Clinical Policy Title: Retinal telescreening for diabetic retinopathy

Clinical Policy Number: 10.01.01

Effective Date: July 1, 2016
Initial Review Date: April 27, 2016
Most Recent Review Date: April 3, 2018
Next Review Date: April 2019

Policy contains:
- Diabetic retinopathy (DR).
- Retinal telescreening.

Related policies:

CP# 06.02.02 Outpatient diabetes self-management training
CP# 18.01.02 Telehealth

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of diabetic retinopathy (DR) telescreening for DR screening, as an alternative to on-site retinopathy screening by an ophthalmologist or optometrist, to be clinically proven and, therefore, medically necessary when the following criteria are met (Villena 2011, Raman 2014, Neubauer 2008):

- Members older than nine years of age with type one diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within three to five years after the onset of diabetes. (Clinical judgment should be used when applying the above criteria to individual members who are under 10 years of age during the prepubertal duration of diabetes, which may be important in the development of microvascular complications.)
- Members with type two diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes is made.
• Subsequent examinations for both type one and type two diabetic patients who do not have any type of nonproliferative diabetic retinopathy (NPDR), proliferative diabetic retinopathy (PDR), or macular edema should be repeated annually by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. *

• Pregnant women with pre-existing diabetes should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of DR. *

• Pregnant women with type one and type two diabetes should have an initial evaluation soon after conception and early in the first trimester and the recommended follow-up for no retinopathy to mild or moderate NPDR every three to 12 months, and for severe NPDR or worse every one to three months.

• Retina telescreening systems are only applicable for individuals who do not have prior-known DR.

• Retinal telescreening is not a replacement for a comprehensive eye examination.

• According to the American Academy of Ophthalmology (AAO) Diabetic Retinopathy updated 2016 Preferred Practice Pattern guidelines, referral to an ophthalmologist is required when there is any NPDR, PDR, or macular edema.

*Items do not apply to women who develop gestational diabetes because such individuals are not at increased risk for DR.

This screening program will follow established guidelines as stated by the American Academy of Ophthalmology 2016 Preferred Practice Pattern guidelines which states the established guideline that should be followed is documented in the publication Telehealth Practice Recommendations for Diabetic Retinopathy, American Telemedicine Association, second edition. Telemed J E Health 2011;17:814-837 5/26/16fp.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other retinopathy telescreenings not used for screening DR are not medically necessary.

• Retinopathy telescreening for following the progression of disease in members who are diagnosed with DR is found to be experimental and investigational.

• Screening or evaluating retinal conditions other than for DR, including, but not limited to, macular degeneration/edema, for screening for retinopathy of prematurity, and for all other indications show insufficient evidence of their clinical value for these indications.

• Final automated retinal screening images should be graded for diabetic retinopathy using a manual process.

Alternative covered services:
Diabetic retinopathy (DR) is a leading cause of vision loss in the United States and occurs as a result of pathologic changes of the retinal vasculature. In 2005 – 2008, the estimated crude prevalence among Americans over the age of 40 with diabetes was 28.5 percent. Although the prevalence of vision-threatening DR is approximately 4.4 percent, the number of affected Americans 40 years or older is expected to triple from 1.2 million in 2005 to 3.4 million in 2050. The prevalence and severity of DR increases with the duration of diabetes; however, it is inversely correlated to glycemic and blood pressure control. Moderate vision loss is most commonly related to retinal leakage within the macula, while severe vision loss usually occurs as a result of neovascularization (PDR) with subsequent hemorrhage or fibrosis.

Early identification and treatment of DR is important since treatment is cost-effective and it reduces vision loss. The American Academy of Ophthalmologists, the American Optometric Association, and the American Diabetes Association recommend an annual dilated eye examination for all people with diabetes, and more frequent eye examinations for people with known DR. Other researchers argue that the frequency of examinations should be stratified to an individual’s risk of progression and vision loss.

