

The Centers for Medicare & Medicaid Services (CMS) seeks public comments on the following clinical quality measure (CQM) and electronic clinical quality measure (eCQM) under development:

Title: Diabetic Foot Assessment and Follow-Up

Description: Percentage of patients 18 years of age and older with diabetes who had a lower-extremity neurological examination, vascular examination, and visual inspection of both feet; who received foot care education at least once in the last 12 months; and who received a follow-up plan of care if the results of the neurological, vascular, or visual inspection are abnormal. This measure will be developed as both a clinical quality measure (CQM) and an eCQM through the revision of an existing CQM: [QID126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy Neurological Evaluation](#).

This document describes the measure’s rationale, intent, and history. We seek comments from the public on the measure’s specifications as well as responses to the queries in the “Questions” section of this document.

Measure rationale: Diabetes affects about 37 million U.S. adults, and the prevalence is increasing as the population ages.¹ Diabetes can cause many serious complications, one of which is ulceration and subsequent lower-extremity amputation (LEA). Estimates indicate that 15 percent of diabetic patients will develop a foot ulcer at some point.² Neurologic (peripheral neuropathy) and vascular (peripheral arterial disease) complications make patients with diabetes particularly vulnerable to unnoticed trauma on the foot, delayed wound healing, and subsequent infection or ischemia leading to LEA. The consequences of LEA are devastating, with a five-year mortality rate of about 50 percent following amputation.³

Regular foot exams and interventions such as patient education about foot care might reduce ulcer incidence and subsequent amputation.^{4, 5} In fact, estimates show that amputations could be reduced by 85 percent by implementing these processes.⁶ Clinical practice guidelines note that patients with diabetes must have their feet examined at least annually to assess for ulcer risk (including neurological, vascular, and visual assessments) and that all patients with diabetes should receive education about foot self-care.^{7, 8, 9} Yet evidence shows that foot assessments are underused in clinical practice.¹⁰ There is also growing concern over disparities in care associated with LEA among patients with diabetes. Non-White patients with diabetes have higher rates of LEA than their White counterparts, and people living in rural areas have higher rates than their peers in urban areas.^{11, 12}

The proposed Diabetic Foot Assessment and Follow-Up quality measure is designed to encourage physicians to provide all diabetic patients with the necessary diabetic foot assessments, foot care education, and appropriate follow-up care, with the goal of preventing LEA.

Measure intent: The intent of this measure is to encourage primary care clinicians to perform the necessary assessments to identify patients with diabetes who are at risk for LEA, to educate them about preventive foot self-care, and to implement a follow-up plan of care to prevent ulcers and subsequent amputations in high-risk patients.

Measure history: The measure concept and specification were developed by the National Committee for Quality Assurance (NCQA), under contract with Mathematica (eCQM Development and Maintenance for Eligible Clinicians; #75FCMC18D0032/75FCMC19F0004). The team developed the measure concept by reviewing clinical guidelines and evidence; scanning related and competing measures; and consulting with a technical expert panel, patient and family advisory board, and expert work group. After developing the concept, the team determined that revising a related measure—[QID126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy Neurological Evaluation](#)—was the most feasible path forward for specification. QID126 currently measures annual neurological evaluations for patients with diabetes and is stewarded by the American Podiatric Medical Association (APMA).

The team solicited APMA’s input on the revisions to QID126 to operationalize the Diabetic Foot Assessment and Follow-Up measure concept. These revisions included the addition of vascular assessment, visual inspection, patient education on foot care, and follow-up care plans for patients with abnormal assessment results.

The team began alpha testing in fall 2022. The team interviewed primary care clinicians, vascular surgeons, and podiatric specialists (n = 11). Interviews focused on the measure’s importance, feasibility, and usability. The team also sought input on the draft measure specification, including numerator and denominator criteria and exclusions.

The alpha testing yielded two main findings: (1) the measure concept represents an area of high importance, assesses the right quality actions, and could contribute to reduced diabetes-related amputations, and (2) the measure assesses quality actions that are within the scope of primary care clinicians. Testing indicated moderate to high feasibility. Test sites demonstrated that most of the measure’s data elements were available in structured fields and were captured as part of the standard workflow.

Next steps for measure development: After the public-comment period ends, the team will review comments and determine whether the measure specification needs to be revised before undergoing quantitative measure testing with clinical sites.

Questions: We seek feedback on all components of the proposed measure and on the following topics:

- To what extent do you feel the Diabetic Foot Assessment and Follow-Up measure will contribute to greater quality of care, reduced ulcers, and reduced LEA for patients with diabetes? What changes, if any, should be made to the measure specification to meet the measure’s intent of reducing LEA?
- How burdensome would this measure be for primary care providers to implement?
- Are the current denominator exclusions appropriate: patients in hospice, palliative care, long-term care, those with frailty (for example, someone with an amputee wheelchair) or advanced illness, and those with bilateral lower extremity amputation? What other denominator exclusions would be appropriate, if any?
- Are the quality actions—neurological assessment, vascular assessment, visual inspection for ulcer, patient education, and documentation of follow-up plans—appropriate for primary care providers? Are the quality actions defined appropriately?

