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

**Measure Number** (*if previously endorsed*)**:** 0062

**Measure Title**: Comprehensive Diabetes Care: Medical Attention for Nephropathy

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Comprehensive Diabetes Care

**Date of Submission**: 4/9/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *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.*   * 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. * 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 Standing 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:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * 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. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **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 Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **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

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.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

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

Process: receiving a nephropathy screening test or having evidence of nephropathy during the measurement year.

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Adults with diabetes (type 1 or 2) >>> Nephropathy screening is performed or evidence of nephropathy is documented>>> Screening results are evaluated >>>Results indicative of nephropathy>>>Health provider determines treatment to delay progression of diabetic nephropathy>>>improvement in diabetes complications and quality of life.

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Table 1. American Diabetes Association (ADA) Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  American Diabetes Association. (2018). Standards of Medical Care in Diabetes – 2018. Diabetes Care 2018; 41(Suppl. 1): S105-S118; doi: 10.2337/dc18-S010  Guideline available from:  <http://care.diabetesjournals.org/content/41/Supplement_1>  2013 Submission  American Diabetes Association. (2013). Standards of Medical Care in Diabetes – 2013. Diabetes Care 2013; 36:S1-e4; doi: 10.2337/dc13-S001  Guideline available from:  <http://care.diabetesjournals.org/content/36/Supplement_1/S11> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2018 Submission  Pg. S105-106  “Screening   * At least once a year, assess urinary (e.g., spot urinary albumin-to-creatinine ratio) and estimated glomerular filtration rate in patients with type 1 diabetes with duration of ≥5 years, in all patients with type 2 diabetes, and in all patients with comorbid hypertension. (B)   Treatment   * In nonpregnant patients with diabetes and hypertension, either an ACE inhibitor or an angiotensin receptor blocker is recommended for those with modestly elevated urinary albumin–to–creatinine ratio (30–299 mg/g creatinine) (B) and is strongly recommended for those with urinary albumin–to creatinine ratio ≥300 mg/g creatinine and/or estimated glomerular filtration rate <60 mL/min/1.73 m2 (A) * Periodically monitor serum creatinine and potassium levels for the development of increased creatinine or changes in potassium when ACE inhibitors, angiotensin receptor blockers, or diuretics are used. (B) * Continued monitoring of urinary albumin–to–creatinine ratio in patients with albuminuria treated with an ACE inhibitor or an angiotensin receptor blocker is reasonable to assess the response to treatment and progression of diabetic kidney disease. (E) * An ACE inhibitor or an angiotensin receptor blocker is not recommended for the primary prevention of diabetic kidney disease in patients with diabetes who have normal blood pressure, normal urinary albumin–to–creatinine ratio (<30 mg/g creatinine), and normal estimated glomerular filtration rate. (B) * When estimated glomerular filtration rate is <60 mL/min/1.73 m2, evaluate and manage potential complications of chronic kidney disease. (E) * Patients should be referred for evaluation for renal replacement treatment if they have an estimated glomerular filtration rate <30 mL/min/1.73 m2. (A) * Promptly refer to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, and rapidly progressing kidney disease. (B)   2013 Submission  Pg. S7-S8  “Screening   * Perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients starting at diagnosis. (B) * Measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate glomerular filtration rate (GFR) and stage the level of chronic kidney disease (CKD), if present. (E)   Treatment   * In the treatment of the nonpregnant patient with modestly elevated (30–299 mg/day) (C) or higher levels (≥300 mg/day) of urinary albumin excretion, either ACE inhibitors or ARBs are recommended. (A) * Reduction of protein intake to 0.8–1.0g/kg body wt per day in individuals with diabetes and the earlier stages of CKD and to 0.8 g/kg body wt per day in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, GFR) and is recommended. (C) * When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of increased creatinine or changes in potassium. (E) * Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is reasonable. (E) * When eGFR is <60 mL/min/1.73 m2, evaluate and manage potential complications of CKD. (E) * Consider referral to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, or advanced kidney disease. (B)” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  Level of evidence and 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 Centre for Evidence-Based Medicine at 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, including:   * + 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  2013 Submission  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 Centre for Evidence-Based Medicine at 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, including:   * + 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   * 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 to historical controls)   + Evidence from case series or case reports   Conflicting evidence with the weight of evidence supporting the recommendation   * E:   Expert consensus or clinical experience |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  Level of Evidence & Description:   * 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 to historical controls)   + Evidence from case series or case reports   Conflicting evidence with the weight of evidence supporting the recommendation  2013 Submission  No additional grades aside from what is listed above |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The ADA does not provide information on the systematic review conducted to support its 2018 or 2013 guideline and the recommendations mentioned above. In lieu of the ADA systematic review, we provide information on two other systematic reviews that support the ADA’s recommendations in Table 4. |
| Estimates of benefit and consistency across studies | See Table 4 below |
| What harms were identified? | See Table 4 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

