Anthem

Clinical UM Guideline

Subject: Retinal Telescreening Systems
Guideline #: CG-MED-35
Status: Reviewed

Publish Date: 04/10/2024
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Description

This document addresses retinal telescreening in the outpatient setting, including its use for the detection of diabetic retinopathy.

Note: Please see the following related document for additional information:

- CG-MED-47 Fundus Photography

Clinical Indications

Medically Necessary:

Retinal telescreening systems in the outpatient setting are considered **medically necessary** for annual diabetic retinopathy screening as an alternative to retinopathy screening by an ophthalmologist or optometrist when **both** of the following criteria are met:

- The individual does not have prior known diabetic retinopathy; **and**
- The imaging and grading technique is performed with a U.S. Food and Drug Administration (FDA) approved device for retinal telescreening.

Not Medically Necessary:

All other uses of retinal telescreening systems in the outpatient setting are considered **not medically necessary,** including, but not limited to those listed below:

- To follow the progression of disease in individuals who have been diagnosed with diabetic retinopathy
- To screen or evaluate retinal conditions other than diabetic retinopathy, including, but not limited to macular degeneration.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
	For the following codes when specified as screening for detection of disease:
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
92229	Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral
ICD-10 Diagnosis	
E08.00-E08.9	Diabetes mellitus due to underlying condition
E09.00-E09.9	Drug or chemical induced diabetes mellitus
E10.10-E10.9	Type 1 diabetes mellitus
E11.00-E11.9	Type 2 diabetes mellitus
E13.00-E13.9	Other specified diabetes mellitus
P70.2	Neonatal diabetes mellitus
Z00.00-Z00.01	Encounter for general adult medical examination
Z01.00-Z01.01	Encounter for examination of eyes and vision
Z13.1	Encounter for screening for diabetes mellitus
Z13.5	Encounter for screening for eye and ear disorders

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed, or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Diabetic retinopathy is a disorder of the retina that eventually will develop to some extent in nearly all individuals with long-standing diabetes. Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults aged 20-74 years in the United States. An estimated 4.1 million Americans are affected by retinopathy with 899,000 affected by vision-threatening retinopathy. It is a highly specific vascular complication occurring in type 1 and type 2 diabetes, with the prevalence being highly dependent upon the duration of the disease. Nearly all individuals with type 1 diabetes and over 60% of individuals with type 2 diabetes who have had lengthy courses of this disease will have some degree of retinopathy. Despite the high pervasiveness of the disease, screening rates are suboptimal, only 11-71% of individuals with diabetes in the U.S receive annual dilated examinations. Screening rates are lower in underserved and minority populations (Ipp, 2021; Patel, 2022).

The American Diabetes Association (ADA) standard of care (2024) recommends a comprehensive eye examination with an

ophthalmologist or optometrist within 5 years after diagnosis for adults with type 1 diabetes and at the time of diagnosis for adults with type 2 diabetes. Annual or biennial screening is recommended in the presence of well controlled glycemia when there is no evidence of retinopathy. When any level of diabetic retinopathy is present, screenings should be replaced with dilated retinal examinations completed by an ophthalmologist or optometrist performed at least annually. Recommendations for children and adolescents with diabetes differ slightly as there is a low risk of development of vision-threatening retinal lesions in individuals under the age of 12. For individuals aged 11 or older, or when puberty has started, a comprehensive eye examination is recommended 3 to 5 years following a diagnosis of type of diabetes. The ADA recommendations include repeat examinations every 2 to 4 years, depending on the level of risk (ElSayed, 2023). The ADA notes that retinal photography, with remote reading or use of an FDA-approved artificial intelligence algorithm, can be an appropriate screening tool for all age groups. Programs which use retinal photography should include pathways for timely referrals for comprehensive eye examinations when indicated (ElSayed, 2023).

Clinical manifestations begin with retinal microaneurysms and hemorrhages progressing to retinal capillary nonperfusion, occlusion of retinal vessels, pathological proliferation of fragile retinal vessels (neovascularization) and macular edema. Visual loss results primarily from macular edema, macular capillary nonperfusion, vitreous hemorrhage, and distortion or traction detachment of the retina. Laser photocoagulation surgery is an established treatment for diabetic retinopathy.

