To Fit or Not to Fit: A Review of Medically Necessary Contact Lenses

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Medical Necessity Is....
“Services or supplies that are proper and needed for the diagnosis or treatment of the patient’s medical conditions, are provided for the diagnosis, direct care and treatment of the patient’s medical condition, meet the standards of good medical practice in the local area and aren’t mainly for the convenience of the patient or the physician.”

Source: www.Medicare.gov

Benefits of Medically Necessary Contact Lenses
Improved visual acuity
Improved peripheral vision
Reduced asthenopia
Reduced suppression
Better option for face or head deformity i.e. can’t wear spectacles
Improved comfort
Support the ocular surface

What Are Medically Necessary Contact Lenses?
Medically and visually necessary contact lens services are for those patients whose visual experience and function is significantly improved through the use of contact lenses rather than spectacle lenses.

Conditions for Medically Necessary Contact Lenses
Examples, not limited to:
- Keratoconus
- Irregular astigmatism
- Corneal transplant
- Corneal graft complication
- Corneal opacities
- Aphakia
- Keratitis
- Dry Eye
- Corneal ulcers
- Corneal neovascularization
- Corneal edema
- Bullous keratopathy
- Corneal degenerations
- Corneal dystrophies
- Corneal irregularities and ectasia
- Corneal disorder due to contact lens
- Congenital anomalies of corneal size and shape
- Acid and Alkaline chemical burn of cornea and conjunctiva
Visually Necessary Criteria

Nystagmus
Anisometropia of at least 3.00 D in any meridian based on spectacle prescription
High ammetropia at least -10.00 D or +10.00 D in either eye in any meridian based on spectacle prescription

First Thing

What is the first thing that is to be documented?

A chief complaint!
- Blurry Vision
- Dry Eye
- Pain

The patient specific information is necessary to support the services provided to each individual. The coverage of services given by a physician is dependent on the purpose of the examination rather than on the ultimate diagnosis of the patient's condition.

Approach

What do you do? Think Evidence Based treatment

What does the patient want? Not always what you would like to provide the patient

What is in the patient’s best interest?

Expectation is the root of all heartache.

Additional Testing

Keratometry
- Only measures middle ~3.0mm

Corneal topography

Horizontal Visible Iris Diameter

Anterior Segment Photography
- There are cases when photography may be necessary to communicate with a lab, capture the details of a fluorescein pattern or document preexisting conditions, such as corneal scarring, microscopic edema or neovascularization.

Endothelial Cell Count
- E.g. Corneal graft

Advantages and Disadvantages of Various Types of Contact Lenses-Overview

<table>
<thead>
<tr>
<th>Lens Types</th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tr>
<td>Rigid gas-permeable (RGP)</td>
<td>Excellent vision... short adaptation period... comfortable to wear... correct most vision problems... easily put on and taken care for... durable with a relatively long life... available in tints (for leading purposes) and bifocals.</td>
<td>Require consistent wear to maintain adaptation... can slip off center of eye more easily than other types... harder to clean... get ready the lenses... require office visits for follow-up care.</td>
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<td>Daily-wear soft lenses</td>
<td>Very short adaptation period... more comfortable and more difficult to dislodge than RGP lenses... available in tints and bifocals... great for active lifestyles.</td>
<td>Do not correct all vision problems... vision may not be as sharp as with RGP lenses... require regular office visits for follow-up care... lenses soil easily and must be replaced.</td>
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<tr>
<td>Extended-wear disposable soft lenses: worn for an extended period of time, usually for an extended period of time then discarded.</td>
<td>Can usually be worn up to seven days without removing.</td>
<td>Do not correct all vision problems... require regular office visits for follow-up care... increases risk of complications... require regular monitoring and professional care.</td>
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<tr>
<td>Planned replacement soft daily wear lenses that are replaced on a planned schedule, most often either every two weeks, monthly or quarterly.</td>
<td>Require simplified cleaning and disinfection... avoid for eye hands... available in most prescriptions.</td>
<td>Vision may not be as sharp as RGP lenses... do correct all vision problems... handling may be more difficult.</td>
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Lens Types

Soft Contact Lenses: Traditional hydrogel lenses and Silicone hydrogel lenses

Generally, hydrogel soft lenses are available in these categories, based on their water content:
- Low water content (less than 40 percent water)
- Medium water content (50 to 60 percent water)
- High water content (more than 60 percent water)
- High water content (more than 60 percent water)

Hydrogels are classified as either ionic or non-ionic. Ionic materials have a negatively charged surface and therefore may attract positively charged proteins in the tear film. Non-ionic hydrogels are treated to reduce this negative surface charge and therefore may be less prone to attract protein deposits.

