterworth Heinemann: 2003: Ch 18.
26. Lee AG, Brazis PW. Ptosis. In: Lee, AG, editor. Clinical pathways in neuro-opthalmology: an evidence-based approach. 2nd ed. New York, NY: Thieme: 2003: Ch 18.
27. McGrath M, Pomerantz J. Plastic Surgery. Townsend Textbook of Surgery. 19th ed. Philadelphia, PA. Elsevier Saunders: 2012: Ch 69.
28. Meyer DR, Stern JH, Jarvis JM, Lininger LL. Evaluating the Visual Field Effects of Blephaoptosis Using Automated Static Perimetry. Opthalmology 1993 May;100(5):651-9.
29. Meyer DR, Linber JV, Powell SR, Odom JV. Quantitating the Superior Field Loss Associated with Ptosis. Arch Opthalmol 1989 Jun;107(6):840-3.
30. Murchison AP, Sires BA, Jian-Amadi A. Margin reflex distance in different ethnic groups. Arch Facial Plast Surg. 2009 Sep-Oct;11(5):303-5.
31. Patel BC. Surgical management of essential blepharospasm. Otolaryngol Clin North Am. 2005 Oct;38(5):1075-98.
32. Patel MP, Shapiro MD, Spinelli HM. Combined hard palate spacer graft, midface suspension, and lateral canthoplasty for lower eyelid retraction: a tripartite approach. Plast Reconstr Surg. 2005 Jun;115(7):2105-14; discussion 2115-7.
33. Purewal BK and Bosniak S. Theories of upper eyelid blepharoplasty. Theories of upper eyelid blepharoplasty. Ophthalmol
34. Riemann CD, Hanson S, Foster JA. A comparison of manual kinetic and automated static perimetry in obtaining ptosis fields. Arch Ophthalmol. 2000 Jan;118(1):65-9.
35. Rizk SS, Matarasso A. Lower eyelid blepharoplasty: analysis of indications and the treatment of 100 patients. Plast Reconstr Surg. 2003 Mar;111(3):1299-306; discussion 1307-8.
36. Robinson FO, Collin JR. Ectropion. In: Yanoff M, Duker JS, editors. Opthalmology. 3rd ed. St Louis, MO: Mosby: 2008: Ch 12.7.
37. Shields M, Putterman A. Blepharoptosis correction. Otolaryngol Head Neck Surg. 2003 Aug;11(4):261-6.
38. Small RG, Meyer DR. Eyelid metrics. Ophthal Plast Reconstr Surg. 2004 Jul;20(4):266-7.
39. Spinelli HM. Evaluation of the patient. In: Spinelli HM, editor. Atlas of aesthetic eyelid and periocular surgery. 1st ed. Philadelphia, PA: Saunders; 2004a. Ch 2.
40. Spinelli HM. Upper lid blepharoplasty. In: Spinelli HM, editor. Atlas of aesthetic eyelid and periocular surgery. 1st ed. Philadelphia, PA: Saunders; 2004b. Ch 4.
41. Spinelli HM. Ptosis and upper eyelid retraction. In: Spinelli HM, editor. Atlas of aesthetic eyelid and periocular surgery. 1st ed. Philadelphia, PA: Saunders; 2004c. Ch 8.
42. Stephenson CB. Upper-eyelid blepharoplasty. Int Ophthalmol Clin. 1997 Summer; 37(3):123-32.
43. Tarrus-Montaner S, Lucarelli MJ, Lemke BN, Dortzbach RK. The surgical treatment of Graves' orbitopathy: a decade of progress. Ophthalmol Clin North Am. 2000 Dec;13(4):693-704.
44. Trussler AP, Rohrich RJ. MOC-PSSM CME article: Blepharoplasty. Plast Reconstr Surg. 2008 Jan;121(1 Suppl):1-10.
45. Tse DT. Involutional ectropion repair. In: Levine MR, editor. Manual of Oculoplastic Surgery. 3rd ed. Philadelphia, PA: Butterworth Heinemann: 2003: Ch 21.
46. Wiezer JS, Michon JJ. Ectropion and entropion: Everted and inverted eyelids In: Fekrat S and Weizer JS, editors. All about your eyes. Durham, NC: Duke University Press; 2006. Ch 5. 45-7.

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MEDICAL POLICY

CORNEAL CROSSLINKING FOR TREATMENT OF KERATOCONUS

Policy # 580

Implementation Date:11/30/16

Review Dates: 5/15/18, 4/14/19, 4/15/20, 4/4/21, 2/22/22, 3/31/23, 4/2/24, 4/1/25

Revision Dates: 10/30/17, 11/10/17, 5/15/18

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Keratoconus is the most common corneal dystrophy in the United States and reportedly affects approximately 1 in every 2,000 Americans. This progressive bilateral eye dystrophy is more prevalent in teens and young adults and is characterized by central steepening and normal thinning of the cornea that impairs visual acuity. Initial treatment usually consists of hard contact lenses which flatten the corneal and help it maintain its shape. As the disease progresses, or if the patient does not tolerate the contact lens therapy, a penetrating keratoplasty (i.e., corneal graft/transplant) is the next line of treatment. As an alternative, a variety of keratorefractive procedures have been attempted, broadly divided into subtractive and additive techniques. These therapies are intended to reduce some of the complications from a corneal transplant. Subtractive techniques include LASIK. In general, results of this technique have been poor. Implantation of intrastromal corneal ring segments represent another technique intended to reinforce the cornea, prevent further deterioration, and potentially obviate the need for a penetrating keratoplasty.

Corneal ectasia is a noninflammatory condition where progressive corneal steepening and thinning occur, whether it is natural (genetic, mechanical, chromosomal, and enzyme abnormalities) or surgically induced (LASIK and PRK). There are different types of corneal ectasia, these include pellucid marginal degeneration, keratoglobus, keratoconus, postkeratorefractive ectasia, and wound ectasia after penetrating keratoplasty (PK). Corneal ectasias can result in significant ocular morbidity and may require surgical intervention.

Another therapy recently developed is corneal collagen crosslinking. Corneal collagen crosslinking involves the application of riboflavin (vitamin B2) drops to the eye and exposure to ultraviolet (UV) light. In some cases, the most superficial layer of the cornea (corneal epithelium) is debrided prior to the administration of eye drops and UV light.

Corneal crosslinking (CXL) is an in-office eye procedure that strengthens the cornea if it has been weakened by keratoconus, other corneal disease, or (rarely) a complication of LASIK surgery. Alternative and brand names for the procedure include corneal crosslinking, corneal collagen crosslinking, C3-R, CCL, and KXL. The minimally invasive CXL procedure involves applying liquid riboflavin (vitamin B2) to the surface of the eye, followed by treatment with a controlled application of ultraviolet light, to eliminate corneal ectasia. The two basic types of corneal crosslinking are Epithelium-off CXL and epithelium-on CXL. In the first type of crosslinking procedure, the thin outer layer (epithelium) of the cornea is removed to allow the liquid riboflavin to penetrate the corneal tissue more easily. In the second procedure (also called transepithelial CXL), the protective corneal epithelium is left intact, requiring a longer riboflavin "loading" time.

In April 2016, the pharmaceutical and medical device company Avedro received FDA approval for the company's KXL System that provides corneal collagen crosslinking for the treatment of progressive keratoconus. The approval includes Avedro's Photrexa Viscous and Photrexa, which are riboflavin solutions used with the KXL System during the procedure.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers epithelium-off corneal crosslinking once per lifetime, per eye, if the following criteria are met:

1. Patient has a diagnosis of keratoconus or corneal ectasia.

2. The medicine used is Photrexa Viscous/Photrexa with the KXL device.

Select Health does NOT cover corneal crosslinking in conjunction with intrastromal ring segment placement as it is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The evidence for corneal CXL in individuals who have keratoconus includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. There is evidence from RCTs, including several pivotal trials, which CXL leads to short-term improvements in corneal steepening, visual acuity compared with untreated eyes, and results from 1 trial have reported that these benefits are maintained at 2 to 3 years. From these RCTs, one can conclude that CXL reduces, and in some cases, reverses the corneal steepening that leads to a reduction in visual acuity in the short-term. Greater uncertainty exists regarding the long-term outcomes of corneal CXL for the treatment of keratoconus. Some retrospective studies have reported positive outcomes to 10 years, although these reports have small sample sizes at long-term follow-up and limited information on the entire population of patients treated with corneal CXL during the same time period. There is a need for prospective studies with larger numbers of patients who are followed over many years to determine whether corneal CXL improves longer-term outcomes. Several trials are ongoing, and their results are expected soon. Longer-term outcomes from large cohorts will also be useful to evaluate potential long-term complications of this new treatment approach.

The evidence in the published peer-reviewed medical literature on the treatment of progressive keratoconus with corneal collagen crosslinking using riboflavin and ultraviolet is evolving. Additional results of well-designed controlled clinical trials are needed to firmly establish the role of this procedure in treating ectasia associated with keratoconus, and to determine the preferred technique (i.e., epithelium-off, epithelium-on).

Select Health

Corneal Crosslinking for Treatment of Keratoconus, continued

There has been a large volume of studies published on corneal crosslinking as it has been available in Europe and other parts of the world since approximately 2002. The search of the literature identified 72 primary studies and 8 systematic reviews for inclusion in this review. A full list of the abstracts for these reviews is available in Appendix A. Fourteen of the studies were pediatric studies. As corneal crosslinking is not FDA approved below age 14, these studies were not included in the overall review. The 63 adult studies included for review involved 3,190 patients with outcomes assessed from 1 month to 10 years (Rechichi et al., 2013). Several studies had outcomes to 5+ years (Galvis et al., 2016, Parissi et al., 2016, Kim at al., 2016). Most studies had outcomes 12 months or less. There was significant heterogeneity to the studies with many comparing outcomes of "epi-on versus epi-off" and others exploring standard versus accelerated regimens. Most studies focused on impact on keratometry measurements and not necessarily impact on changes in refraction or reduction in corneal transplantation. Refractive changes are not as impressive as the keratometric measurements, and data from well-designed randomized studies are limited.

Overall, the 8 systematic reviews supported the efficacy of corneal crosslinking in slowing the progression of keratoconus. The reviews were for the most part from 2016, though, one went as far back as 2013. This suggests the most up-to-date information was available in deriving their conclusions. The Hayes review from 2016 epitomizes the findings of the other systematic reviews, which not only did the evidence seem to support corneal crosslinking as effective and safe, but noted the quality of the literature as being low (despite the volume—most studies are smaller case series and do not have randomization or controls or are retrospective reviews) and only support: "… use of conventional corneal cross-linking (C-CXL) for the treatment of progressive keratoconus in adolescent and adult patients."

Only Godefrooij et al. from 2016 looked at the economic implication of this therapy as it relates to corneal transplant. This study retrospectively assessed transplant occurrence over 3 years and noted a 25% reduction. Limiting the ability to generalize this finding in the US is the fact that this is a Dutch study and corneal transplant access may differ in the Netherlands than in the US. Its retrospective design and lack of other validating studies also limit conclusion on its findings.

Two questions related to corneal crosslinking evaluated in the literature are epithelium-off (epi-off) vs epithelium-on (epi-on) therapy and standard vs. accelerated protocols. Notably, the FDA approval is currently for the standard regimen using the epithelium-off method. With regards to the epi-off vs epi-on, 10 studies were identified specifically comparing epi-on vs epi-off. These studies suffer from multiple methodological issues including poor study design (many, though comparative, were retrospective and lack randomization), were of small size or used different techniques to perform the epi–on portion. These studies generally supported epi-on to have equal benefit to epi-off technique, though the study by Gatziofas et al. from 2016 did not show epi-on to have any benefit on progression of keratoconus. This outcome was also noted in the study by Kocak et al. from 2014. Razmjoo et al., in 2014 noted: "… total epithelium off technique resulted in better improvement of K-max and Q-value."

With regards to standard vs. accelerated protocols, this review identified 11 studies related to use of accelerated protocols. One study combined an accelerated protocol with corneal ring implants making conclusions regarding effectiveness murky at best. Many of the other studies suffer from methodological issues like those seen with the epi-on vs epi off studies. Many were small case series and others lacked a comparative arm. Additionally, though many employed a 10-minute accelerated protocol several studies used a 5-minute protocol. Many of these studies also were of small size. Nonetheless, the studies tended to demonstrate a beneficial effect on keratometry, though they lacked endpoints around visual acuity or corneal transplant impact.

Two studies also looked at corneal crosslinking performed in conjunction with intrastromal corneal rings/implants. One study by Ferenczy et al. in 2015 only looked at 31 patients of which only 10 got CXL with as the study by Gordillo et al. from 2016 looked at 82 patients. These studies focused on impact on keratometry and corneal shape with relatively short study intervals of 1–2 years. Current evidence is insufficient to draw conclusions as to whether the combination of intrastromal corneal rings and CXL were more effective and safer than either alone.

Finally, several studies focused on the safety of the procedure. These studies tended to note a slight increase in corneal hazing which occurred more commonly with the epi-off treatment but resolved in approximately 3 months. Overall, this therapy has few short-term and no apparent long-term safety concerns.

While the goal of therapy is to either halt or reverse a progressive condition (keratoconus or ectasia) the various studies have not all clearly defined "progression." In fact, many studies have either failed to define this starting point of enrollment (eyes with "progressive" disease) or have defined it in a way that may not be acceptable to the ophthalmology community.

In conclusion, the observational evidence for the role of corneal crosslinking has been strong. This data is also supported by several well-designed randomized controlled clinical trials. The most consistent finding of observational and randomized controlled studies has been that corneal crosslinking induces a slight decrease in keratometry values that tends to be maintained over at least a year. This is an important finding, as progressive keratoconus keratometry typically rises over time and is a marker of disease progression.

Billing/Coding Information

CPT CODES

0402T Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)

HCPCS CODES

No specific codes identified

Key References

1. American Academy of Ophthalmology (AAO). Corneal Ectasia PPP – 2013. For additional information visit the AAO website: http://one.aao.org/preferred-practice-pattern/corneal-ectasia-ppp--2013. Accessed on January 5, 2016.
2. Asri D, Touboul D, Fournié P, et al. Corneal collagen crosslinking in progressive keratoconus: multicenter results from the French National Reference Center for Keratoconus. J Cataract Refract Surg. 2011; 37(12):2137-2143.
3. Avedro, Inc. Safety and Efficacy of the corneal collagen cross-linking in eyes with keratoconus. NLM Identifier: NCT01344187. Last updated on December 23, 2015. Available at: http://clinicaltrials.gov/ct2/show/NCT01344187. Accessed on January 05, 2016.
4. Bamdad S, Malekhosseini H, Khosravi A. Ultraviolet A/riboflavin collagen cross-linking for treatment of moderate bacterial corneal ulcers. Cornea. 2015; 34(4):402-406.
5. Caporossi A, Mazzotta C, Baiocchi S, Caporossi T. Long-term results of riboflavin ultraviolet a corneal collagen cross-linking for keratoconus in Italy: the Siena eye cross study. Am J Ophthalmol. 2010; 149(4):585-593.
6. Caporossi A. Mazzotta C. Baiocchi S, et al. Riboflavin-UVA-induced corneal collagen cross-linking in pediatric patients. Cornea. 2012; 31(3):227-231.
7. Chatzis N. Hafezi F. Progression of keratoconus and efficacy of pediatric corneal collagen cross-linking in children and adolescents. J Refract Surg. 2012; 28(11):753-758.
8. Coskunseven E, Jankov MR, Hafezi F. Contralateral eye study of corneal collagen cross-linking with riboflavin and UVA irradiation in patients with keratoconus. J Refract Surg. 2009; 25(4):371-376.
9. De Bernardo M, Capasso L, Tortori A, et al. Trans epithelial corneal collagen crosslinking for progressive keratoconus: 6 months follow up. Cont Lens Anterior Eye. 2014; 37(6):438-441.
10. Derakhshan A, Shandiz JH, Ahadi M, et al. Short-term outcomes of collagen crosslinking for early keratoconus. J Ophthalmic Vis Res. 2011; 6(3):155-159.
11. Ferenczy, P.A., et al., *Femtosecond-assisted intrastromal corneal ring implantation for keratoconus treatment: a comparison with crosslinking combination.* Arq Bras Oftalmol, 2015. 78(2): p. 76-81.
12. Food and Drug Administration. *Photrexa, Photrexa Viscous with the KXL System - NDA 203324/Original 2*. 2016 July 15, 2016 [cited 2017 May 13]; Available from: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/203324Orig2s000ltr.pdf.
13. Food and Drug Administration. *Photrexa, Photrexa Viscous with the KXL System - NDA 203324/Original 1*. 2016 April 15, 2016 [cited 2017 May 13]; Available from: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/203324Orig1s000ltr.pdf.
14. Galvis, V., et al., *Corneal Cross-Linking (with a Partial Deepithelization) in Keratoconus with Five Years of Follow-Up.* Ophthalmol Eye Dis, 2016. 8: p. 17-21.
15. Gatzioufas, Z., et al., *Transepithelial Corneal Cross-linking Using an Enhanced Riboflavin Solution.* J Refract Surg, 2016. 32(6): p. 372-7.
16. Godefrooij, D.A., et al., *Corneal Cross-Linking for Pediatric Keratoconus: Long-Term Results.* Cornea, 2016. 35(7): p. 954-8.
17. Godefrooij, D.A., et al., *Nationwide reduction in the number of corneal transplantations for keratoconus following the implementation of cross-linking.* Acta Ophthalmol, 2016. 94(7): p. 675-678.
18. Godefrooij, D.A., et al., *Predictors for treatment outcomes after corneal crosslinking for keratoconus: a validation study.* Int Ophthalmol, 2016.
19. Gordillo, C.H., et al., *Efficacy of Intrastromal Corneal Ring Segments Combined With Flash Collagen Cross-Linking in Keratoconus.* Cornea, 2016.
20. Greenstein SA, Shah VP, Fry KL, Hersh PS. Corneal thickness changes after corneal collagen crosslinking for keratoconus and corneal ectasia: one-year results. J Cataract Refract Surg. 2011; 37(4):691-700.
21. Grewal DS, Brar GS, Jain R, et al. Corneal collagen crosslinking using riboflavin and ultraviolet-A light for keratoconus: one-year analysis using Scheimpflug imaging. J Cataract Refract Surg. 2009; 35(3):425-432.
22. Hayes Inc (2016). "Conventional Corneal Cross-linking for Treatment of Keratoconus."

