ALLIANCE OF

Wound Care Stakeholders

December 3, 2008

Stephen Boren, MD, MBA
Contractor Medical Director
Wisconsin Physicians Service
111 East Wacker Drive, #950
Chicago, IL 60611

RE: Comments on Draft LCD for Wound Care GSURG- 051

Dear Dr. Boren:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the Wisconsin Physician Services (WPS) draft Local Coverage Determination (LCD) on wound care. The Alliance is a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations whose mission is to promote quality care and patient access to wound care products and services. Many of the physician and clinical organizations who participate in the Alliance have many members who practice as well as conduct clinical research in the areas of wound care. These comments were written with the advice of the following Alliance organizations who possess expert knowledge in complex acute and chronic wounds as well as in wound care research. These include: American Association of Wound Care Management, American College of Certified Wound Specialists, American College of Hyperbaric Medicine, American College of Surgeons, American Professional Wound Care Association; Coalition of Wound Care Manufacturers; and the National Association for the Support of Long Term Care.

As WPS finalizes its LCD on wound care, we would like to offer the Alliance as a resource to you and your staff due to our expertise on this subject. We have listed below an executive summary which addresses our general comments. We have also addressed specific comments (in red) which have been placed directly into the LCD in order to assist you in reviewing our comments in an easier manner.

Executive Summary

We commend WPS for recognizing the importance of providing coverage to Medicare patients for wound care and taking the time and effort to craft a LCD that reflects best practices. This LCD will have a major impact on our Alliance organizations and their patients.

The draft policy is comprehensive; however, the Alliance has concerns that throughout the document there are inconsistencies, inaccurate information, and needed clarification

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in various areas.   First of all, throughout the draft LCD, WPS has placed inaccurate information corresponding to certain CPT codes and has strayed from current CPT code definitions. While we offer our specific comments and changes directly in the document, generally, we recommend that WPS adhere to the actual CPT code book definitions for any of the codes being utilized in this draft policy.

Second, a major portion of this draft policy deals with the debridement of wounds. There are a few types of debridement that can be utilized – at the discretion of the provider based on their assessment of the wound – yet it is not always clear which type of debridement is being referred to in the draft. The Alliance does not endorse the term "serial" debridement, but WPS utilizes different terminology throughout the document to describe debridement and it is very confusing. We recommend that WPS utilize the timing of the debridement (initial and subsequent) rather than the type of debridement. In addition, the Alliance would be happy to address the evidence that exists to define appropriate debridement types and frequency should WPS wish to engage in this dialogue.

Third, there are several areas in this draft policy where there were conflicting statements, inconsistent language and/or areas where it appears that the same information was described multiple times in different manners. We noted these in our specific comments that are stated below.

Specific Comments

Indications and Limitations of Coverage and/or Medical Necessity

This policy addresses non-operating department care of wounds, including but not limited to ulcers, pressure sores, open surgical sites, fistulas, tube sites and tumor erosion sites.

This policy does not address metabolically active human skin equivalent/substitute dressings, burns or hyperbaric oxygen therapy. (Note: see NCD 20.29 for Hyperbaric Oxygen Therapy). (Note: see GSURG-037 Application of Bioengineered Skin Substitutes and Skin Grafting - Part B Physician Services).

In order to be covered under Medicare per Title XVIII of the Social Security Act 1862(a)(1)(A) a service must be reasonable and necessary, which includes services which are safe and effective, furnished in the appropriate setting, and ordered and/or furnished by qualified personnel.

WOUND CARE should employ comprehensive wound management including appropriate control of complicating factors such as unrelieved pressure, infection, vascular and/or uncontrolled metabolic derangement, and/or nutritional deficiency in addition to appropriate debridement. Medicare coverage for WOUND CARE on a continuing basis for a particular wound in a patient requires documentation in the patient's record that the wound is improving in response to the WOUND CARE being provided or that a change in wound care treatment is being implemented if the wound is

stagnant. It is not medically reasonable or necessary to continue a given type of WOUND CARE if evidence of wound improvement cannot be shown as long as the overall goal of care for that patient is healing and not palliation.

