

Via e-mail to Deb.Wohlenhaus@wpsic.com

July 1, 2008

Deborah Wohlenhaus
Mutual of Omaha Insurance Company
P.O. Box 1602
Omaha, NE 68101

RE: Draft LCD for Wound Care (DL15700)

Dear Ms. Wohlenhaus:

On behalf of more than 35,000 occupational therapy professionals represented by the American Occupational Therapy Association (“AOTA”), many of whom provide services to Medicare beneficiaries under Parts A and B of the Medicare program, we submit the enclosed comments in response to the draft local coverage determination (“LCD”) for Wound Care (DL15700) (referred to hereinafter as “draft LCD”). Before commenting on the specific language of the draft LCD, AOTA offers the following general comments and recommendations for your consideration.

GENERAL COMMENTS

Occupational Therapists Are Providers of Wound Care Services

The draft LCD does not acknowledge the breadth of wound care services within the scope of practice of occupational therapists and occupational therapy assistants. AOTA’s *Definition of Occupational Therapy Practice for the AOTA Model Practice Act*¹ appropriately identifies wound care as within the Occupational Therapy scope of practice, as does the AOTA’s *Scope of Practice* document.² Occupational therapists and occupational therapy assistants routinely work with individuals and populations who are at risk for or have sustained wounds.³ Furthermore, both the occupational therapist and the occupational therapy assistant are bound by the Occupational Therapy Code of Ethics to demonstrate competency prior to the delivery of any particular service.⁴ In addition to specific comments below identifying areas of occupational therapy practice, the AOTA requests that any revisions to the draft LCD clearly recognize the role of occupational therapy in the provision of wound care services. Failure to expressly mention occupational therapy when discussing these services is likely to result in confusion regarding whether

¹ *Definition of Occupational Therapy Practice for the AOTA Model Practice Act* (2006).

² *Scope of Practice, American Occupational Therapy Association* (2006).

³ *Wound Management White Paper, American Occupational Therapy Association* (2007).

⁴ *AOTA Occupational Therapy Code of Ethics* (2005), Principle 4.

coverage exists for such services provided by or under the supervision of occupational therapists and unnecessary and costly referrals to other personnel.

Rules of Thumb

Throughout the draft LCD there are “rules of thumb” identified, which attempt to limit coverage to patients whose response to treatment falls outside of these parameters. For example, the following are excerpts from the draft LCD:

Medicare expects that with appropriate care, wound volume or surface dimension should decrease by at least 10 percent per month or wounds will demonstrate margin advancement of no less than 1 mm/week.

...

With appropriate management, it is expected that, in most cases, a wound will reach a state at which its care should be performed primarily by the patient and/or the patient’s caregiver with periodic physician assessment and supervision.

...

A total of no more than five debridement services within a 12 (twelve) month period.

AOTA has grave concerns with the use of “rules of thumb” to predetermine a patient’s need for wound care service. In fact, CMS, through its Medicare Manuals, has stated that the use of rules of thumb on the frequency or duration of therapy and other services is not permitted by CMS and is not an option for contractors.

Please see the following sections for guidance on the prohibition on the use of restrictions on frequency and durations under Medicare (applies to both Parts A and B):

Medicare recognizes that determinations of whether hospital stays for rehabilitation services are reasonable and necessary must be based upon an assessment of each beneficiary’s individual care needs. Therefore, denials of services based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms, “the three hour rule,” or another other “rules of thumb” are not appropriate.⁵

“Rules of thumb” in the MR [medical review] process are prohibited. Intermediaries must not make denial decisions solely on the reviewer’s general inferences about beneficiaries with similar diagnoses or on general data related to utilization. Any “rules of thumb” that would declare a claim not covered solely on the basis of elements, such as, lack of restoration potential, ability to walk a certain number of feet, or degree of stability is unacceptable without individual review of all pertinent facts to determine if coverage may be justified. Medical denial decisions must be based on a detailed and thorough analysis of the beneficiary’s total condition and individual need for care.⁶

⁵ Medicare Benefit Policy Manual (CMS Pub. 100-02), Ch. 1, § 110.1 (General).

⁶ Program Integrity Manual (CMS Pub. 100-08), Ch. 6, § 6.1 (Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills).

Medicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs. Therefore, denial of services based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms is not appropriate.⁷

AOTA urges the removal of the various "rules of thumb" used throughout the draft LCD.

SPECIFIC COMMENTS

Indications and Limitation of Coverage and/or Medical Necessity

Evidence of Wound Healing

The AOTA appreciates that evidence of wound healing is an appropriate outcome measurement to demonstrate medical necessity; however, the AOTA is concerned with the guidance related to demonstrating improvement through wound measurements. The draft LCD does not appear to consider that a wound may increase in size even after treatment is initiated, such as when a pressure ulcer had not yet fully developed, or when the removal of necrotic tissue results in a larger measurable wound or the ability to fully appreciate the extent of the wound. Even with this increased wound size, healing may be occurring. The AOTA recommends that the draft LCD account for situations in which the wound may increase in size with clinically appropriate and medically necessary treatment.

Although the AOTA understands that an occupational therapist is providing an assessment of a wound each time treatment is provided, measurable changes may not be appreciated every treatment. As such, the AOTA urges that weekly documentation of the wound parameters ("drainage, inflammation, swelling, pain, wound dimensions (diameter, depth), necrotic tissue/slough") is more appropriate than requiring such information to be documented each date of service. Furthermore, this standard would be consistent with other CMS guidance related to wound care, such as the guidance for the treatment of pressure ulcers, where CMS sets an appropriate time frame of weekly (unless complications or changes require more frequent documentation) for documenting the wound assessment (including wound location, stage, size, description of the wound bed and surrounding tissue).⁸ Setting a standard of weekly documentation would not be inconsistent with other the draft LCD guidance that "a wound that shows no improvement after 30 days requires a new approach." Measurable improvement is likely to be more evidence when comparing weekly assessments rather than every treatment assessments.