The FDA uses four categories to classify soft lens materials:
- Category 1 = low water, non-ionic
- Category 2 = high water, non-ionic
- Category 3 = low water, ionic
- Category 4 = high water, ionic

Silicone hydrogels have silicone within the hydrogel material to increase the oxygen transmissibility of the lenses.
Lens Types

Gas Permeable (Corneal) Lenses
- Rests entirely on cornea (8.0-10.5mm)
- Custom, proprietary, aspheric designs
- Multiple DK materials
- Pros: Ease of application, great vision, low cost
- Cons: If not ideal fit, possible staining and scarring, easier to dislodge, prone to foreign body and lens

Gas Permeable (Corneal) Lenses Continued
- Large GP/Intra-limbal (10.5-12.0mm depending on HVID)
- Good for previous GP wearers with decentration
- Less movement/better centration
- Less lid interaction so better comfort
- Larger area of cornea on which to bear, better for long-term corneal health

Keratoconus and GP Lenses
- Spectacles: High astigmatism, poor vision
- Corneal gas permeable lenses: Potentially good vision, can be uncomfortable and difficult to fit depending on degree of ectasia
- The corneal lens moves to the steepest part of the cornea

Keratoconus-Custom Soft lenses
- Flexlens-Custom Parameters
- HydraKone-Custom Parameters
- NovaKone
  - Variable Base Curve and “fitting curve”
  - Variable Thickness (0.22 to 0.65mm) to create rigidity of lens
  - Sphere or Toric
- Kerasoft IC
  - Variable Base Curve and periphery
  - Diagnostic Fitting necessary (Dr changes with change in BC)

Lens Types

Piggyback (Tandem)
- Fit GP on top of SCL
- Often same GP lens already using as best-fit
- Use high dk SCL (Silk) using low plus +1.00
- Challenge to avoid SCL inferior edge fluting
- Use when want to keep the same GP fit but patient is symptomatic

Keratoconus-Custom Soft lenses
- Advantages
  - Good comfort
  - Good centration
  - Many parameters
  - Minimal corneal insult
- Disadvantages
  - Worse VA than GP
  - Potential solution toxicity
  - Fitting challenges
**Lens Types**

**Hybrid Lenses**
- GP center with soft skirt
  - Central clearance—good comfort and corneal health—less scarring
  - Peripheral bearing—stability, soft skirt aids in centration
  - Scleral bearing—good comfort and minimal movement
  - Soft lens like comfort
  - Less movement
  - Good VA associated with GP

Disadvantage, learning fit and evaluation, some handling difficulty

**Scleral Lenses**
- Made of GP materials e.g., Boston XO, Boston XO2
  - Corneal scleral (rests partly on cornea and on sclera)
  - Mini scleral (up to 6mm larger than HVID, rests entirely on sclera)
  - Scleral (more than 6mm larger than HVID, rests entirely on sclera)

Gas permeable scleral lens may be considered **medically necessary** for patients who have not responded to topical medications or standard spectacle or contact lens fitting, for the following conditions:
- Corneal ectatic disorders (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Terrien’s marginal degeneration, post-surgical ectasia);
- Corneal scarring and/or vascularization;
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery);
- Ocular surface disease (e.g., severe dry eye, persistent epithelial defects, neurotrophic keratopathy, exposure keratopathy, graft vs. host disease, sequelae of Stevens Johnson syndrome, mucous membrane pemphigoid, post-ocular surface tumor excision, post-glaucoma filtering surgery) with pain and/or decreased visual acuity.

Lenses fit under the eyelids and rest on the relatively insensitive white tissue of the eye, vaulting the damaged cornea and creating a new smooth optical surface that protects the eye from the environment and blink trauma.