23. Hersh PS, Greenstein SA, Fry KL. Corneal collagen crosslinking for keratoconus and corneal ectasia: one-year results. J Cataract Refract Surg. 2011; 37(1):149-160.
24. Kim, T.G., et al., *The Long-term Clinical Outcome after Corneal Collagen Cross-linking in Korean Patients with Progressive Keratoconus.* Korean J Ophthalmol, 2016. 30(5): p. 326-334.
25. Kim, B.Z., et al., *Natural history of corneal haze after corneal collagen crosslinking in keratoconus using Scheimpflug analysis.* J Cataract Refract Surg, 2016. 42(7): p. 1053-9.
26. Kobashi, H., Rong, S.S., & Ciolino, J.B. Transepithelial versus epithelium-off corneal crosslinking for corneal ectasia. *J Cataract Refract Surg*. 2018 Dec;44(12):1507–1516. doi: 10.1016/j.jcrs.2018.08.021
27. Kocak, I., et al., *Comparison of transepithelial corneal collagen crosslinking with epithelium-off crosslinking in progressive keratoconus.* J Fr Ophtalmol, 2014. 37(5): p. 371-6.
28. Kymionis GD, Kontadakis GA, Kounis GA, et al. Simultaneous topography-guided PRK followed by corneal collagen cross-linking for keratoconus. J Refract Surg. 2009; 25(9): S807-811.
29. Kymionis GD, Portaliou DM, Kounis GA, et al. Simultaneous topography-guided photorefractive keratectomy followed by corneal collagen cross-linking for keratoconus. Am J Ophthalmol 2011; 152(5):748-755.
30. Larkin DFP, Chowdhury K, Burr JM, Raynor M, Edwards M, Tuft SJ, Bunce C, Caverly E, Doré C; KERALINK Trial Study Group. Effect of Corneal Cross-linking versus Standard Care on Keratoconus Progression in Young Patients: The KERALINK Randomized Controlled Trial. Ophthalmology. 2021 Nov;128(11):1516-1526. doi: 10.1016/j.ophtha.2021.04.019. Epub 2021 Apr 21. PMID: 33892046.
31. Males, J.J., & Viswanathan, D. Comparative study of long-term outcomes of accelerated and conventional collagen crosslinking for progressive keratoconus. *Eye* (Lond). 2018 Jan;32(1):32–38. doi: 10.1038/eye.2017.296
32. National Institute for Health and Clinical Excellence (NICE). Interventional procedure guidance 466. Photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus. September 2013. Available at: http://www.nice.org.uk/guidance/IPG466. Accessed on January 5, 2016.
33. Ng SM, Hawkins BS, Kuo IC. Transepithelial Versus Epithelium-Off Corneal Crosslinking for Progressive Keratoconus: Findings From a Cochrane Systematic Review. Am J Ophthalmol. 2021 Sep; 229:274-287. doi: 10.1016/j.ajo.2021.05.009. Epub 2021 May 25. PMID: 34048801; PMCID: PMC8599612.
34. Parissi, M., et al., *Corneal Nerve Regeneration After Collagen Cross-Linking Treatment of Keratoconus: A 5-Year Longitudinal Study.* JAMA Ophthalmol, 2016. 134(1): p. 70-8.
35. Polido, J., et al. Long-term Safety and Efficacy of Corneal Collagen Crosslinking in a Pediatric Group With Progressive Keratoconus: A 7-year Follow-up. *Am J Ophthalmol.* 2023 Jun: 250:59-69. doi: 10.1016/j.ajo.2023.01.012. Epub 2023 Jan 20.
36. Raiskup-Wolf F, Hoyer A, Spoerl E, Pillunat LE. Collagen crosslinking with riboflavin and ultraviolet-A light in keratoconus: long-term results. J Cataract Refract Surg. 2008; 34(5):796-801.
37. Raiskup, F., et al. Corneal Crosslinking With Riboflavin and UVA Light in Progressive Keratoconus: Fifteen-Year Results. *Am J Ophthalmo*l. 2023 Jun: 250:95-102. doi: 10.1016/j.ajo.2023.01.022. Epub 2023 Feb 1.
38. Razmjoo, H., et al., *Corneal haze and visual outcome after collagen crosslinking for keratoconus: A comparison between total epithelium off and partial epithelial removal methods.* Adv Biomed Res, 2014. 3: p. 221.
39. Rechichi, M., et al., *Epithelial-disruption collagen crosslinking for keratoconus: one-year results.* J Cataract Refract Surg, 2013. 39(8): p. 1171-8.
40. Seyedian MA, Aliakbari S, Miraftab M, et al. Corneal Collagen Cross-Linking in the Treatment of Progressive Keratoconus: A Randomized Controlled Contralateral Eye Study. Middle East Afr J Ophthalmol. 2015; 22(3):340-345.
41. Stojanovic A, Zhang J, Chen X, et al. Topography-guided transepithelial surface ablation followed by corneal collagen cross-linking performed in a single combined procedure for the treatment of keratoconus and pellucid marginal degeneration. J Refract Surg 2010; 26(2):145-152.
42. Sykakis E, Karim R, Evans JR, et al. Corneal collagen cross-linking for treating keratoconus. Cochrane Database Syst Rev. 2015; CD010621(3).
43. Stulting, R.D., Trattler, W.B., Woolfson, J.M., & Rubinfeld, R.S. Corneal crosslinking without epithelial removal. *J Cataract Refract Surg*. 2018 Nov;44(11):1363–1370. doi: 10.1016/j.jcrs.2018.07.029
44. Topcon Medical Systems, Inc. Safety study of the VEGA UV-A system to treat keratoconus. Last updated January 28, 2013. Available at: http://clinicaltrials.gov/ct2/show/NCT01190306?term=NCT01190306&rank=1. Accessed on January 5, 2016.
45. Vinciguerra P, Albe E, Frueh BE, et al. Two-year corneal cross-linking results in patients younger than 18 years with documented progressive keratoconus. Am J Ophthalmol. 2012; 154(3):520-526.
46. Vinciguerra, R., et al. Corneal Collagen Cross-Linking for Progressive Keratoconus in Pediatric Patients: Up to 14 Years of Follow-up. *Am J Ophthalmol.* 2023. Nov; 255:170-177. doi: 10.1016/j.ajo.2023.07.017. Epub 2023 Jul 20. PMID: 37478962.
47. Wittig-Silva C, Chan E, Islam FM, et al. A randomized, controlled trial of corneal collagen cross-linking in progressive keratoconus: three-year results. Ophthalmology. 2014; 121(4):812-821.

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MEDICAL POLICY

CORNEAL EPITHELIAL OR LIMBAL STEM CELL TRANSPLANT

Policy # 114

Implementation Date:7/02
Review Dates: 10/23/03, 11/18/04, 10/16/06, 12/20/07, 12/18/08, 12/17/09, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 6/8/19, 6/9/20, 5/31/21, 5/8/22, 5/30/23, 6/4/24, 6/1/25
Revision Dates: 10/30/17, 11/10/17, 5/15/18

Description

The normal ocular surface is covered by corneal and conjunctival epithelium. The corneal epithelium is well-known for its rapid self-renewal process, with ultimate tissue regeneration relying on the existence of stem cells located in the limbal epithelium (the junction zone between the corneal and conjunctival epithelia). Total loss or hypofunction of the stem cells can occur as a result of certain conditions that cause damage or alteration of the corneal surface, including:

- Mechanical trauma (e.g., scratch, contact lens, foreign body, trichiasis/distichiasis)
- Chemical or thermal injuries (e.g., toxic effect of contact lens solution, welding, sun exposure off reflective surface)
- Exposure (e.g., incomplete lid closure, restrictive eye disease, proptosis)
- Local corneal dryness
- Systemic disorders (e.g., Sjogren's syndrome, thyroid eye disease, Stevens-Johnson syndrome)
- Neurotrophic keratopathy
- Bullous keratopathy
- Pterygium
- Limbal stem cell deficiency (failure to regenerate epithelial cells)

Normal healing of corneal epithelial defects is prevented, and a unique pathological state ensues, manifested by poor epithelialization (persistent defects or recurrent erosions), chronic stromal inflammation (keratitis mixed with scarring), corneal vascularization, and conjunctival epithelial in-growth. There are 3 basic approaches to obtaining the limbal epithelial cells used in these transplants: autograft, allograft, and tissue culture.

Autograft: The autograft of the limbal corneal epithelium is taken from the healthy eye (e.g., in cases where a chemical injury eradicated the stem cell population in one eye, but not the other) and transplants it to the damaged eye. Then, if needed, the patient receives a corneal transplant.

Allograft: Keratoepithelioplasty (stem cell transplantation from young cadavers) is an allograft of limbal stem cells, obtained from an eye bank or from a living relative, which is transplanted to the damaged limbus.

Tissue culture: More recently in academic centers, researchers have begun to tissue-culture limbal and "prelimbal" stem cells for transplantation. The source can either be human cadavers, human amniotic epithelial cells from placentas, or the contralateral eye. The cultured cells can then be manipulated in a

variety of ways with the common intent of repopulating the patient's corneal epithelial stem cells, in order to support a corneal transplant. The cells taken from the amnion are less- or even non-immunogenic, and thus, implantation of these cells may not require systemic immunosuppressants. Of course, autologous cells taken from the contralateral eye are also non-immunogenic.

In the case of human amniotic epithelial cells, the cultured cells are transferred to and populate the concave surface of a collagen shield, which serves as a carrier for the epithelial cells to the surface of the unhealthy eye. Another method takes the cultured limbal stem cells and places them onto an amniotic membrane that is devoid of its epithelial cells. The amniotic membrane serves as a carrier sheet to implant on the eye surface; such membranes seem to have an innate anti-inflammatory mechanism. A third method involves harvesting perilimbal tissue and using the substantia propria of the conjunctiva as the carrier membrane.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers corneal epithelial or limbal stem cell transplants with autograft, allograft, or tissue cultures including human amniotic epithelial cells.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A review of the literature supports using autologous and standard allograft methods as the standard of care for patients with functional blindness from severe ocular surface disease. Efficacy rates vary from roughly 25%–50% of patients experiencing vision improvement. These outcomes are based principally on objective vision measures rather than patients' perceptions of the quality of their vision. However, most of this evidence is comprised of case series, which limits conclusions about the effect of transplantation on vision improvement.

Tissue culturing ("expansion") methods, however, are truly emerging technologies; with a wide range of techniques as well as outcomes, reflecting the apparent fact that clinical researchers are developing many different approaches in an effort to determine the best method. Most of the studies reported are small case series and case reports.

The largest study identified evaluated 70 transplantations using ex vivo cultivation and expansion of limbal epithelial cells utilizing amniotic membrane as a matrix; patients received up to 4 transplantations per eye. The overall success rate as measured by the rate of corneal epithelialization was 51%; if measured by clear corneas post-surgery, the success rate was 35%. Patients with clear corneas have a final postoperative visual acuity of 0.11, which "enabled them to perform daily activities."

Due to the heterogeneity of both the techniques used and reported outcomes, as well as the lack of controlled trials, it is difficult to estimate the likelihood or magnitude of benefits or risks. The apparent consensus within the ophthalmic literature is that tissue culturing ("expansion") methods are promising but unproven, requiring validation by appropriately designed trials.

Billing/Coding Information

CPT CODES

65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured
65780	Ocular surface reconstruction; amniotic membrane transplantation
65781	; limbal conjunctival autograft (e.g., cadaveric or living donor)
65782	; limbal conjunctival autograft (includes obtaining graft)

HCPCS CODES

V2790	Amniotic membrane for surgical reconstruction, per procedure

Key References

1. Aetna Clinical Policy: Corneal Graft with Amniotic Membrane Transplantation or Limbal Stem Cell Transplantation, number 0293. Available at: http://www.aetna.com/cpb/medical/data/200_299/0293.html (Last accessed May 07, 2018).
2. Akle CA, Adinolfi M, Welsh KI, Leibowitz S, McColl 1. Immunogenicity of human amniotic epithelial cell after transplantation into volunteers, Lancet 1981; 2:1003-5.
3. Blue Cross Blue Shield of Florida Clinical Policy: Amniotic Membrane and Limbal Stem Cell Transplantation for The Treatment of Ocular Conditions, number 02-65000-19. Available at: http://mcgs.bcbsfl.com/?doc=Amniotic%20Membrane,%20Limbal%20Stem%20Cell%20Transplantation%20for%20the%20Treatment%20of%20Ocular%20Conditions (Last accessed May 07, 2018).
4. de Roth A. Plastic repair of conjunctival defects with fetal membrane. Arch Ophthalmol 1940,23:522-5.
5. Geisinger Health Plan Clinical Policy: Amniotic Membrane Transplant for Ocular Surface Defects, number MP267. Available at: https://www.geisinger.org/-/media/OneGeisinger/Files/Policy-PDFs/MP/251-300/MP267-Amniotic-Membrane-Transplant-for-Ocular-Surface-Defects.pdf?la=en (Last accessed May 07, 2018).
6. James SE, Rowe A, Ilari L, Daya S, Martin R. The potential for eye bank limbal rings to generate cultured corneal epithelial allografts. Cornea. 2001 Jul;20(5):488-94. PMID: 1141340.
7. Kim JCI, Tseng SCG. Transplantation of preserved human amniotic membrane for surface reconstruction in severely damaged rabbit corneas. Cornea 1995,14:473-84.
8. Koizumi N, Fullwood NJ, Bairaktaris G, Inatomi T, Kinoshita S, Quantock AJ. Cultivation of corneal epithelial cells on intact and denuded human amniotic membrane. Invest Ophthalmol Vis Sci. 2000 Aug;41(9):2506-13. PMID: 10937561
9. Koizumi N. Inatomi, Quantock AJ et al. Amniotic membrane as a substrate for cultivating limbal epithelial cells for autologous transplantation in rabbits, Cornea 2000; 19:65 71.
10. Koizumi N, Inatomi T, Suzuki T, Sotozono C, Kinoshita S. Cultivated corneal epithelial stem cell transplantation in ocular surface disorders. Ophthalmology. 2001 Sep;108(9):1569-74. PMID: 11535452]
11. Meller D, Pires RTF, Mack RJS, Figueiredo FC et al, Amniotic membrane transplantation for acute chemical or thermal burns. Ophthalmology 2000, 107:980 90.
12. Pellegrini G, Traverso CE, Franzi AT, Zingirian M, Cancedda R, De Luca M. Long-term restoration of damaged corneal surfaces with autologous cultivated corneal epithelium. Lancet. 1997 Apr 5;349(9057):990-3. PMID: 9100626.
13. Rama P, Bonini S, Lambiase A, Golisano O, Paterna P, De Luca M, Pellegrini G. Autologous fibrin-cultured limbal stem cells permanently restore the corneal surface of patients with total limbal stem cell deficiency. Transplantation. 2001 Nov 15;72(9):1478-85. PMID: 11707733
14. Schwab IR, Reyes M, Isseroff RR. Successful transplantation of bioengineered tissue replacements in patients with ocular surface disease. Am J Ophthalmol. 2000 Oct;130(4):543-4. No abstract available. PMID: 11024445
15. Shanbhag, S.S., Kate, A., Ganguly, S., Jakati, S., Deshmukh, R., & Basu, S. Five- to Twelve-Year Outcomes of Autologous Simple Limbal Epithelial Transplantation: Long-Term Corneal Epithelial Imaging and Phenotypic Analysis. Am *J Ophthalmol.* 2025 May; 273: 107-118. doi: 10.1016/j.ajo.2025.02.003. Epub 2025 Feb 7. PMID: 39924137. "Long-term 5–12 year successful restoration of the corneal epithelial phenotype was seen in two-thirds of eyes postautologous SLET. While corneal epithelial reflectivity, and densitometry were relatively better in eyes with successful outcomes, corneal epithelial thickness was similar in all eyes."
16. Sippel KC, Ma JJ, Foster CS. Amniotic membrane surgery.Curr Opin Ophthalmol. 2001 Aug;12(4):269-81. Review. PMID: 11507340
17. Sorsby A, Symons HM. Amniotic membrane grafts in caustic burns of the eye. Br J Ophthalmol 1946; 30:337-45.
18. Sorsby A, Haythorne J, Reed H. Further experience with amniotic membrane grafts in caustic burns of the eye. Br J Ophthalmol 1947,31:409-18
19. Tsai RJ, Li L, Chen J. Reconstruction of damaged corneas by transplantation of autologous limbal epithelial cells. Am J Ophthalmol. 2000 Oct;130(4):543. PMID: 11024443

20. Tseng SCG, Tsubota K. Amniotic Membrane Transplantation for Ocular Surface Reconstruction. In: Ocular Surface Diseases: Medical and Surgical Management Ed. Holland EJ and Mannis MJ, Sringer, in press, 2001.
21. Tsubota K, Satake Y, Kaido M, Shinozaki N, Shimmura S, Bissen-Miyajima H, Shimazaki J. Treatment of severe ocular-surface disorders with corneal epithelial stem-cell transplantation. N Engl J Med. 1999 Jun 3;340(22):1697-703. PMID: 10352161.
22. Twlford JD, Trelford-Sauder M. The amnion in surgery, past and present. Am J Obstet Gynecol 1979; 134:833-845.

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Select Health

MEDICAL POLICY

CORNEAL HYSTERESIS TESTING

Policy # 562

Implementation Date:1/12/15
Review Dates: 10/20/16, 10/19/17, 10/3/18, 10/3/19, 9/30/20, 10/26/21, 9/15/22, 10/3/23, 9/29/24
Revision Dates:

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Description

Glaucoma is a group of diseases that affects the optic nerve; glaucoma is one of the leading causes of blindness. It is generally caused by ocular hypertension, as in the most common type: primary open angle glaucoma (POAG), but not always. Glaucoma can damage your vision gradually and may not be diagnosed until at an advanced state. Another type of glaucoma is acute angle-closure glaucoma, and this presents with completely different symptoms such as severe eye pain, nausea, and vomiting. A third, much less common type of glaucoma, is low-tension glaucoma, and is believed to be related to not enough blood reaching the optic nerve.

Hysteresis is a property of physical systems that do not instantly follow the forces applied to them. The reaction is slow or does not return completely to the original state. Another defines it as the lagging of an effect behind its cause. Corneal hysteresis (CH) is a measure of viscous damping in the corneal tissue. It is the energy absorption capability of the cornea. Corneal hysteresis is determined through inducing the cornea to move following an air pulse. The difference in pressure values at the inward and outward applanation (flattening of the cornea by pressure) event times is defined as corneal hysteresis and the average provides a corrected intraocular pressure (IOP) measurement for an accurate IOP monitoring. Corneal hysteresis is determined by the viscoelastic properties of the corneoscleral shell.

The Goldman applanation tonometry is the most widely used method of measuring intraocular pressure and it is also known that corneal parameters affect the accuracy of this instrument. This instrument is the gold standard in glaucoma measurement.

The Reichert Ocular Response Analyzer (ORA) received 510(k) clearance from the U.S. Food and Drug Administration on January 20, 2004. The approved indications are measurement of intraocular pressure and assessment of biomechanical response of the cornea as tools in the diagnosing and monitoring of patients with glaucoma. There is no requirement in the 510(k) clearance process to submit evidence of extensive safety and efficacy. The measurement of CH by the ORA device has also been proposed as a method to evaluate the potential for post-surgical complications in patients being considered for refractive surgery and for assessing the biomechanical properties of the cornea in keratoconus.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover corneal hysteresis testing as it is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

It has been known for over 30 years that central corneal thickness (CCT) affects IOP measurement. Results from the Ocular Hypertension Treatment Study (OHTS) demonstrated that CCT is an important and independent risk factor for progression to initial glaucoma damage in persons with ocular hypertension. The association between CCT and glaucoma include, thinner corneas giving lower IOP levels, and may be subjected to less aggressive IOP-lowering therapy. Thinner corneas may be a risk factor due to an association with the response of the corneoscleral shell and the ocular vasculature to IOP-induced stress. Patients with thick corneas as determined by corneal pachymetry and ocular hypertension are not as likely to be at risk for progression of glaucoma.