Sharp Debridement

The initial definition of "sharp debridement" is neither consistent with current clinical practice nor other guidance for sharp debridement in the draft LCD. Included within the definition is the requirement that the procedure be performed "while the patient is under local anesthesia." It is not within the scope of practice for an occupational therapist to provide local anesthesia; and, 97597 and 97598, codes that

⁷ Medicare Benefit Policy Manual (CMS Pub. 100-02), Ch. 7, § 20.3 (Use of Utilization Screens and "Rules of Thumb").

⁸ State Operations Manual (CMS Pub. 100-07), Appendix PP (Guidance under F-314).

clearly within the occupational therapy scope of practice, specifically define selective debridement “without anesthesia.” As an alternative, AOTA suggests the following rewording:

Sharp debridement is performed in an office setting or at the patient’s bedside, *and may or may not be performed* while the patient is under local anesthesia.

Non-Selective Debridement Techniques - Whirlpool

The following draft LCD language related to the use of whirlpool for wound care is troublesome to AOTA:

Whirlpool is considered for coverage if medically necessary for the healing of the wound. Generally, whirlpool treatments do not require the skills of a therapist to perform. The skills of a physical therapist may be required to perform an accurate assessment of the patient and the wound to assure the medical necessity of the whirlpool for the specific wound type. Documentation must support the use of skilled personnel in order to be considered for coverage. The skills, knowledge and judgment of a qualified physical therapist might be required when the patient’s condition is complicated by circulatory deficiency, areas of desensitization, complex open wounds, and fractures. Immersion in the whirlpool to facilitate removal of a dressing would not be considered a skilled treatment modality and would not be billable.

This draft text appears to blend concepts related to the delivery of a skilled procedure to the application of a supervised modality, i.e., a whirlpool treatment. The term “supervised” was utilized, for CPT coding purposes, to distinguish modalities that did not require one-to-one constant attendance from modalities that do require constant attendance. Modalities that did not specifically require the constant attendance of qualified personnel were included in the listing of “supervised modalities” to indicate that the qualified personnel would provide the requisite supervision but not necessarily render the specific treatment. The relative value unit assigned to a particular supervised modality was based not only on the staff expense to set up and clean the equipment after use, but also upon the costs of the equipment (acquisition, maintenance and repair). These costs are incurred and should continue to be covered irrespective of the fact that a supervised modality may require a lesser amount of clinician oversight.

Therefore, AOTA requests that the draft LCD reflect the use of whirlpool treatments as a unique modality to be used irrespective of the clinical complexity of the patient. In addition to utilizing the agitation of the whirlpool to loosen and soften necrotic tissue prior to sharp debridement, a whirlpool treatment yields clinical benefits that other therapy modalities do not offer. For example, in order to thoroughly cleanse a chronic wound prior to the application of electrical stimulation, it may be necessary to utilize a whirlpool treatment where the agitation can reach areas otherwise not able to be easily cleansed. Additionally, the whirlpool is often an appropriate modality to use when teaching a patient how to properly clean a wound prior to the application of the wound dressing. Thus, including a whirlpool treatment in the therapy treatment plan, irrespective of whether a patient’s condition is “complicated by circulatory deficiency, areas of desensitization, complex open wounds, and fractures,” may be both medically necessary and clinically efficacious.

Additionally, this section is an example where the failure to mention occupational therapists, referencing only physical therapists, may be misinterpreted as prohibiting coverage for whirlpool treatments as a component of an occupational therapy treatment plan for a patient receiving wound care.

General Information – Documentation Requirements

Contained within the Documentation Requirements section is the same requirement, discussed above, that the wound assessment be documented “at each physician visit.” For the reasons stated above, AOTA requests that the standard be weekly not every treatment. Furthermore, this language should be generic to providers of wound care or include other professionals, such as occupational therapists, who perform wound assessments in conjunction with wound care.

Other examples of the failure to expressly identify occupational therapists as providers of wound care appear in this section. In addition to AOTA’s concern about this omission is the concern expressed earlier regarding whirlpool treatments. AOTA suggests the following alternative language:

Active debridement must be performed under a treatment plan as any other physical therapy *or occupational therapy* service outlining specific goals, duration, frequency, modalities, an anticipated endpoint, and other pertinent factors as they may apply.

When hydrotherapy (whirlpool) is billed by a physical therapist *or an occupational therapist* with CPT codes 97597 or 97598, the documentation must reflect that *clinical reasoning why hydrotherapy was a necessary component of the total wound care treatment.*

We hope that these comments are helpful and greatly appreciate the opportunity to comment on the draft Wound Care LCD. We look forward to continuing dialogue with Mutual of Omaha on these issues as they apply to occupational therapy. Should you have any questions or comments, please contact me at (301) 652-2682 ext. 2019 or via email at cwillmarth@aota.org. Thank you once again for considering the comments submitted above, and for your continued work on the behalf of Medicare beneficiaries.

Sincerely,



Charles Willmarth
Director, State Affairs and Reimbursement and Regulatory Affairs

Enclosures:

Definition of Occupational Therapy Practice for the AOTA Model Practice Act (2006).

Scope of Practice, American Occupational Therapy Association (2006).

Wound Management White Paper, American Occupational Therapy Association (2007).

AOTA Occupational Therapy Code of Ethics (2005), Principle 4.

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