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Medicare Advantage Medical Coverage Policy

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Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

Type Title ID Num	Jurisdiction Medicare Per Administrative Contractors (MACs) Medicare Applicable States/Territories
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NCD	Hydrophilic Contact Lens For Corneal Bandage	80.1		
NCD	Scleral Shell	80.5		
LCD LCA	Nasal Punctum-Nasolacrimal Duct Dilation and Probing with or without Irrigation	<u>L34171</u> <u>A57284</u>	J15 - CGS Administrators, LLC (Part A/B MAC)	кү, он
LCA	Billing and Coding: Amniotic Membrane Billing Guidelines for HCPCS Code V2790	<u>A53441</u>	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD	Eye Prostheses Refractive Lenses	L33737 L33793	DME A - Noridian Healthcare Solutions, LLC (DME MAC)	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT
LCA	Eye Prosthesis – Policy Article Refractive Lenses – Policy Article	<u>A52462</u> <u>A52499</u>	DME B - CGS Administrators, LLC (DME MAC)	IL, IN, KY, MI, MN, OH, WI
	Standard Documentation Requirements for All Claims Submitted to DME MACs	<u>A55426</u>	DME C - CGS Administrators, LLC (DME MAC)	AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, US VI
			DME D - Noridian Healthcare Solutions, LLC (DME MAC)	AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands

Description

The surface layers of the eye consist of the conjunctiva, the sclera (clear covering over the white of the eye) and the cornea (clear covering over the iris and pupil). Both the conjunctiva and cornea are covered by a layer called the epithelium, which completely regenerates every three to 10 days, requiring constant renewal of cells in order to remain healthy. In eyes with ocular surface disease, the epithelium is damaged and treatment depends on the underlying cause.

Dry eye syndrome (also known as dry eyes, dysfunctional tear syndrome, keratitis sicca, keratoconjunctivitis sicca, xerophthalmia or xerosis), is an example of an ocular surface disease and refers to chronic dryness, inflammation and irritation of the cornea and conjunctiva. Dry eye syndrome can occur alone or in conjunction with autoimmune disorders such as rheumatoid arthritis, systemic lupus erythematosus or Sjogren's syndrome. Dry eye syndrome occurs when the eye cannot maintain a normal layer of tears to coat the cornea and conjunctiva. Tear fluid provides lubrication to cleanse and moisten the surface of the eye and contains enzymes which protect the eye against bacteria. Dry eye syndrome is generally due to decreased tear production and/or excessive evaporative loss which may have underlying causes such as anatomical abnormalities, medication side effects or other ocular conditions.

Dry eye syndrome is generally classified as mild, moderate or severe. Although most individuals with dry eyes will experience discomfort, some may be relatively asymptomatic or notice symptoms intermittently.

In severe cases, dry eye symptoms that are unresponsive to treatment may indicate a more serious underlying condition. A nonhealing corneal epithelium may lead to persistent corneal epithelial defects, corneal inflammation or infection and may increase the risk of corneal ulcers.

Dry eye syndrome is diagnosed primarily on the basis of reported symptoms and supporting findings upon history and physical exam. There is no single diagnostic test or set of tests to confirm or rule out the condition. Examples of methods often used to evaluate the ocular surface include, but may not be limited to:

InflammaDry uses a tear sample to detect the inflammatory marker matrix, metalloproteinase-9 (MMP-9), which may be elevated in the tears of individuals with dry eye disease.

Meibography is the imaging and study of the morphology (structure and function) of meibomian glands. Near-infrared dual imaging uses reflective and transilluminated light purportedly to improve meibography techniques (reduce time and discomfort) and enhance results. The LipiScan is one example of a meibography device. The LipiView II is an example of a meibography device capable of ocular surface interferometry involving a three mode ophthalmic camera for imaging the lipid layer of the tear film, meibomian glands, ocular surface and eyelids. In the ocular imaging mode, the device captures high resolution images or video of the ocular surface or eyelids. The lipid imaging mode uses white light interferometry to provide a video color assessment of the tear film distribution over the cornea during blinking. The gland imaging mode relies on near-infrared illumination reflected by the meibomian glands to obtain an image.

- Ocular surface dye staining uses fluorescein to stain for areas of discontinuity in the epithelial surface of the cornea. Lissamine green and Rose Bengal are used to stain areas of devitalized epithelium in the cornea and conjunctiva as well as to determine abnormalities in the tear meniscus height.
- **Phenol red thread test** is similar to the Schirmer test (see below) but uses special red thread instead of paper and no numbing drops are used. The red thread is placed into the lower eyelid, the eyes are gently closed and after approximately five minutes, the thread is removed and evaluated for moisture.

- Schirmer test (tear test) involves the numbing of both eyes and the placement of a special paper strip inside each lower eyelid. The eyes are then gently closed for approximately five minutes and the paper is then removed and evaluated for moisture.
- Slit lamp evaluation is used to examine and assess the conjunctiva, cornea and eyelids.
- **Tear break-up time test (fluorescein eye stain)** uses orange dye on a piece of blotting paper which is placed on the surface of the eye. Blinking spreads the dye to coat the tear film (protective layer) of the eye. The eye is then examined under a blue light.
- **Tear osmolarity** is the measurement of the salt concentration in the tear fluid.

