Medical Coverage Policy | Retinal Telescreening for Diabetic Retinopathy

EFFECTIVE DATE: 09|01|2022
POLICY LAST UPDATED: 06|15|2022

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Retinal telescreening with digital imaging and manual grading of images performed by a primary care provider (PCP), optometrist or ophthalmologist may be considered medically necessary as a screening technique for the detection of diabetic retinopathy or for monitoring and management of disease in individuals diagnosed with diabetic retinopathy.

Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products
Retinal telescreening with digital imaging and manual grading of images performed by a primary care provider (PCP), optometrist or ophthalmologist may be considered medically necessary as a screening technique for the detection of diabetic retinopathy.

Retinal telescreening is considered not medically necessary for all other indications, including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy as the evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare Advantage Plans and Commercial Products
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.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable diagnostic testing and not medically necessary services benefits/coverage.

BACKGROUND

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. 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.

Regulatory Status

Several digital camera and transmission systems (see Table 1 for examples) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Digital image storage and data

communication systems that are designed to be utilized with a variety of cameras have also been cleared for marketing by the FDA. FDA product codes: HKI and NFJ.

Many artificial intelligence analysis systems are in use around the world. As of January 2022, 2 have received marketing clearance from the FDA (Table 2). In 2018, the FDA gave de novo clearance for the automated retinal analysis system (IDx-DR®) that uses artificial intelligence (DEN180001). IDx-DR is indicated "for use by health care providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400." EyeArt® retinal analysis software (Eyenuk) received marketing clearance through the FDA's 510(k)pathway in 2020. It is indicated for use with the Canon CR-2 AF and Canon CR-2 Plus AF cameras in both primary care and eye care settings. Use of automated retinal analysis of images obtained with other cameras would be considered off-label. FDA product code: PIB

CODING

Medicare Advantage Plans

The following code(s) are covered and separately reimbursed when filed by primary care provider (PCP), optometrist or ophthalmologist.

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

Commercial Products

The following code(s) is not medically necessary.

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

Medicare Advantage Plans and Commercial Products

The following code(s) are covered and separately reimbursed when filed by primary care provider (PCP), optometrist or ophthalmologist.

92229 Dilated retinal eye exam point of care automated analysis and report, unilateral or bilateral

92227* Remote imaging for detection of retinal disease (eg, retinopathy in a patient with diabetes) with analysis and report under physician supervision, unilateral or bilateral

***To ensure correct claims processing:**

- PCP's MUST include one of the Category II codes below. Claims filed without one of these additional CPT code(s) will not be reimbursed:
- For optometrists or ophthalmologists, use of CAT II codes is optional and will not impact claims processing.

2022F Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; with evidence of retinopathy (DM)

2023F Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy (DM)

It is incorrect coding to file 92227 and 92228 codes with modifier TC or 26 as the codes include the technical and interpretation and report components.

It is incorrect coding to file for these services using the following CPT code(s):

92250 Fundus Photography with physician review, interpretation and report, unilateral or bilateral

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, August 2022
Provider Update, July 2021
Provider Update, December 2020
Provider Update, August 2019
Provider Update, July 2018

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. PMID2062515
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 ResearchGroup. 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. May2015; 133(5): 518-25. PMID 25741666
10. Abramoff 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 January 18, 2022.
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 January 19, 2022.
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 January 19, 2022.

20. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for Ophthalmology: Posterior Segment Imaging (Extended Ophthalmoscopy and Fundus Photography) (L33567)
21. Centers for Medicare & Medicaid Services. Article - Billing and Coding: Ophthalmology: Posterior Segment Imaging (Extended Ophthalmoscopy and Fundus Photography) (A56726)

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS