

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0285

Measure Title: [Rate of Lower-Extremity Amputation Among Patients With Diabetes \(PQI 16\)](#)

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: [2/24/2014](#)

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 (*includes 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](#).

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 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 that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ 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 that the measured structure leads to a desired health outcome.
- **Efficiency:** ⁶ 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](#) and [methods](#), or Grading of Recommendations, Assessment, Development and Evaluation ([GRADE](#)) [guidelines](#).

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](#); [AQA Principles of Efficiency Measures](#)).

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: Click here to name the process
- ☐ Structure: Click here to name the structure
- ☐ Other: Click here to name what is being measured

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

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.

Patients with diabetes are at high risk of developing neuropathic problems of the lower limbs along with peripheral vascular disease. When these conditions are not diagnosed in the early stage, a window of opportunity is missed to ameliorate symptoms and prevent the development of the foot ulcers, infection, or other causes of limb ischemia that can lead to non-traumatic lower extremity amputation. Lower extremity amputation not only leads to physical disability and loss of quality of life, but also to economic burden (i.e., healthcare costs and industrial disability).

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).

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.

The majority of lower extremity amputations associated with diabetes can be prevented through better primary and specialty care(1). This starts with early identification of diabetes and long-term glycemic control followed by early identification and appropriate therapy of the patient who is at increased risk for ulceration and amputation. Lowering A1C to below or around 7% has been shown to reduce long-term vascular disease if implemented soon after the diagnosis of diabetes. Preventing lower extremity amputation requires a partnership between providers and patients. Patients at risk require lifelong surveillance, examination of the feet at each healthcare visit, risk stratification, and referral for therapeutic footwear and orthoses when needed. Patients and or caregivers must be educated and equipped to fulfill their responsibilities of daily foot inspection, associated foot care practices, and general diabetic management. Early identification and management of the diabetic neuropathy provides an opportunity to alleviate symptoms and prevent the development of major clinical neuropathic endpoint of the lower limbs. When infection or a wound does occur, proper wound care, optimal metabolic control, and early aggressive, appropriate surgical and medical therapy can often preserve function and prevent the loss of limb.

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.

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](#), and [1a.7](#)**
- ☐ US Preventive Services Task Force Recommendation – **complete sections [1a.5](#) and [1a.7](#)**
- ☐ Other systematic review and grading of the body of evidence (e.g., *Cochrane Collaboration*, *AHRQ Evidence Practice Center*) – **complete sections [1a.6](#) and [1a.7](#)**
- ☐ Other – **complete section [1a.8](#)**

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

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

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

Guidelines demonstrate that prevention of the condition (and, by definition, the hospitalization for the condition) is possible.

NGC: 009111. Lipsky BA, Berendt AR, Cornia PB, Pile JC, Peters EJ, Armstrong DG, Deery HG, Embil JM, Joseph WS, Karchmer AW, Pinzur MS, Senneville E. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. Clin Infect Dis. 2012 Jun; 54(12):e132-73. [345 references] (URL: <http://www.guideline.gov/content.aspx?id=37220&search=infectious+diseases+and+diabetic+foot+infections>) (more detail in 1a.4.2)

NGC: 008758. Centre for Clinical Practice. Diabetic foot problems. Inpatient management of diabetic foot problems. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Mar. 31 p. (Clinical guideline; no. 119). URL: <http://www.guideline.gov/content.aspx?id=34831&search=infectious+diseases+and+diabetic+foot+infections>

Guidelines related to management of diabetic foot infection reduce major morbidity, including physical and emotional distress and lost mobility, as well as substantial direct and indirect financial costs. Other guidelines that similarly note that a focus on comprehensive care to optimally manage the patient and (and need for intensive in-hospital care) include:

NGC: 009095. Riethof M, Flavin PL, Lindvall B, Michels R, O'Connor P, Redmon P, Retzer K, Roberts J, Smith S, Sperl-Hillen J, Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Apr. 141 p. [198 references]

NGC: 009416. University of Michigan Health System. Management of type 2 diabetes mellitus. Ann Arbor (MI): University of Michigan Health System; 2012 Sep. 27 p. [17 references]

NGC: 008116. Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Department of Veteran Affairs, Department of Defense; 2010 Aug. 146 p.