The mainstay of DR treatment is aimed at reducing the risk of onset and limiting the progression of the disease. Therefore, retinal assessments should be performed regularly to determine the presence and degree of DR, glycemic control should be optimized, and known risk factors such as blood pressure, dyslipidemia, elevated cholesterol, renal disease, and abdominal obesity should be controlled. Direct ocular therapy should be prescribed when indicated, while vision rehabilitation and low vision aids should to be used to maximize vision if there is a loss.

Until recently, the primary treatment for DR has been focal or grid laser of the retina. Serial intravitreal injections of triamcinolone have been introduced as a treatment option as they have been shown to be effective at reducing diabetic macular edema (DME); however, their use is becoming less common due to significant adverse effects including elevated intraocular pressure and cataract formation. Ranibizumab and bevacizumab are being used with increasing frequency for the treatment of DME; however, they have not yet been approved by the U.S. Food and Drug Administration (FDA) for use in this condition. The recommended treatment of PDR remains panretinal photocoagulation with vitrectomy surgery performed when necessary. It is important to note that treatment of DR is not always aimed at restoration of pre-disease visual acuity, but rather at limiting further deterioration. Patients may report a decrease in visual acuity immediately after therapy, which may manifest in low initial perceptions of treatment satisfaction. However, results from the Early Treatment Diabetic Retinopathy Study (ETDRS) demonstrate that early treatment with either panretinal photocoagulation or vitrectomy prevents long-term disability due to blindness.

DR telescreening systems involve taking digital pictures of the retina of diabetic patients in the primary care physician’s office, and electronically transmitting these pictures to a reading center for evaluation for DR
and macular edema by trained non-physician technicians. Because DR telescreening can be performed in conjunction with a primary care physician office visit without referral to an ophthalmologist or optometrist, these systems have the potential to improve compliance with retinopathy screening. A cost-effectiveness analysis performed by the British National Health Service Centre for Reviews and Dissemination concluded that screening using a digital camera may be more accurate than screening by the general practitioner, and offers an opportunity to reduce costs of diabetic screening, especially as the costs of digital cameras come down. The UK NHS National Coordinating Centre for Health Technology Assessment (NCCHTA) has initiated a primary research project on the value of digital imaging in DR.

A variety of techniques can be used to detect and classify DR, including direct and indirect ophthalmoscopy, stereoscopic color film fundus photography, fluorescein angiography, and mydriatic or nonmydriatic digital color or monochromatic photography. Ophthalmoscopy is the most commonly used technique to screen for DR. However, undilated ophthalmoscopy, especially that done by non-ophthalmologists, has poor sensitivity relative to seven-field stereoscopic color photography. Under typical clinical conditions, direct ophthalmoscopy done by non-ophthalmologists has a sensitivity of approximately 50 percent for the detection of proliferative retinopathy.

The gold standard for the detection and classification of DR is stereoscopic color fundus photographs in seven standard fields, as defined by the ETDRS group. Although this technique is accurate and reproducible, it is labor intensive and requires skilled photographers; skilled photograph readers; and sophisticated photography equipment, film processing, and archiving. The turnaround time from acquisition of the data to interpretation can take weeks in clinical trials. Finally, from the patient’s perspective, it can be time consuming and uncomfortable. In short, seven-field stereoscopic fundus photography is not an ideal screening technique, but it can serve as the standard with which to compare other screening technologies.

When compared with ophthalmoscopy, however, single-field fundus photography has the potential to improve the quality of the evaluation and the numbers of patients evaluated. The use of nonmydriatic fundus photography systems represents a compromise. Although it is apparent that mydriasis improves image quality and sensitivity, particularly in older patients, it is uncertain whether this is outweighed by the disadvantage of dilation related to patient compliance. In other words, the diminished sensitivity of a nonmydriatic photograph may be acceptable if more patients complete the process.