Diabetic retinopathy has few symptoms until vision loss occurs. Ongoing evaluation for retinopathy is of critical importance to allow for early treatment. The “gold standards” for diabetic retinopathy screening include ophthalmological exam by a trained professional using pupillary dilation and stereoscopic 7-field fundus photography by a trained photographer and interpreted by an experienced grader. In a 2014 Clinical Statement by the American Academy of Ophthalmology (AAO) for Screening for Diabetic Retinopathy, it is stated that “Appropriately validated digital imaging technology can be a sensitive and effective screening tool to identify patients with diabetic retinopathy for referral for ophthalmic evaluation and management.” However, it is also noted that “Further studies will be required to assess the implementation of programs that are based on single-field fundus photography in a real clinical setting to confirm the clinical effectiveness and cost-effectiveness of these techniques in improving population visual outcomes.” Access to a specialist and the appropriate equipment may not always be available, as such, retinal telescreening systems have emerged as a way to increase screening for diabetic retinopathy.

Retinal telescreening systems use specialized digital imaging cameras to photograph the retina to obtain wide-field stereoscopic retinal images. The retinal images can be stored and transferred to a central imaging evaluation center for reading by a trained technician. The results are subsequently transmitted back to the physician’s office. The imaging can be performed in conjunction with a primary care physician office visit without referral to an ophthalmologist or optometrist. This technology is an alternative to conventional ophthalmologic examination of the retina. Individuals who live in rural areas may have limited access to ophthalmology specialists and this may result in lower rates for screening for diabetic retinopathy. Outreach clinics are a way to screen those individuals without access to specialized equipment and expertise. Community-based, outreach models for diabetic retinopathy screening have been applied in rural and remote areas of Australia, Canada, and the United Kingdom. The model consists of a photograph being taken instead of a direct exam. The photographic images are taken without pupil dilation. The outreach model has the potential to increase the screening of at-risk individuals in areas where direct access to ophthalmologic specialists is limited. This technology is an alternative to conventional ophthalmologic examination of the retina.

An analysis of the literature shows high-resolution digital stereoscopic fundus photographs are comparable in accuracy to plain film stereoscopic fundus photographs (the gold standard). One study with 290 diabetic participants analyzed the detection of threshold events requiring referral, which consisted of an Early Treatment Diabetic Retinopathy Study (EDTRS) severity level greater than or equal to 53, questionable or definite clinically significant macular edema in either eye, or ungradable images (Fransen, 2002). The sensitivity of digital photography in detecting threshold events was 98.2% and the specificity was 89.7%. The positive predictive value was 69.5% and the negative predictive value was 99.5% for this sample. Other studies have reported high diagnostic accuracy in identifying diabetic retinopathy via telescreening systems (Bragge, 2011; Date, 2019; Farley, 2008; Ku, 2013; Mehraban Far, 2022; Murgatroyd, 2004; Zimmer-Galler, 2006).

The “gold standard” of 35 mm film photography has been shown in studies to be equivalent or superior to conventional ophthalmoscopy in detecting diabetic retinopathy. Thus, the relative equivalence of digital imaging to plain film photography shows retinal telescreening systems, if they meet the criteria for medical necessity, can be a valid alternative to conventional exams by an eye specialist. In a 2015 literature review and analysis by Shi and colleagues, 20 articles involving 1960 participants were reviewed to determine the diagnostic accuracy of telemedicine in diabetic retinopathy. In detecting the absence of diabetic retinopathy, low- or high-risk proliferative diabetic retinopathy, the pooled sensitivity was 80%. In the detection of mild or moderate non-proliferative diabetic retinopathy, the sensitivity exceeded 70%. It was also noted that the diagnostic accuracy was higher when the digital images were obtained through mydriasis than through non-mydriasis. While there were some limitations in this literature review, including heterogeneity, 3 of the included studies had unavailable raw data, and the data was only from published papers, telemedicine can be used widely for diabetic retinopathy screening.

