Medical Coverage Policy | Retinal Telescreening for Diabetic Retinopathy

EFFECTIVE DATE: 03|01|2023
POLICY LAST REVIEWED: 05|15|2024

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 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.

Many artificial intelligence analysis systems are in use around the world. As of January 2022, 2 have received marketing clearance from the FDA. 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.

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.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) is covered and not separately reimbursed for both professional and institutional providers:

92227 Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral

Medicare Advantage Plans

The following CPT 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

92229 Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral (Text revised 1/01/2023)

Commercial Products

The following CPT code(s) are covered when used a screening technique for the **detection only** of diabetic retinopathy 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

92229 Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, 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.

RELATED POLICIES

Non-Reimbursable Health Service Codes

PUBLISHED

Provider Update, July 2024
Provider Update, January/May 2023
Provider Update, August 2022
Provider Update, July 2021
Provider Update, December 2020

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