NGC: 009808-009815 American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care*. 2013; 36(Suppl 1):S11-66. (URL: <http://www.guideline.gov/search/search.aspx?term=diabetes>)

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

Major Recommendations

Quality of evidence (**high-quality, moderate-quality, low-quality, very low-quality**) and strength of recommendation (**strong, weak**) ratings are defined at the end of the "Major Recommendations" field.

Recommendations for Managing Diabetic Foot Infections

I. In Which Diabetic Patients with a Foot Wound Should Infection Be Suspected, and How Should It Be Classified?

Recommendations

1. Clinicians should consider the possibility of infection occurring in any **foot** wound in a patient with diabetes (**strong, low**). Evidence of infection generally includes classic signs of inflammation (redness, warmth, swelling, tenderness, or pain) or purulent secretions, but may also include additional or secondary signs (e.g., nonpurulent secretions, friable or discolored granulation tissue, undermining of wound edges, foul odor) (**strong, low**).
2. Clinicians should be aware of factors that increase the risk for **diabetic foot infections** (DFI) and especially consider infection when these factors are present; these include a wound for which the probe-to-bone (PTB) test is positive; an ulceration present for >30 days; a history of recurrent **foot** ulcers; a traumatic **foot** wound; the presence of peripheral vascular disease in the affected limb; a previous lower extremity amputation; loss of protective sensation; the presence of renal insufficiency; or a history of walking barefoot (**strong, low**).
3. Clinicians should select and routinely use a validated classification system, such as that developed by the International Working Group on the **Diabetic Foot** (IWGDF) (abbreviated with the acronym PEDIS [perfusion, extent (size), depth (tissue loss), infection, sensation (neuropathy)] or **Infectious Diseases Society of America** (IDSA), to classify **infections** and to help define the mix of types and severity of their cases and their outcomes (**strong, high**). The DFI Wound Score may provide additional quantitative discrimination for research purposes (**weak, low**). Other validated **diabetic foot** classification schemes have limited value for infection, as they describe only its presence or absence (**moderate, low**).

II. How Should a Diabetic Patient Presenting with a Foot Infection Be Assessed?

Recommendations

4. Clinicians should evaluate a **diabetic** patient presenting with a **foot** wound at 3 levels: the patient as a whole, the affected **foot** or limb, and the infected wound (**strong, low**).
5. Clinicians should diagnose infection based on the presence of at least 2 classic symptoms or signs of inflammation (erythema, warmth, tenderness, pain, or induration) or purulent secretions. They should then document and classify the severity of the infection based on its extent and depth and the presence of any systemic findings of infection (**strong, low**).
6. The developers recommend assessing the affected limb and **foot** for arterial ischemia (**strong, moderate**), venous insufficiency, presence of protective sensation, and biomechanical problems (**strong, low**).
7. Clinicians should debride any wound that has necrotic tissue or surrounding callus; the required procedure may range from minor to extensive (**strong, low**).

