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, 2016
Next Review Date: October 2017

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

Coverage policy

Keystone First 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:

- 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).
- 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:
  - 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.

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 that includes 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 [CNS], 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**
Keystone First searched PubMed and the databases of:
- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on September 20, 2016. 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 update:

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 the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project (HCUP) National Emergency Department Sample (NEDS) 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 Keystone First members who are at elevated risk of diabetic foot complications.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elraiyah (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Debridement methods for chronic DFUs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Systematic review and meta-analysis of 11 RCTs and three nonrandomized studies (800 total patients).</td>
</tr>
<tr>
<td></td>
<td>• Overall quality: low to moderate with a moderate risk of bias.</td>
</tr>
<tr>
<td></td>
<td>• Autolytic debridement significantly increased healing rate (relative risk [RR] 1.89, 95% confidence interval [CI] 1.35 to 2.64, three RCTs).</td>
</tr>
<tr>
<td></td>
<td>• Larval debridement reduced amputation (RR 0.43, 95% CI 0.21 to 0.88, one RCT and three nonrandomized studies) but did not increase complete healing (RR 1.27, 95% confidence interval [CI] 0.45 to 3.62, one RCT and four nonrandomized studies).</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------</td>
</tr>
</tbody>
</table>
| CI, 0.84 to 1.91. | - Surgical debridement: shorter healing time versus conventional wound care (one RCT).  
- The relative effectiveness of these methods is unclear and evidence for other methods is insufficient.  
- Choice of method should be based on available expertise, patient preferences, the clinical context, and cost. |
| Hingorani (2016) for the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine Guideline | **Key points:**  
- 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). |
| NICE (2015) Treatment of DFUs: guideline | **Key points:**  
- 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.  
- Debridement in the community should only be done by health care professionals with the relevant training and skills, continuing the care described in the person's treatment plan. |
| 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 (CAET) (2013) Conservative Sharp Wound Debridement (CSWD): guideline | **Key points:**  
- CSWDb 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 CSWDb uses an interdisciplinary approach to wound management and is critical to high-acuity wound care.  
- Ensure safe practice of CSWDb regardless of the client care setting: acute/primary care, clinic, community/home care, or long-term care. |
| Wounds International (2013) Guideline | **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...
Citation | Content, Methods, Recommendations
--- | ---
 | 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

<table>
<thead>
<tr>
<th>Key points:</th>
</tr>
</thead>
</table>
| - “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).


<table>
<thead>
<tr>
<th>Key points:</th>
</tr>
</thead>
</table>
| - 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 diabetic foot ulcers.
- More research is needed.

Glossary

**Autolytic debridement** — Uses the body’s own natural enzymes to liquefy necrotic tissue by keeping the wound moist with occlusive or semiocclusive dressings.

**Biochemical (enzymatic) debridement** — Uses topically applied agents that disrupt or digest extracellular proteins (e.g., enzyme collagenase).

**Biological debridement (myiasis)** — Uses sterile maggots to target necrotic tissue relatively painlessly.
Debride — To surgically excise dead, devitalized, or contaminated tissue; remove foreign matter from a wound.

Eschar — Dead tissue that sheds or falls off from healthy skin or appears on the wound surface.

Mechanical debridement — A nonselective method that physically removes debris from the wound. This is suitable for use in inflammatory wounds but not for those with fragile granulation tissue (e.g., wet-to-dry gauze dressings, water jet or ultrasonic irrigation).

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 usually requires no anesthesia. It cannot be used for patients with bleeding disorders or who are immune compromised.

Nonvital tissue — Dead or devitalized tissue (e.g., necrotic tissue and fibrin).

Surgical debridement — Uses instruments such as scissors, scalpels, or curettes to remove viable as well as nonviable tissue. It may require anesthesia for pain and/or the control of bleeding, and must be performed by a qualified professional. It cannot be used for patients with bleeding disorders or who are immune compromised.

Ulcer — Lesion of the skin that is accompanied by the formation of pus and necrosis of surrounding tissue, usually resulting from inflammation or ischemia.

References

Professional society guidelines/other:


Peer-reviewed references:


Clinical trials:


**CMS National Coverage Determination (NCDs):**

No NCDs identified as of the writing of this policy.

**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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11000</td>
<td>Debridement of extensive eczematous or infected skin; up to 10 percent of body surface</td>
<td></td>
</tr>
<tr>
<td>11042</td>
<td>Debridement, subcutaneous tissue (includes epidermis and dermis, if performed)</td>
<td></td>
</tr>
<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>
<td></td>
</tr>
<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>
<td></td>
</tr>
<tr>
<td>97597</td>
<td>Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), one wound, (eg, 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>
<td></td>
</tr>
<tr>
<td>+97598</td>
<td>Each additional 20 sq cm or part there of, list additionally to primary code</td>
<td></td>
</tr>
<tr>
<td>97602</td>
<td>Removal of devitalized tissue from wound(s), nonselective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion) including topical application(s), wound assessment, and instruction(s) for ongoing care per session</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>E09.621</td>
<td>Drug or chemical induced diabetic foot ulcer</td>
<td></td>
</tr>
<tr>
<td>E10.621</td>
<td>Diabetic foot ulcer (Type I diabetes)</td>
<td></td>
</tr>
<tr>
<td>E11.621</td>
<td>Diabetic foot ulcer (Type II diabetes)</td>
<td></td>
</tr>
<tr>
<td>L97.401-L97.429</td>
<td>Chronic ulcer, unspecified heal and mid-foot</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No codes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>