MASSACHUSETTS

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Medical Policy

Retinal Telescreening for Diabetic Retinopathy

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Policy Number: 065

BCBSA Reference Number: 9.03.13 (For Plans internal use only)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Retinal telescreening with digital imaging and manual grading of images may be considered **MEDICALLY NECESSARY** as a screening technique for the detection of diabetic retinopathy.

Digital retinal imaging with image interpretation by artificial intelligence software that is approved by the U.S. Food and Drug Administration (eg, IDX-DR, EyeArt) may be considered **MEDICALLY NECESSARY** for screening for diabetic retinopathy.

Retinal telescreening is considered **INVESTIGATIONAL** for all other indications, including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral
92250	Fundus photography with interpretation and report

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue, and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
92229	Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral

Description

Diabetic Retinopathy

Diabetic retinopathy is the leading cause of blindness among adults aged 20 to 74 years in the United States. The major risk factors for developing diabetic retinopathy are the duration of diabetes and severity of hyperglycemia. After 20 years of disease, almost all patients with type 1 and more than 60% of patients with type 2 diabetes will have some degree of retinopathy.[1,] Other factors that contribute to the risk of retinopathy include hypertension and elevated serum lipid levels.

Diabetic retinopathy progresses, at varying rates, from asymptomatic, mild non-proliferative abnormalities to proliferative diabetic retinopathy, with new blood vessel growth on the retina and posterior surface of the vitreous. The 2 most serious complications for vision are diabetic macular edema and proliferative diabetic retinopathy. At its earliest stage (non-proliferative retinopathy), the retina develops microaneurysms, intraretinal hemorrhages, and focal areas of retinal ischemia. With the disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). As the disease progresses, retinal blood vessels are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). The new blood vessels that occur in proliferative diabetic retinopathy may fibrose and contract, resulting in tractional retinal detachments with significant vision loss. Severe vision loss with proliferative retinopathy arises from vitreous hemorrhage. Moderate vision loss can also arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or non-proliferative stages of the disease. Although proliferative disease is the main cause of blinding in diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

Treatment

With early detection, diabetic retinopathy can be treated with modalities that can decrease the risk of severe vision loss. Tight glycemic and blood pressure control is the first line of treatment to control diabetic retinopathy, followed by laser photocoagulation for patients whose retinopathy is approaching the high-risk stage. Although laser photocoagulation is effective at slowing the progression of retinopathy and reducing visual loss, it causes collateral damage to the retina and does not restore lost vision. Focal macular edema (characterized by leakage from discrete microaneurysms on fluorescein angiography) may be treated with focal laser photocoagulation, while diffuse macular edema (characterized by generalized macular edema on fluorescein angiography) may be treated with grid laser photocoagulation. Corticosteroids may reduce vascular permeability and inhibit vascular endothelial growth factor production, but are associated with serious adverse events including cataracts and glaucoma, with damage to the optic nerve. Corticosteroids can also worsen diabetes control. Vascular endothelial growth factor inhibitors (eg, ranibizumab, bevacizumab, pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), are also used for the treatment of diabetic macular edema and proliferative diabetic retinopathy.

Digital Photography and Transmission Systems for Retinal Imaging

A number of photographic methods have been evaluated that capture images of the retina to be interpreted by expert readers, who may or may not be located proximately to the patient. Retinal imaging can be performed using digital retinal photographs with (mydriatic) or without (non-mydriatic) dilation of the pupil. One approach is mydriatic standard field 35-mm stereoscopic color fundus photography. Digital fundus photography has also been evaluated as an alternative to conventional film photography and has become the standard in major clinical trials. Digital imaging has the advantage of easier acquisition, transmission, and storage. Digital images of the retina can also be acquired in a primary care setting and evaluated by trained readers in a remote location, in consultation with retinal specialists.