In a 2015 study by Mansberger and colleagues, 567 participants were randomized to receive either telemedicine with a nonmydriatic camera in a primary care clinic (n=296) or traditional surveillance with an eye care professional (n=271) and were followed for 5 years. After 2 years, telemedicine was offered to all participants. During the 6-month or less time period, the telemedicine group participants were more likely to receive a diabetic retinopathy screening examination when compared with the traditional surveillance group (94.6% [280/296] versus 43.9% [119/271]; 95% confidence interval [CI], 46.6%-54.8%; p<0.001). The telemedicine group was also more likely to receive diabetic retinopathy screening exams in the 6- to 18-month timeframe (53.0% [157/296] versus 33.2% [90/271]; 95% CI, 16.5%-23.1%; p<0.001). After 2 years when telemedicine was offered to both groups, there was no difference between the groups in the percentage of diabetic retinopathy screening examinations. These results suggest that primary care clinics can use telemedicine to screen for diabetic retinopathy and monitor for worsening of disease.

Digital retinal imaging can be obtained by a trained non-physician photographer in the primary care physician’s office, thus obviating the need for separate annual ophthalmology evaluation for diabetic retinopathy. This may increase an individual’s adherence to annual retinal exams, a critical component of diabetic care. Digital imaging appears to be a highly sensitive test and may be considered an important option for increasing the screening rate. However, it should be noted retinal telescreening is not a substitute for a comprehensive ophthalmologic examination.

Once the digital retinal images are obtained, the grading of the images is done via a manual process by trained retinal specialists or trained readers. With an estimated 4.1 million Americans affected by retinopathy, there has been interest in the development of software algorithms for automated screening of retinal images to identify individuals with diabetic retinopathy in need of referral to the retinal specialist. Algorithms have been developed capable of reading the digital retinal signals of diabetic retinopathy. One automated system, IDx-DR (Digital Diagnostics, Coralville, IA), has been reviewed and approved by the FDA’s premarket review pathway which is a regulatory pathway for some low- to moderate-risk novel devices for which there is no prior legally marketed device (FDA, 2018). The IDx-DR approval is for detection of greater than a mild level of diabetic retinopathy in adults who have diabetes.

In a 2018 study by van der Heijden and colleagues, the authors sought to determine how the performance of an automated device compared to retinal specialists when reading digital retinal images. In this study, three retinal specialists manually graded the images

using the International Clinical Diabetic Retinopathy Severity Scale (ICDR) classification score and the EURODIAB classification systems. The retinal specialists scores were then compared to the IDx-DR device. A total of 898 participants had images with sufficient quality for analysis. Using EURODIAB, referable diabetic retinopathy was diagnosed in 22 participants and using ICDR classification, referable diabetic retinopathy was diagnosed in 73 participants. When compared to human grading using EURODIAB, the IDx-DR device showed a sensitivity for referable diabetic retinopathy of 91% (95% CI: 0.69-0.98), specificity of 84% (95% CI: 0.81-0.86), positive predictive value of 12% (95% CI: 0.08-0.18) and negative predictive value of 100% (95% CI: 0.99-1.00). When compared to human grading using the ICDR classification, the IDx-DR system showed a sensitivity of 68% (95% CI: 0.56-0.79), specificity of 86% (95% CI: 0.84-0.88), positive predictive value of 30% (95% CI: 0.24-0.38), and negative predictive value of 97% (95% CI: 0.95-0.98). Approximately 70% of the retinal images which were classified as referable diabetic retinopathy based on the ICDR score were classified as no referable diabetic retinopathy by the retina specialists when using the EURODIAB score. There are limitations to this study which includes a small number of participants deemed to have referable diabetic retinopathy. The authors note the number of participants identified with diabetic retinopathy in the study was lower than expected and speculate the smaller number of referrals was due to tight blood glucose control in the targeted population. There were technical problems at the beginning of the study which resulted in some of the grading of the images being lost. There were also some retinal images that were considered of insufficient quality by the IDx-DR device. One of the strengths of the study was that it was implemented in clinical practice. The study was able to include participants with all possible presentations of diabetic retinopathy. Use of the automated grading system is expected to result in a large reduction in retinal images that require human grading.