COMMENT/RECOMMENDATION: The Alliance recommends that the above language be added in order to reflect current best practices.

Evidence of improvement includes measurable changes (decreases) of one or more of the following:

- Drainage
- Inflammation
- Swelling
- Pain
- Wound Dimensions (diameter, depth)
- Necrotic tissue/slough

COMMENT/RECOMMENDATION: The Alliance recommends adding the following metrics for wound improvement to the above list:

- Odor
- Increase in granulating tissue.
- Exudate reduction
- Tunneling and Undermining

Such evidence must be documented with each date of service provided. A wound that shows no improvement after 30 days requires a new approach, which may include physician reassessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment approach.

COMMENT: The Alliance has concerns with the above paragraph. First, we believe that there are other qualified providers that can and do reassess non healing wounds. Second, we are concerned about the 30 day requirement as written. If a patient (and therefore the wound) suffers a setback, for example a severe heart attack, the 30 day clock should reset. WPS has not made any provision in this draft policy for the 30 day clock to restart should there be a setback or a stall in healing. The Alliance believes that the resetting of the 30 days is very important as different interventions will be taken to treat the patient depending on their status. We would also like to have WPS clarify when the actual 30 day requirement would begin.

RECOMMENDATION: The Alliance believes the sentence needs to be modified to read as follows, "A wound that shows no improvement after 30 days requires a new approach, which may include a reassessment by a qualified provider of underlying infection, metabolic, nutritional or vascular problems inhibiting wound healing or a new treatment approach. If a patient suffers a medical or surgical condition that negatively impacts wound healing progression – whether a stall or a setback in healing - then the 30 day requirement would reset."

Debridement is defined as the removal of foreign material and/or devitalized or contaminated tissue from or adjacent to a traumatic or infected wound until surrounding healthy tissue is exposed. This LCD applies to debridement of localized areas such as wounds and ulcers. It does not apply to the removal of extensive eczematous or infected skin.

COMMENT/RECOMMENDATION: The Alliance recommends that an additional sentence be added to this paragraph (taken from your draft policy below) which reads as follows: "Providers should select a debridement method most appropriate to the type of wound, the amount of devitalized tissue, and the condition of the patient, the setting, and the provider's experience."

Debridements of the wound(s), if indicated, must be performed judiciously and at appropriate intervals. 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.

COMMENT: The Alliance believes the information contained in this sentence conflicts with earlier definitions of wound healing provided by WPS in this draft document. Previously, WPS stated that evidence of improvement includes measureable changes (decreases) of the following and listed 6 measures. The Alliance believes that WPS should use the definition and not include specific values.

However, if WPS should decide to include a value, as providers, clinicians and researchers, we are not aware of any evidence that would support the statement, "Medicare expects that with appropriate care, wound volume or surface dimension will demonstrate margin advancement of no less than 1 mm/week."

The rationale for this is the following: The wound will not heal 1 mm/wk in the initial 30 day time frame. The wound is within the inflammatory and early proliferative phase of healing at this time frame and much of the improvement is at the biochemical and cellular level and not measurable at the macroscopic level. Margin migration will not occur until a wound is fully granulated (depth fully eliminated) and epithelial migration can proceed. Surface area can reduce at this early time frame but it is secondary to contraction which can be asymmetrical and difficult to measure as described in this policy. Additionally, the 1 mm/wk does not take into account the initial size of the wound. .

RECOMMENDATION: The Alliance recommends that WPS be consistent in its definitions, and recommends removing references to the 1 mm/wk. The Alliance also recommends that the sentence be modified to read, "Medicare expects that with appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should generally decrease by 10 percent per month."

Medicare expects the wound care treatment plan to be modified in the event that appropriate healing is not achieved.

Surgical debridement is excision or wide resection of all dead or devitalized tissue, possibly including excision of the viable wound margin.

COMMENT: It appears that WPS is not utilizing the CPT code descriptors from the CPT coding book when defining surgical debridement. The Alliance submits that the AMA approved definitions for CPT codes should be used and the CPT codes referred to as surgical debridement.