Table 2. American Association of Clinical Endocrinologists (AACE)

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  AACE/American College of Endocrinology (ACE). Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan-2015. 2015. Endocrine Practice. Vol 21 (Suppl1). URL:  <https://www.aace.com/files/dm-guidelines-ccp.pdf>  2013 Submission  AACE. Medical Guidelines for Clinical Practice For Developing A Diabetes Mellitus Comprehensive Care Plan. Endocrine Practice. 2011 Vol 17, Suppl 2: 1-53 **URL:** <http://journals.aace.com/doi/abs/10.4158/EP.17.S2.1> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2018 Submission  Pg. 16  “3.Q9 – Recommendation 28   * Beginning 5 years after diagnosis in patients with T1D (if diagnosed before age 30) or at diagnosis in patients with T2D and those with T1D diagnosed after age 30, annual assessment of serum creatinine to determine the estimated glomerular filtration rate (eGFR) and urine albumin excretion rate (AER) should be performed to identify, stage, and monitor progression of diabetic nephropathy (**Grade C; Best EL 3**). Patients with nephropathy should be counseled regarding the need for optimal glycemic control, blood pressure control, dyslipidemia control, and smoking cessation (**Grade B; Best EL 2**). In addition, they should have routine monitoring of albuminuria, kidney function electrolytes, and lipids (**Grade B; Best EL 2**). Associated conditions such as anemia and bone and mineral disorders should be assessed as kidney function declines (**Grade D; Best EL 4**). Referral to a nephrologist is recommended well before the need for renal replacement therapy (**Grade D; Best EL 4**).   2013 Submission  Pg. 11  ***“3.Q10.1. Diabetic Nephropathy***  **• R36.** Beginning 5 years after diagnosis in patients with T1DM and at diagnosis in patients with T2DM, an annual assessment of serum creatinine to estimate the glomerular filtration rate (GFR) and urine albumin excretion should be performed to identify, stage, and monitor progression of diabetic nephropathy (**Grade D; Best EL 4**). Patients with diabetic nephropathy should be counseled regarding the increased need for optimal glycemic control, blood pressure control, dyslipid­emia control, and smoking cessation (**Grade A; Best EL 1**). When therapy with angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers is initi­ated, renal function and serum potassium levels must be closely monitored (**Grade A; Best EL 1**).” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  **Numerical Descriptor (evidence level)**  2 Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT)  2 Nonrandomized controlled trial (NRCT)  2 Prospective cohort study (PCS)  2 Retrospective case-control study (RCCS)  3 Cross-sectional study (CSS)  3 Surveillance study (registries, surveys, epidemiologic study, retrospective chart  review, mathematical modeling of database) (SS)  3 Consecutive case series (CCS)  3 Single case reports (SCR)  4 No evidence (theory, opinion, consensus, review, or preclinical study) (NE)  a Adapted from (1): *Endocr Pract*. 2010;16:270-283.  b 1, strong evidence; 2, intermediate evidence; 3, weak evidence; and 4, no evidence.  2013 Submission  1 Meta-analysis of randomized controlled trials (MRCT)  1 Randomized controlled trials (RCT)  4 No evidence (theory, opinion, consensus, review, or preclinical study) (NE)  a Adapted from (1): *Endocr Pract*. 2010;16:270-283.  b 1, strong evidence; 2, intermediate evidence; 3, weak evidence; and 4, no evidence. |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  1 Meta-analysis of randomized controlled trials (MRCT)  1 Randomized controlled trials (RCT)  a Adapted from (1): *Endocr Pract*. 2010;16:270-283.  b 1, strong evidence; 2, intermediate evidence; 3, weak evidence; and 4, no evidence.  