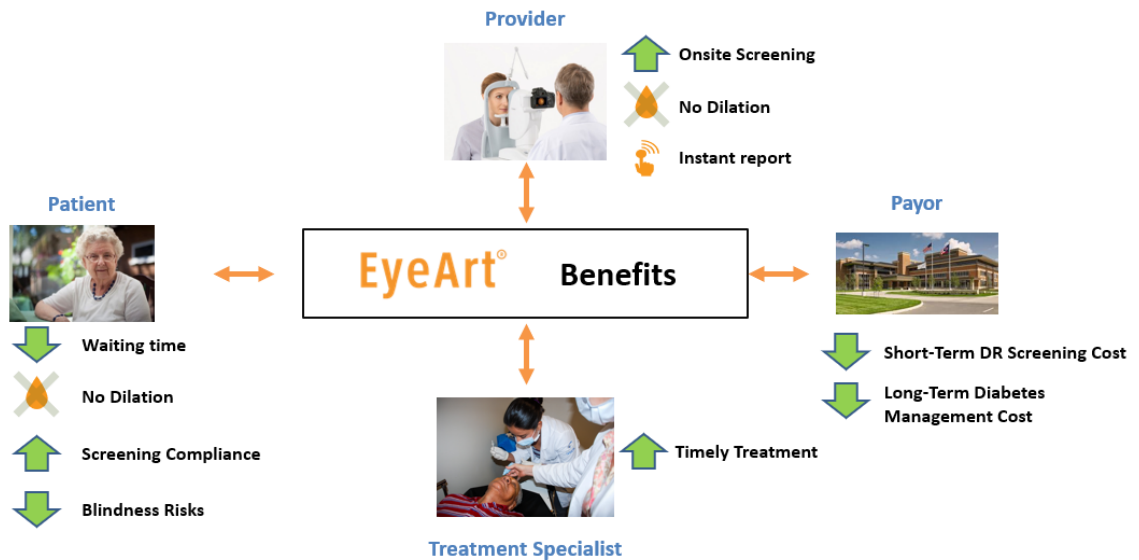


EYENUK		Diabetic Retinopathy Screening Report
Patient Information		General Information
Patient ID: 123-456-789		Referring Location: Dr. Lee's
Patient Name: Emily S. Jones		Referring Provider: Dr. Charlie Halliwell
Date of Birth: 23-Nov-1992		Encounter ID: 1007-456-789
Gender: Male		EyeArt Control ID: 565145
Submission Date: 2019/03/15 13:45		Dilation Status: Not Dilated
Diabetic Retinopathy Screening Summary		
Screening Results: Positive for vision threatening diabetic retinopathy.		
Right Eye: Signs of Moderate NPDR (2-3) without macular edema detected		Left Eye: Signs of Moderate NPDR (2-3) with macular edema detected
Macula Centered		Macula Centered
Optic Centered		Optic Centered
*Do not use the above thumbnail images for diagnostic purposes.		
ICD-10 Diagnosis Codes		
E11.3391 Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye		
E11.3312 Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye		
Plan and Recommendations		
Immediate referral to ophthalmologist for evaluation of vision threatening diabetic retinopathy.		
As per ADA recommendations, emphasize the importance of controlling blood sugar, cholesterol and blood pressure as well as the importance of routine follow-up with an ophthalmologist regardless of whether visual symptoms are present or absent.		
Report Date: 2019/03/15 12:47		

rDR Positive

vtDR Positive



EYEART PROSPECTIVE PIVOTAL CLINICAL TRIAL

942 patients, 15 centers, ETDRS gold standard

	More than mild DR	Vision-threatening DR
Sensitivity	96%	92%
Specificity	88%	94%
Imageability at primary care sites	97% (dilate if needed) 90% (first attempt without dilation)	



Indications for Use

The EyeArt system is indicated for use by healthcare providers to automatically detect referable diabetic retinopathy (DR) and vision-threatening DR in eyes of adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.

EyeArt has U.S. FDA 510(k) clearance, CE marking as class 2a medical device, and Health Canada license.