- Should the neurological assessment component require the Semmes-Weinstein monofilament AND at least one additional assessment (pinprick, vibration, ankle reflexes), or should it require only the monofilament?
- Should the measure require documentation of ulcer risk level (for example, high risk, medium risk, or low risk) in addition to documentation of completed lower-extremity assessments? What are the benefits and burdens of documenting ulcer risk level?
- Is the definition of “follow-up care” in the measure specification appropriate? If not, how should the definition be refined?
- Should this measure be stratified by patient characteristics, such as race and ethnicity, to identify opportunities to address disparities in care?

References

- ¹ Centers for Disease Control and Prevention. “National Diabetes Statistics Report.” 2021. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>.
- ² Margolis, David J., D. Scot Malay, Ole J. Hoffstad, Charles E. Leonard, Thomas MaCurdy, Karla López de Nava, Yang Tan, et al. “Incidence of Diabetic Foot Ulcer and Lower-Extremity Amputation Among Medicare Beneficiaries, 2006 to 2008.” Agency for Healthcare Research and Quality, 2011. <https://www.ncbi.nlm.nih.gov/books/NBK65149/>.
- ³ Armstrong, D.G., M.A. Swerdlow, A.A. Armstrong, M.S. Conte, W.V. Padula, and S.A. Bus. “Five-Year Mortality and Direct Costs of Care for People with Diabetic Foot Complications Are Comparable to Cancer.” *Journal of Foot and Ankle Research*, vol. 13, no. 16, 2020. <https://doi.org/10.1186/s13047-020-00383-2>.
- ⁴ Lavery, L.A., R.P. Wunderlich, and J.L. Tredwell. “Disease Management for the Diabetic Foot: Effectiveness of a Diabetic Foot Prevention Program to Reduce Amputations and Hospitalizations.” *Diabetes Research and Clinical Practice*, vol. 70, no. 1, 2005, pp. 31–37. <https://doi.org/10.1016/j.diabres.2005.02.010>.
- ⁵ Adiewere, P., R.B. Gillis, S. Imran Jiواني, A. Meal, I. Shaw, and G.G. Adams. “A Systematic Review and Meta-Analysis of Patient Education in Preventing and Reducing the Incidence or Recurrence of Adult Diabetes Foot Ulcers (DFU).” *Heliyon*, vol. 4, no. 5, 2018, p. e00614. <https://doi.org/10.1016/j.heliyon.2018.e00614>
- ⁶ Centers for Disease Control and Prevention. “Health and Economic Benefits of Diabetes Interventions.” 2019. <https://www.cdc.gov/chronicdisease/programs-impact/pop/diabetes.htm>.
- ⁷ Boulton, A.J.M., D.G. Armstrong, S.F. Albert, R.G. Frykberg, R. Hellman, M.S. Kirkman, L.A. Lavery, et al. “Comprehensive Foot Examination and Risk Assessment: A Report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with Endorsement by the American Association of Clinical Endocrinologists.” *Diabetes Care*, vol. 31, no. 8, 2008, pp. 1679–1685. <https://doi.org/10.2337/dc08-9021>.
- ⁸ American Diabetes Association. “12. Retinopathy, Neuropathy, and Foot Care: *Standards of Medical Care in Diabetes—2022*.” *Diabetes Care*, vol. 44, supplement no. 1, 2022, pp. S185–S194. https://diabetesjournals.org/care/article/45/Supplement_1/S185/138917/12-Retinopathy-Neuropathy-and-Foot-Care-Standards. Accessed May 30, 2022.
- ⁹ Bus, S.A., L.A. Lavery, M. Monteiro-Soares, A. Rasmussen, A. Raspovic, I.C.N. Sacco, and J.J. Netten on behalf of the International Working Group on the Diabetic Foot. “Guidelines on the Prevention of Foot Ulcers in Persons with Diabetes (IWGDF 2019 Update).” *Diabetes/Metabolism Research and Reviews*, vol. 36, no. S1, 2020. <https://doi.org/10.1002/dmrr.3269>.
- ¹⁰ Quach, T.V., and M.H. Goldschmidt. (2019). Evaluating a Program Process Change to Improve Completion of Foot Exams and Amputation Risk Assessments for Veterans with Diabetes. *Federal Practitioner*, 36(Suppl 7), S10–S15.
- ¹¹ Haw, J.S., M. Shah, S. Turbow, M. Egeolu, and G. Umpierrez. “Diabetes Complications in Racial and Ethnic Minority Populations in the USA.” *Current Diabetes Reports*, vol. 21, no. 2, 2021. <https://doi.org/10.1007/s11892-020-01369-x>.
- ¹² Akinlotan, Marvellous A., Kristin Primm, Jane N. Bolin, Abdelle L. Ferdinand Cheres, JuSung Lee, Timothy Callaghan, and Alva O. Ferdinand. “Racial, Rural, and Regional Disparities in Diabetes-Related Lower-Extremity Amputation Rates, 2009–2017.” *Diabetes Care*, vol. 44, no. 9, September 2021, pp. 2053–2060. <https://doi.org/10.2337/dc20-3135>.