Clinical Policy Title: Debridement of diabetic foot ulcers

Clinical Policy Number: 06.02.04

Effective Date: January 1, 2016
Initial Review Date: October 19, 2015
Most Recent Review Date: October 19, 2017
Next Review Date: October 2018

Related policies:

CP# 16.03.03  Negative pressure wound therapy for chronic ulcers
CP# 18.02.01  Full body hyperbaric oxygen therapy (HBOT)
CP# 16.03.01  Bioengineered skin substitutes for ulcers and wound care
CP# 16.02.02  Growth factors for wound healing

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’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 Select Health of South Carolina 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. Select Health of South Carolina’s 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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of debridement of diabetic foot ulcers (DFUs) to be clinically proven and, therefore, medically necessary when all of the following criteria are met (Elraiyah, 2016; Hingorani, 2016; Lipsky, 2012):

- Debridement is indicated 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 or to prepare the site of 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 semiocclusive dressings).
  - Biochemical (e.g., enzyme collagenase).

Policy contains:
- Surgical/sharp debridement.
- Mechanical.
- Autolytic.
- Biochemical.
- Biological (sterile maggots).
Biological using sterile maggots.

- The procedure is carried out by a qualified professional when his or her scope of practice and state and local laws allow it, and his or her professional training is sufficient to provide the beneficiary skills. A qualified professional includes the following (NICE, 2015; Lipsky, 2012):
  - A physician, podiatrist, non-physician practitioner (NPP), physical therapist (PT), or an occupational therapist (OT) who is licensed or certified by the state to furnish such services.
  - Physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) 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 NPP. 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 manufacturers’ 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 (DM) is DFU. The most significant causative factors are neuropathy and peripheral arterial disease (PAD). PAD, ulcer, and neuropathy are costly and disabling lower extremity conditions that can lead to amputation if not properly treated (Centers for Disease Control and Prevention [CDC], 2015).

Successful diagnosis and treatment of patients with DFUs involves a holistic approach of optimal diabetes control, effective local wound care, infection control, pressure relieving strategies, and restoring pulsatile blood flow. Chronic wounds have underlying pathogenic abnormalities that cause necrotic tissue to accumulate. To facilitate wound progression, repeated removal of necrotic tissue may be necessary throughout the lifespan of the chronic wound.

**Debridement:**

Debridement is an important component of standard wound treatment for DFUs (Frykberg, 2015). It 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. 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 (Fife, 2011). 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. 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, NPPs (e.g., PA, clinical nurse specialist, and NP) 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.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s (AHRQ’s) National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 31, 2017. Search terms were: “Wound Healing” (MeSH), “Debridement” (MeSH), and “Diabetes Complications” (MeSH).

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified one systematic review (Edwards, 2010), one health technology assessment (Canadian Agency for Drugs and Technologies in Health [CADTH], 2014), and four evidence-based guidelines (National Institute for Health and Care Excellence [NICE], 2015; Rodd-Nielsen, 2013; Wounds International, 2013; Lipsky, 2012) 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 (RCTs) 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.