Summary

Retinopathy telescreening and risk assessment with digital imaging systems are proposed as an alternative to conventional dilated fundus examination in diabetic individuals. Digital imaging systems use a digital fundus camera to acquire a series of standard field color images and/or monochromatic images of the retina of each eye. Captured digital images may be transmitted via the Internet to a remote center for interpretation, storage, and subsequent comparison.

Summary of Evidence

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with optometrist or ophthalmologist image interpretation, the evidence includes systematic reviews and a randomized controlled trial (RCT). Relevant outcomes are test validity, change in disease status, and functional outcomes. Data from systematic reviews have demonstrated there is concordance between direct ophthalmoscopy and grading by mydriatic or non-mydriatic photography and remote evaluation. An RCT that compared a telemedicine screening program with traditional surveillance found that patients who were randomized to the telemedicine arm were more likely to undergo screening (95% vs. 44%). There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given evidence from the Early Treatment Diabetic Retinopathy Study that early retinopathy treatment improves outcomes, coupled with studies showing high concordance between the screening methods used in the Early Treatment Diabetic Retinopathy Study, and an RCT demonstrating higher uptake of screening with a telescreening strategy, a strong chain of evidence can be made that telescreening is associated with improved health outcomes. Digital imaging systems have the additional advantages of short examination time and the ability to perform the test in the primary care physician setting. For individuals who cannot or would not be able to access an eye care professional at the recommended screening intervals, the use of telescreening has a low risk and is very likely to increase the likelihood of retinopathy detection. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with automated image interpretation, the evidence includes studies comparing the validity of automated scoring of digital images to human image grading. Relevant outcomes are test validity, change in disease

status, and functional outcomes. Early detection of diabetic retinopathy is critical to vision preservation. The primary benefit of an automated screening system is to increase the rate of screening for a population that is seeing substantially increased rates of diabetes. A 2021 study found wide variability in diagnostic performance across 7 different artificial intelligence algorithms, indicating that each marketed software needs to be evaluated separately, in a diverse population, and with the specific camera and dilation specified. The version of the software, which can change frequently, is also key to evaluating performance characteristics. The pivotal study for the IDx-DR system met its predefined threshold when compared to the criterion standard of expert photography and image evaluation from a centralized site. The EyeArt versions 2.0 and 2.1.0 artificial intelligence software have been evaluated in a prospective pivotal trial and 2 large non-concurrent trials (30,000 and 100,000 encounters) in patients who had previously been screened as part of diabetic retinopathy screening programs. When used as an alternative to human grading, the sensitivity to detect diabetic retinopathy was above 90%. Detection of retinopathy (sensitivity) is the most critical feature for referral to an eye care specialist, and is highest in patients who have treatable disease. Annual screening would detect retinopathy as the disease progresses, mitigating the impact of false negatives. Automated annual screening at the same time as a routine diabetes check-up will improve health outcomes of patients with diabetes by increasing the rate of screening in accordance with the annual screening recommendation, thereby allowing earlier detection and treatment of diabetic retinopathy. This method minimizes delays in screening patients with diabetes, reduces strains on a limited resource of eye care specialists, and encourages referral to specialists for patients who screen positive for retinopathy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
5/2024	Annual policy review. References updated. Policy statements unchanged.
5/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
8/2021	Annual review. New medically necessary indications described. Automated image analysis may be considered medically necessary for screening for diabetic retinopathy. Effective 8/1/2021.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
1/2021	Clarified coding information
8/2020	Annual review. Investigational statement added on automated image analysis. Effective 8/1/2020.
4/2019	Annual review. Description, summary and references updated. Policy statements unchanged.
4/2018	Annual review. New references added
4/2017	Annual review. New references added
5/2016	Annual review. New references added
5/2016	Clarified coding information.
12/2014	Annual review. New references added.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
1/2014	Annual review. New references added
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
2/2012	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
9/2008	New policy describing covered and non-covered indications. Effective 9/1/2008.