In 2020, another automated device, EyeArt (Eyenuk, Inc., Los Angeles, CA) was granted FDA approval for marketing in the US. In 2017, Tufail and colleagues evaluated the performance of three automated diabetic retinopathy image assessment systems, Retmarker (not marketed in the US), iGradingM (not marketed in the US) and the EyeArt. In total, 102,856 retinal images from 20,258 consecutive individual's screened were included for analysis. Sensitivity for EyeArt's ability to detect any retinopathy was 94.7% (95% CI: 94.2-95.2%), for referable retinopathy (human graded as either ungradable, maculopathy, preproliferative, or proliferative) was 93.8% (95% CI: 92.9-94.6%), and for proliferative retinopathy alone was 99.6% (95% CI: 97.0-99.9%). The EyeArt's specificity, was just 20%. Although the specificity was relatively low, the proportion of potentially sight-threatening retinopathy correctly identified was 93.8%, and of the most severe retinopathy (proliferative retinopathy), virtually all cases received the appropriate classification. EyeArt is indicated by the FDA for use:

> …by healthcare providers to automatically detect more than mild diabetic retinopathy and vison-threatening diabetic retinopathy (severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy and/or diabetic macular edema) in eyes of adults diagnosed with diabetes who have not been previously diagnosed with more than mild diabetic retinopathy.

In 2021, Ipp and associates reported on a multicenter cross-sectional diagnostic study which compared the detection rate of diabetic retinopathy using an artificial intelligence (AI) system against the clinical reference standard. Individuals with diabetes had two digital color fundus photographs (CFP) taken of each eye before undergoing dilatation and CFP imaging by certified staff (n=893). The AI system results were compared against the standard imaging photographs in order to identify more-than-mild diabetic retinopathy (mtmDR) up to vision threatening diabetic retinopathy (vtDR). In the identification of mtmDR, the AI system reported a sensitivity of 95.5% and a specificity of 85.0%. In the identification of vtDR, the AI system reported a sensitivity of 95.1% and a specificity of 89.0%. The study took place in multiple sites including primary care, general ophthalmology and retina specialty centers. There were similar sensitivity, specificity, and imageability rates for mtmDR and up to vtDR at the primary care and eye care sites. The authors note that automated AI screening system can eliminate reported barriers summarizing:

> In this study, comparable efficacy was demonstrated by the AI system across primary care and eye care facilities. Therefore, patients can receive prompt, accurate, and consistent detection of mtmDR or vtDR at their facility of choice without specialist involvement. Furthermore, this prompt detection at primary care may help eliminate the disparity in care for patients who live far from eye care specialists. The rapid on-site eye-level DR detection by the AI system enables prompt diagnosis allowing for same-day referral requests for follow-up care, improving the chances of preventing vision loss.

Retinal telescreening for other conditions

The use of teleretinal screening programs have been evaluated for other retinal diseases. In a systematic review and meta-analysis, Mehraban Far and associates (2022) compared the diagnostic accuracy of teleretinal screening and face-to-face examination in either diabetic retinopathy or age-related macular degeneration (AMD). In the three studies (n=697) evaluating the diagnostic accuracy of telescreening for AMD, the calculated sensitivity was 0.71 (95% CI: 0.49 to 0.86) and the calculated specificity was 0.88 (95% CI: 0.85 to 0.90). While the initial results may be encouraging, the current body of evidence has not shown that teleretinal screening is an accurate tool similar to a traditional office-based examination. Furthermore, routine screening of visual acuity, including for causes such as AMD, is not generally in accordance with standards of medical practice, whether in be in an office-based setting, or through teleretinal screening.

Screening recommendations

In 2015, an estimated 2.91 million individuals aged 60 or older were living with impaired visual acuity (best corrected visual acuity (BCVA) worse than 20/40 but better than 20/200). An additional 760,000 individuals were living with blindness (BCVA of 20/200 or worse). There is limited evidence to support screening for visual impairment in asymptomatic older adults. The United States Preventive Services Task Force (USPSTF) and the Canadian Task Force on Preventive Health Care (CTFPHC) does not recommend screening for impaired vision in adults aged 65 and older without vision problems or risk factors for impaired vision (USPSTF, 2022; Wilson, 2018).