**Scleral Lenses**
- Scleral lenses are filled with sterile saline at insertion, creating a reservoir of fluid that continuously bathes the ocular surface with oxygenated artificial tears.
**Scleral Lenses**

Scleral Lenses Create:
A new transparent, smooth optical surface over the irregular, damaged or diseased cornea
An expanded artificial tear reservoir that provides constant lubrication while maintaining necessary oxygen supply

**Benefits of Scleral Lenses**
Reestablishes a healthy and stable ocular surface environment that supports healing and reduces symptoms
- Mitigating pain and photophobia
Improves blurry vision by masking surface corneal irregularities and transmitting a sharp image to the back of the eye
Prevents damage by protecting and shielding the cornea and conjunctiva against the environment and eyelids

**Scleral Lenses**

Pros:
- Great Vision - Optics centered on visual axis
- Great Comfort
- No Corneal Bearing, better for corneal health long-term
- Numerous fit/design options
- Customization

Cons:
- Difficulty to apply and remove
- Higher initial cost
- Special cleaning/care techniques

**Case Report: Keratoconus**

- 26 year old Caucasian male referred for CL evaluation
- History of Keratoconus, never worn a CL
- Slit Lamp: steep cornea
- s/p corneal collagen crosslinking OU ~ 5 months prior
- MR OD +0.75 -1.25 x 080 20/30+2
- OS +0.75 -3.50 x 123 20/30-2
- PHNI OD/OS

**Case Report: Keratoconus**
Case Report: Keratoconus
Biofinity Toric 8.7BC/14.5Diam
OD +1.00 -1.25 x 080 20/30 OR -0.25 SI
OS +1.00 -2.25 x 110 20/30+2 OR plano
Subjective improvement in visual quality

Pellucid Marginal Degeneration
Non-inflammatory
Progressive
Peripheral thinning 1 mm from limbus
Inferior thinning most common from 4 to 8 o’clock

Treatment options (similar to keratoconus):
• Spectacles: high astigmatism, poor vision
• Corneal gas permeable lenses: potentially good vision, comfort level varies from tolerable to intolerable, can be challenging depending on degree of ectasia
• Hybrid: potentially good vision, good comfort, possibly challenging fit
• Scleral lenses: vaults cornea resulting in good comfort; good vision
• Penetrating Keratoplasty – less likely due to thinning at periphery

Penetrating Keratoplasty
Complications:
High astigmatism
Ocular surface disease

Treatment options:
• Spectacles: high astigmatism, poor vision
• Corneal gas permeable lenses/Reverse Geometry: potentially good vision, questionable comfort, possibly challenging fit
• Hybrid: potentially good vision, good comfort, possibly challenging fit
• Scleral lenses: vaults cornea resulting in good comfort; good vision

Post-LASIK ectasia
Complications:
Progressive steepening after LASIK
Myopic shift
Loss of uncorrected acuity
Increase in irregular astigmatism

Treatment options:
• Spectacles: high astigmatism, poor vision
• Corneal gas permeable lenses: potentially good vision, questionable comfort, possibility challenging fit
• Hybrid: potentially good vision, good comfort, possibly challenging fit
• Scleral lenses: vaults cornea resulting in good comfort; good vision

Therapeutic Contact Lenses
Conditions recalcitrant to other treatment modalities may heal more readily with the use of a therapeutic contact lenses (TCLs).
Nearly every lens type can be used in a therapeutic capacity.

The five main uses of a TCL:
1. Relief of ocular pain
   • The relief of pain is the common aim of treatment in ocular conditions resulting in corneal epithelial abnormalities.
2. Promotion of corneal healing
3. Mechanical protection and support
4. Maintaining corneal hydration
5. Drug delivery

Therapeutic Contact Lenses
What to consider when choosing a lens:
1. The purpose of lens use, which may be more than one
2. The physiological requirements of the eye(s) being treated
3. How must progress be monitored
4. Is there more than one viable option, the lens design or material may be changed, sometimes several times, to obtain the best clinical effect suited to the corneal condition concerned
Essentials of Fitting a TCL

- Wherever possible avoid the use of topical anesthetics as this may mask the pain/discomfort associated with a poor fitting lens. In certain circumstances the use of topical anesthetic is unavoidable.
- The lens fit should be assessed after approximately 20 minutes.
- A well fitting TCL should have good corneal coverage with appropriate movement characteristics for the underlying condition being managed.
- Peripheral lens fit is also very important as e.g. lens edge fluting may gives rise to discomfort etc.

- A large lens with a fitting erring on the flat side, that centers well is the preferred option in cases such as e.g. corneal edema and conditions where the corneal epithelium is not intact.
- Steeper fitting lenses are better for eyes with irregular corneal topography, for vaulting or splinting of the corneal surface or where pain relief is a main aim.
- Air pockets/bubbles should be avoided under the lens/over cornea.