III. When and from Whom Should a Consultation Be Requested for a Patient with a Diabetic Foot Infection?

Recommendations

8. For both outpatients and inpatients with a DFI, clinicians should attempt to provide a well-coordinated approach by those with expertise in a variety of specialties, preferably by a multidisciplinary **diabetic foot** care team (**strong, moderate**). Where such a team is not yet available, the primary treating clinician should try to coordinate care among consulting specialists.
9. **Diabetic foot** care teams can include (or should have ready access to) specialists in various fields; patients with a DFI may especially benefit from consultation with an **infectious** disease or clinical microbiology specialist and a surgeon with experience and interest in managing DFIs (**strong, low**).
10. Clinicians without adequate training in wound debridement should seek consultation from those more qualified for this task, especially when extensive procedures are required (**strong, low**).
11. If there is clinical or imaging evidence of significant ischemia in an infected limb, the developers recommend the clinician consult a vascular surgeon for consideration of revascularization (**strong, moderate**).
12. The developers recommend that clinicians unfamiliar with pressure off-loading or special dressing techniques consult **foot** or wound care specialists when these are required (**strong, low**).
13. Providers working in communities with inadequate access to consultation from specialists might consider devising systems (e.g., telemedicine) to ensure expert input on managing their patients (**strong, low**).

IV. Which Patients with a Diabetic Foot Infection Should Be Hospitalized, and What Criteria Should They Meet before Being Discharged?

Recommendations

14. The developers recommend that all patients with a severe infection, selected patients with a moderate infection with complicating features (e.g., severe peripheral arterial disease [PAD] or lack of home support),

and any patient unable to comply with the required outpatient treatment regimen for psychological or social reasons be hospitalized initially. Patients who do not meet any of these criteria, but are failing to improve with outpatient therapy, may also need to be hospitalized (**strong, low**).

15. The developers recommend that prior to being discharged, a patient with a DFI should be clinically stable; have had any urgently needed surgery performed; have achieved acceptable glycemic control; be able to manage (on his/her own or with help) at the designated discharge location; and have a well-defined plan that includes an appropriate antibiotic regimen to which he/she will adhere, an off-loading scheme (if needed), specific wound care instructions, and appropriate outpatient follow-up (**strong, low**).

V. When and How Should Specimen(s) Be Obtained for Culture from a Patient with a Diabetic Foot Wound?

Recommendations

16. For clinically uninfected wounds, the developers recommend not collecting a specimen for culture (**strong, low**).
17. For infected wounds, the developers recommend that clinicians send appropriately obtained specimens for culture prior to starting empiric antibiotic therapy, if possible. Cultures may be unnecessary for a mild infection in a patient who has not recently received antibiotic therapy (**strong, low**).
18. The developers recommend sending a specimen for culture that is from deep tissue, obtained by biopsy or curettage after the wound has been cleansed and debrided. The developers suggest avoiding swab specimens, especially of inadequately debrided wounds, as they provide less accurate results (**strong, moderate**).

VI. How Should an Antibiotic Regimen for a Diabetic Foot Infection Be Initially Selected and Modified? (See question VIII for recommendations for antibiotic treatment of osteomyelitis)

Recommendations

19. The developers recommend that clinically uninfected wounds not be treated with antibiotic therapy (**strong, low**).
20. The developers recommend prescribing antibiotic therapy for all infected wounds, but caution that this is often insufficient unless combined with appropriate wound care (**strong, low**).
21. The developers recommend that clinicians select an empiric antibiotic regimen on the basis of the severity of the infection and the likely etiologic agent(s) (**strong, low**).
 - a. For mild to moderate infections in patients who have not recently received antibiotic treatment, the developers suggest that therapy just targeting aerobic gram-positive cocci (GPC) is sufficient (**weak, low**).
 - b. For most severe infections, the developers recommend starting broad-spectrum empiric antibiotic therapy, pending culture results and antibiotic susceptibility data (**strong, low**).
 - c. Empiric therapy directed at *Pseudomonas aeruginosa* is usually unnecessary except for patients with risk factors for true infection with this organism (**strong, low**).
 - d. Consider providing empiric therapy directed against methicillin-resistant *Staphylococcus aureus* (MRSA) in a patient with a prior history of MRSA infection; when the local prevalence of MRSA colonization or infection is high; or if the infection is clinically severe (**weak, low**).
22. The developers recommend that definitive therapy be based on the results of an appropriately obtained culture and sensitivity testing of a wound specimen as well as the patient's clinical response to the empiric regimen (**strong, low**).
23. The developers suggest basing the route of therapy largely on infection severity. The developers prefer parenteral therapy for all severe, and some moderate, DFIs, at least initially (**weak, low**), with a switch to oral agents when the patient is systemically well and culture results are available. Clinicians can probably use highly bioavailable oral antibiotics alone in most mild, and in many moderate, infections and topical therapy for selected mild superficial infections (**strong, moderate**).
24. The developers suggest continuing antibiotic therapy until, but not beyond, resolution of findings of infection, but not through complete healing of the wound (**weak, low**). The developers suggest an initial antibiotic course for a soft tissue infection of about 1–2 weeks for mild infections and 2–3 weeks for moderate to severe infections (**weak, low**).