Congdon et al. (2006) reported on an observational study to measure the impact of CCT and corneal hysteresis as anatomic and physiologic parameters to the clinical features and history of progressive worsening among patients with glaucoma, ocular hypertension, or suspected glaucoma. They concluded that the relationship between corneal features and glaucoma is more complex than simple anatomic thickness. The authors also concluded that it is not clear what corneal hysteresis measures but that it does appear that this variable describes the response of the cornea to rapid deformation. In this study, hysteresis was more closely associated with eyes that demonstrated progressive change than was the CCT. They have also proposed that their results may give information about responsiveness of the eye to mean IOP or changes in IOP and should refocus interest to the behavior of the cornea rather than just the thickness of the cornea. The authors did cite several limitations to their study. This includes patient selection for the study as the participants were from an urban area serviced by a tertiary care facility. The data or clinical information gathered for the study was based on retrospective chart review. There was no standardized protocol for the measurement of some key outcomes. This study was only to report associations among corneal thickness, corneal deformability, and glaucoma damage. There was no determination of how to direct patient care or to how improve patient outcomes.

Other published peer-reviewed literature consisted of studies evaluating correlations and associations between CH and established measures of intraocular pressure and CCT (Kotecha, 2006; Medeiros, 2006; Shah, 2006, 2007). These studies also do not demonstrate how CH measurement can be used to enhance patient management and improve patient health outcomes.

Additional studies again do not reflect how the measurement of CH will enhance patient management and improve health outcomes (Hager, 2007; Herndon, 2006; Pepose, 2007; Lam, 2007; Bochman, 2008; Kotecha, 2006, 2007; Kirwan, 2006).

Keratoconus is a noninflammatory condition of unknown etiology affecting the central cornea characterized by thinning and bulging of the cornea. It may significantly affect vision due to irregular astigmatism and corneal scarring. Keratoconic eyes are known to be less rigid and more elastic than normal eyes and possibly may have a different hysteresis than normal eyes. One possible measure of ocular rigidity in keratoconus is hysteresis. The American Academy of Ophthalmology (AAO) does not mention measurement of CH in its Preferred Practice Pattern for the evaluation and management of Primary Open Angle Glaucoma.

Some of the recently published peer-reviewed literature consists of studies that evaluate correlations and associations between CH and established measures of intraocular pressure and CCT. (Vanderwalle, 2009; Mangouritsas, 2009; Kopito, 2010; Renier, 2010; Carbonaro, 2010; Sullivan-Mee, 2009; Shah, 2008; Bayer, 2010; Schweitzer, 2010; Saad, 2009; Fontes, 2011; Bayoumi, 2010; Lau and Pye, 2011). These studies do not demonstrate how CH measurement can be used to enhance patient management

and improve health outcomes. There is insufficient evidence available from the peer-reviewed literature to validate the clinical role for measurement of corneal hysteresis.

An updated literature review completed in October 2016 suggest corneal hysteresis may have a future as an independent predictor of glaucoma risk, but questions remain on the: 1) inter- and intra-machine reliability of measurements, and 2) clinical application of measurements. Anecdotally, although corneal hysteresis measurements using the Reichert ORA is receiving increased adoption in some academic medical centers, it has not yet achieved widespread adoption to become the standard of care. These findings were supported by a prospective longitudinal study by Zhang published in 2016 which looked at 186 eyes of 133 patients with mean follow-up of 3.8 years. This study found baseline corneal hysteresis (CH) was significant in the univariable and multivariable models and were associated with faster rate of nerve fiber layer (RNFL) decline on spectral-domain OCT imaging. The study also found no relationship between RNFL decline and central corneal thickness (CCT) when adjusted for CH thickness, suggesting that CH may be a more important variable than CCT measurement for ophthalmic ultrasound for corneal pachymetry.

A second prospective cross-sectional study of 323 eyes in 323 patients in India by Kaushik et al., in 2012, found significantly lower CH in POAG and NTG vs. normal subjects, regardless of IOP. The study agreed with prior studies demonstrating CH as highly correlated with Goldmann-tonometry IOP. The article theorizes that an eye with higher CH has a “better damping effect” and may explain why some eyes with ocular hypertension do not develop glaucoma. The study also found that when controlled for CH and corneal resistance factor (CRF), CCT was no longer associated with Goldmann-tonometry IOP. The findings were also supported in an observational cohort study by Medeiros et al., in 2013, on 114 eyes of 68 patients followed for an average of 4 years which found GAT IOP was significantly influenced by CCT, but not by CH, suggesting utility of CH as an independent predictor of glaucoma. It also found a statistically significant relationship between CCT and CH.

Billing/Coding Information

CPT CODES

92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report

HCPCS CODES

No specific codes identified

Key References

1. Bayer A, Sahin A, Hürmeric V, et al. Intraocular pressure values obtained by ocular response analyzer, dynamic contour tonometry, and Goldmann tonometry in keratokonic corneas. J Glaucoma. 2010 Oct-Nov; 19(8):540-5.
2. Bayoumi NH, Bessa AS, El Massry AA. Ocular response analyzer and Goldmann applanation tonometry: a comparative study of findings. J Glaucoma. 2010 Dec; 19(9):627-31.
3. Bochmann F, Ang GS and Azuara-Blanco A. Lower corneal hysteresis in glaucoma patients with acquired pit of the optic nerve (APON). Graefes Arch Clin Exp Ophthalmol, May 2008; 246(5): 735-738.
4. Carbonaro F, Andrew T, Mackey DA, et al. Comparison of three methods of intraocular pressure measurement and their relation to central corneal thickness. Eye (Lond). 2010 Jul;24(7):1165-70.
5. Congdon NG, Broman AT, et al. Central corneal thickness and corneal hysteresis associated with glaucoma damage. American Journal of Ophthalmology, May 2006, Vol. 141, Issue 5.
6. Deol, M., D. A. Taylor and N. M. Radcliffe (2015). "Corneal hysteresis and its relevance to glaucoma." Curr Opin Ophthalmol 26(2): 96-102.
7. ECRI Institute. Hotline Response. Central Corneal thickness measurement for the diagnosis of glaucoma and ocular hypertension. April 2010.
8. Elsheikh A, Wang D, Rama P, et al. Experimental assessment of human corneal hysteresis. Curr Eye Res, March 2008; 33(3): 205-213.
9. Fontes BM, Ambrósio R Jr, Velarde GC, et al. Ocular response analyzer measurements in keratoconus with normal central corneal thickness compared with matched normal control eyes. J Refract Surg, 2011 Mar;27(3):209-15.
10. Gatinel D, Chaabouni S, Adam PA, Munck J, et al. Corneal hysteresis, resistance factor, topography, and pachymetry after corneal lamellar flap. J Refract Surg, January 2007; 23(1): 76-84.
11. Hager A, Loge K, Kutschan A and Wiegand W. [The effect of cataract and vitreoretinal surgery on central corneal thickness and corneal hysteresis]. Klin Monatsbl Augenheilkd, March 2008; 225(3): 207-211.
12. Jorge JM, Gonzalez-Meijome JM, et al. Correlations between corneal biomechanical properties measured with the ocular response analyzer and ICare rebound tonometry. J Glaucoma, Sept 2008; 17(6): 442-448.

13. Kirwan Caitriona, O'keefe Michael and Lanigan Bernadette. Corneal hysteresis and intraocular pressure measurement in children using the Reichert Ocular Response Analyzer. American Journal of Ophthalmology, December 2006, Vol. 142, Issue 6.
14. Kopito R, Gaujoux T, Montard R, et al. Reproducibility of viscoelastic property and intraocular pressure measurements obtained with the Ocular Response Analyzer. Acta Ophthalmol. 2010 Aug 25.
15. Kotecha A, Elsheikh A, Roberts CR, et al. Corneal thickness- and age-related biomechanical properties of the cornea measured with the ocular response analyzer. IOVS, December 2006, Vol. 47, No. 12.
16. Kotecha A. What biomechanical properties of the cornea are relevant for the clinician? Surv Ophthalmol, November 2007; 52 Suppl 2: S109-114.
17. Lam A, Chen D, Chiu R and Chui WS. Comparison of IOP measurements between ORA and GAT in normal Chinese. Optom Vis Sci, September 2007; 84(9): 909-914.
18. Lau W, Pye D. Changes in corneal biomechanics and applanation tonometry with induced corneal swelling. Invest Ophthalmol Vis Sci. 2011 Feb 23.
19. Lu F, Xu S, Qu J, Shen M, Wang X, et al. Central corneal thickness and corneal hysteresis during corneal swelling induced by contact lens wear with eye closure. Am J Ophthalmol, April 2007; 143(4): 616-622.
20. Mangouritsas G, Morphis G, Mourtzoukos S, et al. Association between corneal hysteresis and central corneal thickness in glaucomatous and non-glaucomatous eyes. Acta Ophthalmol. 2009 Nov;87(8):901-5.
21. Martinez-de-la-Casa J, Garcia-Feijoo J, et al. Ocular response analyzer versus Goldmann applanation tonometry for intraocular pressure measurements. IOVS, October 2006, Vol. 47, No. 10.
22. Medeiros FA and Weinreb RN. Evaluation of the influence of corneal biomechanical properties on intraocular pressure measurements using the ocular response analyzer. J Glaucoma 2006; 15(5): 364-370.
23. Medeiros, F. A., D. Meira-Freitas, R. Lisboa, T. M. Kuang, L. M. Zangwill and R. N. Weinreb (2013). "Corneal hysteresis as a risk factor for glaucoma progression: a prospective longitudinal study." Ophthalmology 120(8): 1533-1540.
24. Medeiros, F. A. (2013). "Author reply: To PMID 23642371." Ophthalmology 120(12): e85-86.
25. Ortiz D, Shabayek MH, et al. Corneal biomechanical properties in normal, post-laser in situ keratomileusis, and keratoconic eyes. Cataract Refract Surg, August 2007; 33(8): 1371-1375.
26. Pepose JS, Feigenbaum SK, Qazi MA, et al. Changes in corneal biomechanics and intraocular pressure following LASIK using static, dynamic, and noncontact tonometry. American Journal of Ophthalmology, January 2007, Vol. 143, Issue 1.
27. Renier C, Zeyen T, Fieuws S, et al. Comparison of ocular response analyzer, dynamic contour tonometer and Goldmann applanation tonometer Int Ophthalmol. 2010 Dec; 30(6):651-9.
28. Saad A, Lteif Y, Azan E, et al. Biomechanical properties of keratoconus suspect eyes. Invest Ophthalmos Vis Sci. 2009 Dec 30.
29. Schweitzer C, Roberts CJ, Mahmoud AM, et al. Screening of forme gruste keratoconus wth the ocular response analyzer. Invest Ophthalmol Vis Sci. 2010 May;51(5):2403-10.
30. Shah S, Laiquzzaman M, Cunliffe I and Mantry S. The use of the Reichert ocular response analyser to establish the relationship between ocular hysteresis, corneal resistance factor and central corneal thickness in normal eyes. Cont Lens Anterior Eye, December 2006; 29(5): 257-262.
31. Shah S, Laiquzzaman M, Bhojwani R, Mantry S and Cunliffe I. Assessment of the biomechanical properties of the cornea with the ocular response analyzer in normal and keratoconic eyes. Investigative Ophthalmology & Visual Science, July 2007; 48(7): 3026-3031.
32. Shah S, Laiquzzaman M, Mantry S and Cunliffe I. Ocular response analyser to assess hysteresis and corneal resistance factor in low tension, open angle glaucoma and ocular hypertension. Clin Experiment Ophthalmol, August 2008; 36(6): 508-513.
33. Sullivan-Mee M, Gerhardt G, Halverson KD, et al. Repeatability and reproducibility for intraocular pressure measurement by dynamic contour, ocular response analyzer and Goldmann applanation tonometry. J Glaucoma. 2009 Dec:18(9):666-73.
34. Sullivan-Mee M, Billingsley SC, Patel AD, Halverson KD, et al. Ocular Response Analyzer in subjects with and without glaucoma. Optom Vis Sci, June 2008; 85(6): 463-470.
35. Sullivan-Mee, M., D. Pensyl and K. Halverson (2013). "Corneal hysteresis and glaucoma progression." Ophthalmology 120(12): e85.
36. Sun L, Shen M, Wang J et al. Recovery of corneal hysteresis after reduction of intraocular pressure in chronic primary angle-closure glaucoma. Am J Ophthalmol. 2009 Jun:147(6):1061-6., 1066.e1-2.
37. Touboul D, Roberts C, Kerautret J, Garra C, et al. Correlations between corneal hysteresis, intraocular pressure, and corneal central pachymetry. J Cataract Refract Surgery 2008; 34(4): 616-622.
38. Vandewalle E, Vandenbroeck S, Stalmans I, et al. Comparison of ICare, dynamic contour tonometer, and ocular response analyzer with Goldmann applanation tonometer in patients with glaucoma, Eur J Ophthalmol. 2009 Sep-Oct;19(5):783-9.
39. Zhang, C., A. J. Tatham, R. Y. Abe, A. Diniz-Filho, L. M. Zangwill, R. N. Weinreb and F. A. Medeiros (2016). "Corneal Hysteresis and Progressive Retinal Nerve Fiber Layer Loss in Glaucoma." Am J Ophthalmol. 166: 29-36.

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Select Health

MEDICAL POLICY

CORNEAL TOPOGRAPHY/PACHYMETRY TESTING (COMPUTER-ASSISTED KERATOGRAPHY)

Policy # 245

Implementation Date: 10/15/04
Review Dates: 12/20/07, 12/18/08, 12/17/09, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/16/18, 6/8/19, 6/9/20, 5/30/21, 1/5/22, 5/8/22, 5/30/23, 6/4/24, 6/1/25
Revision Dates: 7/26/06, 6/30/16, 1/12/22

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Of all the technologies currently available, corneal topography provides the most detailed information about the curvature of the cornea. Using a very sophisticated computer and software, thousands of measurements are taken and analyzed in just seconds. The computer generates a color map from the data. This information is useful to evaluate and correct astigmatism, monitor corneal disease, and detect irregularities in the corneal shape. The map is interpreted much like other topography maps. The cool shades of blue and green represent flatter areas of the cornea, while the warmer shades of orange and red represent steeper areas. This corneal map allows the physician to formulate a "3-D" perspective of the cornea's shape. Measuring astigmatism is important for planning refractive surgery, fitting contact lenses, and calculating intraocular lens power.

Corneal pachymetry is a noninvasive ultrasonic technique for measuring corneal thickness and has been used primarily in the evaluation of persons with corneal diseases and in the assessment of people at risk for glaucoma. Ultrasonic corneal pachymetry is performed by placing an ultrasonic probe on the central cornea, after the cornea has been anesthetized with a topical anesthetic. A technician can operate the pachymeter, and it normally takes less than 30 seconds per eye to complete measurements.

Corneal pachymetry may be useful in assessing candidates for penetrating keratoplasty (corneal transplant) and assessing graft failure and the need for regrafting in corneal transplant recipients by aiding in the early diagnosis and treatment of graft rejection. Corneal pachymetry may also be useful in assessing the response to treatment of corneal transplant rejection. Corneal pachymetry has also been used to assess the progression of disease in patients with certain corneal dystrophies and degenerative diseases.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers corneal topography/pachymetry testing in *limited circumstances*. The medical literature has shown use of this technology can have a positive impact in member health outcomes.

Conditions for which coverage is provided:

- Anomalies of corneal size and shape
- Corneal ectasia
- Fuchs corneal dystrophy

Select Health

- Keratoconus
- Lameller keratoplasty
- Marginal degeneration of the cornea
- Mechanical complications of corneal graft
- Mooren's Ulcer
- Nodular degeneration of the cornea
- Post-operative corneal transplant
- Post-operative high astigmatism after cataract or glaucoma surgery or lens implant surgery
- Pseudophakic bullous keratopathy
- Pterygium
- Secondary corneal edema

Select Health does NOT cover corneal topography/pachymetry performed as a pre-service evaluation or post-surgical assessment of patients undergoing non-covered vision correction surgery.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

The Ocular Hypertension Treatment Study, a prospective randomized controlled clinical trial of glaucoma treatment in persons with elevated intraocular pressure (greater than or equal to 24 mm Hg), found central corneal thickness a statistically significant predictor of development of glaucoma. Corneal thickness was measured only after the study was initiated and was not used to guide therapy. For the enrolled patients, the Ocular Hypertension Treatment Study results identified central corneal thickness < 556 microns and a vertical or horizontal cup to disc ratio > 0.4 (vertical or horizontal) as risk factors for glaucomatous damage.

The Ocular Hypertension Treatment Study results suggest that intraocular pressure measurements need to be adjusted for abnormally thick or thin corneas. The target intraocular pressure is lower for a thin cornea and higher for a thick cornea. Eyes with thick corneas have a true IOP that is lower than the measured IOP. Conversely, eyes with thin corneas have a true IOP that is greater than the measured IOP. Thus, individuals with thicker corneas may be misclassified as having ocular hypertension.

The Ocular Hypertension Treatment Study is the first to establish corneal thickness as a risk factor for glaucoma. However, the conclusions of OHTS are limited to persons with ocular hypertension (> 24 mm Hg), and do not establish the value of corneal pachymetry for screening persons without ocular hypertension. In addition, there are no prospective clinical outcome studies demonstrating the clinical utility of corneal pachymetry in selecting patients for therapy, for guiding therapy, and improving clinical outcomes.

Select Health

Based on the results of this study, the American Academy of Ophthalmology Preferred Practice Pattern on Evaluation of the Glaucoma Suspect recommends measurement of corneal thickness with electronic pachymetry in evaluating the glaucoma suspect.

Repeat measurements of corneal thickness for glaucoma are not necessary unless the patient has corneal diseases or surgery affecting corneal thickness. Changes in corneal thickness with age are minimal in adulthood, with estimated changes of 0.006–0.015 mm per decade.