No single modality satisfies all the requirements for a screening program. Currently the preferred method for screening is a retinal photographic service based on digital systems. In any one region, the screening program that is adopted is likely to be a compromise between efficacy of the method, the existing infrastructure, and local expertise.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other
evidence-based practice centers.

- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 12, 2018. Search terms were: “ophthalmology,” “diabetic retinopathy,” “photography,” and “retina.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Treatment modalities exist that can prevent or delay the onset of DR, and prevent loss of vision, in a large proportion of patients with diabetes. The diabetic control and complication trial (DCCT) established that intensive diabetes management to obtain near-euglycemic control can prevent and delay the progression of DR in patients with diabetes. Timely laser photocoagulation therapy can also prevent loss of vision in a large proportion of patients with severe NPDR and PDR and/or macular edema. Since some patients with vision-threatening pathologies may not have symptoms, ongoing evaluation for retinopathy is a valuable and required strategy.

An American Academy of Ophthalmology Preferred Practice Pattern on Diabetic Retinopathy (American Academy of Ophthalmology, 2016) states: "Some studies have shown that screening programs using digital images taken with or without dilation may enable early detection of diabetic retinopathy along with an appropriate referral. Digital cameras with stereoscopic capabilities are useful for identifying subtle neovascularization and macular edema. Studies have found a positive association between participating in a photographic screening program and subsequent adherence to receiving recommended comprehensive dilated eye examinations by a clinician. Of course, such screening programs are more relevant when access to ophthalmic care is limited. Screening programs should follow established guidelines. Given the known gap in accessibility of direct ophthalmologic screening, fundus photographic screening programs may help increase the chances that at-risk individuals will be promptly referred for more detailed evaluation and management."

Screening strategies depend on the rates of appearance and progression of DR and on risk factors that alter these rates. Vision-threatening retinopathy virtually never appears in type 1 patients in the first three to five years of diabetes or before puberty. Over the subsequent two decades, nearly all type 1 patients develop retinopathy. Up to 21 percent of patients with type 2 diabetes have recently been found to have
retinopathy at the time of first diagnosis of diabetes, and most develop some degree of retinopathy over subsequent decades.

The evidence suggests that either conventional 35-mm color photography or digital imaging systems can meet the relevant quality standards for annual eye examination to detect DR, with the advantage that image acquisition can be performed in the primary care setting. Questions regarding the accuracy of imaging that involves fewer than seven fields or does not involve dilation of the pupil require additional study; currently available evidence suggests that the seven-field imaging, either with conventional 35-mm color film or with digital cameras, provides the highest sensitivity.

Policy updates:

A prospective trial (n=51) compared the nonmydriatic 200 degrees ultra-widefield scanning laser ophthalmoscope versus onsite mydriatic ophthalmologic examination for diabetic retinopathy (Neubauer 2008). All imagess were obtained with an undilated pupil, and no additional clinical information was used for evaluation. A total of five images (9.8 percent) were not gradable due to insufficient quality. Clinically four eyes had PDR, while nine had none, five mild, 19 moderate and 14 severe nonproliferative diseases. Of the gradable 46 images, a clinically significant macular edema was present in 28 eyes clinically. On Optomap, all eyes with PDR were detected as being proliferative, and a sensitivity of 94 percent at a specificity of 100% was obtained for all graders to detect more than mild DR. Agreement between Optomap retinopathy grading and clinical assessment was good with unweighted kappas of 0.68, 0.68 and 0.51. Assessment of sensitivities was 93, 93 and 89 percent at specificities of 89, 72 and 83 percent. The authors concluded that the Optomap panoramic 200 nonmydriatic images are of sufficient quality to assess DR and therefore fulfill the basic requirements for telescreening programs.