2013 Submission  2 Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT)  2 Nonrandomized controlled trial (NRCT)  2 Prospective cohort study (PCS)  2 Retrospective case-control study (RCCS)  3 Cross-sectional study (CSS)  3 Surveillance study (registries, surveys, epidemiologic study, retrospective chart  review, mathematical modeling of database) (SS)  3 Consecutive case series (CCS)  3 Single case reports (SCR)  a Adapted from (1): *Endocr Pract*. 2010;16:270-283.  b 1, strong evidence; 2, intermediate evidence; 3, weak evidence; and 4, no evidence. |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  Grading of Recommendations; How Different Evidence Levels  Can Be Mapped to the Same Recommendation Grade   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Best evidence level | Subjective factor impact | Two-thirds consensus | Mapping | Recommendation Grade | | 2 | None | Yes | Direct | B | | 1 | Negative | Yes | Adjust down | B | | 3 | Positive | Yes | Adjust up | B | | 3 | None | Yes | Direct | C | | 2 | Negative | Yes | Adjust down | C | | 4 | Positive | Yes | Adjust up | C | | 4 | None | Yes | Direct | D | | 3 | Negative | Yes | Adjust down | D | | 1,2,3,4 | Positive | No | Adjust down | D |   Starting with the left column, best evidence levels (BELs), subjective factors, and con­sensus map to recommendation grades in the right column. When subjective factors have little or no impact (“none”), then the BEL is directly mapped to recommendation grades. When subjective factors have a strong impact, then recommendation grades may be adjusted up (“positive” impact) or down (“negative” impact). If a two-thirds consensus cannot be reached, then the recommendation grade is D. NA, not applicable (regardless of the presence or absence of strong subjective factors, the absence of a two-thirds con­sensus mandates a recommendation grade D).  Reprinted from reference 1: *Endocr Pract*. 2010;16:270-283.  2013 Submission  Grading of Recommendations; How Different Evidence Levels  Can Be Mapped to the Same Recommendation Grade   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Best evidence level | Subjective factor impact | Two-thirds consensus | Mapping | Recommendation grade | | 1 | None | Yes | Direct | A | | 2 | Positive | Yes | Adjust up | A | | 4 | None | Yes | Direct | D | | 3 | Negative | Yes | Adjust down | D | | 1, 2, 3, 4 | NA | No | Adjust down | D |   Starting with the left column, best evidence levels (BELs), subjective factors, and con­sensus map to recommendation grades in the right column. When subjective factors have little or no impact (“none”), then the BEL is directly mapped to recommendation grades. When subjective factors have a strong impact, then recommendation grades may be adjusted up (“positive” impact) or down (“negative” impact). If a two-thirds consensus cannot be reached, then the recommendation grade is D. NA, not applicable (regardless of the presence or absence of strong subjective factors, the absence of a two-thirds con­sensus mandates a recommendation grade D). |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Best evidence level | Subjective factor impact | Two-thirds consensus | Mapping | Recommendation Grade | | 1 | None | Yes | Direct | A | | 2 | Positive | Yes | Adjust up | A |   2013 Submission   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Best evidence level | Subjective factor impact | Two-thirds consensus | Mapping | Recommendation Grade | | 2 | None | Yes | Direct | B | | 1 | Negative | Yes | Adjust down | B | | 3 | Positive | Yes | Adjust up | B | | 3 | None | Yes | Direct | C | | 2 | Negative | Yes | Adjust down | C | | 4 | Positive | Yes | Adjust up | C | |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The AACE guideline evidence review is listed in Table 4. |
| Estimates of benefit and consistency across studies | See Table 4 below |
| What harms were identified? | See Table 4 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | See Table 4 below |

