

Pathways to Reduce Amputations



New American Diabetes Association (ADA) Standards of Care (SOC) - 2023

Foot Care Recommendations¹



12.21 Perform a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations. **A**

12.22 The examination should include inspection of the skin, assessment of foot deformities, neurological assessment (10-g monofilament testing with at least one other assessment: pinprick, temperature, vibration), and vascular assessment, including pulses in the legs and feet. **B**

12.23 Individuals with evidence of sensory loss or prior ulceration or amputation should have their feet inspected at every visit. **A**

12.24 Obtain a prior history of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy, and renal disease and assess current symptoms of neuropathy (pain, burning, numbness) and vascular disease (leg fatigue, claudication). **B**

12.25 Initial screening for peripheral arterial disease should include assessment of lower-extremity pulses, capillary refill time, rubor on dependency, pallor on elevation, and venous filling time. Individuals with a history of leg fatigue, claudication, and rest pain relieved with dependency or decreased or absent pedal pulses should be referred for ankle-brachial index and for further vascular assessment as appropriate. **B**

12.26 A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet (e.g., those on dialysis, those with Charcot foot, those with a history of prior ulcers or amputation, and those with peripheral arterial disease). **B**

12.27 Refer individuals who smoke and have a history of prior lower-extremity complications, loss of protective sensation, structural abnormalities, or peripheral arterial disease to foot care specialists for ongoing preventive care and lifelong surveillance. **B**

12.28 Provide general preventive foot self-care education to all people with diabetes, including those with loss of protective sensation, on appropriate ways to examine their feet (palpation or visual inspection with an unbreakable mirror) for daily surveillance of early foot problems. **B**

12.29 The use of specialized therapeutic footwear is recommended for people with diabetes at high risk for ulceration, including those with loss of protective sensation, foot deformities, ulcers, callous formation, poor peripheral circulation, or history of amputation. **B**

12.30 For chronic diabetic foot ulcers that have failed to heal with optimal standard care alone, adjunctive treatment with randomized controlled trial-proven advanced agents should be considered. Considerations might include negative-pressure wound therapy, placental membranes, bioengineered skin substitutes, several acellular matrices, autologous fibrin and leukocyte platelet patches, and **Topical Oxygen Therapy**. **A**

Topical Oxygen Therapy (TOT)

TOT has been studied vigorously in recent years, with several high-quality RCTs and at least five systematic reviews and meta-analyses all supporting its efficacy in healing chronic DFUs at 12 weeks.²⁻⁶

- ✓ Topical oxygen therapy devices allow for home-based therapy rather than the need for daily visits to specialized centers.
- ✓ **Very high participation with very few reported adverse events** combined with improved healing rates makes this therapy another attractive option for advanced wound care.

If DFUs fail to heal despite appropriate wound care, adjunctive advanced therapies, such as TOT, should be instituted and are best managed in a multidisciplinary manner. Once healed, all individuals should be enrolled in a formal comprehensive prevention program focused on reducing the incidence of recurrent ulcerations and subsequent amputations.

POINTING CLINICIANS TO RCT-BACKED, CLINICALLY PROVEN THERAPIES...



The SOC is developed by the ADA's multidisciplinary Professional Practice Committee, which comprises expert diabetes health care professionals (HCPs). It includes the most current evidence-based recommendations for diagnosing and treating adults and children with all forms of diabetes. ADA's grading system uses **A**, **B**, **C**, or **E** to show the evidence level that supports each recommendation.

A = Recommendations with A level evidence are based on large well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population for which they are appropriate.

“For chronic diabetic foot ulcers that have failed to heal with optimal standard care alone, adjunctive treatment with RCT proven advanced agents should be considered, including TOT – “A” grade rating.¹”

It is agreed that the initial treatment and evaluation of ulcerations include the following five basic principles of ulcer treatment¹:

1. Offloading of plantar ulcerations
 2. Debridement of necrotic, nonviable tissue
 3. Use of physiologic, topical dressings
 4. Revascularization of ischemic wounds when necessary
 5. Management of infection: soft tissue or bone
- However, despite following the above principles, 60%+ of ulcerations will become chronic and remain open at one year.⁷ In those situations, advanced wound therapy can play a role. Medicaid and Medicare coverage for TOT are lagging behind the latest ADA SOC update recommendation for TOT as an adjunctive therapy for these non-healing ulcers.
 - It has been determined that if a wound fails to show a reduction of 50% or more after 4 weeks of appropriate wound management (i.e., the five basic principles above), consideration should be given to the use of advanced wound therapy.^{1,8}
 - Treatment of these chronic wounds is best managed in a multidisciplinary setting.¹

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