Billing/Coding Information

CPT CODES

Covered for the outlined conditions above

76514 Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)

92025 Computerized corneal topography, unilateral or bilateral, with interpretation and report

HCPCS CODES

No specific codes identified

ICD-10 CODES

Anomalies of corneal size and shape

Q11.2 Microphthalmos
Q13.4 Other congenital corneal malformations
H18.70 Unspecified corneal deformity

Corneal ectasia

H18.711 Corneal ectasia, right eye
H18.712 Corneal ectasia, left eye
H18.713 Corneal ectasia, bilateral
H18.719 Corneal ectasia, unspecified eye

Fuchs corneal dystrophy

H18.511 Endothelial corneal dystrophy, right eye
H18.512 Endothelial corneal dystrophy, left eye
H18.513 Endothelial corneal dystrophy, bilateral
H18.519 Endothelial corneal dystrophy, unspecified eye
H18.521 Epithelial (juvenile) corneal dystrophy, right eye
H18.522 Epithelial (juvenile) corneal dystrophy, left eye
H18.523 Epithelial (juvenile) corneal dystrophy, bilateral
H18.529 Epithelial (juvenile) corneal dystrophy, unspecified eye

Keratoconus

H18.601 Keratoconus, unspecified, right eye
H18.602 Keratoconus, unspecified, left eye
H18.603 Keratoconus, unspecified, bilateral
H18.609 Keratoconus, unspecified, unspecified eye
H18.611 Keratoconus, stable, right eye
H18.612 Keratoconus, stable, left eye
H18.613 Keratoconus, stable, bilateral
H18.619 Keratoconus, stable, unspecified eye
H18.621 Keratoconus, unstable, right eye
H18.622 Keratoconus, unstable, left eye
H18.623 Keratoconus, unstable, bilateral

Select Health

Corneal Topography/Pachymetry Testing (Computer-assisted Keratography), continued

H18.629	Keratoconus, unstable, unspecified eye

Lameller keratoplasty

H16.071	Perforated corneal ulcer, right eye
H16.072	Perforated corneal ulcer, left eye
H16.073	Perforated corneal ulcer, bilateral
H16.079	Perforated corneal ulcer, unspecified eye
H16.301	Unspecified interstitial keratitis, right eye
H16.302	Unspecified interstitial keratitis, left eye
H16.303	Unspecified interstitial keratitis, bilateral
H16.309	Unspecified interstitial keratitis, unspecified eye
H16.331	Sclerosing keratitis, right eye
H16.332	Sclerosing keratitis, left eye
H16.333	Sclerosing keratitis, bilateral
H16.339	Sclerosing keratitis, unspecified eye
H17.10	Central corneal opacity, unspecified eye
H17.11	Central corneal opacity, right eye
H17.12	Central corneal opacity, left eye
H17.13	Central corneal opacity, bilateral
H18.20	Unspecified corneal edema
H18.221	Idiopathic corneal edema, right eye
H18.222	Idiopathic corneal edema, left eye
H18.223	Idiopathic corneal edema, bilateral
H18.229	Idiopathic corneal edema, unspecified eye
H18.30	Unspecified corneal membrane change
H18.501	Unspecified hereditary corneal dystrophies, right eye
H18.502	Unspecified hereditary corneal dystrophies, left eye
H18.503	Unspecified hereditary corneal dystrophies, bilateral
H18.509	Unspecified hereditary corneal dystrophies, unspecified eye

Marginal degeneration of the cornea

H18.461	Peripheral corneal degeneration, right eye
H18.462	Peripheral corneal degeneration, left eye
H18.463	Peripheral corneal degeneration, bilateral
H18.469	Peripheral corneal degeneration, unspecified eye
H18.49	Other corneal degeneration

Mechanical complications of corneal graft

T85.318A	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, initial encounter
T85.318D	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, subsequent encounter
T85.318S	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, sequela
T85.328A	Displacement of other ocular prosthetic devices, implants and grafts, initial encounter
T85.328D	Displacement of other ocular prosthetic devices, implants and grafts, subsequent encounter
T85.328S	Displacement of other ocular prosthetic devices, implants and grafts, sequela
T85.398A	Other mechanical complication of other ocular prosthetic devices, implants and grafts, initial encounter
T85.398D	Other mechanical complication of other ocular prosthetic devices, implants and grafts, subsequent encounter
T85.398S	Other mechanical complication of other ocular prosthetic devices, implants and grafts, sequela

Mooren's Ulcer

Corneal Topography/Pachymetry Testing (Computer-assisted Keratography), continued

H16.051	Mooren's corneal ulcer, right eye
H16.052	Mooren's corneal ulcer, left eye
H16.053	Mooren's corneal ulcer, bilateral
H16.059	Mooren's corneal ulcer, unspecified eye

Nodular degeneration of the cornea

H18.451	Nodular corneal degeneration, right eye
H18.452	Nodular corneal degeneration, left eye
H18.453	Nodular corneal degeneration, bilateral
H18.459	Nodular corneal degeneration, unspecified eye

Post-operative corneal transplant

T86.8401	Corneal transplant rejection, right eye
T86.8402	Corneal transplant rejection, left eye
T86.8403	Corneal transplant rejection, bilateral
T86.8409	Corneal transplant rejection, unspecified eye
T86.8411	Corneal transplant failure, right eye
T86.8412	Corneal transplant failure, left eye
T86.8413	Corneal transplant failure, bilateral
T86.8419	Corneal transplant failure, unspecified eye
T86.8421	Corneal transplant infection, right eye
T86.8422	Corneal transplant infection, left eye
T86.8423	Corneal transplant infection, bilateral
T86.8429	Corneal transplant infection, unspecified eye
T86.8481	Other complications of corneal transplant, right eye
T86.8482	Other complications of corneal transplant, left eye
T86.8483	Other complications of corneal transplant, bilateral
T86.8489	Other complications of corneal transplant, unspecified eye
T86.8491	Unspecified complication of corneal transplant, right eye
T86.8492	Unspecified complication of corneal transplant, left eye
T86.8493	Unspecified complication of corneal transplant, bilateral
T86.8499	Unspecified complication of corneal transplant, unspecified eye
Z94.7	Corneal transplant status

Post-operative high astigmatism after cataract or glaucoma surgery or lens implant surgery

H52.211	Irregular astigmatism, right eye
H52.212	Irregular astigmatism, left eye
H52.213	Irregular astigmatism, bilateral
H52.219	Irregular astigmatism, unspecified eye
H52.201	Unspecified astigmatism, right eye
H52.202	Unspecified astigmatism, left eye
H52.203	Unspecified astigmatism, bilateral
H52.209	Unspecified astigmatism, unspecified eye

Pseudophakic bullous keratopathy

H18.10	Bullous keratopathy, unspecified eye
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral

Pterygium

H11.001	Unspecified pterygium of right eye
H11.002	Unspecified pterygium of left eye
H11.003	Unspecified pterygium of eye, bilateral
H11.009	Unspecified pterygium of unspecified eye

Corneal Topography/Pachymetry Testing (Computer-assisted Keratography), continued

H11.011	Amyloid pterygium of right eye
H11.012	Amyloid pterygium of left eye
H11.013	Amyloid pterygium of eye, bilateral
H11.019	Amyloid pterygium of unspecified eye
H11.021	Central pterygium of right eye
H11.022	Central pterygium of left eye
H11.023	Central pterygium of eye, bilateral
H11.029	Central pterygium of unspecified eye
H11.031	Double pterygium of right eye
H11.032	Double pterygium of left eye
H11.033	Double pterygium of eye, bilateral
H11.039	Double pterygium of unspecified eye
H11.041	Peripheral pterygium, stationary, right eye
H11.042	Peripheral pterygium, stationary, left eye
H11.043	Peripheral pterygium, stationary, bilateral
H11.049	Peripheral pterygium, stationary, unspecified eye
H11.051	Peripheral pterygium, progressive, right eye
H11.052	Peripheral pterygium, progressive, left eye
H11.053	Peripheral pterygium, progressive, bilateral
H11.059	Peripheral pterygium, progressive, unspecified eye
H11.061	Recurrent pterygium of right eye
H11.062	Recurrent pterygium of left eye
H11.063	Recurrent pterygium of eye, bilateral
H11.069	Recurrent pterygium of unspecified eye

Secondary corneal edema

H18.211	Corneal edema secondary to contact lens, right eye
H18.212	Corneal edema secondary to contact lens, left eye
H18.213	Corneal edema secondary to contact lens, bilateral
H18.219	Corneal edema secondary to contact lens, unspecified eye
H18.231	Secondary corneal edema, right eye
H18.232	Secondary corneal edema, left eye
H18.233	Secondary corneal edema, bilateral
H18.239	Secondary corneal edema, unspecified eye

Key References

1. Alimisi,, S., Miltsakakis, D., & Klyce,, S. (1996). Corneal topography for intraocular lens power calculations. Journal of Refractive Surgery, 12 (2), S309-S311. Abstract retrieved October 16, 2000 from PubMed database.
2. American Academy of Ophthalmology Refractive Errors Panel. (2002). Refractive errors. Retrieved January 2, 2004 from http://www.guideline.gov/summary/summary.aspx?doc_id=3545&nbr=2771&string=corneal+AND+topography.
3. Bechmann, M, et al. Central corneal thickness measurements with retinal optical coherence tomography device versus standard ultrasonic pachymetry. *Cornea*, 2001;20(1):50-54.
4. BlueCross BlueShield Association, Medical Policy Reference Manual. (1997, November). Corneal topography / computer-assisted photokeratoscopy (9.03.05). Retrieved January 2, 2004 from BlueWeb.
5. Brandt, JD, Beiser, JA, Kass, MA, et al. Central corneal thickness in the Ocular Hypertension Treatment Study (OHTS). *Ophthalmology*, 2001;108(10):1779-1788.
6. CIGNA Healthcare Medicare Administration. Medicare Part B Carrier Local Medicare Review Policies. Tennessee. (1996). Computer corneal topography. Retrieved January 2, 2004 from http://www.cignamedicare.com/partb/lmrp/tn/cms_fu/9621-01.htm.
7. Doughty, MJ, Zaman, ML. Human corneal thickness and its impact on intraocular pressure measures: A review and meta-analysis approach. *Surv Ophthalmol*, 2000;44(5):367-408.
8. Giraldez Fernandez MJ, Diaz Rey A, Cervino A, Yerbra-Pimentel E. A comparison of two pachymetric systems: Slit-scanning and ultrasonic. *CLAO J*, 2002;28(4):221-223.
9. Gordon, MO, Beiser, JA, Brandt, JD, et al. The Ocular Hypertension Treatment Study: Baseline factors that predict the onset of primary open angle glaucoma. *Arch Ophthalmol*, 2002;120(6):714-719.
10. Hayes Medical Technology Directory. (2001, May). Computerized corneal topography systems (COMP0203). Retrieved January 2, 2004 from Hayes Inc Online.
11. Kass, MA, Heuer, DK, Higginbotham, EJ, et al. The Ocular Hypertension Treatment Study: A randomized trial determines that topical ocular hypertensive medication delays or prevents the onset of primary open-angle glaucoma. *Archiv Ophthalmol*, 2002;120(6):701-713.
12. Lee, GA, et al. The corneal thickness and intraocular pressure story: Where are we now? *Clin Experiment Ophthalmol*, 2002;30(5):334-337.

13. Morrow, G.L., & Stein, R.M. (1992). Evaluation of corneal topography: Past, present and future trends. Canadian Journal of Ophthalmology, 27 (5), 213-225.
14. Palmberg, P. Answers from the ocular hypertension treatment study. *Archiv Ophthalmol*, 2002;120 (6):829-830.
15. Phillips, LL, Cakanac, CJ, Eger, MW, Lilly, ME. Central corneal thickness and measured IOP: A clinical study. *Optometry*, 2003;74(3)
16. Rainer, G, Petternel, V, Findl, O, et al. Comparison of ultrasound pachymetry and partial coherence interferometry in the measurement of central corneal thickness. *J Cataract Refract Surg*, 2002;28(12):2142-2145.
17. Reinstein, DZ, Silverman, RH, Raevsky, T, et al. Arc-scanning very high-frequency digital ultrasound for 3D pachymetric mapping of the corneal epithelium and stroma in laser in situ keratomileusis. *J Refract Surg*, 2000;16(4):414-430.
18. Schallhorn, S.C., Reid, J.L., Kaupp, S.E., Blanton, C.L., Zoback, L., Goforth, H., Flowers, C.W., & McDonnell, P.J. (1998). Topographic detection of photorefractive keratectomy. *Ophthalmology*, 105 (3), 507-516.
19. Singh, RP, et al. Central corneal thickness, tonometry and ocular dimensions in glaucoma and ocular hypertension. *J Glaucoma*, 2001;10(3):206-210.
20. Smith, R.J., Chan, W.K., & Maloney, R.K. (1998). The prediction of surgically induced refractive change from corneal topography. *American Journal of Ophthalmology*, 125 (1), 44-53.
21. Whitacre, MM, Stein RA, Hassanein K. The effect of corneal thickness on applanation tonometry. *Am J Ophthalmol*, 1993;115:592-596.
22. Wilson, S.E., & Klyce, S.D. (1991). Advances in the analysis of corneal topography. *Survey of Ophthalmology*, 35 (4), 269-277.

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MEDICAL POLICY

EXCIMER LASER EYE SURGERY (LASIK, PRK, PTK)

Policy # 119

Implementation Date: 11/15/00
Review Dates: 2/27/01, 4/15/02, 10/23/03, 11/18/04, 10/16/06, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 10/13/11, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/3/19, 9/30/20, 10/26/21, 9/15/22, 10/3/23, 9/29/24
Revision Dates: 7/26/06

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

LASIK stands for laser assisted in-situ keratomileusis and is a combination of 2 refractive procedures: automated lamellar keratoplasty (ALK) and photorefractive keratectomy (PRK), using the excimer laser. This laser refractive surgery can correct a wide range of myopia (nearsightedness) and hyperopia (farsightedness), as well as astigmatism. ALK is the use of a high-tech microkeratome or femtosecond laser to create a corneal flap that is "folded" back to expose the corneal tissue that is subsequently ablated by the computer-controlled excimer laser (PRK). This is an outpatient procedure performed under local anesthesia.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers excimer laser surgery for patients meeting the following criteria:

A. For **LASIK**, **all** the following criteria must be met:
   1. Visual acuity, "best-corrected," is 20/40 or worse
   2. Vision cannot be adequately corrected using corrective lens or contact lens, or patient is intolerant to contact lens
   3. Patient has one of the following medical conditions:
      a. Keratoconus post-corneal transplant

B. For **Photorefractive Keratectomy (PRK), all** the following criteria must be met:
   1. Visual acuity, "best-corrected," is 20/40 or worse
   2. Vision cannot be adequately corrected using corrective lens or contact lens/patient intolerant to contact lens
   3. Patient has one of the following medical conditions:
      a. Epithelial basement membrane dystrophy
      b. Keratoconus post-corneal transplant
      c. Salzmann's degeneration
      d. Severe corneal epithelial erosions
      e. Superficial corneal dystrophies (granular, lattice, and Reis-Buckler's)

C. For **Phototherapeutic Keratectomy (PTK), all** the following criteria must be met:

1. Visual acuity, "best-corrected," is 20/40 or worse
2. Vision cannot be adequately corrected using corrective lens or contact lens/patient intolerant to contact lens
3. Pathology or irregularity located in the anterior 100 microns (one-third) of the cornea, where the proposed total treatment area is at least 400 microns in thickness

D. Contraindications:

- Blepharitis
- Dry eye
- Lagophthalmos
- Patients who have previously undergone radial keratotomy (RK) are subject to increased risk of undesirable outcomes and complications
- Patients whose refractive history is unstable (because accurate pre-treatment baseline refraction for the calculation of the desired correction cannot be obtained)
- Patients with a history of either glaucoma or keloid formation
- Patients with history of or active Herpes simplex virus infections or Herpes zoster infections
- Patients with uncontrolled vascular disease or autoimmune diseases (because these patients have difficulty in corneal healing and are more susceptible to corneal melting)
- Patients younger than 18 years of age
- Uncontrolled posterior uveitis or anterior uveitis
- Women who are pregnant or nursing, due to the potential for temporary fluctuation in vision (refraction) with pregnancy or nursing

SELECT HEALTH ADVANTAGE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Photorefractive Keratectomy (PRK) uses a computerized laser for corneal reshaping. The excimer laser produces a beam of ultraviolet light in pulses that last only a few billionths of a second. Each pulse removes a microscopic amount of tissue by evaporating it, producing very little heat, and usually leaving underlying tissue almost untouched. Overall, the surgery takes approximately 10−20 minutes; however, the use of the laser beam lasts only 15−40 seconds. In patients with myopia, corneal tissue is removed in its center to flatten it, while in hyperopia, corneal tissue is removed at its periphery, to create corneal steepening. Astigmatism describes a corneal contour which is not perfectly symmetrical, like the shape of a back of a spoon. The amount of tissue removal thus varies along different corneal meridians.

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Laser in-situ Keratomileusis (LASIK), in this technique the epithelial layer of the cornea is pulled back, creating a flap and the stromal bed of the cornea is reshaped with the laser. Finally, the protective layer is repositioned without sutures and is secure after five minutes of air-drying. The LASIK procedure appears to be gaining in popularity. Removal of tissue from the stromal bed is more precise in comparison to PRK or ALK. Additionally, compared to PRK, LASIK is associated with fewer healing complications and is less painful since the epithelial surface of the cornea remains intact. The location and amount of tissue removed is similar to that described for PRK.

Phototherapeutic Keratectomy (PTK) functions by removing anterior stromal opacities or eliminating elevated corneal lesions while maintaining a smooth corneal surface. Complications of PTK include refractive errors most commonly hyperopia, corneal scarring, and glare.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

CPT CODES

65400	Excision of lesion, cornea (keratectomy, lamellar, partial, except pterygium)
65760	Keratomileusis
65765	Keratophakia
65767	Epikeratoplasty
65771	Radial keratotomy
66999	Unlisted procedure, anterior segment of eye

HCPCS CODES

S0800	Laser in-situ keratomileusis (LASIK)
S0810	Photorefractive keratectomy (PRK)
S0812	Phototherapeutic keratectomy (PTK)

Key References

1. American Academy of Ophthalmology Laser in-situ keratomileusis, LASIK.
2. Gallo JP, Raizman MN, Phototherapeutic Keratectomy for Superficial Corneal disorders. Int, Ophthalmology Clinics. 1997;37(1): 155-70.
3. Gill KS, Sitbon JR, Trocme SD, Phototherapeutic Keratectomy. AORN Journal. 1997; 66(2): 242-4, 246, 248-52.
4. Hayes Medical Technology Directory. Photorefractive Keratectomy. 1996 Jan 22PHOTO3020.14: 3-25.
5. Thompson, VM. Excimer Laser Phototherapeutic Keratectomy: Clinical and Surgical Aspects. Ophthalmic Surgery Lasers. 1995: 26 (5): 461-72 Sep-Oct.
6. Zuckerman SJ, Aquavella J. and Park, SB. Analysis of the Efficacy and Safety of Excimer Laser PTK in the Treatment of Corneal Disease. Corena. 1996; 15(1): 9-14.