RECOMMENDATION: As such, the Alliance recommends that this sentence be modified to read, "Surgical debridement (CPT 11040-11044), as defined by the CPT 2009 book states, "***The removal of tissue by surgical means by cutting outside or beyond the wound margin in whole or in part".***

This is usually carried out in the operating theatre under anesthesia by a surgeon.

COMMENT: The Alliance disagrees with this sentence. The CPT 11000 series codes are not usually carried out in the operating room. They are more often carried out in wound care centers.

RECOMMENDATION: As such, the Alliance recommends that WPS not designate a location regarding where this procedure is usually done. We recommend that this sentence is deleted.

It is frequently used for deep tissue infection, drainage of abscess or involved tendon sheath, or debridement of bone.

COMMENT: This sentence is not consistent with the CPT code book for surgical debridement codes. Again, the Alliance is concerned that WPS is adding information into the definitions already established by the CPT code book.

RECOMMENDATION: We recommend that this sentence be deleted from the draft policy.

Sharp debridement is the removal of dead or foreign material just above the level of viable tissue, and is performed in an office setting or at the patient's beside with or without the use of local anesthesia. Sharp debridement is less aggressive than surgical debridement but has the advantage of rapidly improving the healing conditions in the ulcer. These typically are the services of recurrent, superficial or repeated wound care.

COMMENT: Sharp Debridement is included in the CPT 97597 code.

RECOMMENDATION: The Alliance would recommend that WPS utilize the definition of sharp debridement from the CPT code book since sharp selective debridement is included in the CPT 97597 code.

Debridement is used in the management and treatment of wounds or ulcers of the skin and underlying tissue. Providers should select a debridement method most appropriate to the type of wound, the amount of devitalized tissue, and the condition of the patient, the setting, and the provider's experience.

COMMENT: The Alliance believes that this sentence is better utilized in the first paragraph about debridement above.

RECOMMENDATION: Therefore, the Alliance recommends that this sentence should be deleted.

Debridements of the wound(s), if indicated, must be performed judiciously and at appropriate intervals. With the appropriate care, wound volume or surface dimension should decrease, once the size and depth of involvement and the extent of the undermining has been established. Interim outcomes should be established for the wound. These short-term goals help the clinician recognize wound improvement and serve to confirm the patient's wound-healing response. Medicare expects the wound-care treatment plan to be modified in the event that appropriate healing is not achieved. Providers who report debridement services to Medicare must pay close attention to CPT code definitions for debridements. The following coding guideline(s) is here for emphasis:

CPT codes 11040–11044 are used to report surgical removal (debridement) of devitalized tissue from wounds. CPT codes 11040–11044 are payable to physicians and qualified non-physician practitioners licensed by the state to perform the services.

CPT codes 97597–97598 are used to report selective (including sharp) and non-selective debridement of devitalized tissue and are payable to physicians as well as qualified non-physician practitioners, licensed physical therapists and licensed occupational therapists, if operating within their legal scope of practice.

COMMENT: The Alliance would like to point out that WPS has erroneously stated that CPT codes 97597-97598 are used to capture selective and non selective debridement. CPT codes 97597-97598 are only used to capture selective debridement. CPT code 97602 captures non-selective debridement and should be added to these guidelines.

RECOMMENDATION: As such, the Alliance recommends that "non-selective" be deleted from the definition guideline for 97597-97598 and CPT code 97602 be added to the list of code definitions for debridement utilized above. The Alliance recommends that the guidance language for CPT 97602 read as follows, "Removal of devitalized tissue from wound(s) non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion) including topical applications(s), wound assessment and instruction(s) for ongoing care, per session."

Removal of non-tissue integrated fibrin exudates, crusts, biofilms or other materials from a wound without removal of tissue does not meet the definition of any debridement code and may not be reported as such.