Summary of clinical evidence:

<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Villena JE, et al. (2011) | **Key points:**  
  - Of 311 patients screened, appropriate retinal images were obtained in 222 subjects (93.2 percent).  
  - DR was detected in 282 patients (23.1 percent) (95 percent confidence interval [CI]: 20.71 – 25.44); 249 patients (20.4 percent) (95 percent CI: 18.1 – 22.6) had nonproliferative DR and 33 (2.7 percent) (95 percent CI: 1.8 – 3.6) had proliferative DR. In 32 patients (11.3 percent), DR was unilateral.  
  - The frequency of DR was the same in both sexes.  
  - Prevalence of blindness was twice as frequent in patients with DR as in those without it (9.4 percent and 4.6 percent, respectively) (P = 0.001).  
  - The frequency of DR at diagnosis was 3.5 percent and it increased with the duration of diabetes.  
  - DR was more frequent in patients with arterial hypertension, macrovascular or microvascular complications, and hemoglobin A1C (HbA1C) >7.0 percent and in those treated with insulin or sulfonylureas.  
  - It was less prevalent in those with HbA1C <7.0 percent, with greater body mass index, and who had been treated with metformin. |
The prevalence of DR in patients with type 2 diabetes was 23.1 percent. Nonproliferative retinopathy accounted for 77.0 percent of cases. Although less prevalent than in a previous report, it doubled the frequency of blindness in the people affected. A national DR screening program should be considered to detect this prevalent condition early and treat it in a timely fashion.

Raman R, et al. (2014)

How accurate is the diagnosis of DR on telescreening?

Key points:
- Compared were the prevalence of DR between an ophthalmologist-based and an ophthalmologist-led model on two different samples of people self-reporting with diabetes in rural South India. 3,522 people with diabetes mellitus underwent ophthalmologist-based DR screening and 4,456 people with diabetes underwent ophthalmologist-led (telescreening) DR screening.
- In the ophthalmologist-led program (telescreening), fundus photographs were transmitted to the base hospital for further evaluation and grading.
- A total of 519 people (14.7 percent) were diagnosed to have DR in the ophthalmologist-based model, and 853 people (19.1 percent) in the ophthalmologist-led model (p <0.0001).
- More sight-threatening retinopathies were found in the ophthalmologist-led model than in the ophthalmologist-based model (6.3 percent versus 5 percent).
- The ophthalmologist-led (telescreening) model did not underestimate the prevalence of DR.
- The authors concluded, because telescreening obviates the need for travel by an ophthalmologist, it is a good method for DR screening in rural areas of India.

Neubauer (2008)

Nonmydriatic screening for diabetic retinopathy by ultra-widefield scanning laser ophthalmoscope

Key points:
- A prospective trial (n=51) compared the nonmydriatic 200 degrees ultra-widefield scanning laser ophthalmoscope versus onsite mydriatic ophthalmologic examination for diabetic retinopathy.
- All images were obtained with an undilated pupil, and no additional clinical information was used for evaluation.
- A total of five images (9.8%) were not gradable due to insufficient quality.
- Clinically four eyes had PDR, while nine had none, five mild, 19 moderate and 14 severe nonproliferative diseases.
- Of the gradable 46 images, a clinically significant macular edema was present in 28 eyes clinically.
- On Optomap, all eyes with PDR were detected as being proliferative, and a sensitivity of 94% at a specificity of 100% was obtained for all graders to detect more than mild DR.
- Agreement between Optomap retinopathy grading and clinical assessment was good with unweighted kappas of 0.68, 0.68 and 0.51.
- Assessment of sensitivities was 93, 93 and 89% at specificities of 89, 72 and 83%.
- The authors concluded that the Optomap panoramic 200 nonmydriatic images are of sufficient quality to assess DR and therefore fulfill the basic requirements for telescreening programs.

References

Professional society guidelines/other:


Peer-reviewed references:


CMS National Coverage Determinations (NCDs):

80.6 Intraocular photography. CMS Medicare Coverage Database Web site. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=56&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=intraocular+photography&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAACAAACAAAAA&. Accessed February 12, 2018.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.
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