1/2014	Annual review. New references added

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Garg S, Davis RM. Diabetic retinopathy screening update. Clin Diabetes. 2009;27(4):140-145.
2. Fundus photographic risk factors for progression of diabetic retinopathy. ETDRS report number 12. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology. May 1991; 98(5 Suppl): 823-33. PMID 2062515
3. Grading diabetic retinopathy from stereoscopic color fundus photographs--an extension of the modified Airlie House classification. ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology. May 1991; 98(5 Suppl): 786-806. PMID 2062513
4. American Diabetes Association. Standards of Medical Care in Diabetes-2020 Abridged for Primary Care Providers. Clin Diabetes. Jan 2020; 38(1): 10-38. PMID 31975748
5. Moss SE, Klein R, Kessler SD, et al. Comparison between ophthalmoscopy and fundus photography in determining severity of diabetic retinopathy. Ophthalmology. Jan 1985; 92(1): 62-7. PMID 2579361
6. Kinyoun JL, Martin DC, Fujimoto WY, et al. Ophthalmoscopy versus fundus photographs for detecting and grading diabetic retinopathy. Invest Ophthalmol Vis Sci. May 1992; 33(6): 1888-93. PMID 1582794
7. Shi L, Wu H, Dong J, et al. Telemedicine for detecting diabetic retinopathy: a systematic review and meta-analysis. Br J Ophthalmol. Jun 2015; 99(6): 823-31. PMID 25563767
8. Bragge P, Gruen RL, Chau M, et al. Screening for presence or absence of diabetic retinopathy: a meta-analysis. Arch Ophthalmol. Apr 2011; 129(4): 435-44. PMID 21149748
9. Mansberger SL, Sheppler C, Barker G, et al. Long-term Comparative Effectiveness of Telemedicine in Providing Diabetic Retinopathy Screening Examinations: A Randomized Clinical Trial. JAMA Ophthalmol. May 2015; 133(5): 518-25. PMID 25741666
10. Abràmoff MD, Lavin PT, Birch M, et al. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. NPJ Digit Med. 2018; 1: 39. PMID 31304320
11. U.S. Food and Drug Administration. EyeArt 510(k) Summary (K200667). August 3, 2020. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200667.pdf. Accessed February 20, 2024.
12. Ipp E, Liljenquist D, Bode B, et al. Pivotal Evaluation of an Artificial Intelligence System for Autonomous Detection of Referrable and Vision-Threatening Diabetic Retinopathy. JAMA Netw Open. Nov 01 2021; 4(11): e2134254. PMID 34779843
13. Bhaskaranand M, Ramachandra C, Bhat S, et al. The Value of Automated Diabetic Retinopathy Screening with the EyeArt System: A Study of More Than 100,000 Consecutive Encounters from People with Diabetes. Diabetes Technol Ther. Nov 2019; 21(11): 635-643. PMID 31335200
14. Heydon P, Egan C, Bolter L, et al. Prospective evaluation of an artificial intelligence-enabled algorithm for automated diabetic retinopathy screening of 30 000 patients. Br J Ophthalmol. May 2021; 105(5): 723-728. PMID 32606081
15. Lee AY, Yanagihara RT, Lee CS, et al. Multicenter, Head-to-Head, Real-World Validation Study of Seven Automated Artificial Intelligence Diabetic Retinopathy Screening Systems. Diabetes Care. May 2021; 44(5): 1168-1175. PMID 33402366
16. Kim TN, Aaberg MT, Li P, et al. Comparison of automated and expert human grading of diabetic retinopathy using smartphone-based retinal photography. Eye (Lond). Jan 2021; 35(1): 334-342. PMID 32341536
17. American Academy of Ophthalmology. Diabetic Retinopathy Preferred Practice Pattern. 2019. https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp. Accessed February 20, 2024.

18. Horton MB, Brady CJ, Cavallerano J, et al. Practice Guidelines for Ocular Telehealth-Diabetic Retinopathy, Third Edition. Telemed J E Health. Apr 2020; 26(4): 495-543. PMID 32209018
19. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Intraocular Photography (80.6). 1979; https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=56&ver=1. Accessed February 20, 2024.