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Select Health

Excimer Laser Eye Surgery (Lasik, PRK, PTK)

Select Health

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MEDICAL POLICY

IMPLANTED INTRAOCULAR DEVICES FOR THE TREATMENT OF GLAUCOMA

Policy # 471
Implementation Date: 12/13/10
Review Dates: 12/15/11, 7/18/13, 5/7/15, 4/14/16, 4/27/17, 10/6/18, 7/30/19, 3/18/20, 5/30/21, 5/8/22, 5/30/23, 6/4/24, 6/1/25
Revision Dates: 4/1/14, 8/1/19, 8/28/19, 5/1/20, 5/13/22, 5/31/22, 7/11/23, 9/19/24

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Glaucoma is a group of eye diseases traditionally characterized by elevated intraocular pressure (IOP). However, glaucoma is more accurately described as disease affecting the optic nerve rather than a disease of high-pressure. It is the second leading cause of irreversible blindness worldwide and can damage vision so gradually one may not notice any loss of vision until the disease is at an advanced stage. Standard therapy involves topical medications and/or surgical intervention. The most performed laser surgical procedures are laser iridotomy and laser trabeculoplasty. This surgery may fail due to scarring, so aqueous shunting procedures have become more popular alternatives when drugs fail to control IOP.

Aqueous shunts (e.g., Ahmed, Baerveldt, Krupin, EX-PRESS) drain aqueous humor from the anterior chamber using canals, filters or valves. The incisional approach cuts through conjunctiva and sclera. Complications from these devices included corneal endothelial failure, infection and erosion of conjunctiva. Minimally Invasive Glaucoma Surgery (MIGS) is used in mild to moderate open angle glaucoma where medication is not necessarily improving IOP. Microstent surgery (e.g., IStent, IStent inject, Hydrus Microstent) is typically performed in conjunction with cataract extraction. The incisional approach is like cataract surgery. Later devices (e.g., Xen45 Gel Stent, iStent infinite) appear useful in refractory glaucoma and can be done with or without cataract surgery.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers the following aqueous shunt/stent devices:

- **EX-PRESS Mini Glaucoma Shunt, or**
- **Xen45 Gel Stent**

When the following criteria are met:

1. A diagnosis of open-angle glaucoma or pseudoexfoliative glaucoma
2. Failure of control of IOP with maximum tolerated medical therapy

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B. Select Health covers the following valves/implants:

- **Ahmed Valve, or**
- **Baerveldt Implant**

When the following criteria are met:

1. Any diagnosis of glaucoma, including primary open-angle, pseudoexfoliative, neovascular, uveitic, and chronic angle-closure
2. Failure of control of IOP with maximum tolerated medical therapy

C. Select Health covers the following stents:

- **iStent, or**
- **iStent inject, or**
- **iStent infinite, or**
- **Hydrus Microstent**

When the following criteria are met:

1. The procedure is combined with cataract surgery (can NOT be a standalone procedure, with the exception of iStent infinite);
2. Patient has a diagnosis of open-angle glaucoma or pseudoexfoliative glaucoma
3. Patient is currently using at least one eyedrop for control

Select Health considers insertion of a drug-eluting implant, including: 1) punctal dilation and implant removal when performed, into the lacrimal canaliculus, or 2) into the anterior chamber or trabecular meshwork of the eye, as experimental/investigational for the treatment of glaucoma or ocular hypertension because its long-term safety and effectiveness has not been established.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

EX-PRESS Shunt: A Medical Technology Assessment performed in December 2009 identified 9 primary literature papers, but no systematic reviews related to internal aqueous devices, including the EX-PRESS device. Of the 9 papers, a total of 744 eyes were treated in studies examining EX-PRESS, trabeculectomy vs. EX-PRESS and a variety of other mixed study designs. The mean follow-up time following the procedure was between 7.5 and 36.9 months.

Most of the papers referenced a statistically significant decrease in intraocular pressure following the EX-PRESS procedure. Primary post-operative endpoints were generally > 5 mmHg and < 18–20 mmHg IOP (the accepted IOP is generally between 10–21 mmHg).

The published literature is, however, conflicted with regards to complications. For instance, Rivier et al. remarked that implantation of the shunt under the conjunctiva was associated with a complication rate approaching 30% despite good IOP control. Fewer complications, such as erosion of the conjunctiva and hypotony, were observed when EX-PRESS was placed under a sclera flap. Maris et al. and Reinthal et al. reported that when the device was implanted under a sclera flap, it had similar IOP-lowering efficacy with a lower complication rate than with trabeculectomy.

Of the 4 papers that compared EX-PRESS to trabeculectomy, 3 reported higher success rates with the EX-PRESS device. The fourth only remarked that the implant was equally as safe and effective as the standard of care. None of the 9 papers compared the EX-PRESS device to pharmacologic solutions.

The technology assessment concluded, though, some data is lacking related to long-term efficacy and complications, the preponderance of evidence demonstrates internal aqueous shunts, such as the EX-PRESS device to be equally effective and safe in the treatment of glaucoma.

XEN45 Gel Stent: This stent was FDA approved in July 2016. A recent review of the published evidence identified 2 systematic reviews and 8 primary studies which evaluated the efficacy, safety, and durability of the XEN45 gel stent. Regarding safety, several case reports included in this review (Fea et al. and Fernandez-Garcia) identify unique adverse events; the large prospective study by Schlenker et al. perhaps best identifies safety issues with the XEN45 stent. This European study compares XEN45 to trabeculectomy. This is relevant as the XEN45 has been available in Europe for a number of years, and thus, provider experience better represents what might be expected long-term in the U.S. Comparison to trabeculecotmy is also relevant as this is a much more invasive procedure, considered the most definitive, but also has significant potential adverse effects. This study showed no statistical difference in failure or safety concerns, though, numerically XEN45 appeared to have a better profile. Most notably the study by Sheybani et al. assessing flow dynamics demonstrated the risk of hypotomy is low with the XEN45 stent.

With regards to efficacy, the systematic reviews by Manasses et al. in 2016 and Vinod in 2017 describe the comparative outcomes of the XEN device to other stents/shunts for the treatment of glaucoma. In the Manasses study, it was noted IOP-lowering reached normal levels of IOP form > 20 mm Hg to ~13 mm and med reduction average 1.8 meds from 2.7 preoperative to 0.9 with no reported complications. This was noted to be comparable or superior to other stents/shunts available including Cypass stent and iStent with a lower complication rate, especially as it relates to hypotony. Vinod et al. identified similar outcomes with reduction in medications by ~1.8 meds over a two-year time period and complete success (defined as sustained IOP reduction < 18 mm Hg) achieved in 47% of patients studied. This systematic review also noted a low level of complications including transient hypotony (13%) and choroidal effusion (8.7%), though, these also resolved spontaneously unlike what has been seen with Cypass.

Lastly, a study by Gregori et al. from 2017 showed 80.7% complete response rate at 12 months with similar reduction in medication use post-procedure. It noted no significant complications. Similarly, studies by Galal et al. and Perez-Torregrosa demonstrated high levels of efficacy in patients who had failed medical therapy. Galal et al. noted complete success in 42% at 12 months with greater than 12 mm Hg IOP decrease and a reduction in medication use by approximately 1.6 meds per patient on average at 12 months. Perez-Torregrosa identified improvement IOP of nearly 30% at 12 months with over 97% reduction in medication use.

The studies appear to demonstrate the XEN45 stent to be safe and effective in lowering IOP in patients inadequately responsive to medical management. Evidence suggests potential reduced side effects compared to some MIGS devices. The volume of evidence remains limited despite the availability of this

device in Europe for several years and the lack of more head-to-head comparisons to other MIGS devices.

iStent: A 2017 search of published literature identified 4 systematic reviews including a Hayes Brief report and 18 primary studies. These studies included more than 1,305 patients dating from 2009 to 2016. As these devices have been approved in Europe for several years, many of the older studies are of European origin. Though several of the studies were larger randomized prospective studies, most studies suffered from methodological weaknesses in that they were smaller case series without comparative arms and often were retrospective in their analyses. Nearly all studies focus on the first-generation iStent leading to limitations to conclusions regarding the iStent injector.

The systematic reviews support the efficacy of the iStent device as measured in IOP-lowering in patients undergoing simultaneous cataract surgery. The two reviews by Malvankar-Mehta et al. from 2015, also support efficacy of iStent in lowering IOP as a standalone procedure. The Hayes review from 2016, which was updated in 2017 also focuses on the use of multiple stents, a practice reported to occur not uncommonly, and notes the body of evidence is of very low-quality limiting that ability to make a statement as to the efficacy and safety of this approach.

The published studies also support efficacy of iStent in lowering IOP, though, many of the studies are of small size, lack randomization, and are of short duration with outcomes typically measured to 12 months or less. Two studies, Arriola-Villalobos et al. (2012) and Tan et al. (2016) looked at outcomes out to 54 months and 30 months, respectively. These studies support the durability of the effect in lowering IOP in patients, though, both studies only assessed iStent in patients with associated cataract surgery.

As noted by Wellik et al. in 2015, the devices have a good safety profile based on the iStent Study Group. The most common complication across studies was early post-operative stent occlusion and malposition, which was observed in 2.6% to 18.0% of study subjects. Across all studies, malposition and occlusion necessitated surgical intervention (neodymium-doped yttrium aluminum garnet laser, recombinant tissue plasminogen activator, or stent revision) in a range of 4.5% to 11.3% of study subjects. This review also noted the occurrence of hyphema, ranging from 2.3% to 70.0%, however, specific definitions of what constituted normal bleeding versus complicated bleeding were not given. Other adverse events were rare.

Multiple studies assessed the impact of iStent implant (in addition to cataract surgery which itself can lower IOP on medication usage post-procedure. The evidence from the studies suggests a post-procedure reduction in medication use, ranging from 0.48 to 1.7 medications in time periods, as long as 3 years post-procedure.

The evidence tends to identify the longer the measurement period after the procedure, the more likely the patient may once again need medication to control their intraocular hypertension. Whether this represents a loss of durability of the iStent or a natural progression of the disease is not identified in the studies.

In conclusion, there is a moderate-sized body of literature of low-to-moderate quality that demonstrates implantation of the first generation iStent device is safe and likely effective in lowering IOP and improving intraocular pressure control post-cataract surgery in patients with glaucoma. Evidence is less robust for the iStent inject with most studies using the first generation iStent device. Additionally, the effectiveness of the iStent is suggested as a standalone treatment but the evidence is inadequate to draw conclusions in this setting.

iStent infinite: The iStent infinite consists of 3 iStent inject W stents placed into the trabecular meshwork over at least 4 clock hours. In 8/2022, the FDA granted 510(k) clearance for the device as a stand-alone or in conjunction with cataract surgery. As Sarkisian et al in 2023 in a multi-center single-arm prospective study (n=72) of the device as a stand-alone treatment in open angle glaucoma, the primary response endpoint was met in 73.4% of the “Failed [prior cilioablative and incisional glaucoma] Surgery” and in 90.9% of the “Max Tolerated Medical Therapy” subgroups, with mean IOP reduction at 12 months of 5.9 mmHg and 8.1 mmHg, respectively.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0450T	; each additional device (List separately in addition to code for primary procedure)
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	; with graft (revised)
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
67121	Removal of implanted material, posterior segment; intraocular

HCPCS CODES

C1783	Ocular implant, aqueous drainage assist device
L8612	Aqueous shunt

Key References

1. Ahmed, II, Katz, L. J., et al. (2014). Prospective evaluation of microinvasive glaucoma surgery with trabecular microbypass stents and prostaglandin in open-angle glaucoma. J Cataract Refract Surg 40(8): 1295-300; PMID: 25088627.
2. Alcon. (2010) Ex-PRESS Opthalmic Glaucoma Device. Alcon. Available: http://www.alcon.com/en/alcon-products/surgical.aspx. Date Accessed: November 1, 2010.
3. American Academy of Ophthalmology Glaucoma Panel. (2010) Preferred Practice Pattern® (PPP) for Primary Open-Angle Glaucoma. September 11, 2010. American Academy of Ophthalmology..Available: http://one.aao.org/CE/PracticeGuidelines/PPP_Content.aspx?cid=93019a87-4649-4130-8f94-b6a9b19144d2#relatedLinks. Date Accessed: November 2, 2010.
4. Arriola-Villalobos, P., et al., *Glaukos iStent inject(R) Trabecular Micro-Bypass Implantation Associated with Cataract Surgery in Patients with Coexisting Cataract and Open-Angle Glaucoma or Ocular Hypertension: A Long-Term Study.* J Ophthalmol, 2016: p. 1056573.
5. Bengtsson, B., et al., Fluctuation of intraocular pressure and glaucoma progression in the early manifest glaucoma trial. Ophthalmology, 2007. 114(2): p. 205-9.

6. Buchacra, O., et al., *One-year analysis of the iStent trabecular microbypass in secondary glaucoma.* Clin Ophthalmol, 2011. **5**: p. 321-6.
7. Craven, E.R., et al., *Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: two-year follow-up.* J Cataract Refract Surg, 2012. 38(8): p. 1339-45.
8. De Feo, F, Bagnis, A, Bricola, G, et al. (2009). Efficacy and safety of a steel drainage device implanted under a scleral flap. Can J Ophthalmol 44.4: 457-62.
9. De Gregorio, A., et al., Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. Int Ophthalmol, 2017.
10. de Jong, LA. (2009). The Ex-PRESS glaucoma shunt versus trabeculectomy in open-angle glaucoma: a prospective randomized study. Adv Ther 26.3: 336-45.
11. De Moraes, C.G., et al., Rate of visual field progression in eyes with optic disc hemorrhages in the ocular hypertension treatment study. Arch Ophthalmol, 2012. 130(12): p. 1541-6.
12. Fea, A.M., *Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma: randomized double-masked clinical trial.* J Cataract Refract Surg, 2010. 36(3): p. 407-12.
13. Fea, A.M., et al., *Prospective unmasked randomized evaluation of the iStent inject ((R)) versus two ocular hypotensive agents in patients with primary open-angle glaucoma.* Clin Ophthalmol, 2014. 8: p. 875-82.
14. Ferguson, T.J., et al., *Clinical evaluation of a trabecular microbypass stent with phacoemulsification in patients with open-angle glaucoma and cataract.* Clin Ophthalmol, 2016. 10: p. 1767-1773.
15. Fernandez-Garcia, A., C. Romero, and N. Garzon, "Dry Lake" technique for the treatment of hypertrophic bleb following XEN((R)) Gel Stent placement. Arch Soc Esp Oftalmol, 2015. 90(11): p. 536-8.
16. Galal, A., et al., XEN Glaucoma Implant with Mitomycin C 1-Year Follow-Up: Result and Complications. J Ophthalmol, 2017. 2017: p. 5457246.
17. Garway-Heath, D.F., et al., The United Kingdom Glaucoma Treatment Study: a multicenter, randomized, placebo-controlled clinical trial: design and methodology. Ophthalmology, 2013. 120(1): p. 68-76.
18. Hayes, Inc. (2018, August 22). Hydrus Microstent. Retrieved from https://evidence.hayesinc.com/report/pg.hydrus
19. Hayes. *iStent Trabecular Micro-Bypass (Glaukos Corp.) in Combination with Cataract Surgery for Treatment of Open-Angle Glaucoma*. 2017 March 17, 2016 [cited 2017 September 12].
20. https://www.aao.org/eyenet/article/migs-update-code-combined-glaucoma-procedures
21. Jacobs, D.S. Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis. December 16, 2019 [cited 2020 February 27]; Available from https://www.uptodate.com/contents/open-angle-glaucoma-epidemiology-clinical-presentation-and-diagnosis?search=jacobs%20open-angle%20glaucoma&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4
22. Jacobs, D.S. Open-angle glaucoma: Treatment. February 5, 2020 [cited 27 February 2020]; Available from: https://www.uptodate.com/contents/open-angle-glaucoma-treatment?search=jacobs%20open-angle&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
23. Kanner, EM, Netland, PA, Sarkisian, SR, Jr., et al. (2009). Ex-PRESS miniature glaucoma device implanted under a scleral flap alone or combined with phacoemulsification cataract surgery. J Glaucoma 18.6: 488-91.
24. Lewis, R.A., Ab interno approach to the subconjunctival space using a collagen glaucoma stent. J Cataract Refract Surg, 2014. 40(8): p. 1301-6.
25. Maier, P.C., et al., Treatment of ocular hypertension and open angle glaucoma: meta-analysis of randomised controlled trials. BMJ, 2005. 331(7509): p. 134.
26. Malvankar-Mehta, M.S., et al., iStent as a Solo Procedure for Glaucoma Patients: A Systematic Review and Meta-Analysis. PLoS One, 2015. 10(5): p. e0128146.
27. Malvankar-Mehta, M.S., et al., iStent with Phacoemulsification versus Phacoemulsification Alone for Patients with Glaucoma and Cataract: A Meta-Analysis. PLoS One, 2015. 10(7): p. e0131770.
28. Manasses, D.T. and L. Au, The New Era of Glaucoma Micro-stent Surgery. Ophthalmol Ther, 2016. 5(2): p. 135-146.
29. Maris, PJ, Jr., Ishida, K, Netland, PA. (2007). Comparison of trabeculectomy with Ex-PRESS miniature glaucoma device implanted under scleral flap. J Glaucoma 16.1: 14-9.
30. Patel, I., T.A. de Klerk, and L. Au, *Manchester iStent study: early results from a prospective UK case series.* Clin Experiment Ophthalmol, 2013. 41(7): p. 648-52.
31. Perez-Torregrosa, V.T., et al., Combined phacoemulsification and XEN45 surgery from a temporal approach and 2 incisions. Arch Soc Esp Oftalmol, 2016. 91(9): p. 415-21.
32. Peters, D., B. Bengtsson, and A. Heijl, Lifetime risk of blindness in open-angle glaucoma. Am J Ophthalmol, 2013. 156(4): p. 724-30.
33. Pinto Ferreira, N., L. Abegao Pinto, and C. Marques-Neves, XEN Gel Stent Internal Ostium Occlusion: Ab-Interno Revision. J Glaucoma, 2017. 26(4): p. e150-e152.
34. Richter, G. M., Takusagawa, H. L., Sit., A. J., Rosdahl, J. A., Chopra, V., Ou, Y., Kim, S. J., & WuDunn, D. Trabecular Procedures Combined with Cataract Surgery for Open-Angle Glaucoma. *American Academy of Ophthalmology*. 2024; 131:370-382.
35. Rivier, D, Roy, S, Mermoud, A. (2007). Ex-PRESS R-50 miniature glaucoma implant insertion under the conjunctiva combined with cataract extraction. J Cataract Refract Surg 33.11: 1946-52.
36. Sarkisian SR, et al. Effectiveness and Safety.
37. Schlenker, M.B., et al., Efficacy, Safety, and Risk Factors for Failure of Standalone Ab Interno Gelatin Microstent Implantation versus Standalone Trabeculectomy. Ophthalmology, 2017.
38. Sheybani, A., H. Reitsamer, and Ahmed, II, Fluid Dynamics of a Novel Micro-Fistula Implant for the Surgical Treatment of Glaucoma. Invest Ophthalmol Vis Sci, 2015. 56(8): p. 4789-95.
39. Spiegel, D., et al., *Coexistent primary open-angle glaucoma and cataract: interim analysis of a trabecular micro-bypass stent and concurrent cataract surgery.* Eur J Ophthalmol, 2009. 19(3): p. 393-9.
40. Stein, J.D., et al., Cost-effectiveness of medications compared with laser trabeculoplasty in patients with newly diagnosed open-angle glaucoma. Arch Ophthalmol, 2012. 130(4): p. 497-505.
41. Stein, JD, Herndon, LW, Brent Bond, J, et al. (2007). Exposure of Ex-PRESS Miniature Glaucoma Devices: case series and technique for tube shunt removal. J Glaucoma 16.8: 704-6.

