**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**: 2609 (New Measure)**

Measure Title: **Diabetes Care for People with Serious Mental Illness: Eye Exam**

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: **7/25/2014**

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| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process

**Patients who received an eye exam**

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**Not applicable.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

**Not applicable.**

This is

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

**The rate in this measure relates to the desired outcome in the following way: Patient with serious mental illness (schizophrenia, bipolar I disorder, or major depression) and diabetes 🡪 Health care provider conducts eye examination (retinal) 🡪 Eye exam results are evaluated 🡪 Eye exam results are positive for diabetic retinopathy 🡪 Health provider and patient discuss behavior modifications and/or treatment options 🡪 Patient modifies his/her behavior and/or receives treatment for diabetic retinopathy 🡪 Patient has significant reduction or prevention of diabetic retinopathy and improved long-term clinical outcome/quality of life (desired outcome).**

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

**American Academy of Ophthalmology Retina Panel. (2008). Preferred Practice Pattern Guidelines. Diabetic Retinopathy. American Academy of Ophthalmology. 1-43.**

**URL:** [**http://one.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp--september-2008-4th-print**](http://one.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp--september-2008-4th-print)

**American Diabetes Association. (2014). Standards of Medical Care in Diabetes. Guideline available from:** [**http://care.diabetesjournals.org/content/37/Supplement\_1/S14.full.pdf+html**](http://care.diabetesjournals.org/content/37/Supplement_1/S14.full.pdf+html)**, accessed June 11, 2014.**

**American Geriatrics Society. (2003). Guidelines for Improving the Care of the Older Person with Diabetes Mellitus). California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes. American Geriatrics Society. 51(5 Suppl). JAGS.**

**URL:** [**http://web.missouri.edu/~brownmb/pt415/case/burnett/diabetes-guide-AGS.pdf**](http://web.missouri.edu/~brownmb/pt415/case/burnett/diabetes-guide-AGS.pdf)

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**American Academy of Ophthalmology - 2008**

**Recommendations for Examination (Page 23):**

* **Visual acuity (Grade A: I)**
* **Slit-lamp biomicroscopy (Grade A:III)**
* **Intraocular pressure (Grade A:III)**
* **Gonioscopy when indicated (Grade A:III)**
* **Dilated funduscopy including stereoscopic examination of posterior pole (Grade A:I)**
* **Examination of the peripheral retina and vitreous (Grade A:III)**
  + **A dilated pupil is necessary to ensure optimal examination of the retina, because only 50% of eyes are correctly classified for the presence and severity of retinopathy through undilated pupils (Grade A:I). Slit-lamp biomicroscopy with accessory lenses is the recommended method to evaluate retinopathy in the posterior pole and midperipheral retina (Grade A:III). The examination of the peripheral retina is best performed with indirect ophthalmoscopy or with slit-lamp biomicroscopy, combined with a contact lens (Grade A:III).**

**Recommended Eye Examination Schedule for Patients with Diabetes:**

**Type 1:**

* **3-5 years after diagnosis (Grade A:II)**
* **Recommended follow up: yearly (Grade A:II)**

**Type 2:**

* **Recommended time of first examination : at time of diagnosis (Grade A:II)**
* **Recommended follow up: yearly (Grade A:II)**

**Prior to Pregnancy (Type 1 or Type 2):**

* **Recommended time of first examination: prior to conception and early in the first trimester**
* **Recommended follow up: (No retinopathy to mild or moderate NPDR: every 3-12 months (Grade A:I), Severe NPDR or worse: ever 1-3 months (Grade A:I)**

**American Diabetes Association (Standards of Care) – 2014**

**Retinopathy Screening (pg. Pg. S44):**

* **Adults with type I diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes (Grade B)**
* **Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes (Grade B)**
* **If there is no evidence of retinopathy for one or more exams, then exams every 2 years may be considered. If diabetic retinopathy is present, subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. If retinopathy is progressing or sight threatening, then examinations will be required more frequently (Grade B)**
* **High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While a retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional (Grade E)**
* **Women with preexisting diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum (Grade B)**

**Treatment:**

* **Promptly refer patients with any level of macular edema, severe NPDR, or any PDR to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy (Grade A)**
* **Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high risk PDR, clinically significant macular edema, and in some cases severe NPDR (Grade A)**
* **Anti-vascular endothelial growth factor (VEGF) therapy is indicated for diabetic macular edema (Grade A)**
* **The presence of retinopathy is not a contradiction to aspirin therapy for cardioprotection, as this therapy does not increase the risk of retinal hemorrhage (Grade A)**

