



**SANDHILLS  
CENTER**



# Debridement of diabetic foot ulcers

Clinical Policy ID: CCP.1200

Recent review date: 11/2021

Next review date: 3/2023

Policy contains: Autolytic; biochemical; biological (sterile maggots); debridement; diabetes; mechanical; ulcer.

*This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Sandhills Center when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Sandhills Center clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.*

## Coverage policy

Debridement of diabetic foot ulcers is clinically proven and, therefore, medically necessary when all of the following criteria are met (Elraiyah, 2016; Hingorani, 2016; Lipsky, 2012):

- Any of the following indications:
  - For any wound requiring removal of deep-seated foreign material, devitalized or nonviable tissue at the level of skin, subcutaneous tissue, fascia, muscle, or bone.
  - To promote optimal wound healing.
  - To prepare the site for appropriate surgical intervention.
- Types of debridement may include one or more of the following:
  - Surgical/nonsurgical sharp wound debridement.
  - Mechanical (e.g., wet-to-dry gauze dressings, water jet, or ultrasonic irrigation).
  - Autolytic (e.g., moist occlusive or semioclusive dressings).
  - Biochemical (e.g., enzyme collagenase).
  - Biological using sterile maggots.
- The procedure is carried out by a qualified professional in accordance with his or her scope of practice and consistent with state and local laws, and his or her professional training is sufficient to provide the beneficiary skills. A qualified professional includes any of the following (Lipsky, 2012; National Institute for Health and Care Excellence, 2015):
  - A physician, podiatrist, non-physician practitioner, physical therapist, or an occupational therapist who is licensed or certified by the state to furnish such services.

- Physical therapist assistants and occupational therapy assistants when working under the supervision of a qualified therapist, within the scope of practice allowed by state law.
- Educated and trained therapists (staff or auxiliary personnel) qualified to furnish therapy services under direct supervision, incident to a physician or non-physician practitioner. Personnel may or may not be licensed as therapists, but meet all of the requirements for therapists, with the exception of licensure.

## Limitations

If there is no necrotic, devitalized, fibrotic, or other tissue or foreign matter present that would interfere with wound healing, the debridement service is not medically necessary.

Documentation for each treatment visit must include all of the following:

- A detailed description of the procedure and the method (e.g., scalpel, scissors, 4x4 gauze, wet-to-dry, or enzyme).
- Frequent wound measurements.
- Description of the appearance of the wound (e.g., size, depth, stage, and/or bed characteristics).
- Type of tissue or material removed.
- The use of a qualified professional.

Debridement with topical enzymes is used when the necrotic substances to be removed from a wound are protein, fiber, and collagen. The manufacturer's product insert contains indications, contraindications, precautions, dosage, and administration guidelines; it is the clinician's responsibility to comply with those guidelines.

Autolytic debridement is contraindicated for infected wounds.

Severe ischemia is a relative contraindication to the use of sharp debridement for removing slough, necrotic tissue, and surrounding callus (Game, 2016).

## Alternative covered services

- Antibiotic therapy.
- Bioengineered skin substitutes.
- Granulocyte colony-stimulating factors.
- Hyperbaric oxygen therapy.
- Intensive wound therapy.
- Negative pressure wound therapy.
- Off-loading.

## **Background**

One of the most common chronic complications of diabetes mellitus is diabetic foot ulcer. The most significant causative factors are neuropathy and peripheral arterial disease. Peripheral arterial disease, ulcer, and neuropathy are costly and disabling lower extremity conditions that can lead to amputation if not properly treated (National Institute of Diabetes and Digestive and Kidney Diseases, 2017).

Successful treatment of patients with diabetic foot ulcers involves a holistic approach of optimal diabetes control, effective local wound care, infection control, pressure relieving strategies, and restoration of pulsatile blood flow.

Chronic wounds have underlying pathogenic abnormalities that cause necrotic tissue to accumulate. To facilitate wound healing, repeated removal of necrotic tissue may be necessary throughout the lifespan of the chronic wound.

Debridement involves removal of necrotic tissue, foreign debris, bacterial growth, callus, wound edge, and wound bed tissue from chronic wounds in order to stimulate the wound healing process (Frykberg, 2015). Debridement may reduce pressure, help drain secretions, allow full inspection of the underlying tissues, and optimize the effectiveness of topical preparations. Several procedures may be required to accomplish adequate debridement.

Debridement procedures require different levels of skill and training (Manna, 2021). In some cases, only superficial slough needs removing. In other cases, deep layers of viable tissue (e.g., bone) may be removed. They are performed in-hospital and in specialty outpatient clinics.

Methods of debridement are classified as excisional, selective, or nonselective (Manna, 2021):

- Excisional debridement is the sharp removal of tissue using instruments such as scissors, scalpels, or curettes to remove viable as well as nonviable tissue. It requires anesthesia and/or the control of bleeding and is performed by a physician.
- Nonsurgical (or conservative) sharp debridement refers to removal of loose, nonviable tissue with the aid of scalpel, scissors, or curette above the level of viable tissue. It is less extensive and aggressive than surgical debridement and requires no anesthesia. Physicians, non-physician practitioners, or a therapist (but not an assistant, aide, or any other personnel) may provide this service within their scope of practice and consistent with state and local law.
- Nonselective debridement is the gradual removal of nonviable tissue and is generally not performed by a physician. These methods include mechanical (e.g., wet-to-dry gauze dressings, water jet or ultrasonic irrigation), autolytic, biochemical (e.g., enzyme collagenase), and biological using sterile maggots.

## Findings

We identified: one Cochrane systematic review of six randomized controlled trials (Edwards, 2010); one health technology assessment inclusive of one systematic review, one meta-analysis, two randomized controlled trials, one randomized controlled trial with a cost-effectiveness analysis, and seven relevant guidelines (Canadian Agency for Drugs and Technologies in Health, 2014); and four evidence-based guidelines (Lipsky, 2012; National Institute for Health and Care Excellence, 2015; Rodd-Nielsen, 2013; Wounds International, 2013) for this policy. There is currently a discrepancy between clinical practice and the scientific evidence for improved healing as a result of debridement. All guidelines recommend a multidisciplinary approach to diabetic wound care.

Debridement is effective for speeding up ulcer healing, but the most effective method is unclear. Surgical or non-surgical sharp debridement is the gold standard technique, despite conflicting evidence of clinical efficacy; the need for further surgical/sharp debridement should be determined at each dressing change. Low-to-moderate quality evidence from randomized controlled trials suggests clostridial collagenase ointment (biochemical debridement) and hydrogels may offer improved clinical outcomes. Less robust evidence suggests other modern dressings and biological techniques may reduce pain and be more acceptable to patients.

The choice of debriding agent for difficult-to-heal surgical wounds should be based on impact on comfort, odor control and other aspects relevant to patient acceptability, type and location of wound, and total costs. Surgical/sharp debridement should be carried out by experienced practitioners with specialist training in wound care that includes sharp wound debridement. Practitioners must be able to distinguish tissue types, understand anatomy to avoid damage to blood vessels, nerves and tendons, and demonstrate high-level clinical decision-making skills in assessing a safe and effective level of debridement.

Other methods may be appropriate in certain situations:

- As an interim measure (e.g., by practitioners without the necessary skill sets to carry out sharp debridement; methods include the use of a monofilament pad or larval therapy).

- For patients in whom sharp debridement is contraindicated or unacceptably painful.
- When another debridement technique may be more beneficial for the patient.
- For patients who have expressed another preference.

In 2016, we identified one new systematic review/meta-analysis of 11 randomized controlled trials and three nonrandomized studies (n = 800 total patients) (Elraiyah, 2016), one new guideline (Hingorani, 2016), and no new economic studies for this policy. The results of the new analysis and recommendations from The Society for Vascular Surgery, in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine, are consistent with previous findings. Several effective debridement methods are available for use. Initial sharp debridement of the diabetic foot ulcer is preferred with choice of subsequent debridement method based on available expertise, patient preferences, the clinical context, and cost. No changes to the policy are warranted.

A new cross-sectional study analyzed the magnitude and impact of diabetic foot ulcers presenting to emergency departments in the United States from 2006 to 2010 (Skrepnek, 2015). Using data of more than 1 million cases from the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project National Emergency Department Sample discharge records, multivariable analysis found significant clinical and economic burden of diabetic foot ulcers, particularly among the rural and working poor. Those living in rural areas were at a significantly higher risk of major amputation, minor amputation, and inpatient death than those living in urban locales ( $P < .05$ ). Medicaid beneficiaries were at significantly higher risk for major or minor amputations than Medicare patients ( $P < .05$ ). Finally, low income was associated with a significantly higher risk of major amputation ( $P < .05$ ). While this study does not change previous findings, it further establishes the need for effective screening, prevention, and coordinated care among enrollees who are at elevated risk of diabetic foot complications.

In 2017, we added an evidence-based guideline by International Working Group on the Diabetic Foot (Game, 2016). Their general recommendations are consistent with previous guidelines in this policy. Their statement on severe ischemia as a relative contraindication to sharp debridement was added to this policy's limitations.

In 2018, we added no new information to the policy. The policy ID was changed from CP# 06.02.04 to CCP.1200.

In 2019, we added two systematic reviews and meta-analyses (Michailidis, 2018; Wang, 2019) with no changes to the policy required.

In 2020, we added several Local Coverage Articles and Local Coverage Determinations to the reference list, but no policy changes are warranted.

In 2021, we updated the reference list and found no new relevant literature to add to the policy.

## References

On August 26, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Wound Healing" (MeSH), "Debridement" (MeSH), and "Diabetes Complications" (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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## Policy updates

10/2015: initial review date and clinical policy effective date: 1/2016

10/2016: Policy references updated.

10/2017: Policy references updated. Limitations modified.

10/2018: Policy references updated. Policy ID changed.

10/2019: Policy references updated.

11/2020: Policy references updated.

11/2021: Policy references updated.