COMMENT: This sentence is erroneous since the CPT codes 97597 and 97598 already include this activity thus making the statement inconsistent with current CPT coding language. The CPT code book states the following:

- ***The removal of devitalized tissue including slough, fibrin, exudates, crusts, and other non-tissue materials from wounds***
- 97597 total wound(s) surface area ≤ 20 cm2;
- 97598 total wound(s) surface area > 20 cm2 and is billed once per patient per event
- 97597/97598:
  - Occasional bleeding and pain may occur, and the routine application of a topical or local anesthetic does not elevate active wound care management to excisional surgical debridement and includes:
  - Selective removal of fibrin or necrotic tissue of any description by sharp dissection including scissors, scalpel, tweezers, curette
  - Selective removal of necrotic tissue of any description by high pressure water jet

RECOMMENDATION: The Alliance recommends the removal of this sentence as it is incorrect.

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. Wound care that can be performed by the patient or the patient's caregiver will be considered to be maintenance care.

COMMENT: We believe that this language is not pertinent to debridement codes. We also would like to emphasize that comprehensive care is not limited to, for example, metabolic disorders. The Alliance has attached a proposed draft of a Palliative Care LCD for your consideration to also adopt. (addendum 1)

RECOMMENDATION: The Alliance would like to recommend that the language above be deleted and add the following language, "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 presenting goal of wound care. All patients presenting for chronic wound care should undergo a complete medical assessment appropriate to the nature and condition of the wound including screening and/or testing for underlying etiology, vascular status, nutritional status, and complicating co-morbidities. This initial assessment should result in a specific plan of care with ongoing management. Periodic reassessment and plan of care revision should occur. If it

is determined that the goal of care is not wound closure, the patient should be managed following appropriate palliative care standards as described in the Palliative Care LCD."

Wounds or ulcers that are juxtaposition, involve contiguous areas, or on the same extremity are considered to reflect only one debridement service. Thus, multiple units of services for these should not be billed.

COMMENT: The Alliance does not believe that the information provided in the previous two sentences is correct or reflective of current practice. Wounds that are located on the same extremity may require separate evaluation, decision-making and procedures resulting in different plans of care. Medicare recognizes this situation exists and has approved the use of modifier 59 for such instances. Since this vehicle already exists for the billing of this service, it is our position that the statement as provided by the Alliance below is more reflective of current practice and guidelines for wound care. Moreover, the information provided in the WPS draft document seems to be reflective of guidelines for both the 11000 codes as well as the 97000 codes. However, the CPT codes for the 97000 series are procedural codes and are chosen based on the surface area of the wound(s). It would not be appropriate to utilize these codes for guidance in this area. As such, WPS should clarify that this statement is only reflective of the 11000 series CPT codes.

RECOMMENDATION: The Alliance would like to recommend that the language above be changed to read as follows: "Wounds or ulcers that are in juxtaposition or involve contiguous areas are considered to reflect only one debridement service. Wounds significantly separated or of different etiologies may require different levels of debridement and should be able to be described and billed separately as appropriate when utilizing modifier 59."

Repeated debridements are not the same service as the original debridement service.

COMMENT: The Alliance believes that this sentence is inaccurate and misleading. It appears that WPS is suggesting that only one debridement should be necessary. This is simply not clinically realistic. Clinicians cannot mandate ahead of time what type of debridement will be necessary. There is no set structure as they are determined by the wound and the patient.

RECOMMENDATION: The Alliance recommends that this sentence be deleted.

CPT codes 11043 and 11044 are codes that describe deep debridement of the muscle and bone.

These original debridements typically are true surgical debridements. However, once the initial debridement of muscle and/or bone has been performed, there typically is no true necrotic muscle or bone there to be subsequently debrided. Equally important, once true debridements have been performed, further debridements are not actually bone or muscle: just because there is a Stage IV ulcer, additional debridements are not necessarily bone

and/or muscle debridements. The issue in billing for debridement services is not the stage of the wound; it is what procedure is actually being performed. A Stage III wound should not be automatically billed with CPT code 11043 nor should a Stage IV wound automatically be billed with a CPT code 11044 for further (repeated) debridements. Recurrent debridements most commonly are described by the CPT codes 11040, 97597, or 97598.