**General Recommendations:**

* **Optimize HbA1c control to reduce the risk or slow the progression of retinopathy (Grade A)**
* **Optimize blood pressure control to reduce the risk or slow the progression of retinopathy (Grade A)**

**American Geriatrics Society Guidelines - 2003**

**Eye Care Recommendations (Page S272):**

* **The older adult who has new-onset diabetes should have an initial screening dilated-eye examination performed by an eye-care specialist with funduscopy training (Grade IIB)**
* **The older adult who has diabetes and who is at high risk for eye disease (symptoms of eye disease present; evidence of retinopathy, glaucoma, or cataracts on an initial dilated-eye examination or subsequent examinations during the prior 2 years; HbA1c ≥8.0%; type 1 diabetes; or blood pressure ≥140/80) on the prior examination should have a screening dilated-eye examination performed by an eye-care specialist with funduscopy training at least annually. Persons at lower risk may have a dilated-eye examination at least every 2 years (Grade IIB)**

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

**American Academy of Ophthalmology Grading System:**

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| **Ratings of Importance** | |
| **Rating** | **Definition** |
| **Level A** | **Defined as Most Important** |

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| **Ratings of Strength of Evidence** | |
| **Rating** | **Definition** |
| **Level I** | **Includes evidence obtained from at least one properly conducted, well-designed, randomized, controlled trial. It could include a meta-analyses of randomized controlled trials** |
| **Level II** | **Includes evidence obtained from the following:**   * **Well-designed controlled trials without randomization** * **Well-designed cohort or case-control analytic studies, preferably from more than one center,** * **Multiple-time series with or without the intervention** |
| **Level III** | **Includes evidence obtained from one of the following:**   * **Descriptive studies,** * **Case reports,** * **Reports or expert committees/organizations (e.g., PPP panel consensus with external peer review)** |

**American Diabetes Association Grading System:**

|  |  |
| --- | --- |
| **Level of Evidence** | **Description** |
| **A** | **Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted multicenter trial,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Center for Evidence-Based Medicine at the University of Oxford** |
| **Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted trial at one or more institutions,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **B** | **Supportive evidence from well-conducted cohort studies:**   * **Evidence from a well-conducted prospective cohort study or registry,** * **Evidence from a well-conducted meta-analysis of cohort studies** |
| **Supportive evidence from a well-conducted case-control study** |
| **E** | **Expert consensus or clinical experience** |

**American Geriatric Society Grading System:**

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| --- | --- |
| **Quality of Evidence** | |
| **Level** | **Description** |
| **Level II** | **Evidence from at least one well-designed clinical trial without randomization, from cohort or case controlled analytic studies, from multiple time-series studies, or from dramatic results in uncontrolled experiments** |

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| **Strength of Evidence** | |
| **Strength** | **Description** |
| **B** | **Moderate evidence to support the use of a recommendation; clinicians should do this most of the time** |

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**American Academy of Ophthalmology Grading System:**

|  |  |
| --- | --- |
| **Ratings of Importance** | |
| **Rating** | **Definition** |
| **Level B** | **Defined as moderately important** |
| **Level C** | **Defined as relevant, but not critical** |

**American Diabetes Association Grading System:**

|  |  |
| --- | --- |
| **Grade** | **Level of Evidence** |
| **C** | **Supportive evidence from poorly controlled or uncontrolled studies:**   * **Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results** * **Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)** * **Evidence from case series or case reports** |
| **Conflicting evidence with the weight of evidence supporting the recommendation** |

**American Geriatric Society Grading System:**

|  |  |
| --- | --- |
| **Quality of Evidence** | |
| **Level** | **Description** |
| **Level I** | **Evidence from at least one properly designed randomized, controlled trial** |
| **Level III** | **Evidence from respected authorities, based on clinical experience, descriptive studies, or reports of expert committee** |

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| --- | --- |
| **Strength of Evidence** | |
| **Strength** | **Description** |
| **A** | **Good evidence to support the use of recommendation; clinicians should do this all the time** |
| **C** | **Poor evidence to support or to reject the use of a recommendation; clinicians may or may not follow the recommendation** |
| **D** | **Moderate evidence against the use of a recommendation; clinicians should not do this** |
| **E** | **Good evidence against the use of a recommendation; clinicians should not do this** |

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**Not applicable.**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**Not applicable.**