**Policy updates:**

In 2016, we identified one new systematic review/meta-analysis (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 DFU 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 DFUs presenting to emergency departments in the United States from 2006 to 2010 (Skrepnek, 2015). Using data of more than 1 million cases from AHRQ Healthcare Cost and Utilization Project National Emergency Department Sample discharge records, multivariable analysis found significant clinical and economic burden of DFUs, 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 < 0.05). Medicaid beneficiaries were at significantly higher risk for major or minor amputations than Medicare patients (p < 0.05). Finally, low income was associated with a significantly higher risk of major amputation (p < 0.05). While this study does not change previous findings, it further establishes the need for effective screening, prevention, and coordinated care among Select Health of South Carolina members 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 being a relative contraindication to sharp debridement was added to this policy’s limitations.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Elraiyah (2016)</strong></td>
<td><strong>Key points:</strong></td>
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| Debridement methods for chronic DFUs | - Systematic review and meta-analysis of 11 RCTs and three nonrandomized studies (800 total patients).  
- Overall quality: low to moderate with a moderate risk of bias.  
- Results presented as relative risk [RR], 95% confidence interval [CI].  
- Autolytic debridement significantly increased healing rate (1.89, 1.35 - 2.64, three RCTs).  
- Larval debridement reduced amputation (0.43, 0.21 - 0.88, one RCT and three nonrandomized studies) but did not increase complete healing (1.27, 0.84 - 1.91).  
- Surgical debridement: shorter healing time v. conventional wound care (one RCT).  
- Relative effectiveness of these methods is unclear and insufficient evidence for other methods.  
- Choice of method should be based on available expertise, patient preferences, the clinical context, and cost. |
| **Game (2016) for the IWGDF**    | **Key points:**                    |
| Guideline: prevention and management of foot problems in diabetes | - Clean ulcers regularly with clean water or saline, debride when possible to remove debris from the wound surface, and dress them with a sterile, inert dressing to control excessive exudate and maintain a warm, moist environment to promote healing. (GRADE strength of recommendation: Strong; Quality of Evidence: Low).  
- In general remove slough, necrotic tissue, and surrounding callus with sharp debridement in preference to other methods, taking relative contra-indications such as severe ischemia into account. (Strong; Low). |
| **Hingorani (2016) for the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine** | **Key points:**                    |
| Guideline: management of the diabetic foot | - Initial sharp debridement of all infected DFUs and urgent surgical intervention for foot infections involving abscess, gas, or necrotizing fasciitis (grade 1B, strong recommendation, moderate-quality evidence).  
- Follow current Infectious Diseases Society of America (IDSA) guidelines (ungraded).  
- Sharp debridement of all devitalized tissue and surrounding callus material from DFUs at one- to four-week intervals (grade 1B, strong recommendation, moderate-quality evidence).  
- Subsequent choice of debridement method based on clinical context, availability of expertise and supplies, patient tolerance and preference, and cost-effectiveness (grade 2C, weak recommendation, low-quality or very-low-quality evidence). |
<p>| <strong>NICE (2015)</strong>                  | <strong>Key points:</strong>                    |
| Guideline: treatment of DFUs     | - In-hospital debridement should only be done by a multidisciplinary foot care service, using the technique that best matches clinical expertise and experience, ulcer site, and patient preference. |</p>
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| **CADTH (2014)** Comparative effectiveness, cost-effectiveness and guidelines for debridement procedures | **Key points:**  
- Analysis included one systematic review, one meta-analysis, two RCTs, one RCT with a cost-effectiveness analysis (CEA), and seven relevant guidelines.  
- Overall quality: low to moderate with high risk of bias.  
- Despite contrasting evidence of clinical efficacy, surgical debridement is often part of standard care for DFUs.  
- Clostridial collagenase ointment (biochemical debridement) and hydrogels may offer improved clinical outcomes, although the evidence is from RCTs with methodological limitations.  
- Callus debridement is recommended to reduce focal plantar pressure, but no specific technique for removal was recommended. |
| **Rodd-Nielsen for the Canadian Association for Enterostomal Therapy (2013)** Guideline: conservative sharp wound debridement (CSWD) | **Key points:**  
- CSWD requires specific knowledge and training (i.e., advanced preparation beyond the basic entry to nursing practice) and a supervised regulatory process for assessing clinician skills.  
- Optimal CSWD uses an interdisciplinary approach to wound management and is critical to high-acuity wound care.  
- Ensure safe practice of CSWD regardless of the client care setting: acute/primary care, clinic, community/home care, or long-term care. |
| **Wounds International (2013)** Guideline: wound management in DFUs | **Key points:**  
- Debridement may be a one-off procedure or ongoing for wound maintenance.  
- Gold standard technique for tissue management in DFUs is regular, local, sharp debridement carried out by experienced practitioners (e.g., a specialist podiatrist or nurse) with specialist training:  
  - Ability to distinguish tissue types and understand anatomy to avoid damage to blood vessels, nerves, and tendons.  
  - Skilled in assessing the most safe and effective debridement level.  
  - Performed in the clinic or at the bedside.  
- Further debridement should be determined at each dressing change. Relative effectiveness of methods was not determined.  
- Other methods may be appropriate as interim measures when sharp debridement is contraindicated or unacceptably painful, when other techniques are more effective, or when patients express another preference. |
| **Lipsky (2012) for the IDSA** Guideline: diagnosis and treatment of diabetic foot infections | **Key points:**  
- “Standard/good wound care” includes sharp debridement of callus and other wound debris or eschar, moist wound healing, and pressure or weight displacement of the affected foot area. Other considerations include ensuring adequate arterial perfusion to the site and controlling any concomitant infection. (Strong recommendation, level of evidence expert opinion.) |
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).

