Medical Coverage Policy | Retinal Telescreening for Diabetic Retinopathy

EFFECTIVE DATE:09|01|2017
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OVERVIEW
Retinopathy telescreening and risk assessment with digital imaging systems are used 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 by trained readers, storage, and subsequent comparison

MEDICAL CRITERIA
Not applicable.

PRIOR AUTHORIZATION
Not applicable.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial
Retinal telescreening with digital imaging and manual grading of images performed by an 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 BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial
Retinal telescreening with digital imaging and manual grading of images performed by a 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

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 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 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 nonproliferative abnormalities to proliferative diabetic retinopathy (PDR), 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 (DME) and PDR. At its earliest stage (nonproliferative retinopathy), the retina develops microaneurysms, intraretinal hemorrhages, and focal areas of retinal ischemia. With 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 PDR 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 nonproliferative 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.

Screening

There is potential value in screening for diabetic retinopathy because diabetic retinopathy has few visual or ocular symptoms until vision loss develops. Because treatments are primarily aimed at preventing vision loss, and retinopathy can be asymptomatic, it is important to detect disease and begin treatment early in the process. Annual dilated, indirect ophthalmoscopy, coupled with biomicroscopy or 7-standard field stereoscopic 30□ fundus photography, has been considered the screening technique of choice. Because these techniques require a dedicated visit to a competent eye care professional, typically an ophthalmologist, retinopathy screening is underutilized. This underuse has resulted in the exploration of remote retinal imaging, using film or digital photography, as an alternative to direct ophthalmic examination of the retina.

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 (VEGF) production, but are associated with serious adverse events including cataracts and glaucoma, with damage to the optic nerve. Corticosteroids also can worsen diabetes control. VEGF inhibitors (eg ranibizumab, bevacizumab, pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), are being evaluated for the treatment of DME and PDR.

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 (nonmydriatic) dilating 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. 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.

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with optometrist or ophthalmologist image interpretation, the evidence includes retrospective studies comparing the accuracy of digital screening with standard methods, systematic reviews of these studies, and 1 randomized controlled trial (RCT). Relevant outcomes include test accuracy and validity, change in disease status, and functional outcomes. A number of studies have reported on the agreement between direct ophthalmoscopy and photography and between standard film and digital imaging in terms of the presence and stage of retinopathy. The studies have generally found high levels of agreement between retinal examination and imaging. There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given evidence from the large Early Treatment Diabetic Retinopathy Study (ETDRS) that early retinopathy treatment improves outcomes, coupled with studies showing high concordance between the screening methods used in ETDRS and 1 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 interv technology results in a meaningful 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 retrospective studies comparing the accuracy of automated scoring of digital images with standard methods. Relevant outcomes include test accuracy and validity, change in disease status, and functional outcomes. The available studies have tended to report high sensitivity with moderate specificity, although there is variability across studies. In addition, available studies have reported on different automated interpretation systems. These scoring systems have potential to improve screening in the primary care setting. However, given the variability in test characteristics across different systems, there is uncertainty about the accuracy of automated scoring systems in practice. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 and are currently available (product codes: HKI and NFJ). Several Brand names are IRIS Intelligent Retinal Imaging System™, DigiScope®, The Fundus AutoImager , ImageNet™ Digital Imaging System, and Zeiss FF450 Fundus Camera and the VISUPAC Digital Imaging System

CODING

Note: it is incorrect coding to file for these services using 92250 Fundus Photography with physican review, interpretation and report, unilateral or bilateral

Blue CHiP for Medicare

The following codes are covered when filed by optometrist or ophthalmologist

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

92228 Remote imaging for monitoring and management of active retinal disease (eg, diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral

Commercial

The following codes are covered when filed by optometrist or ophthalmologist

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

The following code is not medically necessary
92228 Remote imaging for monitoring and management of active retinal disease (e.g., diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral

RELATED POLICIES
None

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