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**Not applicable.**

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**Not applicable.**

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**Not applicable.**

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

**Not applicable.**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**Not applicable.**

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

**Not applicable.**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

**Evidence highlights the need and importance of eye health monitoring in diabetics, especially among vulnerable populations:**

**American Academy of Ophthalmology:**

**The American Academy of Ophthalmology offers both diagnosis and treatment guidelines for eye-related care in diabetic populations. In addition to taking a detailed history (duration of diabetes, past HbA1c control, medications, medical history, and ocular history), the American Academy of Ophthalmology recommends performing a full examination consisting of the following tests: visual acuity, slit-lamp biomicroscopy, intraocular pressure, gonioscopy when indicated, dilated funduscopy including stereoscopic examination of the posterior pole, and examination of the peripheral retina and vitreous. The American Academy of Ophthalmology also provides a recommended eye examination schedule for patients with diabetes (see section 1a.4.2).**

**American Diabetes Association:**

**The American Diabetes Association’s guidance is directed towards the performance of eye examinations for retinopathy on individuals with diabetes. Accordingly, the American Diabetes Association recommends prevention and mitigation of conditions that contribute to the development of diabetic retinopathy in addition to the screening of and treatment for eye conditions in diabetic populations.**

**American Geriatrics Society:**

**This evidence is structured on the performance of an eye examination on older adults with diabetes. Based on this evidence, older adults with new-onset diabetes should receive an initial screening dilated-eye exam performed by an eye-care specialist with funduscopy training. Additionally, those with diabetes at high risk for eye disease should receive an eye exam at least annually (those at a lower risk may receive an eye examination every two years).**

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

**American Academy of Ophthalmology Grading System:**

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| --- | --- |
| **Ratings of Importance** | |
| **Rating** | **Definition** |
| **Level A** | **Defined as Most Important** |

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| --- | --- |
| **Ratings of Strength of Evidence** | |
| **Rating** | **Definition** |
| **Level I** | **Includes evidence obtained from at least one properly conducted, well-designed, randomized, controlled trial. It could include a meta-analyses of randomized controlled trials** |
| **Level II** | **Includes evidence obtained from the following:**   * **Well-designed controlled trials without randomization** * **Well-designed cohort or case-control analytic studies, preferably from more than one center,** * **Multiple-time series with or without the intervention** |
| **Level III** | **Includes evidence obtained from one of the following:**   * **Descriptive studies,** * **Case reports,** * **Reports or expert committees/organizations (e.g., PPP panel consensus with external peer review)** |

**American Diabetes Association Grading System:**

|  |  |
| --- | --- |
| **Level of Evidence** | **Description** |
| **A** | **Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted multicenter trial,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Center for Evidence-Based Medicine at the University of Oxford** |
| **Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted trial at one or more institutions,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **B** | **Supportive evidence from well-conducted cohort studies:**   * **Evidence from a well-conducted prospective cohort study or registry,** * **Evidence from a well-conducted meta-analysis of cohort studies** |
| **Supportive evidence from a well-conducted case-control study** |
| **E** | **Expert consensus or clinical experience** |

**American Geriatric Society Grading System:**

|  |  |
| --- | --- |
| **Quality of Evidence** | |
| **Level** | **Description** |
| **Level II** | **Evidence from at least one well-designed clinical trial without randomization, from cohort or case controlled analytic studies, from multiple time-series studies, or from dramatic results in uncontrolled experiments** |

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| **Strength of Evidence** | |
| **Strength** | **Description** |
| **B** | **Moderate evidence to support the use of a recommendation; clinicians should do this most of the time** |

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**American Academy of Ophthalmology Grading System:**

|  |  |
| --- | --- |
| **Ratings of Importance** | |
| **Rating** | **Definition** |
| **Level B** | **Defined as moderately important** |
| **Level C** | **Defined as relevant, but not critical** |

**American Diabetes Association Grading System:**

|  |  |
| --- | --- |
| **Grade** | **Level of Evidence** |
| **C** | **Supportive evidence from poorly controlled or uncontrolled studies:**   * **Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results** * **Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)** * **Evidence from case series or case reports** |
| **Conflicting evidence with the weight of evidence supporting the recommendation** |