Relief of Pain

Bullous Keratopathy
- In a patient with a painful eye with no visual potential
- In a patient not fit for graft surgery
- As a temporary measure where a patient is going to have a penetrating keratoplasty at some future date

Filamentary Keratitis
- Severe persistent cases may benefit from the use of TCLs

Thygeson’s Superficial Punctate Keratitis
- TCL acts as a pressure bandage relieving pain and foreign body sensation

Helping Those in Need

Promotion of Corneal Healing

Recurrent Corneal Erosion: Anterior membrane dystrophies
- Anterior membrane dystrophies can produce intermittent epithelial breakdown and are associated with corneal surface problems. E.g. Anterior basement membrane dystrophy aka map-dot fingerprint dystrophy. This produces foreign body sensations, pain and photophobia.
- Consider extended wear basis with a disposable lens with removal and replacement as deemed necessary.
Promotion of Corneal Healing

Traumatic Corneal Abrasions
- Abrasions over 4mm may benefit from TCL, epithelium reportedly heals more quickly.
- Smaller severe persistent cases may benefit from the use of TCLs

Persistent Epithelial Defects (PEDs)
- Chronic management problem, cornea is more vulnerable to infection and is associated with a high rate of ulceration and perforation.
- Disposables can provide mechanical protection from the lids while new epithelium lays down
- Epithelial defects that don’t heal with conventional treatment (lubrication, bandage contact lens) Scleral lenses/devices provide constant hydration and mechanical protection from the lids while new epithelium lays down

Case Report: Persistent Epithelial Defect
- 49 year old Caucasian male
- History of Toxic Epidermal Necrolysis to sulfa drug 20 years ago
- Ocular complications include severe dry eye, keratinized lid margins OU, scarring resulting in shortened fornices OU
- History of penetrating keratoplasty x3 OS ultimately leading to perforation and a prosthesis OS

Case Report: Persistent Epithelial Defects
- Multiple penetrating keratoplasty procedures OD
- Most recent was 3 months prior and secondary to perforation
- Developed persistent epithelial defect that did not heal with lubrication or bandage contact lens
- Treated with overnight wear of a scleral device (PROSE) with daily monitoring and removal
- Vigamox instilled in lens reservoir with saline for prophylaxis

Persistent Epithelial Defects

<table>
<thead>
<tr>
<th>Day</th>
<th>Image</th>
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<tbody>
<tr>
<td>1</td>
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<tr>
<td>5</td>
<td><img src="image5" alt="Day 5" /></td>
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Promotion of Corneal Healing

Chemical Injuries

- A chemical burn to the eye is often associated with epithelial and stromal damage/ulceration
- The presence of a TCL may inhibit the travel of certain proteolytic enzymes present in the tear film to the stroma, therefore preventing the progressive ulcerative process following chemical injuries
- In theory, the anoxia and slight trauma caused by a TCL may stimulate vascular in-growth and the subsequent stromal vascularization may prevent the ulcerative process?

Promotion of Corneal Healing

Post Operative Epithelial Disorders

Many ophthalmic surgical procedures can result in temporary corneal epithelial defects.

For example:

- Vitrectomy (in ~25% of diabetics)
- Post penetrating keratoplasty in the early post operative period
- Kerato-refractive procedures e.g. PRK, LASIK
- Cataract extraction (wound leakage i.e. positive Seidel’s test)

Soft TCLs may be used in order to minimize post surgical epithelial trauma, provide a stable healing environment and promote healing.

Promotion of Corneal Healing

Penetrating Keratoplasty (PK)

Where an existing graft has perforated:

- A silicone hydrogel TCL may be used to reform the anterior chamber.

Other possible uses post PK include:

- Delayed epithelial healing of more than one week
- Epithelial filament formation
- Steps in host graft junction
- Protection to loose sutures

Mechanical Protection and Support

Corneal Wound Leakage Post Ophthalmic Surgery

- E.g. cataract surgery or penetrating keratoplasty, provides mechanical splinting of the wound and aids sealing of the leaking wound

Corneal Laceration

- With small perforations (less than 2mm) without tissue loss, structural support may be achieved and the integrity of the eye maintained, by the use of a TCL

Trabeculectomy

- Leaking drainage bleb in the initial post operative period-need a large diameter TCL to fit over the bleb

Promotion of Corneal Healing

Cranial nerve palsies

- E.g. Trigeminal (5th) nerve palsy, Facial (7th) nerve palsy
- Scleral lenses useful in providing protection and comfort

Cranial nerve palsies

- Scleral lenses may prevent symblepharon

Maintaining Corneal Hydration

Cicatrizing Conjunctival Disease

Corneal involvement associated with cicatrization of the conjunctiva occurs in conditions such as e.g. Stevens-Johnson syndrome, ocular pemphigoid, chemical burns, trachoma and severe dry eye.