Individuals are often educated in self-management and environmental coping strategies to alleviate early symptoms of mild dry eyes. These approaches are generally recommended regardless of the severity of the condition or other treatments in progress. Examples include, but may not be limited to, the following:

- Avoidance of air currents, fans or vents
- Frequent blinking when reading or using computer
- Frequent breaks from visually demanding tasks
- Increasing ambient humidity with humidifiers
- Moisture chamber spectacles or eyeglass side shields
- Over-the-counter (nonprescription) topical lubricant eye drops, gels, ointments
- Warm compresses

For moderate cases of dry eye syndrome, topical anti-inflammatory agents (eg, nonsteroidal anti-inflammatory or corticosteroid drops) or other prescription medications may be used. Procedures may be necessary when medical treatments have failed. Examples of treatments for dry eye syndrome or severe ocular surface disease include, but may not be limited to, the following:

- Amniotic membrane graft uses sterilized cryopreserved or dehydrated tissue from the amnion (innermost layer of the placenta) to reconstruct damaged ocular surfaces and promote healing (eg, Ambio2, Ambio5, AmbioDisk, AmnioGraft, Prokera Classic, Prokera Clear, Prokera Plus, Prokera Slim).
- Autologous eye drops (autologous serum tears) have been proposed for dry eye syndrome and are made by mixing the individual's serum with other substances.
- **Bandage contact lens** is a regular-sized contact lens (usually soft) without refractive power that acts as a protective barrier and helps maintain a moist corneal surface to promote healing. The lens is not intended to correct vision and is generally temporary.
- **Conjunctival flap** involves the surgical removal and relocation of a thin flap of conjunctiva to cover damaged corneal tissue and to provide mechanical and nutritional support in order to facilitate healing.

- **Electromechanical neurostimulation (eg, iTear)** is applied externally to the side of the nose above the nostril to deliver electrical currents via an oscillating tip. This is purported to stimulate the lacrimal gland to increase tear production via vibratory stimulation of the external nasal nerve in adults.
- Electrothermal heat (eg, TearCare System) is applied to the upper and lower eyelids via a wearable device, which offers a patented open-eye feature, purported to work with the eyes natural blinking to facilitate clearing of meibomian gland obstructions while in a liquid state. Following the thermal eyelid treatment, the provider may remove any residual gland obstruction with a single-use clearing instrument (similar to blunt-tipped tweezers or forceps) provided with each pair of eyelid devices.
- Intense pulsed light (IPL) delivers bursts of light at specific wavelengths. The light energy is converted to heat. IPL therapy has been suggested as a treatment for dry eye syndrome.
- Intraductal probing (eg, Maskin protocol) is performed by applying local or topical anesthetic and introducing a thin stainless-steel wire probe into the meibomian gland orifices to forcefully expel any obstructing material and restore patency.
- Prosthetic replacement of the ocular surface ecosystem (PROSE), also called the Boston Equalens, is a type of fully customized gas permeable hard scleral contact lens for use in individuals with irregular astigmatism and severe dry eye symptoms when all standard available treatments have been exhausted. Extensive customized fitting is required.
- Punctal plugs are placed in the puncta to slow the loss of tears from the eye's surface. The plugs may be temporary (made of dissolvable collagen or absorbable material) or semi-permanent (made of silicone).
 If the plugs are effective, the openings to the lacrimal drainage system may be surgically closed (occlusive punctoplasty or closure of the lacrimal punctum).
- Scleral shells are used as an artificial support and protective covering for a shrunken, sightless or damaged eye. The scleral shell may serve as a protective barrier against tear evaporation and is usually hand painted to cosmetically match the other eye.
- **Tarsorrhaphy** is the temporary or permanent surgical fusion of the upper and lower eyelid margins to protect the cornea in conditions causing incomplete eyelid closure (eg, Graves' disease, Bell's palsy) or to facilitate healing of difficult to treat corneal lesions.
- Therapeutic hydrophilic contact lenses (scleral contact lenses) (eg, BostonSight) are larger in diameter than regular contact lenses, allowing tear reservoirs to form under the lenses, thereby keeping the corneas lubricated. A scleral lens is typically used to improve vision in persons with corneal irregularities. Unlike conventional contact lenses, scleral lenses rest completely on the sclera, the outer white portion of the surface of the eye, to create a fluid-filled space or reservoir over the affected cornea. This smooth liquid overlay fills in bumps on the corneal surface to improve vision.
- Thermal pulsation systems (eg, iLux, LipiFlow) are devices that purport to treat dry eye via the application of localized heat to the inner eyelid surface and intermittent pressure to the outer eyelid. The iLux has the additional capability to capture and save digital images and video of the meibomian glands.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria.

Ocular Surface Disease Diagnosis and Treatments

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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, multiple layers	
68360	Conjunctival flap; bridge or partial (separate procedure)	
68362	Conjunctival flap; total (such as Gunderson thin flap or purse string flap)	
67999	Unlisted procedure, eyelids	
67880	Construction of intermarginal adhesions, median tarsorrhaphy, or canthorrhaphy;	

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67882	Construction of intermarginal adhesions, median tarsorrhaphy, or canthorrhaphy; with transposition of tarsal plate	
68760	Closure of the lacrimal punctum; by thermocauterization, ligation, or laser surgery	
68761	Closure of the lacrimal punctum; by plug, each	
68801	Dilation of lacrimal punctum, with or without irrigation	
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method	
83861	Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity	
92071	Fitting of contact lens for treatment of ocular surface disease	
92499	Unlisted ophthalmological service or procedure	
CPT® Category III Code(s)	Description	Comments
0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral	
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	
0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans- illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	
0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral	
HCPCS Code(s)	Description	Comments
A4262	Temporary, absorbable lacrimal duct implant, each	
A4263	Permanent, long-term, nondissolvable lacrimal duct implant, each	
V2530	Contact lens, scleral, gas impermeable, per lens (for contact lens modification, see 92325)	
V2531	Contact lens, scleral, gas permeable, per lens (for contact lens modification, see 92325)	
V2627	Scleral cover shell	
V2790	Amniotic membrane for surgical reconstruction, per procedure	
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Change Summary

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