42. Tan, S.Z. and L. Au, *Manchester iStent study: 3-year results and cost analysis.* Eye (Lond), 2016. 30(10): p. 1365-1370.
43. Vandewalle, E., T. Zeyen, and I. Stalmans, *The iStent trabecular micro-bypass stent: a case series.* Bull Soc Belge Ophtalmol, 2009(311): p. 23-9.
44. Vinod, K. and S.J. Gedde, Clinical investigation of new glaucoma procedures. Curr Opin Ophthalmol, 2017. 28(2): p. 187-193.
45. Vold S, Ahmed, II, Craven ER, et al. Two-year COMPASS trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. Ophthalmology. Oct 2016;123(10):2103-2112. PMID 27506486
46. Voskanyan, L., et al., *Prospective, unmasked evaluation of the iStent(R) inject system for open-angle glaucoma: synergy trial.* Adv Ther, 2014. 31(2): p. 189-201.
47. Wellik, S.R. and E.A. Dale, *A review of the iStent((R)) trabecular micro-bypass stent: safety and efficacy.* Clin Ophthalmol, 2015. 9: p. 677-84.

Revision History

Revision Date	Summary of Changes
7/11/23	For Commercial Plan Policy, added coverage criteria for iStent infinite device.
9/19/24	For Commercial Plan Policy, simplified requirement in criterion #C-3 as follows: “Patient is currently using at least one eyedrop for control.”

Select Health

MEDICAL POLICY

INTRASTROMAL CORNEAL RING IMPLANTATION (INTACS PROCEDURE)

Policy # 282
Implementation Date: 9/30/05
Review Dates: 10/16/06, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/3/19, 9/30/20, 10/26/21, 9/15/22, 10/3/23, 9/29/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Intrastromal corneal ring segments (ICRS) are small semicircular segments of a material called PMMA (polymethylmethacrylate), which is implanted in the cornea for the treatment of mild myopia and keratoconus. The only currently FDA approved devices are manufactured by Addition Technology Inc. (ATI), under the trade name INTACS. These devices have the advantage of removability or exchangeability for different sized segments, and for maintaining a more natural corneal shape than is provided by LASIK.

The procedure involves the placement of two plastic segments within the periphery of the cornea (the stroma). These segments flatten the central cornea without removing tissue to better focus light. The segments are made of the same material that has been implanted in human eyes after cataract surgery for nearly 50 years.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers intrastromal corneal ring segment (INTACS) implantation for keratoconus in *limited circumstances* as outlined in the FDA Human Device Exemption (HDE) approval.

All the following conditions must be met to qualify for coverage of INTACS in patients with keratoconus:

1. The patient is at least 21 years of age; and
2. Have progressive deterioration of vision; and
3. Can no longer achieve adequate functional vision on a daily basis with their contact lenses or eyeglasses; and
4. Have clear central corneas; and
5. Have corneal thickness of 450 microns or greater at the proposed incision site; and
6. Corneal transplantation is the only option other than INTACS to improve vision.

Select Health does NOT cover intrastromal corneal ring segment implantation for myopia or any other indication. Use of ICRS implantation in these circumstances is excluded from coverage and meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Intrastromal corneal ring segment transplantation for any indication lacks well-controlled, multicenter trials, comparing the effectiveness, safety, and durability of this treatment compared to current standard therapies. Additionally, most of the noncontrolled trials are of European or South American origin creating potential bias involving regional variations to the performance of eye surgery in general, which may impact the outcomes.

Lack of randomized, placebo/sham-controlled trials of adequate size and duration leave conclusions about the efficacy of the ICRS transplantation open to question due to selection bias and random error. A lack of long-term follow-up studies limits any conclusions about the durability of ICRS inserts. Only when these issues are adequately addressed can determination of effectiveness in routine practice settings be addressed, where it is likely that outcomes will be less successful than trial settings.

Colin et al., Miranda et al., and Sigano have all demonstrated sustained outcomes up to ~12 months in small groups of patients with keratoconus. Alios et al. and Hellstedt et al., in more recent articles from 2005, have also demonstrated similar efficacy and safety out to one year. The cumulative effect of these small independent studies is to validate that the inserts are likely effective and safe at least out to one year.

No studies revealed significant safety concerns, though, several cases of nonserious infectious complications have been reported.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved INTACS under the Human Device Exemption (HDE) on July 23, 2004 (H040002).

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

65785 Implantation of intrastromal corneal ring segments

HCPCS CODES

No specific codes identified

Key References

1. Alió, J.L., Artola, A., Ruiz-Moreno, J.M., Hassanein, A., Galal, A., & Awadalla, M.A. Changes in keratoconic corneas after intracorneal ring segment explantation and reimplantation. Ophthalmology. 2004 Apr; Vol. 111 (4), pp. 747−51.
2. Boxer Wachler BS, Christie JP, et al. INTACS for keratoconus. Ophthalmology. 2003; 110(5):1031−1040.
3. Colin J, Cochener B, Savary G, Malet F. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg. 2000;26(8): 1117−1122.
4. Colin J; Cochener B; Savary G; Malet F; Holmes-Higgin D. INTACS inserts for treating keratoconus: one-year results. Ophthalmology. 2001 Aug; Vol. 108 (8), pp. 1409−14.

Select Health

5. Food and Drug Administration. HDE approval for INTACS® prescription inserts for keratoconus. 2004 July 23. Available: http://www.accessdata.fda.gov/cdrh_docs/pdf4/h040002a.pdf
6. Güell JL Are intracorneal rings still useful in refractive surgery? Current Opinion in Ophthalmology. 2005 Aug; Vol. 16(4), pp. 260−5.
7. Hayes Technology Brief: Intacs™ (Addition Technology Inc.) for Keratoconus. Lansdale, PA: Winifred S. Hayes, Inc, 2005.
8. Miranda D; Sartori M; Francesconi C; Allemann N; Ferrara P; Campos M. Ferrara intrastromal corneal ring segments for severe keratoconus. Journal of Refractive Surgery. 2003 Nov−Dec; Vol. 19 (6), pp. 645−53.
9. Rapuano CJ, Sugar A, et al. Intrastromal corneal ring segments for low myopia: a report by the American Academy of Ophthalmology. Ophthalmology. 2001;108: (10):1922−1928.
10. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with INTACS. Am J Ophthalmol. 2003;135(1):64-70.
11. Siganos D; Ferrara P; Chatzinikolas K; Bessis N; Papastergiou G Ferrara intrastromal corneal rings for the correction of keratoconus. Journal of Cataract and Refractive Surgery. 2002, Nov; Vol. 28 (11), pp. 1947−51.

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MEDICAL POLICY

OZURDEX IMPLANT

Policy # 435

Implementation Date: 2/9/10

Review Dates: 8/16/11, 8/16/12, 8/20/15, 8/25/16, 8/17/17, 7/18/18, 6/8/19, 6/9/20, 5/30/21, 5/8/22, 5/30/23, 6/4/24, 6/1/25

Revision Dates: 5/19/11, 9/16/13, 8/15/14, 6/4/21, 6/17/22

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

There are many reasons patients develop visual impairment; some are treatable, and some are not. For the treatable causes of visual impairment such as branch retinal vein occlusions (BRVO) and central retinal vein occlusion (CRVO), macular edema is the most common cause of vision loss. For uveitis inflammation in the uvea, retina and surrounding blood vessels also result in macular edema which reduces visual acuity, and if progressive, can lead to permanent vision loss of vessels.

Therapies used to treat these varied conditions are aimed at reducing macular edema and associated tissues destruction. Treatment options for RVO include laser photocoagulation and medical therapy with either vascular endothelial growth factor (VEGF) inhibitors or intravitreal glucocorticoids. Laser therapy is also usually initiated in patients with CRVO and neovascularization. Medical therapy is first-line treatment for CRVO patients with macular edema and is an alternative to laser therapy in patients with BRVO or in those who respond sub-optimally to laser therapy. Duration of treatment for BRVO and CRVO varies based on the treatment modality and response to treatment but can last several weeks to months. The main goals of treatment include improvement or stabilization of visual acuity. Depending upon the degree of ischemia or presence of macular edema, there may be need for retinal laser to prevent further vision loss or intravitreal injections of anti-VEGF agents or corticosteroids to recover vision.

For uveitis, the standard therapy is typically intraocular injections with corticosteroids such as triamcinolone, systemic steroids, or other immunosuppressors or intraocular injections of VEGF inhibitors.

The Ozurdex implant is FDA approved for the treatment of BRCO/CRVO, treatment of non-infectious uveitis affecting the posterior segment of the eye, and treatment of diabetic macular edema in patients who are pseudophakic or who are phakic and scheduled for cataract surgery. It delivers 0.7 mg of dexamethasone via a specifically designed single-use plastic applicator into the intraocular space. Following ophthalmic administration (Ozurdex), dexamethasone is absorbed through the aqueous humor and distributed into the local tissues, with only minimal systemic absorption occurring. Ophthalmic doses are metabolized locally. Dexamethasone intravitreal implant (Ozurdex) was approved for macular edema due to branch or central retinal vein occlusion in June 2009 and for non-infectious posterior uveitis in September 2010.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers Ozurdex dexamethasone intraocular implant for its FDA approved indications as a proven therapy when specific prior authorization criteria are met.

Coverage criteria: (must meet **ALL** the following)

1. Patient has one of the following conditions;
    a. Chronic non-infectious uveitis affecting the posterior segment of the eye
    b. Macular edema following branch retinal vein occlusion (BRVO)
    c. Macular edema following central retinal vein occlusion (CRVO)
    d. Diabetic macular edema
2. If the patient has non-infectious posterior uveitis, there must be documented evidence for lack of response or intolerance to recently administered intraocular steroids
3. Patient does not have any of the following contraindications
    a. Ocular or periocular infections, including herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases
    b. Advanced glaucoma
    c. Aphakic eyes with rupture of the posterior lens capsule
    d. Anterior chamber intraocular lens (ACIL) and rupture of the posterior lens capsule
    e. Hypersensitivity to prednisone

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

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Summary of Medical Information

An updated technology assessment of Ozurdex was completed in July 2013. No systematic reviews and fifteen primary studies were identified which met inclusion criteria for this review. The majority (82%) of the studies examined Ozurdex for the treatment of retinal vein occlusion and three (18%) studied the use of Ozurdex for the treatment of uveitis. More than 3,977 patients and 3,985 eyes were treated, though, some of these were part of the control group consisting of a sham treatment (articles dated from 2010 to 2013, 41% of which were published in 2013).

Of note, none of the studies included in this report compared dexamethasone implant therapy to other available intraocular corticosteroid injections. Several looked at the relative effectiveness of Ozurdex to the anti-VEGF therapies bevacizumab and ranibizumab. Most studies were compared to observation or sham therapy. This limits any conclusions that can be drawn as to the superior efficacy or safety of this therapy as is relates to other corticosteroids.

Only one study by Arcinue et al. compared Ozurdex to another medical therapy in a head-to-head analysis. In this trial, Ozurdex outperformed the comparator (Retisert) in every endpoint, except for the durability of a second implant.

Additionally, methodological weaknesses identified in the studies, besides the lack of an appropriate active comparator, are the small size and lack of randomization of many of the studies. Study sizes ranged from nine eyes to 1,267 eyes studied, but this is deceiving, in that except for the manufacturer registry trials no study was larger than thirty-four eyes being studied and none of these studies used randomization. This allows for investigator selection bias to impact the observed outcomes. Even the actual number of eyes studies in the registry trials is much smaller than the trial summaries might indicate as for the two registry trials published by Haller et al. related to RVO, though, the actual number of patients studied was 1,267 and 1,256, respectively, the number of eyes treated with the FDA approved dosage of 0.7 mg was only 427 and 421, respectively. As noted earlier, these studies had no active comparator. The uveitis studies only had seventy-seven and forty-one eyes treated, again, with no active comparator used in these studies.

In June 2014, the US Food and Drug Administration (FDA) has approved the Ozurdex 0.7 mg dexamethasone intravitreal implant as a treatment option for pseudophakic and phakic diabetic macular edema (DME) patients. The Ozurdex indication makes it the first corticosteroid approved for use in certain DME patients. The FDA approved Ozurdex for these patient groups based on the results of the Macular Edema: Assessment of Implantable Dexamethasone in Diabetes (MEAD) study. MEAD includes 2 multicenter 3-year sham-controlled, masked, randomized clinical studies assessing the proportion of patients with 15 or more letters of improvement in best-corrected visual acuity (BCVA) from baseline. The most common adverse events in the study included cataracts and elevated intraocular pressure (IOP). An increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles.

An update of the published literature identified several new studies available since the last review. One study by Ramu et al et al. in 2015 was a randomized prospective multicenter study of 100 patients. It suggested a schedule of Ozurdex injections every 5 months was not inferior to PRN Ozurdex guided by levels of macular edema. Potentially, this could lead to cost savings as patients who had no macular edema would not require an injection solely due to a rigid treatment protocol. Another randomized multi-center 3-year study of Ozurdex vs. placebo in diabetic macular edema by Maturi et al. in 2016, demonstrated visual improvement despite higher risk of elevated intraocular pressure. The study was limited in not comparing Ozurdex to the current standard care of diabetic macular edema, e.g., intravitreal anti-VEGF injection. One retrospective study by Zheng, et al. in 2016 of n=15 eyes of 14 patients reported 5 out of 9 patients with baseline edema demonstrated improvement with low risk of developing increased eye pressure at 3 months. The study was limited by selection bias (likely that patients who had steroid response to topical/injected steroids were excluded). Although the study was limited to 3 months of follow-up, the duration of effect of Ozurdex is thought to be 1−3 months.

Two studies published in 2017 also assessed efficacy and safety of Ozurdex. Calyo et al., in a single-armed clinical trial, evaluated efficacy of Ozurdex in reduction of macular edema in diabetic patients in the setting of cataract surgery (Calvo et al). The study suggested efficacy, although the study has significant limitations, namely the lack of a control arm vs. the standard of care topical therapy of prednisolone QID and ketorolac QID. Additionally, the study failed to address cost-efficacy issues. The other study by Banerjee et al. was a 2-year single-center randomized study of 138 patients suggesting that Ozurdex did not improve anatomic success (as defined by foveal thickness) in eyes with proliferative diabetic retinopathy undergoing retinal detachment repair with silicone oil.

Billing/Coding Information

CPT CODES

67027 Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous

67028 Intravitreal injection of a pharmacologic agent (separate procedure)

HCPCS CODES

J7312 Injection, dexamethasone (Ozurdex), intravitreal implant, 0.1mg

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Key References

1. Adan, A, Pelegrin, L, Rey, A, et al. (2013). Dexamethasone Intravitreal Implant for Treatment of Uveitic Persistent Cystoid Macular Edema in Vitrectomized Patients. Retina.
2. American Academy of Ophthalmology. (2012) Uveitis and Catatact Surgery American Academy of Ophthalmology. Available: http://one.aao.org/ce/practiceguidelines/guidelines_content.aspx?cid=b60c2137-995a-4652-98c2-fb69eafc29c3#section4. Date Accessed: April 10, 2013.
3. Arcinue, CA, Ceron, OM, Foster, CS. (2013). A Comparison Between the Fluocinolone Acetonide (Retisert) and Dexamethasone (Ozurdex) Intravitreal Implants in Uveitis. J Ocul Pharmacol Ther.
4. Argon laser photocoagulation for macular edema in branch vein occlusion. The Branch Vein Occlusion Study Group. Am J Ophthalmol (1984). 98.3: 271-82.
5. Banerjee PJ, Quartilho A, Bunce C, Xing W, Zvobgo TM, Harris N, Charteris DG. Slow-Release Dexamethasone in Proliferative Vitreoretinopathy: A Prospective, Randomized Controlled Clinical Trial. Ophthalmology. 2017 Jun;124(6):757-767. doi: 10.1016/j.ophtha.2017.01.021. Epub 2017 Feb 23.
6. Bastakis, G.G., Dimopoulos, D., Stavrakakis, A., & Pappas, G. (2019). Long-term efficacy and duration of action of dexamethasone implant, in vitrectomised and non-vitrectomised eyes with persistent diabetic macular oedema. Eye (Lond), 33(3):411-418. doi: 10.1038/s41433-018-0219-8
7. Berker, N, Batman, C. (2008). Surgical treatment of central retinal vein occlusion. Acta Ophthalmol 86.3: 245-52.
8. Calvo P, Ferreras A, Al Adel F, Dangboon W, Brent MH. Effect of an Intravitreal Dexamethasone Implant on Diabetic Macular Edema After Cataract Surgery. Retina. 2017 Feb 10. doi: 10.1097/IAE.0000000000001552.
9. Chen, HC, Wiek, J, Gupta, A, et al. (1998). Effect of isovolaemic haemodilution on visual outcome in branch retinal vein occlusion. Br J Ophthalmol 82.2: 162-7.
10. Chung, EJ, Lee, H, Koh, HJ. (2008). Arteriovenous crossing sheathotomy versus intravitreal triamcinolone acetonide injection for treatment of macular edema associated with branch retinal vein occlusion. Graefes Arch Clin Exp Ophthalmol 246.7: 967-74.
11. Coscas, G, Coscas, F, Zucchiatti, I, et al. (2011). SD-OCT pattern of retinal venous occlusion with cystoid macular edema treated with Ozurdex(R). Eur J Ophthalmol 21.5: 631-6.
12. Covert, DJ. (2013) Retinal vein occlusion: Epidemiology, clinical manifestations, and diagnosis. January 9, 2013. Up to Date. Available: http://www.uptodate.com/contents/retinal-vein-occlusion-epidemiology-clinical-manifestations-and-diagnosis?source=search_result&search=branch+retinal+vein+occlusion&selectedTitle=1~8#H7614470. Date Accessed: April 9, 2013.
13. Covert, DJ. (2013) Retinal vein occlusion: Treatment. January 24, 2013. Up to Date. Available: http://www.uptodate.com/contents/retinal-vein-occlusion-treatment?source=search_result&search=branch+retinal+vein+occlusion&selectedTitle=2~8. Date Accessed: April 16, 2013.
14. European Medicines Agency. (2013) Ozurdex. September 18, 2012. European Medicines Agency. Available: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001140/human_med_001367.jsp&mid=WC0b01ac058001d124. Date Accessed: April 16, 2013.
15. Eylea. (2013) Eyelea (aflibercept) Injection. March 2013. Eylea. Available: http://www.eylea.us/?WHGRedir=1. Date Accessed: April 23, 2013.
16. Feist, RM, Ticho, BH, Shapiro, MJ, et al. (1992). Branch retinal vein occlusion and quadratic variation in arteriovenous crossings. Am J Ophthalmol 113.6: 664-8.
17. Fluocinolone acetonide ophthalmic--Bausch & Lomb: fluocinolone acetonide Envision TD implant. Drugs R D. (2005). 6.2:116-9.
18. Food and Drug Administration. (2012) NDA US Department of Health and Human Services Available: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022315s007lbl.pdf. Date Accessed: April 10 2013.
19. Gewaily, D, Greenberg, PB. (2009). Intravitreal steroids versus observation for macular edema secondary to central retinal vein occlusion. Cochrane Database Syst Rev.1: CD007324.
20. Green, WR, Chan, CC, Hutchins, GM, et al. (1981). Central retinal vein occlusion: a prospective histopathologic study of 29 eyes in 28 cases. Retina 1.1: 27-55.
21. Gold Standard. (2013) Dexamethasone. Gold Standard. Available: https://www.clinicalkey.com/#!/ContentPlayerCtrl/doPlayContent/6-s2.0-174/{"scope":"all","query":"ozurdex"}. Date Accessed: April 16, 2013.
22. Haller, JA, Bandello, F, Belfort, R, Jr., et al. (2010). Randomized, sham-controlled trial of dexamethasone intravitreal implant in patients with macular edema due to retinal vein occlusion. Ophthalmology 117.6: 1134-1146 e3.
23. Haller, JA, Bandello, F, Belfort, R, Jr., et al. (2011). Dexamethasone intravitreal implant in patients with macular edema related to branch or central retinal vein occlusion twelve-month study results. Ophthalmology 118.12: 2453-60.
24. Han, DP, Heuer, DK. (2012). Intravitreal corticosteroid therapy: putting the problem of glaucoma in perspective. Arch Ophthalmol 130.3: 380-2.
25. Hayreh, SS, Zimmerman, MB, Podhajsky, P. (1994). Incidence of various types of retinal vein occlusion and their recurrence and demographic characteristics. Am J Ophthalmol 117.4: 429-41.
26. Hayreh, SS, Podhajsky, PA, Zimmerman, MB. (2011). Natural history of visual outcome in central retinal vein occlusion. Ophthalmology 118.1: 119-133 e1-2.
27. Hayward, E. (2011). PSS25 the Cost-Effectiveness of Ozurdex® (Dexamethasone Intravitreal Implant in Applicator) Compared With Observation for the Treatment of Macular Oedema Following Central and Branch Retinal Vein Occlusion. International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 14.7: A506-A506.
28. He, Y., Ren, X., Hu, B., Lam, W., & Li, X. (2018). A meta-analysis of the effect of a dexamethasone intravitreal implant versus intravitreal anti-vascular endothelial growth factor treatment for diabetic macular edema. *BMC Ophthalmology, 18*(1). doi: 10.1186/s12886-018-0779-1
29. Infirmary, NEE. (2013) Branch Retinal Vein Occlusion. NY Eye & Ear Infirmary. Available: http://www.nyee.edu/faqlist.html?key=4=faq. Date Accessed: April 9, 2013.
30. Jabs, DA, Nussenblatt, RB, Rosenbaum, JT, et al. (2005). Standardization of uveitis nomenclature for reporting clinical data. Results of the First International Workshop. Am J Ophthalmol 140.3: 509-16.