VII. When Should Imaging Studies Be Considered to Evaluate a Diabetic Foot Infection, and Which Should Be Selected?

Recommendations

25. The developers recommend that all patients presenting with a new DFI have plain radiographs of the affected foot to look for bony abnormalities (deformity, destruction) as well as for soft tissue gas and radio-opaque foreign bodies (**strong, moderate**).
26. The developers recommend using magnetic resonance imaging (MRI) as the study of choice for patients who require further (i.e., more sensitive or specific) imaging, particularly when soft tissue abscess is suspected or the diagnosis of osteomyelitis remains uncertain (**strong, moderate**).

27. When MRI is unavailable or contraindicated, clinicians might consider the combination of a radionuclide bone scan and a labeled white blood cell scan as the best alternative (**weak, low**).

VIII. How Should Osteomyelitis of the Foot in a Patient with Diabetes Be Diagnosed and Treated?

Recommendations

28. Clinicians should consider osteomyelitis as a potential complication of any infected, deep, or large foot ulcer, especially one that is chronic or overlies a bony prominence (**strong, moderate**).
29. The developers suggest doing a probe-to-bone test for any DFI with an open wound. When properly conducted and interpreted, it can help to diagnose (when the likelihood is high) or exclude (when the likelihood is low) diabetic foot osteomyelitis (DFO) (**strong, moderate**).
30. The developers suggest obtaining plain radiographs of the foot, but they have relatively low sensitivity and specificity for confirming or excluding osteomyelitis (**weak, moderate**). Clinicians might consider using serial plain radiographs to diagnose or monitor suspected DFO (**weak, low**).
31. For a diagnostic imaging test for DFO, the developers recommend using MRI (**strong, moderate**). However, MRI is not always necessary for diagnosing or managing DFO (**strong, low**).
32. If MRI is unavailable or contraindicated, clinicians might consider a leukocyte or antigranulocyte scan, preferably combined with a bone scan (**weak, moderate**). The developers do not recommend any other type of nuclear medicine investigations (**weak, moderate**).
33. The developers suggest that the most definitive way to diagnose DFO is by the combined findings on bone culture and histology (**strong, moderate**). When bone is debrided to treat osteomyelitis, the developers suggest sending a sample for culture and histology (**strong, low**).
34. For patients not undergoing bone debridement, the developers suggest that clinicians consider obtaining a diagnostic bone biopsy when faced with specific circumstances, e.g., diagnostic uncertainty, inadequate culture information, failure of response to empiric treatment (**weak, low**).
35. Clinicians can consider using either primarily surgical or primarily medical strategies for treating DFO in properly selected patients (**weak, moderate**). In noncomparative studies each approach has successfully arrested infection in most patients.
36. When a radical resection leaves no remaining infected tissue, the developers suggest prescribing antibiotic therapy for only a short duration (2–5 days) (**weak, low**). When there is persistent infected or necrotic bone, the developers suggest prolonged (≥ 4 weeks) antibiotic treatment (**weak, low**).
37. For specifically treating DFO, the developers do not currently support using adjunctive treatments such as hyperbaric oxygen therapy, growth factors (including granulocyte colony-stimulating factor), maggots (larvae), or topical negative pressure therapy (e.g., vacuum-assisted closure) (**weak, low**).