- Scleral lenses may be particularly useful, as they will also retain a reasonable tear layer which prevents corneal dehiscence and keratinization

Chemical Burns

- Scleral lenses may prevent symblepharon
Maintaining Corneal Hydration

Scleral lenses/ocular surface prosthetics
• Provide continuous corneal hydration
• Protect conjunctival and corneal tissue
• Non-invasive, reversible
• Can be used in conjunction with other therapy

Drug Delivery

Hydrogel SCLs alter the pharmacokinetics and effectiveness of topically applied drugs. Hydrogel lenses soaked in medication and then placed on the eye generally give very high levels of medication to the eye that diminish with time, this may be preferred to frequent application of ophthalmic drops. This is may be appropriate when corneal protection and high levels of medications are needed.
• Risk of producing toxic reaction, i.e. keratopathy due to prolonged corneal exposure to certain drugs.

Contact Lenses For Infant Aphakia

Silsoft (B+L)
• Limited parameters: 23-32D in 3 D steps and nothing beyond 32D (Optical quality at higher powers is questionable)
• Base curves: only 7.5, 7.7, 7.9mm
• Diameter: only 11.3mm
• Good stability on the eye
• Good comfort
• Silicone elastomer lens providing the highest oxygen permeability of any soft or rigid lens material currently available (340)

Drug Delivery

GP contact lenses offer the following advantages over soft lenses:
• High oxygen transmissibility
• Optically superior to hydrogel and/or silicone lenses
• Ability to correct unwanted cylinder
• Flexibility in design (customize curve, power, diameter)
• Cost – significantly less expensive
• Ease of handling (insertion and removal)
• Safety profile – low bacterial and protein adherence

Contact Lenses For Infant Aphakia

Over-refraction Preferences:
• Birth to 2 years of age:
  • Not walking? overcorrect by 2-3 D
  • Walking? overcorrect by 1-1.50 D
2 years of age and beyond:
• Full distance Rx with plano/+3.00 bifocal OU

BostonSight® PROSE

BostonSight® PROSE (prosthetic replacement of the ocular surface ecosystem) is a treatment pioneered by Boston Foundation for Sight to restore vision, support healing, reduce symptoms and improve quality of life for patients suffering with complex corneal disease.
Restoring Sight – Reclaiming Lives
Since 2002 more than 2000 patients have had their sight restored thanks to PROSE.

There are currently at least an estimated 57,000 people in the United States alone who could benefit from PROSE.

"I went from being an active working single mom to being totally incapacitated. PROSE gave me my life back after 17 years of pain, FDA studies, and no success in treating any of my symptoms." – PROSE Patient

PROSE Devices
PROSE uses FDA-approved custom designed and fabricated prosthetic devices to replace or support impaired ocular surface system functions that protect and enable vision.

PROSE Devices
The prosthetic devices created during PROSE are transparent domes, about the size of a nickel, made of gas-permeable plastic that allows oxygen to reach the ocular surface.

PROSE Treatment
Individual customization for fit, comfort, and vision
- Iterative process involving both "fit " and "vision" parameters
- Substantial "chair time" with patient, requiring expertise in vision correction, prosthetic device fitting, ocular pathophysiology, and DTF (Design-to-Fit) platform.

PROSE Treatment
Patient or caregiver must be trained in daily insertion and removal.

PROSE Treatment CAD/CAM platform "Design-to-Fit" Web based
- Mathematical construction Spline functions (U.S. patent #5,452,031)
- Front and back surfaces that are malleable and junctionless
- Matched haptic-to-sclera contour
- Spherical, toric, and "quad" profiles
- Specialized optics: front surface cylinder, asphericity, (HOA correction)
BostonSight® PROSE Provider Network - US

Boston Foundation for Sight
Needham, MA

Bascom Palmer Eye Institute
Plantation, FL

USC Eye Institute
Los Angeles, CA

Alkek Eye Center
Houston, TX

Weill Cornell Eye Associates
New York, NY

Kellogg Eye Center
Ann Arbor, MI

Illinois Eye and Ear Infirmary
Chicago, IL

Brooke Army Medical Center
San Antonio, TX

North Shore – LIJ Health System
Great Neck, NY

The Proctor Foundation
San Francisco, CA

Wilmer Eye Institute
Baltimore, MD

Flaum Eye Institute
Rochester, NY