Table 3. American Geriatrics Society (AGS) Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  American Geriatrics Society (AGS). 2013. Guidelines Abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 Update. American Geriatrics Society Panel on the Care for Older Adults with Diabetes Mellitus. Journal of American Geriatric Society. 2013 November; 61 (11): 2020-2026. Doi:10.1111/jgs.12514  URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064258/pdf/nihms583558.pdf>  2013 Submission  American Geriatrics Society (AGS). 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. May 2013; 51, Suppl 5, JAGS  URL: |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2018 Submission  “A test for the presence of albuminuria should be performed in individuals at  diagnosis of type 2 DM. After the initial screening and in the absence of previously demonstrated macro- or microalbuminuria, a test for the presence of  microalbuminuria should be performed annually. (IIIA)  2013 Submission  Pg. 272  “A test for the presence of microalbumin should be performed at diagnosis in patients with type 2 DM. After the initial screening and in the absence of previously demonstrated macro- or microalbuminuria, a  test for the presence of microalbumin should be performed annually. (IIIA)” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  Quality of Evidence   * Level III: Evidence from respected authorities based on clinical experience, descriptive studies, or reports of expert comittees   Strength of Evidence   * A: Good evidence to support the use of a recommendation; clinicians should do this all the time   2013 Submission  Same as above |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  Quality of Evidence   * Level I: Evidence from at least one properly randomized controlled trial * Level II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series, or from dramatic results in uncontrolled experiments   Strength of Evidence   * B: Moderate evidence to support the use of a recommendation clinicians “should do this most of 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   2013 Submission  Same as above |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The AGS does not provide information on the systematic review conducted to support its guideline and the recommendations mentioned above. In lieu of the AGS systematic review, we provide information on two other systematic reviews that support the AGS’s recommendations in Table 4. |
| Estimates of benefit and consistency across studies | See Table 4 below |
| What harms were identified? | See Table 4 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | See Table 4 below |