Select Health

31. Kanski, JJ. (2011) Clinical Ophthalmology: A Systematic Approach. Elsevier. Available: https://www.clinicalkey.com/#!/ContentPlayerCtrl/doPlayContent/3-s2.0-B9780702040931000112/{"scope":"all","query":"uveitis"}. Date Accessed: April 11, 2013.
32. Klein, R, Klein, BE, Moss, SE, et al. (2000). The epidemiology of retinal vein occlusion: the Beaver Dam Eye Study. Trans Am Ophthalmol Soc 98: 133-41; discussion 141-3.
33. Klein, R, Moss, SE, Meuer, SM, et al. (2008). The 15-year cumulative incidence of retinal vein occlusion: the Beaver Dam Eye Study. Arch Ophthalmol 126.4: 513-8.
34. Lowder, C, Belfort, R, Jr., Lightman, S, et al. (2011). Dexamethasone intravitreal implant for noninfectious intermediate or posterior uveitis. Arch Ophthalmol 129.5: 545-53.
35. Maturi RK, Pollack A, Uy HS, Varano M, Gomes AM, Li XY, Cui H, Lou J, Hashad Y, Whitcup SM; Ozurdex MEAD Study Group. Intraocular Pressure in Patients with Diabetic Macular Edema Treated with Dexamethasone Intravitreal Implant in the 3-Year MEAD Study. Retina. 2016 Jun;36(6):1143-52. doi: 10.1097/IAE.0000000000001004.
36. Mayer, WJ, Remy, M, Wolf, A, et al. (2012). Comparison of intravitreal bevacizumab upload followed by a dexamethasone implant versus dexamethasone implant monotherapy for retinal vein occlusion with macular edema. Ophthalmologica 228.2: 110-6.
37. Merkoudis, N, Granstam, E. (2013). Treatment of macular edema associated with retinal vein occlusion using sustained-release dexamethasone implants in a clinical setting. Eur J Ophthalmol: 0.
38. Meyer, LM, Schonfeld, CL. (2013). Secondary Glaucoma After Intravitreal Dexamethasone 0.7 mg Implant in Patients with Retinal Vein Occlusion: A One-Year Follow-Up. J Ocul Pharmacol Ther.
39. Mitchell, P, Smith, W, Chang, A. (1996). Prevalence and associations of retinal vein occlusion in Australia. The Blue Mountains Eye Study. Arch Ophthalmol 114.10: 1243-7.
40. Moisseiev, E, Goldstein, M, Waisbourd, M, et al. (2013). Long-term evaluation of patients treated with dexamethasone intravitreal implant for macular edema due to retinal vein occlusion. Eye (Lond) 27.1: 65-71.
41. Natural history and clinical management of central retinal vein occlusion. The Central Vein Occlusion Study Group. Arch Ophthalmol (1997).115.4: 486-91.
42. Querques, L, Querques, G, Lattanzio, R, et al. (2013). Repeated intravitreal dexamethasone implant (Ozurdex(R)) for retinal vein occlusion. Ophthalmologica 229.1: 21-5.
43. Rajesh, B., Zarranz-Ventura, J., Fung A.T., Busch C., Sahoo, N.K., Rodriguez-Valdes, P.J., Sarao V, Mishra, S.K., … Chhablani, J. International Ozurdex Study Group. (2019). Safety of 6000 intravitreal dexamethasone implants. *Br J Ophthalmol*. doi: 10.1136/bjophthalmol-2019-313991
44. Ramu J, Yang Y, Menon G, Bailey C, Narendran N, Bunce C, Quartilho A, Prevost AT, Hykin P, Sivaprasad S; OZDRY Study Group. A Randomized Clinical Trial Comparing Fixed vs Pro-re-nata Dosing of Ozurdex in Refractory Diabetic Macular Oedema (OZDRY study). Eye (Lond). 2015 Dec;29(12):1603-12. doi: 10.1038/eye.2015.214. Epub 2015 Oct 23.
45. Risk factors for branch retinal vein occlusion. The Eye Disease Case-control Study Group. Am J Ophthalmol. (1993).116.3: 286-96.
46. Rogers, S, McIntosh, RL, Cheung, N, et al. (2010). The prevalence of retinal vein occlusion: pooled data from population studies from the United States, Europe, Asia, and Australia. Ophthalmology 117.2: 313-9 e1.
47. Rosenbaum, JT. (2013) Uveitis: Treatment. December 5. Up to Date. Available: http://www.uptodate.com/contents/uveitis-treatment?source=search_result&search=uveitis+treatment&selectedTitle=1~150#H4. Date Accessed: April 16, 2013.
48. RxList. (2013). Lucentis. February 26, 2013. RxList. Available: http://www.rxlist.com/lucentis-drug/indications-dosage.htm. Date Accessed: April 23, 2013.
49. Ryan, SJ. (2013) Brach Vein Occulsion. Elsevier. Available: https://www.clinicalkey.com/#!/ContentPlayerCtrl/doPlayContent/3-s2.0-B9781455707379000539/{"scope":"all","query":"brvo"}. Date Accessed: April 11, 2013.
50. Scott, IU, Ip, MS, VanVeldhuisen, PC, et al. (2009). A randomized trial comparing the efficacy and safety of intravitreal triamcinolone with standard care to treat vision loss associated with macular Edema secondary to branch retinal vein occlusion: the Standard Care vs Corticosteroid for Retinal Vein Occlusion (SCORE) study report 6. Arch Ophthalmol 127.9: 1115-28.
51. Singer, MA, Bell, DJ, Woods, P, et al. (2012). Effect of combination therapy with bevacizumab and dexamethasone intravitreal implant in patients with retinal vein occlusion. Retina 32.7: 1289-94.
52. Specialists, A. S. o. R. (2014). "Allergan Gains FDA Approval for Ozurdex Use in Certain DME Patients." Retrieved September 15, 2014, from http://www.asrs.org/education/clinical-updates/298/allergan-gains-fda-approval-for-ozurdex-use-in-certain-dme-patients.
53. Squizzato A, ME, Bozzato S, Dentali F, Ageno W. (2010). Antithrombotic and fibrinolytic drugs for retinal vein occlusion: a systematic review and a call for action. Thromb Haemost. 2010;103(2):271.
54. Williams, GA, Haller, JA, Kuppermann, BD, et al. (2009). Dexamethasone posterior-segment drug delivery system in the treatment of macular edema resulting from uveitis or Irvine-Gass syndrome. Am J Ophthalmol 147.6: 1048-54, 1054 e1-2.
55. Yeh, WS, Haller, JA, Lanzetta, P, et al. (2012). Effect of the duration of macular edema on clinical outcomes in retinal vein occlusion treated with dexamethasone intravitreal implant. Ophthalmology 119.6: 1190-8.
56. Zhao, J, Sastry, SM, Sperduto, RD, et al. (1993). Arteriovenous crossing patterns in branch retinal vein occlusion. The Eye Disease Case-Control Study Group. Ophthalmology 100.3: 423-8.
57. Zheng A, Chin EK, Almeida DR, Tsang SH, Mahajan VB. Combined Vitrectomy and Intravitreal Dexamethasone (Ozurdex) Sustained-Release Implant. Retina. 2016 Nov;36(11):2087-2092.

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MEDICAL POLICY

TELESCOPIC IMPLANTS FOR MANAGEMENT OF VISUAL IMPAIRMENT ASSOCIATED WITH MACULAR DEGENERATION

Policy # 489

Implementation Date: 9/6/11
Review Dates: 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 11/30/18, 12/12/19, 12/6/20, 10/26/21, 1/13/23, 12/21/23, 12/1/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Macular degeneration is a disease associated with aging that gradually destroys sharp, central vision. Central vision is needed for seeing objects clearly and for common daily tasks such as reading and driving. Macular degeneration can be divided into two general classifications of disease: dry macular degeneration and wet macular degeneration. Dry macular degeneration may affect one eye or both eyes. If only one eye is affected, the patient may not notice any or much change in their vision because their good eye compensates for the weak one.

The Implantable Miniature Telescope (IMT) (Vision Care Ophthalmic Technologies, Ltd., Saratoga, CA), along with the cornea, enlarges images in front of the eye approximately 2.2X (times) or 2.7X their normal size (depending on the model used). The magnification allows central images to be projected onto healthy perimacular areas of the retina instead of the macula alone, where breakdown of photoreceptors and loss of vision has occurred. This helps reduce the blind spot and allows the patient to distinguish and discern images that may have been unrecognizable or difficult to see.

This device is typically implanted into only one eye, allowing maintenance of peripheral vision in the other eye. The telescope prosthesis is available in nominal magnifications of 2.2X and 3X, containing two micro lenses (front positive lens and back negative lens) in an air-filled glass tube (4 mm in length) that, with the optics of the cornea, constitutes a magnifying system to enlarge retinal images of the central visual field. The prosthesis magnification improves distance, or near visual acuity, in conjunction with standard spectacle correction for ametropia, presbyopia, or further external magnification.

Implantation of the prosthesis is performed under local anesthesia during a procedure that takes approximately 45 minutes. The natural lens of the eye is removed through a small incision at the limbus (the area where the cornea meets the sclera) and the new lens system is inserted. The artificial lens systems can consist of miniature telescope prosthesis, or a combination of lenses implanted either in the capsular bag of the native lens, or one in front of and one behind the iris. Viscoelastic fluid is used during the implantation process to facilitate the insertion and is then removed by irrigation or aspiration. The eye then processes images according to which lens system is used. If a single lens is used, images in the treated eye are enlarged by the implanted lens system and focused on the macula, while the other eye is used for peripheral vision. If a system of two separate lenses is used, the lenses are rotationally aligned to deflect a magnified image away from the most damaged part of the macular and towards a less damaged area. After the implantation procedure, patients are usually required to undergo a period of visual rehabilitation.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover telescopic lens implants for the treatment of visual impairment associated with macular degeneration or any other condition, as the coverage of visual aids is specifically excluded in the Select Health Certificate of Coverage.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Two systematic reviews were identified concerning the Implantable Miniature Telescope (IMT) and compared IMT to a variety of external visual aids, including high magnification lenses and external telescopes. These reviews support implantable telescopic lenses as able to improve vision but did not note any improvement in visual function over external magnifying devices outside of quality-of-life issues.

This was echoed by the National Institutes for Clinical Excellence (NICE) in their review, completed in 2008. This review concluded that there is currently insufficient long-term evidence on both efficacy and safety. NICE concluded that IMT is efficacious in that near and distance visual acuity, reading speed, and improved ability to navigate surroundings improves with the therapy. As for safety, one reviewer noted that in addition to the potential risk of corneal decomposition and corneal and macular edema, this particular procedure has more risks than standard cataract surgery.

Four primary literature articles were found concerning telescopic implants for MD. Two similar endpoints were of interest in the majority of the published literature, uncorrected visual acuity and line improvement (the ability to read finer lines during an ophthalmologic exam). Alio et al. (2004) implanted IMT in 40 eyes, and these patients were followed for 12 months. Mean preoperative uncorrected distance visual acuity improved from 20/160 to 20/80 and from 20/125 to 20/50 for near visual acuity. A study of 217 patients found that at one year, 67% of implanted eyes achieved a 3-line (or more) improvement in the eye-chart test for uncorrected distance visual acuity vs. 13% of fellow eye controls. Line improvements were shown in two additional papers, illustrating the IMTs ability to improve both distance and near visual acuity.

Endothelial cell density (ECD) depletion, device explantation, and inflammatory deposits were noted having complications with either the device or procedure. Net loss of ECD increased from three months to two years.

Current evidence suggests a benefit of IMT for patients with age-related macular degeneration. However, there is a significant lack of long-term data concerning corneal erosion, device explantation, edema, and endothelial cell loss as noted in all the literature located for this review. Additionally, no studies have identified improved health outcomes over current standard therapies with the use of these devices.

A 2017 literature review found one study (Grzybowski et al., 2017) reviewed seven types of intraocular lenses, including the IMT. The article recommends that more independent clinical study is needed. Therefore, current studies have insufficient high-quality evidence demonstrating long-term efficacy and safety.

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Billing/Coding Information

CPT CODES

0308T Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis

HCPCS CODES

C1840 Lens, intraocular (telescopic)

Key References

1. Alio, JL, Mulet, EM, Jose, M, et al. (2004). Intraocular telescopic lens evaluation in patients with age-related macular degeneration. J Cataract Refract Surg 30.6: 1177-89.
2. American Academy of Ophthalmology. (2010) Statement from the American Academy of Ophthalmology regarding FDA-Approved Implantable Miniature Telescope for End-Stage Age-Related Macular Degeneration Patients Last Update: July 8, 2010. American Academy of Opthalmology (AAO). Available: http://www.aao.org/newsroom/release/20100708.cfm. Date Accessed: August 1, 2011.
3. Arroyo, JG. (2011) Age-related macular degeneration: Treatment and prevention. Last Update: June 3, 2011. UpToDate. Available: http://www.uptodate.com/contents/age-related-macular-degeneration-treatment-and-prevention?source=search_result&selectedTitle=1~68. Date Accessed: July 13, 2011.
4. Australia and New Zealand Horizon Scanning Network (AZHSN). (2007) Implantable miniature telescope for macular degeneration. August.
5. Boyer, D., K. B. Freund, C. Regillo, M. H. Levy and S. Garg (2015). "Long-term (60-month) results for the implantable miniature telescope: efficacy and safety outcomes stratified by age in patients with end-stage age-related macular degeneration." Clin Ophthalmol 9: 1099-1107.
6. CentraSight. (2011) Are you a candidate? Last Update: 2011. CentraSight. Available: http://www.centrasight.com/centrasight_candidate. Date Accessed: July 13, 2011.
7. Examiner. (2010) Telescopic implants reverse blindness in macular degeneration patients. Last Update: 2011. examiner.com. Available: http://www.examiner.com/medical-technology-in-pittsburgh/telescopic-implants-reverse-blindness-macular-degeneration-patients. Date Accessed: July 13, 2011.
8. Eyes Ears Care. (2011) Reading Glasses for Macular Degeneration. Last Update: 2011. Eyes Ears Care. Available: http://eyesearscare.info/Reading-Glasses-Macular-Degeneration/. Date Accessed: August 2, 2011.
9. Food and Drug Administration (FDA). (2008) VisionCare Ophthalmic Technologies Implantable Miniature Telescope. Last Update: Septemeber 2, 1998. US Department of Health & Human Services. Available: http://www.fda.gov/ohrms/dockets/ac/09/briefing/2009-4423b1-10-%20P050034%20Amendment%20013-014%20-%20Volume%20II%20of%20IV.pdf. Date Accessed: July 15, 2011.
10. Food and Drug Administration (FDA). (2010) PMA - Premarket Approval: IMPLANTABLE MINIATURE TELESCOPE (IMT) Last Update: March 31, 2011 (Supplement 5). US Department of Health & Human Services. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=10572. Date Accessed: August 2, 2011.
11. Gohel, PS, Mandava, N, Olson, JL, et al. (2008). Age-related macular degeneration: an update on treatment. Am J Med 121.4: 279-81.
12. Grzybowski, A., W. Wasinska-Borowiec, J. L. Alio, P. Amat-Peral and J. Tabernero (2017). "Intraocular lenses in age-related macular degeneration." Graefes Arch Clin Exp Ophthalmol.
13. Hitt, E. (2010) Bevacizumab and Ranibizumab Both Safe for Age-Related Macular Degeneration. Last Update: October 12, 2008. Medscape. Available: http://www.medscape.com/viewarticle/730279. Date Accessed: July 28, 2011.
14. Hudson, HL, Lane, SS, Heier, JS, et al. (2006). Implantable miniature telescope for the treatment of visual acuity loss resulting from end-stage age-related macular degeneration: 1-year results. Ophthalmology 113.11: 1987-2001.
15. Hudson, HL, Stulting, RD, Heier, JS, et al. (2008). Implantable telescope for end-stage age-related macular degeneration: long-term visual acuity and safety outcomes. Am J Ophthalmol 146.5: 664-673.
16. Macular Photocoagulation Study Group. (1986). Recurrent choroidal neovascularization after argon laser photocoagulation for neovascular maculopathy. Macular Photocoagulation Study Group. Arch Ophthalmol 104.4: 503-12.
17. Macular Photocoagulation Study Group. (1991). Argon laser photocoagulation for neovascular maculopathy. Five-year results from randomized clinical trials. Macular Photocoagulation Study Group. Arch Ophthalmol 109.8: 1109-14.
18. Maculareyeware.com. (2011) Macular Eyewear Distance Viewing. Last Update: 2011. Maculareyeware.com. Available: http://www.maculareyewear.com/?utm_source=google&utm_medium=cpc&utm_campaign=mac&gclid=CPjplYOcnqoCFQh2gwodbCT76A. Date Accessed: August 2, 2011.
19. Mayo Clinic Staff. (2010) Dry Macular Degeneration. Last Update: November 12, 2010. Mayo Clinic. Available: http://www.mayoclinic.com/health/medical/IM00255. Date Accessed: July 12, 2011.
20. National Eye Institute. (2011) Facts About Age-Related Macular Degeneration. Last Update. National Eye Institute. Available: http://www.nei.nih.gov/health/maculardegen/armd_facts.asp. Date Accessed: July 12, 2011,
21. National Institute for Health and Clinical Excellence (NICE). (2008) Implantation of miniature lens systems for advanced age-related macular degeneration. National Institute for Health and Clinical Excellence (NICE) [UK]. August
22. National Institute for Health and Clinical Excellence (NICE). (2008) Interventional procedure overview of implantation of lens systems for advanced age-related macular degeneration. Last Update: November 2008. National Institute for Health and Clinical Excellence (NICE) [UK]. Available: http://www.nice.org.uk/nicemedia/live/11921/40489/40489.pdf. Date Accessed: July 26, 2011.
23. Primo, SA. (2010). Implantable miniature telescope: lessons learned. Optometry 81.2: 86-93.
24. VisionCare Ophthalmic Technologies. (2011) Implantable Telescope Technology. Last Update: 2011. VisionCare. Available: http://www.visioncareinc.net/technology. Date Accessed: July 13, 2011.