**American Geriatric Society Grading System:**

|  |  |
| --- | --- |
| **Quality of Evidence** | |
| **Level** | **Description** |
| **Level I** | **Evidence from at least one properly designed randomized, controlled trial** |
| **Level III** | **Evidence from respected authorities, based on clinical experience, descriptive studies, or reports of expert committee** |

|  |  |
| --- | --- |
| **Strength of Evidence** | |
| **Strength** | **Description** |
| **A** | **Good evidence to support the use of recommendation; clinicians should do this all the time** |
| **C** | **Poor evidence to support or to reject the use of a recommendation; clinicians may or may not follow the recommendation** |
| **D** | **Moderate evidence against the use of a recommendation; clinicians should not do this** |
| **E** | **Good evidence against the use of a recommendation; clinicians should not do this** |

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**:

* **American Academy of Ophthalmology: 1980-2010**
* **American Diabetes Associtaiton: 1976-2012**
* **American Geriatrics Society: 1978-2000**

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

**American Academy of Ophthalmology:**

**When developing their guidelines, the American Academy of Ophthalmology drew from evidence obtained from primarily randomized controlled trials, prospective studies, and evidence reviews.**

**Specifically, the American Academy of Ophthalmology reviewed:**

* **8 randomized controlled trials**
* **3 prospective cohort studies**
* **3 evidence reviews**
* **2 population based studies**
* **1 longitudinal study**
* **1 randomized trial**
* **1 clinical report**
* **1 retrospective cohort study**

**American Diabetes Association:**

**The American Diabetes Association’s retinopathy and eye examination guidelines are primarily based upon evidence obtained from randomized controlled trials and evidence reviews.**

**Specifically, the guidelines were based upon evidence obtained from:**

* **5 randomized controlled trials**
* **5 evidence reviews**
* **3 randomized trials**
* **1 multicenter trial**
* **1 prospective study**
* **1 longitudinal analyses**
* **1 population based cohort study**

**American Geriatrics Society:**

**The American Geriatrics Society’s retinopathy and eye examination guidelines are primarily based upon evidence obtained from randomized controlled trials. Specifically, two randomized clinical trials demonstrated that screening for and treatment of diabetic retinopathy has the potential to slow the progression of diabetic eye disease and permanent visual loss. Additionally, the American Geriatrics Society developed its guidelines cognizant of studies which have showed that the quality of diabetic retinopathy screening is highest among eye-care specialists. (Screening for Diabetic Retinopathy: articles reviewed – large clinical series and formal epidemiologic studies of defined populations, Effectiveness of screening and monitoring tests for diabetic retinopathy – a systematic review).**

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

**Overall, the quality of evidence supporting the guidelines and this measure is medium to strong with several randomized controlled trials and systematic reviews to support the performance of annual eye examination in diabetic patients.**

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

**The prevention of diabetic retinopathy and other diabetic-related eye conditions can be extremely cost effective by preventing the costs necessary for patients disabled with vision loss. Once identified during screening, treatment initiated for retinopathy may be 90% effective in preventing vision loss in diabetic patients (American Academy of Ophthalmology). Diabetic retinopathy and other diabetes-related eye complications are currently the number one cause of blindness among adults aged 20-74 years. Accordingly, effective screening for and management of such conditions has the potential to prevent or delay the onset of long-term vision loss in diabetic patients. Such screening efforts have been shown to be cost-effective for those at a high risk of retinopathy and may serve as a mechanism to identify patients who may be good candidates for laser photocoagulation surgery to prevent vision loss (American Diabetes Association). Randomized controlled trials have shown that screening for and treatment of diabetic retinopathy can reduce the progression of long term and permanent vision loss. Multiple studies and decision analytic models have demonstrated that eye examination and retinopathy screening is cost-effective for high risk individuals, However, it is important to note that annual screening for those at a low risk for retinopathy may not be cost-effective (thereby informing the less-frequent recommendations for low risk patients). Additionally, eye examination for diabetic retinopathy may also have the secondary effect of detecting other eye conditions such as cataracts, glaucoma, and refractive errors (American Geriatrics Society).**

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**One study (Hansen et al 2004) identified minimal harms associated with receiving dilated eye examinations. Minor discomforts may stem from having the eyes dilated. One additional harm may include the misclassification of the level of diabetic retinopathy due to possible false negative exam results. These harms can be mitigated with regular subsequent eye exams based on the guidelines. These potential harms do not out weight the benefits of having regular eye examinations to delay diabetic retinopathy.**

**Hansen AB, Hartvig, NV, Jensen, MS, Borch-Johnsen K, et al. (2004). Diabetic retinopathy screening using diabetic non-mydriatic fundus photography and automated image analysis. Acta Opthalmologica. 82(6): 666-672.**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

**There have been no new studies that contradict the current body of evidence.**

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

**Not applicable.**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

**Not applicable.**