

POLICY TITLE	RETINAL TELESCREENING FOR DIABETIC RETINOPATHY
POLICY NUMBER	MP 2.086

CLINICAL BENEFIT	☑ MINIMIZE SAFETY RISK OR CONCERN.
	☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.
	☐ ASSURE APPROPRIATE LEVEL OF CARE.
	☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.
	☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.
	☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	3/1/2025

POLICYPRODUCT VARIATIONSDESCRIPTION/BACKGROUNDRATIONALEDEFINITIONSBENEFIT VARIATIONSDISCLAIMERCODING INFORMATIONREFERENCESPOLICY HISTORY

#### I. POLICY

Retinal Telescreening with digital imaging and manual grading of images may be considered **medically necessary** as a screening technique for the detection of diabetic retinopathy.

Digital retinal imaging with image interpretation by artificial intelligence software that is approved by the U.S. Food and Drug Administration (e.g., IDX-DR, EyeArt) may be considered **medically necessary** for screening for diabetic retinopathy.

Retinal Telescreening is considered **investigational** for all other indications, including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

#### Cross-references:

MP 2.028 Eye Care

MP 2.056 Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma

MP 2.085 Optical Coherence Tomography OCT of the Anterior Eye Segment

#### **II. PRODUCT VARIATIONS**

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.



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**FEP PPO** - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <a href="https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies">https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies</a>

#### III. DESCRIPTION/BACKGROUND

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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 by trained readers, storage, and subsequent comparison.

#### **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 duration of diabetes and severity of hyperglycemia. After 20 years of disease, almost all patients with type 1 and greater 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 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.

#### **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



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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 (e.g., ranibizumab, bevacizumab, pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), are being evaluated 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 (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.

#### **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

Table 1. Digital Camera and Transmission Systems Cleared by FDA for Retinal Telescreening

Clearance
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RetinaVue™ Network REF 901108 PACS Medical Image System	Welch Allyn	K181016	2018
IRIS Intelligent Retinal Imaging System™	Ora Inc.	K141922	2015
EyeSuite Imaging	Haag-Streit AG	K142423	2014
CenterVue Digital Retinography System (DRS)	Welch Allyn	K101935	2010
ImageNet™ Digital Imaging System	Topcon Medical Systems		2008
The Fundus Autolmager	Visual Pathways		2002
Zeiss FF450 Fundus Camera and the VISUPAC Digital Imaging System	Carl Zeiss Meditec		2001
DigiScope®	Eye Tel Imaging with Johns Hopkins Medicine		1999

FDA: Food and Drug Administration.

**Table 2. Automated Analysis Systems** 

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Automated Analysis Systems	Manufacturer	Clearance	Approved
IDx-DR Artificial Intelligence Analyzer for	IDx, LLC	DEN180001	2018
the Topcon NW400			
EyeArt®	Eyenuk	K200667	2020

## IV. RATIONALE Top

#### SUMMARY OF EVIDENCE

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



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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.

V. Definitions <u>Top</u>

N/A

VI. BENEFIT VARIATIONS Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and



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providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER Top

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

#### **VIII. CODING INFORMATION**

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
92227	92228	92229						

Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved.

ICD-10-CM Diagnosis Codes	Description
E08.00	Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E08.10	Diabetes mellitus due to underlying condition with ketoacidosis without coma
E08.11	Diabetes mellitus due to underlying condition with ketoacidosis with coma
E08.21	Diabetes mellitus due to underlying condition with diabetic nephropathy
E08.22	Diabetes mellitus due to underlying condition with diabetic chronic kidney disease
E08.29	Diabetes mellitus due to underlying condition with other diabetic kidney complication



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ICD-10-CM Diagnosis Codes	Description
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E08.37X1	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, right eye
E08.37X2	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, left eye
E08.37X3	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, bilateral
E08.37X9	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, unspecified eye
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene
E08.59	Diabetes mellitus due to underlying condition with other circulatory complications
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy
E08.620	Diabetes mellitus due to underlying condition with diabetic dermatitis
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E08.628	Diabetes mellitus due to underlying condition with other skin complications
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E08.638	Diabetes mellitus due to underlying condition with other oral complications
E08.649	Diabetes mellitus due to underlying condition with other specified complication
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia



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ICD-10-CM Diagnosis Codes	Description
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E09.00	Drug or chemical induced diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E09.10	Drug or chemical induced diabetes mellitus with ketoacidosis without coma
E09.21	Drug or chemical induced diabetes mellitus with diabetic nephropathy
E09.22	Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease
E09.29	Drug or chemical induced diabetes mellitus with other diabetic kidney complication
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E09.37X1	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E09.37X2	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E09.37X3	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E09.37X9	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E09.39	Drug or chemical induced diabetes mellitus with other diabetic ophthalmic complication
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy
E09.44	Drug or chemical induced diabetes mellitus with neurological complications with diabetic amyotrophy
E09.49	Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication
E09.51	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy without gangrene
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E09.59	Drug or chemical induced diabetes mellitus with other circulatory complications
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic



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ICD-10-CM Diagnosis Codes	Description
	arthropathy
E09.618	Drug or chemical induced diabetes mellitus with other diabetic arthropathy
E09.620	Drug or chemical induced diabetes mellitus with diabetic dermatitis
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E09.628	Drug or chemical induced diabetes mellitus with other skin complications
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E09.638	Drug or chemical induced diabetes mellitus with other oral complications
E09.649	Drug or chemical induced diabetes mellitus with hypoglycemia without coma
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E09.69	Drug or chemical induced diabetes mellitus with other specified complication
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E09.9	Drug or chemical induced diabetes mellitus without complications
E10.A0	Type 1 diabetes mellitus, presymptomatic, unspecified
E10.A1	Type 1 diabetes mellitus, presymptomatic, Stage 1
E10.A2	Type 1 diabetes mellitus, presymptomatic, Stage 2
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma
E11.21	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral



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ICD-10-CM Diagnosis Codes	Description
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E13.00	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E13.10	Other specified diabetes mellitus with ketoacidosis without coma
E13.21	Other specified diabetes mellitus with diabetic nephropathy
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease



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ICD-10-CM Diagnosis Codes	Description
E13.29	Other specified diabetes mellitus with other diabetic kidney complication
E13.36	Other specified diabetes mellitus with diabetic cataract
E13.37X1	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E13.37X2	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E13.37X9	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E13.39	Other specified diabetes mellitus with other diabetic ophthalmic complication
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.51	Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
E13.59	Other specified diabetes mellitus with other circulatory complications
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy
E13.618	Other specified diabetes mellitus with other diabetic arthropathy
E13.620	Other specified diabetes mellitus with diabetic dermatitis
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
E13.628	Other specified diabetes mellitus with other skin complications
E13.630	Other specified diabetes mellitus with periodontal disease
E13.638	Other specified diabetes mellitus with other oral complications
E13.649	Other specified diabetes mellitus with hypoglycemia without coma
E13.65	Other specified diabetes mellitus with hyperglycemia



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ICD-10-CM Diagnosis Codes	Description
E13.69	Other specified diabetes mellitus with other specified complication
E13.8	Other specified diabetes mellitus with unspecified complications
E13.9	Other specified diabetes mellitus without complications

IX. REFERENCES Top

- 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. PMID 2062515
- 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 Research Group. 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. May 2015; 133(5): 518-25. PMID 25741666
- Abràmoff MD, Lavin PT, Birch M, et al. Pivotal trial of an autonomous Al-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.
- 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



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## **MEDICAL POLICY**

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- 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 intelligenceenabled 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.
- 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
- 20. Blue Cross Blue Shield Association Medical Policy Reference Manual. 9.03.13, Retinal Telescreening for Diabetic Retinopathy April 2024.

#### X. POLICY HISTORY

MP 2.086	<b>09/30/2020 Minor Review.</b> Added statement that Digital retinal imaging with automated image interpretation is considered investigational for the detection of diabetic retinopathy.
	<b>07/13/2021 Minor Review.</b> Changed automated image interpretation from INV to MN, Moved codes 92228 and 92229 from INV to MN. Background/rationale updated. References updated. Coding reviewed and updated. Tables 1 and 2 are updated.
	<b>02/24/2022 Minor Review.</b> Added Intraocular Photography to policy with criteria. Added statement for not medically necessary for retinopathy screening in individuals treated with chloroquine and hydroxychlorquine. Policy guideline added. Summary of Evidence updated. Product Variations updated. References added and updated.
	<b>06/10/2022 Administrative Update.</b> ICD-10 codes added to policy.
	<b>08/10/2022 Minor Review.</b> Criteria around Intraocular and fundus photography removed. Code 92250 removed. ICD-10 codes updated. Policy will just be around Retinal Telescreening. References updated.
	04/14/2023 Consensus Review. No change to policy statement. Coding
	reviewed. References updated.
	<b>08/19/2024 Administrative Update.</b> Added ICD-10 codes E10.A0-E10.A2 eff 10/1/2024.



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11/14/2024 Consensus Review. No change to policy statement. Coding
reviewed. References updated.

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