IX. In Which Patients with a Diabetic Foot Infection Should Surgical Intervention Be Considered, and What Type of Procedure May Be Appropriate?

Recommendations

38. The developers suggest that nonsurgical clinicians consider requesting an assessment by a surgeon for patients with a moderate or severe DFI (**weak, low**).
39. The developers recommend urgent surgical intervention for most foot infections accompanied by gas in the deeper tissues, an abscess, or necrotizing fasciitis, and less urgent surgery for wounds with substantial nonviable tissue or extensive bone or joint involvement (**strong, low**).
40. The developers recommend involving a vascular surgeon early on to consider revascularization whenever ischemia complicates a DFI, but especially in any patient with a critically ischemic limb (**strong, moderate**).
41. Although most qualified surgeons can perform an urgently needed debridement or drainage, the developers recommend that in DFI cases requiring more complex or reconstructive procedures, the surgeon should have experience with these problems and adequate knowledge of the anatomy of the foot (**strong, low**).

X. What Types of Wound Care Techniques and Dressings are Appropriate for Diabetic Foot Wounds?

Recommendations

42. Diabetic patients with a foot wound should receive appropriate wound care, which usually consists of the following:
- a. Debridement, aimed at removing debris, eschar, and surrounding callus (**strong, moderate**). Sharp (or surgical) methods are generally best (**strong, low**), but mechanical, autolytic, or larval debridement techniques may be appropriate for some wounds (**weak, low**).
 - b. Redistribution of pressure off the wound to the entire weight-bearing surface of the foot ("off-loading"). While particularly important for plantar wounds, this is also necessary to relieve pressure caused by dressings, footwear, or ambulation to any surface of the wound (**strong, high**).

- c. Selection of dressings that allow for moist wound healing and control excess exudation. The choice of dressing should be based on the size, depth, and nature of the ulcer (e.g., dry, exudative, purulent) (**strong, low**).
- 43. The developers do not advocate using topical antimicrobials for treating most clinically uninfected wounds.
- 44. No adjunctive therapy has been proven to improve resolution of infection, but for selected **diabetic foot** wounds that are slow to heal, clinicians might consider using bioengineered skin equivalents (**weak, moderate**), growth factors (**weak, moderate**), granulocyte colony-stimulating factors (**weak, moderate**), hyperbaric oxygen therapy (**strong, moderate**), or negative pressure wound therapy (**weak, low**).

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

The guideline is structured into six sections based on the review questions. Evidence in each section is presented in the summary of GRADE (Grading of Recommendations Assessment, Development and

In updating this guideline the panel followed the newly created Grading of Recommendations Assessment, Development and Evaluation (GRADE) system recommended by **Infectious Diseases Society of America (IDSA)** (see the "Rating Scheme for the Strength of the Recommendations" fields, see URL).

This included systematically weighting the quality of the available evidence and grading the recommendations. To evaluate evidence, the panel followed a process consistent with other IDSA guidelines, including a systematic weighting of the quality of the evidence and the grade of recommendation. High-quality evidence does not necessarily lead to strong recommendations; conversely, strong recommendations can arise from low-quality evidence if one can be confident that the desired benefits clearly outweigh the undesirable consequences. The main advantages of the GRADE approach are the detailed and explicit criteria for grading the quality of evidence and the transparent process for making recommendations.

This system requires that the assigned strength of a recommendation be either "strong" or "weak." The main criterion for assigning a "strong" recommendation is that the potential benefits clearly outweigh the potential risks. The panel chair and vice-chair reviewed all the recommendation gradings and then worked with the panel to achieve consensus via teleconference and e-mail.

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.)

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

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**
- ☐ No → **report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7**

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

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

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

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

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.)

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

Complete section [1a.7](#)

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

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

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

Complete section [1a.7](#)

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?