Table 4. Additional Systematic Reviews

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| **Citations** | AACE Diabetes Care Plan Guidelines. Endocrine Practice. 2011. Vol 17, Suppl 2: 1-53  **URL:** http://journals.aace.com/doi/abs/10.4158/EP.17.S2.1 | Li R, Zhang P, Barker LE, Chowdhury FM, Zhang X. Cost-effectiveness of interventions to prevent and control diabetes mellitus: a systematic review. Diabetes Care. 2010. 33(8):1872-1894.  **URL:** <http://care.diabetesjournals.org/content/33/8/1872.full.pdf+html> |
| **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?** | This measure assesses whether diabetic patients were screened for nephropathy if they did not already have evidence of nephropathy during the measurement year. The measure is based on clinical guidelines. Evidence provides support for the timing of screenings, specific screening tests, and treatment based on screening results. Screening tests recommended by the guideline include microalbumin and serum creatinine. Treatment recommendations from the guidelines include medications, counseling, nephrologist referral, close monitoring of urine albumin excretions, and close monitoring of nephropathy progression. | |
| **Grade assigned for the quality of the quoted evidence with definition of the grade** | |  |  | | --- | --- | |  |  | | Numerical descriptor (evidence level) | | | | Semantic descriptor (reference methodology) | |  | | | |  | | 1 | | | | Randomized controlled trials (RCT) | | 2 | | | | Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT) | | 2 | | | | Nonrandomized controlled trial (NRCT) | | 2 | | | | Prospective cohort study (PCS) | |  | | | |  | | 3 | | | | Cross-sectional study (CSS) | | 3 | | | | Surveillance study (registries, surveys, epidemiologic study, retrospective chart  review, mathematical modeling of database) (SS) | |  | | | |  | |  | | | |  | | 4 | | | | No evidence (theory, opinion, consensus, review, or preclinical study) (NE) |   1=strong evidence; 2=intermediate evidence; 3=weak evidence; and 4=no evidence. | No grading provided |
| **Provide all other grades and associated definitions of the evidence in the grading system** | 1 Meta-analysis of randomized controlled trials (MRCT)  2 Retrospective case-control study (RCCS)  3 Single case reports (SCR)  3 Consecutive case series (CCS) | N/A |
| **What is the time period covered by the body of evidence?** | 1993-2008 | 1993-2007 |
| **Quantity and Quality of Body of Evidence** | Screening  Measurement of albumin to creatinine ratio: Clinical Practice Guideline No Evidence  Use of glomerular filtration rate (GFR) in screening for nephropathy: 1 Cross-sectional study  Estimation of GFR: 1 surveillance study  Treatment  Medication treatment to prevent onset or delay progression of diabetic nephropathy: 4 randomized controlled trials, 1 Prospective cohort study, 2 Review/no evidence  Normalization of albumin excretion to decrease nephropathy progression: 2 randomized controlled trials  Restricting protein intake in patients nephropathy: 1 meta-analysis of nonrandomized prospective or case-controlled trials  Referral of stage 4 chronic kidney disease patients to nephrologist: opinion/no evidence | Seventeen studies for interventions end stage renal disease or nephropathy were identified. The interventions included screenings for microalbuminuria and treatment options to delay the progression of nephropathy. The studies included RCTs, cohort studies, observational studies, and clinical trials. |
| **What is the overall quality of evidence across studies in the body of evidence?** | The overall quality of evidence for the measure focus is high. Guidelines supporting the measure include recommendations for the screening and treatment of nephropathy.  Evidence for treatment options to prevent nephropathy onset and delay the progression of nephropathy have the strongest evidence with the most RCTs.  The evidence supporting screenings for nephropathy is weaker in comparison to the nephropathy treatment evidence. This evidence includes clinical trials, cross sectional studies, surveillance studies, and large cohorts studies as opposed to RCTs. Evidence for nephropathy screenings also include literature reviews. Despite this weaker evidence for nephropathy screenings, the linkage to improved nephropathy outcomes through screening is high. Regular nephropathy screenings offer the opportunity for early detection of diabetic nephropathy and early treatment to delay progression of the disease. | |
| **Estimates of benefit and consistency across studies in body of evidence – what are the estimates of benefits?** | The evidence supporting this measure can be categorized into evidence for nephropathy screening and evidence for nephropathy treatments. Screening is a crucial step in delaying the onset or progression of nephropathy in diabetics. The results from one study cited that the average life expectancy increases from four to 14 years with nephropathy screening and interventions (Borch-Johnson, 1993). In addition, the study cited a decrease in the need for dialysis and kidney transplants by 21% to 63% (Borch-Johnson, 1993). The onset of nephropathy is can also be delayed by six to 24 years and therefore, reduces the mortality rates of deaths due to nephropathy (Borch-Johnsen, 1993).  Another treatment method identified by the guidelines supporting this measure includes referral to a nephrologist. An important aspect of referral includes timeliness. Data suggests that the early referral to a nephrologist can improve mortality rates and lifespan of patients on dialysis. Patients that begin treatment with a nephrologist over a year before starting dialysis live longer lives, on average, than patients that were referred within four months of starting dialysis. Screening for nephropathy is a necessary component of determining the stage of kidney disease. Therefore, the benefit of regular screenings will lead to earlier specialized treatment and improved outcomes for diabetic nephropathy.  Borch-Johnsen K, Wenzel H, Viberti GC, Mogensen CE. Is screening and intervention for microalbuminuria worthwhile in patients with insulin dependent diabetes? BMJ. 1993; 306: 1722-1725. | |
| **What harms were studied and how do they affect the net benefit (benefits over harms)?** | The harms associated with the screening and treatment of nephropathy stem from adverse effects that are associated with pharmacotherapy and other treatment options (dialysis and kidney transplant). One study suggested higher risks to patients when using combined medication therapies as opposed to monotherapy (Halimi et al., 2009).  Halimi JM, Asmar R, Ribstein J. Optimal nephroprotection: Use, misuse and misconceptions about blockade of the renin-angiotensin system. Lessons from the ONTARGET and other recent trials. Diabetes Metab. 2009; 35:425-430. | |
| **Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?** | Numerous studies have been conducted since the systematic reviews we cite in this table, none of which change the conclusion that medical attention for nephropathy for individuals with diabetes is appropriate. | |

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**1a.4 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.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

N/A

**1a.4.2 What process was used to identify the evidence?**

N/A

**1a.4.3.** **Provide the citation(s) for the evidence.**

N/A