LOW FREQUENCY, NON-CONTACT, NON-THERMAL ULTRASOUND

Guideline Number: MPG192.05
Approval Date: February 12, 2020

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POLICY SUMMARY

Overview

For the purposes of this policy, wound care is defined as care of wounds that are refractory to healing or have complicated healing cycles either because of the nature of the wound itself or because of complicating metabolic and/or physiological factors. This definition excludes management of acute wounds, the care of wounds that normally heal by primary intention such as clean, incised traumatic wounds, surgical wounds that are closed primarily and other postoperative wound care not separately payable during the surgical global period.

UnitedHealthcare would expect that wound care may be necessary for the following types of wounds:

- Wounds with biofilm.
- Surgical wounds that must be left open to heal by secondary intention.
- Infected open wounds induced by trauma or surgery.
- Wounds associated with complicating autoimmune, metabolic, and vascular or pressure factors.
- Open or closed wounds complicated by necrotic tissue and/or eschar.

Wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. Eventual wound closure with or without grafts, skin replacements or other surgery (such as amputation, wound excision, etc.) should be the goal of most chronic wound care. UnitedHealthcare payment for professional wound care procedures requires that all applicable adjunctive measures are also employed as part of comprehensive wound management. Such adjunctive measures include but are not limited to appropriate control of complicating factors such as pressure (i.e., off-loading, padding, and appropriate footwear), infection, vascular insufficiency, metabolic derangement and/or nutritional deficiency. Wound care in the absence of such measures, when they are indicated, is not considered to be medically reasonable and necessary.

While complete healing of the wound may be the primary objective, a secondary desired objective is that, with appropriate management, a wound may reach a state at which its care should be performed primarily by the member and/or the member’s caregiver with periodic physician assessment and supervision.

Guidelines

Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) (for ongoing care, per day) describes a system that uses continuous low-frequency ultrasonic energy to produce and propel a mist of liquid and deliver continuous low-frequency ultrasound to the wound bed. This modality is often referred to as “MIST Therapy.”

Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) will be considered reasonable and necessary wound therapy and therefore eligible for coverage by UnitedHealthcare when provided as wound therapy for any of the following clinical conditions:

- Wounds and ulcers which are too painful for sharp or excisional debridement and have failed conventional debridement with documentation supporting the same.
- Wounds and ulcers meeting UnitedHealthcare coverage for debridement but with documented contraindications to sharp or excisional debridement.
- Wounds and ulcers meeting UnitedHealthcare coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care.

Coverage for Low Frequency, non-contact, non-thermal ultrasound is as follows:
- Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided two to three times per week to be considered reasonable and necessary. The length of individual treatments will vary per wound size.
- Observable, documented improvements in the wound(s) should be evident after six treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size; or improved granulation tissue. Continuing treatments for wounds demonstrating no improvement after six treatments is considered not reasonable and necessary.
- No more than 18 treatments within a six week period will be considered reasonable and necessary.

This type of therapy is included in the payment for the treatment of the same wound with other active wound care management or wound debridement. Low frequency, non-contact, non-thermal ultrasound treatments would be separately billable if other active wound management and/or wound debridement is not performed.

**Documentation Requirements**

Documentation supporting the medical necessity should be legible, maintained in the member's medical record, and must be made available to UnitedHealthcare upon request. The services should be medically necessary based on the member's documentation of a medical evaluation of the member's condition, diagnosis, and plan.

In the member's medical record, there must be clearly documented evidence of the progress of the wound’s response to treatment at each physician visit. This documentation at a minimum should include:
- Current wound volume (surface dimensions and depth).
- Presence (and extent of) or absence of obvious signs of infection.
- Presence (and extent of) or absence of necrotic, devitalized or non-viable tissue.
- Other material in the wound that is expected to inhibit healing or promote adjacent tissue breakdown.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>97610</td>
<td>Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day</td>
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**Coding Clarification:** For ICD-10 Diagnosis codes see the related Local Coverage Determinations.

**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.
REFERENCES

CMS Local Coverage Determinations (LCDs) and Articles

<table>
<thead>
<tr>
<th>LCD</th>
<th>Article</th>
<th>Contractor</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>L37166 (Wound Care)</td>
<td>A55818 (Billing and Coding: Wound Care)</td>
<td>First Coast</td>
<td>FL, PR, VI</td>
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<td>L35125 (Wound Care)</td>
<td>A53001 (Billing and Coding: Wound Care)</td>
<td>Novitas</td>
<td>AR, CO, DC, DE, LA, MD, MS, NM, NJ, OK, PA, TX</td>
<td>AR, CO, DC, DE, LA, MD, MS, NM, NJ, OK, PA, TX</td>
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<td>L37228 (Wound Care)</td>
<td>A55909 (Wound Care Coding Companion for Wound Care L37228)</td>
<td>WPS</td>
<td>AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
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<td>L34427 (Outpatient Occupational Therapy)</td>
<td>A53773 (Billing and Coding: Low frequency, non-contact, non-thermal ultrasound)</td>
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<td>L34428 (Outpatient Physical Therapy)</td>
<td>A54555 (Billing and Coding: Low frequency, non-contact, non-thermal ultrasound)</td>
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<td>A56175 (Low frequency, non-contact, non-thermal ultrasound (CPT code 97610))</td>
<td>CGS</td>
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CMS Transmittals

- Transmittal 2845, Change Request 8572, Dated 12/27/2013 (January 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS))
- Transmittal 3156, Change Request 9014, Dated 12/22/2014 (January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS))

MLN Matters

- Article MM8482, 2014 Annual Update to the Therapy Code Lists
- Article MM9014, January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)

UnitedHealthcare Commercial Policy

Warming Therapy and Ultrasound Therapy for Wounds

Other

National Correct Coding Initiative Coding Policy Manual for Medicare Services

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Policy Summary Overview</th>
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<tr>
<td>02/12/2020</td>
<td>Added language to clarify, <em>while complete healing of the wound may be the primary objective, a secondary desired objective is that</em>, with appropriate management, it is expected that, in most cases, a wound <em>may</em> reach a state at which its care should be performed primarily by the member and/or the member’s caregiver with periodic physician assessment and supervision.</td>
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<td>Action/Description</td>
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|      | **Documentation Requirements**  
|      | • Added language to indicate [wound care] services should be medically necessary based on the member’s documentation of a medical evaluation of the member’s condition, diagnosis, and plan  
|      | **Supporting Information**  
|      | • Updated References section to reflect the most current information |

**TERMS AND CONDITIONS**

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.