The AAO practice parameter (2020) recommends comprehensive medical eye examinations in asymptomatic individuals without eye disease risk factors with increased age-based frequency:

- Up to age 40 years: Every 5 to 10 years
- 40 to 54 years: Every 2 to 4 years
- 55 to 64 years: Every 1 to 3 years
- 65 years or older: Every 1 to 2 years

Comprehensive medical eye examinations serve to detect ocular disease, visual dysfunction, or ophthalmic signs of systemic disease at a treatable stage in order to prevent or slow the progression of disease and preserve visual function. Eye examinations can lead to the diagnosis of systemic disease, possibly preventing serious illness or premature death.

Summary

The value of annual diabetic retinopathy screening is well supported by the clinical evidence. The use of retinal telescreening provides expanded access to this service while the diagnostic accuracy is supported by the clinical evidence. Currently there is a

paucity of evidence to support retinal telescreening for macular degeneration and eye conditions other than diabetic retinopathy in the outpatient setting.

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Government Agency, Medical Society, and Other Authoritative Publications:

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion and References sections.
Reviewed	02/16/2023	MPTAC review. Updated Discussion and References sections.
	12/28/2022	Updated Coding section with 01/01/2023 CPT changes; revised descriptor for 92229.
Reviewed	02/17/2022	MPTAC review. Updated Discussion and References sections.
Reviewed	02/11/2021	MPTAC review. Updated Discussion/General Information, References and Index sections. Reformatted Coding section; added diagnosis codes.
	12/29/2020	Updated Coding section; added CPT 92229 effective 01/01/2021.
	12/16/2020	Updated Coding section with 01/01/2021 CPT changes; revised descriptors.
Reviewed	05/14/2020	MPTAC review. Updated References sections.
Reviewed	06/06/2019	MPTAC review. Updated Discussion/General Information and References sections.
Revised	07/26/2018	MPTAC review. Removed “the final images are graded for diabetic retinopathy using a manual process” from the MN statement. Removed “when the final retinal images are graded using an automatic process only (for example, artificial neural networks)” from the NMN statement. Clarified the scope is for use in the outpatient setting. Updated Description, Discussion/General Information, References, and Index sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated References section.
Reviewed	02/02/2017	MPTAC review. Updated Background/Overview and References sections.
Revised	02/04/2016	MPTAC review. Updated Clinical Indications to remove requirement of Diabetic Retinopathy Study seven standard fields (DRS7) from the Medically Necessary and Not Medically Necessary statements. Updated Description, Discussion/General Information and Reference sections.
Reviewed	11/05/2015	MPTAC review. Updated Description, Discussion/General Information and Reference sections. Removed ICD-9 codes from Coding section.
Revised	11/13/2014	MPTAC review. Updated Discussion/General Information and References.
Reviewed	11/14/2013	MPTAC review. Updated Description and References.
Reviewed	11/08/2012	MPTAC review. Updated Discussion/General Information, References and Index.
Revised	11/17/2011	MPTAC review. Removal from medical necessity statement “Pharmacologic dilation of the pupils takes place prior to image capture.” Removal from not medically necessary statement “To evaluate the retina through undilated pupils.” Updated Discussion/General Information and References. Updated Coding section; removed S0625 deleted 12/31/2011.
Reviewed	11/18/2010	MPTAC review. Updated Discussion/General Information, References and Index. Updated Coding section with 01/01/2011 CPT changes.
Reviewed	02/25/2010	MPTAC review. Updated References and Web Sites.
Reviewed	02/26/2009	MPTAC review. Updated References and Web Sites. Removed Place of Service.
	10/01/2008	Updated Coding section with 10/01/2008 ICD-9 changes.
Reviewed	02/21/2008	MPTAC review. References updated.
New	03/08/2007	MPTAC review. Initial document development. Transferred content from MED.00052 Retinal Telescreening Systems; Investigational/Not Medically Necessary indications changed to Not Medically Necessary. References updated.

services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.