Select Health

25. WebWire. (2009) Telescopic Lenses Can Help Vision Loss From Macular Degeneration. Last Update: May 10, 2009. WebWire.com. Available: http://www.webwire.com/ViewPressRel.asp?aId=94623. Date Accessed: August 2, 2011.

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MEDICAL POLICY

VISION THERAPY AND LOW-VISION REHABILITATION

Policy # 242
Implementation Date: 3/1/04
Review Dates: 1/13/05, 1/27/06, 2/16/06, 2/15/07, 2/21/08, 2/26/09, 2/18/10, 2/17/11, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/2/19, 2/4/20, 2/2/21, 1/23/22, 2/1/23, 1/30/24, 2/1/25
Revision Dates:5/3/18, 10/11/18, 7/26/19, 1/27/22

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Description

Low-vision therapy is designed to improve the performance of activities of daily living in persons with vision impairment or loss, whose sight cannot be corrected to normal or near-normal levels by any typical restorative process (i.e., correction of refractive error, medically indicated corneal transplantation, or cataract surgery). Vision impairment, or loss of vision (ranging from low-vision to total blindness), may result from a primary eye diagnosis such as macular degeneration, retinitis pigmentosa, or glaucoma; or it may result as a condition secondary to another primary diagnosis such as diabetes mellitus, acquired immune deficiency syndrome (AIDS), or an infection. Therapy for those with vision impairment, or loss of vision, maximizes the use of residual vision and provides practical adaptations and training to increase functional ability, personal safety, and independence.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

1. **Vision Therapy**

   Select Health covers vision therapy for the following conditions:

   - Convergence insufficiency (the eyes are unable to work together when looking at nearby objects), per recommendation of an ophthalmologist
   - Traumatic brain injury, per recommendation of a neurologist or concussion specialist

2. **Low Vision Rehabilitation**

   Select Health covers low-vision rehabilitation for the following conditions:

   - Low-vision rehabilitation (LVR)*
   - Age-related macular degeneration
   - Glaucoma
   - Visual field deficits following a stroke or neuro trauma

*LVR services are considered reasonable and necessary only for patients with a visual impairment, a clear medical need, and the potential to improve significantly from the services.

Select Health does NOT cover vision therapy for the following conditions:

- Amblyopia
- Esotropia
- Exotropia (a form of strabismus in which one or both eyes turn outward) without convergence insufficiency
- Nystagmus (involuntary eye movement)
- Myopia (nearsightedness)
- Presbyopia (farsightedness)
- Convergence excess (eye muscle balance which causes the eyes to want to aim more inward during reading and close work)
- Divergence insufficiency (unusual form of strabismus with esotropia and diplopia only at a distance and singular binocular vision at near)
- Divergence excess (exotropia at a distance)
- Reading or learning disabilities, including dyslexia
- Developmental delays

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

According to the Agency for Healthcare Research and Quality (AHRQ) report, vision therapy, historically, has not been well-studied, principally due to its general lack of reimbursement, which is associated with low demand for evidence secondarily due to a variety of methodologic challenges. Concurrent with this realization has been the publication of assorted clinical trials reporting a variety of vision therapy-related outcomes. Results of such studies suggest that: 1) methodologic issues are still being resolved, and 2) vision therapy seems to help with reading and other vision ADL issues, but evidence is only fair, and 3) vision therapy does not necessarily improve other quality of life issues (e.g., depression, loneliness). To

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date, there have been no randomized controlled trials (RCTs) that have evaluated the effectiveness and cost-effectiveness of different models of care in low vision.

Randomized controlled trials (RCTs) and other rigorous types of experimental designs tend to be difficult to conduct for various types of therapy. Aside from the few types of more common and medically-oriented therapy (such as for stroke and trauma), it is difficult to control for multiple factors that may confound study results, such as the presence of comorbidities, differences in physical home environments, and varying availability of caregiver support. Because population groups with particular types of therapy needs may be small, as well as diverse, it is difficult to accrue sufficiently large numbers of individuals into RCTs so that potentially confounding factors would be evenly distributed between an intervention group and a control group. Further, whereas research funding in the larger healthcare system facilitates and motivates the identification of potential enrollees for clinical trials, the more diffuse and less coordinated system encompassing much of therapy is not as able to identify potential enrollees. Measurement of outcomes across the continuum of care (i.e., for the multiple types and sites of service that may be involved in therapy), is particularly challenging and not well-developed to date. Despite these challenges, therapy has started to become a more evidence-based specialty. Investigators call for an increase in systematic technology assessment of devices, drugs, and services used in therapy.

When reviewing the literature for vision therapy, the American Academy of Ophthalmology (AAO) committee on low-vision therapy did not identify any level 1 or level 2 evidence. All recommendations were based on level 3 evidence. Level 3 evidence consists of observational studies and case reports. It lacks the rigor of randomized trials and allows for observer bias to possibly impact the study results.

More recently, a multicenter randomized clinical trial from 2004–2006 with a 4-month follow-up of 126 veterans with vision in the better-seeing eye of 20/100 to 20/500, with 64 randomized to study group and 62 to control. Intervention was of low-vision exam, counseling, and prescription, and provision of low-vision device and 6 weekly sessions of therapy. Average face-to-face time with a low-vision therapist was 10.5 hours. Results suggested statistically significant improvement in visual reading ability, mobility, visual information processing, visual motor skills, and overall visual function. Strengths of the study include strict protocol and multiple assessment methods for functional visual metrics. Limitations include possible Hawthorne effect due to lack of sham treatment in control group.

Subsequently, a follow up multicenter randomized clinical trial from 2010–2014 with a 4-month follow-up of 323 veterans with macular disease and best-corrected vision in the better eye of 20/50 to 20/100 comparing changes in overall visual function and 4 functional domains. Interventions included randomization of n=163 to study group of visual therapy with low-vision devices vs n=160 to control group of basic low-vision services with low-vision devices without therapy. Visual therapy group received a mean of 1.9 therapy sessions, completed 9.8 homework sessions, and spent mean therapy time of 234 minutes. Findings of the intervention included statistically significant improvement in visual ability, reading acuity, reading speed, visual motor skill, and overall visual ability. However, no difference in mobility or quality-of-life scores was found between the two groups. Subset analysis additionally demonstrated that visual therapy did not benefit the BCVA better-eye 20/50 to 20/63 group, while the “worse than 20/63” to 20/200 group did benefit.

A single center RCT of 67 patients in the United Kingdom from 2016, with n=35 randomized to home visit-based visual therapy intervention and n=32 to waiting list control arm over an 18-month period. Intervention consisted of 1–11 home visits to assess needs and for training and support, such as low-vision aids, pill organizer provision, long cane training. Number of visits determined by visual therapy officer. Results suggested improvement in visual function using the 48-item Veterans Affairs Low Vision Visual Functioning Questionnaire. However, there was no difference in secondary outcome measures, including, well-being scores, loneliness scores, and health status scores.

Another multicenter randomized study was performed by Nollett of 85 patients with low-vision and depression, randomized to problem-solving treatment, and referral to patient’s physician (or a waiting list control). This study concluded that “neither active intervention would reduce depression by the minimal clinically important difference, although both did appear better than current standard of care.” A study of 255 patients in India which patients were enrolled in a low-vision therapy program demonstrated significant improvements in vision-related quality of life and on the Veterans Affairs Low Vision Visual Functioning Questionnaire.

Billing/Coding Information

CPT CODES

92065	Orthoptic and/or pleoptic training, with continuing medical direction and evaluation
92066	Orthoptic training; under supervision of a physician or other qualified health care professional
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one on one) patient contact by the provider, each 15 minutes
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one on one contact by provider, each 15 minutes
97537	Community/work reintegration training (eg, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes

HCPCS CODES

No specific codes identified

Key References

1. Acosta R, Henshaw K. Acosta R, Henshaw K. Reading aids for adults with low vision (protocol for a Cochrane Review). In: The Cochrane Library, Issue 3/03.
2. Acton, J. H., B. Molik, H. Court and T. H. Margrain (2016). "Effect of a Home Visit-Based Low Vision Rehabilitation Intervention on Visual Function Outcomes: An Exploratory Randomized Controlled Trial." Invest Ophthalmol Vis Sci 57(15): 6662-6667.
3. Agency for Healthcare Research and Quality, Vision Rehabilitation: Care and Benefit Plan Models. Literature Review. 10/2002. Rockville, MD. Performed by The Lewin Group. http://www.ahrq.gov/clinic/vision/
4. American Academy of Ophthalmology - Medical Specialty Society. Vision Rehabilitation Committee; Preferred Practice Patterns Committee. Date Released: 1994 Feb (updated 2001 Feb). Robert M. Christiansen, MD, Chair.
5. Barton JJS, Ranalli PJ. Vision therapy: Occlusion, prisms, filters, and vestibular exercises for mild traumatic brain injury. Surv Ophthalmol. 2020 Aug 19: S0039-6257(20)30124-7. doi: 10.1016/j.survophthal.2020.08.001. Epub ahead of print. PMID: 32827496.
6. Bischoff P. Long-term results of low vision rehabilitation in age-related macular degeneration. Doc Ophthalmol. 1995;89(4):305-11. PMID: 7493532
7. Corcoran Consulting Group. (2018). Medicare Reimbursement for Low Vision Rehabilitation (VCOT) - FAQ. [online] Available at: https://www.corcoranccg.com/products/faqs/low-vision-rehabilitation-2/ [Accessed 4 May 2018].
8. Ehrlich, J. R., L. V. Ojeda, D. Wicker, S. Day, A. Howson, V. Lakshminarayanan and S. E. Moroi (2016). "Head-Mounted Display Technology for Low Vision Rehabilitation and Vision Enhancement." Am J Ophthalmol.
9. EL, B. (2018). Vision concerns after mild traumatic brain injury. - PubMed – NCBI. [online] Ncbi.nlm.nih.gov. Available at: https://www.ncbi.nlm.nih.gov/pubmed/?term=25619534 [Accessed 14 May 2018].
10. Fletcher DC, editor. Low Vision Rehabilitation: Caring for the Whole Person. Ophthalmology Monograph, American Academy of Ophthalmology. Unknown date.
11. Gothwal, V. K. and S. Bharani (2015). "Outcomes of Multidisciplinary Low Vision Rehabilitation in Adults." Invest Ophthalmol Vis Sci 56(12): 7451-7461.
12. Hayes Report: Vision Therapy for Visual Dysfunctions, Dyslexia, Other Reading Disabilities, 10/2002.
13. Hinds A, Sinclair A, Park J, Suttie A, Paterson H, Macdonald M. Impact of an interdisciplinary low vision service on the quality of life of low vision patients. Br J Ophthalmol. 2003 Nov;87(11):1391-6. PMID: 14609841
14. Kenneth J. Ciuffreda OD, PhD, William V. Padula OD, Patrick Quaid MSOptom, PhD, Daniella Rutner OD, MS Associate Clinical Professor and Chief, "Letter to the Editor: Reply to Barton and Ranalli", Survey of Ophthalmology (2021), doi: https://doi.org/10.1016/j.survophthal.2021.01.007
15. KJ, K. (2018) Vision Disturbances Following Traumatic Brain Injury. – PubMed- NCBI. [online] Ncbi.nlm.nih.gov. Available at: https://www.ncbi.nlm.nih.gov/pubmed/?term=12036500 [Accessed 14 May 2018].
16. McCabe P, Nason F, Demers Turco P, Friedman D, Seddon JM. Evaluating the effectiveness of a vision rehabilitation intervention using an objective and subjective measure of functional performance. Ophthalmic Epidemiol. 2000 Dec;7(4):259-70. PMID: 11262673
17. National Horizon Scanning Centre (UK). Opto-electronic low vision aids for the visually impaired. 2003.
18. Paul J. Ranalli , Jason J.S. Barton , Reply to Ciuffreda et al, Survey of Ophthalmology (2021), doi: https://doi.org/10.1016/j.survophthal.2021.01.006
19. Program Memorandum Department of Health & Human Services (DHHS) Intermediaries/Carriers Centers for Medicare & Services (CMS) Transmittal AB-02-078 Medicaid S Date: 5/29/02 CHANGE REQUEST 2083 SUBJECT: Provider Education Article: Medicare Coverage of Rehabilitation Services for Beneficiaries With Vision Impairment.
20. Raasch TW, Leat SJ, Kleinstein RN, Bullimore MA, Cutter GR. Evaluating the value of low-vision services. J Am Optom Assoc. 1997 May;68(5):287-95. Review. PMID: 9170794

Select Health

21. Russell W, Harper R, Reeves B, Waterman H, Henson D, McLeod D. Randomized controlled trial of an integrated versus an optometric low vision rehabilitation service for patients with age-related macular degeneration: study design and methodology. Ophthalmic Physiol Opt. 2001 Jan;21(1):36-44. PMID: 11220039
22. Nollett, C. L., N. Bray, C. Bunce, R. J. Casten, R. T. Edwards, M. T. Hegel, S. Janikoun, S. E. Jumbe, B. Ryan, J. Shearn, D. J. Smith, M. Stanford, W. Xing and T. H. Margrain (2016). "Depression in Visual Impairment Trial (DEPVIT): A Randomized Clinical Trial of Depression Treatments in People With Low Vision." Invest Ophthalmol Vis Sci 57(10): 4247-4254.
23. Padula WV, e. (2018). The consequence of spatial visual processing dysfunction caused by traumatic brain injury (TBI). – PubMed – NCBI. [online] Ncbi.nlm.nih.gov. Available at: https://www.ncbi.nlm.nih.gov/pubmed/?term=28440687 [Accessed 14 May 2018].
24. RA, A. (2018). Visual problems associated with traumatic brain injury. - PubMed - NCBI. [online] Ncbi.nlm.nih.gov. Available at: https://www.ncbi.nlm.nih.gov/pubmed/?term=29488253 [Accessed 14 May 2018].
25. Scott IU, Smiddy WE, Schiffman J, Feuer WJ, Pappas CJ. Quality of life of low-vision patients and the impact of low-vision services. Am J Ophthalmol. 1999 Jul;128(1):54-62. PMID: 10482094
26. Stelmack, J. A., X. C. Tang, D. J. Reda, S. Rinne, R. M. Mancil, R. W. Massof and L. S. Group (2008). "Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT)." Arch Ophthalmol 126(5): 608-617.
27. Stelmack, J. A., X. C. Tang, Y. Wei, D. T. Wilcox, T. Morand, K. Brahm, S. Sayers, R. W. Massof and L. I. S. Group (2016). "Outcomes of the Veterans Affairs Low Vision Intervention Trial II (LOVIT II): A Randomized Clinical Trial." JAMA Ophthalmol.
28. Stelmack J. Quality of life of low-vision patients and outcomes of low-vision rehabilitation. Optom Vis Sci. 2001 May;78(5):335-42. Review. PMID: 11384011
29. Thiagarajan P, e. (2018). Oculomotor neurorehabilitation for reading in mild traumatic brain injury (mTBI): an integrative approach. – PubMed – NCBI. [online] Ncbi.nlm.nih.gov. Available at http://www.ncbi.nlm.nih.gov/pubmed/?term=24284470 [Accessed 14 May 2018].
30. US Department of Veterans Affairs (VATAP): Adams E, Flynn K, Alligood E, Johnson T. Optical devices for adults with low vision: a systematic review of published studies of effectiveness. Technology Assessment Unit, Office of Patient Care Services/03: 45.
31. Vision Rehabilitation PPP - 2017. [online] American Academy of Ophthalmology. Available at: https://www.aao.org/preferred-practice-pattern/vision-rehabilitation-ppp-2017 [Accessed 4 May 2018].
32. Vision, Learning and Dyslexia. Policy Statement formulated by a Task Force representing the College of Optometrists in Vision Development, the American Optometric Association, and the American Academy of Optometry. Approved By: College of Optometrists in Vision Development, 10/1996; American Academy of Optometry, 1/1997; American Foundation for Vision Awareness, 2/1997; American Optometric Association, 3/1997; Optometric Extension Program Foundation, 4/1997
33. Vision Therapy: Information for Health Care and Other Allied Professionals. A Joint Organizational Policy Statement of the American Academy of Optometry and the American Optometric Association. Approved by; American Academy of Optometry, 5/1999 American Optometric Association/99 College of Optometrists in Vision Development, 10/19/99 Optometric Extension Program Foundation, November/98.
34. Watson GR. Low vision in the geriatric population: rehabilitation and management. J Am Geriatr Soc. 2001 Mar;49(3):317-30. Review. PMID: 11300245
35. Wolffsohn JS, Cochrane AL. Design of the low vision quality-of-life questionnaire (LVQOL) and measuring the outcome of low-vision rehabilitation. Am J Ophthalmol. 2000 Dec;130(6):793-802. PMID: 11124300

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