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

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

1a.7.4. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [Click here to enter date range](#)

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)

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)

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)

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

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.

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?

Formal environmental scans of the literature, including routine Pub-Med searches.

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

Evidence on Impact

Diabetes is the leading cause of lower extremity amputation among adults in the US, with more than 60 percent of non-traumatic lower-extremity amputation occurring in people with diabetes (1). Lower-extremity amputation is a common complication of diabetes, affecting up to 15 percent of all diabetics in their lifetimes (2). Infection, neuropathy and microvascular disease are among the precipitating factors leading to lower-extremity amputation. Proper long-term glucose control, diabetes education and foot care are some of the interventions that contribute to reduction in the incidence of these lower-extremity amputations. Some observational studies have shown that high quality education and care can reduce lower-extremity amputation, though no studies have reported that low quality care is associated with increased lower-extremity amputation rates (3-4).

Within the diabetic community, the incidence of lower-extremity amputation has been reported as 375 per 100,000 person-years for non-insulin-dependent diabetes mellitus (NIDDM), and 388 per 100,000 person-years for insulin-dependent diabetes mellitus (IDDM). The twenty-five year cumulative risk for lower extremity amputation in both the NIDDM and IDDM populations was 11 percent (5). While the full etiology of factors leading to amputation are unknown, it is believed that a combination of factors contribute to the high rate of amputation in the diabetic population.

Clinical Evidence

Within the diabetic community, the incidence of lower-extremity amputation has been reported as 375 per 100,000 person-years for non-insulin-dependent diabetes mellitus (NIDDM), and 388 per 100,000 person-years for insulin-dependent diabetes mellitus (IDDM). The 25 year cumulative risk for lower extremity amputation in both the NIDDM and IDDM populations was 11 percent (6).

Lower extremity amputation is a common complication of diabetes, affecting up to 15 percent of all diabetics in their lifetimes (7). In the United States, diabetes is the leading cause of non-traumatic

amputations with more than 60 percent of non-traumatic lower extremity amputation occurring in people with diabetes (8).

Two controlled studies have identified clinical risk factors for amputation among diabetics in an HMO (3) and in a Veterans Affairs (VA) medical center (9), both settings with relatively good access to care. Selby and Zhang (6) found that the level of glucose control, duration of diabetes, and baseline systolic blood pressure were major clinical predictors of amputation.

References:

1. Genuth S. Insights from the diabetes control and complications trial/epidemiology of diabetes interventions and complications study on the use of intensive glycemic treatment to reduce the risk of complications of type 1 diabetes. *Endocr Pract* 2006;12 Suppl 1:34-41.
2. Homer CJ, Szilagyi P, Rodewald L et al. Does quality of care affect rates of hospitalization for childhood asthma? *Pediatrics* 1996;98:18-23.
3. Ollendorf DA, Kotsanos JG, Wishner WJ et al. Potential economic benefits of lower-extremity amputation prevention strategies in diabetes. *Diabetes Care* 1998;21:1240-1245.
4. Rogers LC, Bevilacqua NJ. Organized programs to prevent lower-extremity amputations. *J Am Podiatr Med Assoc* 2010;100:101-104.
5. Chukwueke I, Cordero-Macintyre Z. Overview of type 2 diabetes in Hispanic Americans. *Int J Body Compos Res* 2010;8:77-81.
6. Humphrey LL, Palumbo PJ, Butters MA et al. The contribution of non-insulin-dependent diabetes to lower-extremity amputation in the community. *Arch Intern Med* 1994;154:885-892.
7. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. *Diabetes Care* 1998;21:2161-2177.
8. Centers for Disease Control and Prevention (CDC). *National Diabetes Fact Sheet, 2011*. 2011.
9. Young BA, Maynard C, Reiber G, Boyko EJ. Effects of ethnicity and nephropathy on lower-extremity amputation risk among diabetic veterans. *Diabetes Care* 2003;26:495-501.