Selection of dressing should be based on the size, depth, and nature of the ulcer (e.g., dry, exudative, purulent) (strong, low).

Clinicians without adequate training in wound debridement should seek consultation from more qualified clinicians for this task, especially when extensive procedures are required (strong, low).

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| Edwards (2010)  | • Systematic review of four RCTs of hydrogel versus gauze or standard care, one RCT of surgical debridement versus standard care, and one small RCT of larvae versus hydrogel.  
• Overall quality: low with high risk of bias.  
• Hydrogels are significantly more effective in healing DFUs than gauze or standard care (RR 1.84, 95% CI 1.3 to 2.61).  
• No significant benefit of surgical debridement over standard treatment.  
• Insufficient evidence of the effects of larval therapy on DFUs.  
• More research is needed. |

**Key points:**

**References**

**Professional society guidelines/other:**


Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice
guideline for the diagnosis and treatment of diabetic foot infections. Clinical infectious diseases: an

recommendations for conservative sharp wound debridement: an executive summary. Journal of
wound, ostomy, and continence nursing: official publication of The Wound, Ostomy and Continence

Peer-reviewed references:

Debridement procedures for managing diabetic foot ulcers: a review of clinical effectiveness, cost-
effectiveness, and guidelines. Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); 2014. National Center for Biotechnology Information website.

2010; (1): Cd003556.


Frykberg RG, Banks J. Challenges in the treatment of chronic wounds. Advances in wound care. 2015;
4(9): 560 – 582.

Skrepnek GH, Mills JL Sr., Armstrong DG. A diabetic emergency one million feet long: Disparities and
burdens of illness among diabetic foot ulcer cases within emergency departments in the United States,

CMS National Coverage Determination (NCDs):

A53001 Wound Care. CMS website. https://www.cms.gov/medicare-coverage-database/details/article-

A53296 Wound Care & Debridement – Provided by a Therapist, Physician, NPP or as Incident-to


Local Coverage Determinations (LCDs):


Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>11000</td>
<td>Debridement of extensive eczematous or infected skin; up to 10 percent of body surface</td>
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<tr>
<td>CPT Code</td>
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<td>Comments</td>
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<tr>
<td>11042</td>
<td>Debridement, subcutaneous tissue (includes epidermis and dermis, if performed)</td>
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<tr>
<td>11043</td>
<td>Debridement, muscle and/or fascia (includes epidermis, dermis and subcutaneous tissue, if performed); first 20 sq cm or less</td>
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<tr>
<td>11044</td>
<td>Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed), first 20 sq cm or less</td>
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<tr>
<td>97597</td>
<td>Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), one wound, (e.g., fibrin, devitalized epidermis and/or dermis, debris, biofilm) including topical application(s), wound assessment, use of whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less</td>
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<tr>
<td>+97598</td>
<td>Each additional 20 sq cm or part thereof, list additionally to primary code</td>
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<tr>
<td>97602</td>
<td>Removal of devitalized tissue from wound(s), nonselective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion) including topical application(s), wound assessment, and instruction(s) for ongoing care per session</td>
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<tr>
<th>ICD-10 Code</th>
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<tbody>
<tr>
<td>E09.621</td>
<td>Drug or chemical induced diabetic foot ulcer</td>
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<tr>
<td>E10.621</td>
<td>Diabetic foot ulcer (Type I diabetes)</td>
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<tr>
<td>E11.621</td>
<td>Diabetic foot ulcer (Type II diabetes)</td>
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<tr>
<td>L97.401-L97.429</td>
<td>Chronic ulcer, unspecified heal and mid-foot</td>
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<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
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