COMMENT: The Alliance strongly disagrees with the information provided in this paragraph. There are times when subsequent debridements are required, for example if there is more necrosis or the wound extends further.

RECOMMEN DATION: The Alliance recommends that this paragraph be modified to read as follows, "Subsequent debridements may be required following the initial debridement of chronic wounds as determined by the extent of the wound and the underlying pathophysiology. The extent of these debridements will be determined by the condition of the wound and may require removal of deep tissue including muscle or bone. It is anticipated that during the typical course of wound healing that the level and complexity of debridement will diminish over time."

Care of chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers through use of Electrical Stimulation (ES) or Electromagnetic Therapy (ET) is covered under the limitations detailed in the National Coverage Determination (NCD) published in the CMS Internet-Only Manual (IOM) Pub. 100-03, National Coverage Determinations Manual, Chapter 1, Part 4, Section 270.1. Medicare would not expect ES/ET to be used as the initial treatment modality. The use of ES/ET will be covered as part of a therapy care plan only after standard wound therapy has been tried for at least 30 days and there are no measurable signs of healing. Medicare would not expect the treatment of a wound to include both ES and ET. If measurable signs of healing (e.g., decrease in wound size/surface or volume, decrease in amount of exudates and decrease in amount of necrotic tissue) have not been demonstrated within any 30-day period, ES/ET should be discontinued.

COMMENT: At the beginning of the draft LCD, WPS provided a list of measureable signs of healing. In order to be consistent, WPS should include the entire list of measureable signs of healing.

RECOMMENDATION: The Alliance recommends that WPS be consistent with requirements for measureable signs of healing. As such, the list should read:

Evidence of improvement includes measurable changes (decreases) of ***one or more*** of the following:

- Drainage
- Inflammation
- Swelling
- Pain
- Wound Dimensions (diameter, depth)

- Necrotic tissue/slough

The Alliance recommends adding the following metrics for wound improvement to the above list:

- Odor
- Increase in granulating tissue.
- Exudate reduction
- Tunneling and Undermining

Additionally, ES/ET must be discontinued when the wound demonstrates a 100 percent epithelialized wound bed. See the CMS policy for full text.

Negative Pressure Wound Therapy (97605-97606): involves the application of controlled or intermittent negative pressure to a properly dressed wound cavity. Suction (negative pressure) is applied under airtight wound dressings to promote the healing of open wounds resistant to prior treatments or wounds in complex patients.

COMMENT/RECOMMENDATION: The Alliance recommends that the additional language provided above be added to the sentence in order to make the sentence consistent with current Medicare policy.

Negative pressure wound therapy facilitates the removal of excessive exudates that inhibit wound healing and creates mechanical tension on tissues that has positive cellular and biochemical effects on healings.

COMMENT/RECOMMENDATION: The Alliance recommends that the additional language included above be added as it more accurately reflects the definition of NPWT.

Medicare coverage will be considered for negative pressure wound therapy when it is used as an adjunct to surgery, an alternative to surgery, or a therapy for refractory chronic wounds.

Negative Pressure Wound Therapy Criteria: All of the following must be met:

• Wound is free of untreated osteomyelitis; and

COMMENT/RECOMMENDATION: The Alliance recommends that to be consistent with current Medicare policy WPS change the terminology used above from active to untreated osteomyelitis.

• Wound is free of eschar or most other nonviable or necrotic tissue and macroscopic contamination; and

COMMENT/RECOMMENDATION: The Alliance recommends that the additional language included above be added in order to be more consistent with generally accepted standards of care and manufacturers use of the technology.

• Medical record documents appropriate nutritional assessment(s) and interventions; and
• Wound does not contain exposed arteries or veins.

At least ONE of the following conditions must be present and documented:

o Pressure ulcers, Stage III or IV;
o Venous or arterial insufficiency ulcers;
o Dehisced wounds or wounds with exposed hardware or bone;
o Neuropathic ulcers
o Complications of surgically-created or traumatic wound where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment.

Selective debridement refers to the removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue. Occasional bleeding and pain may occur.
The routine application of a topical or local anesthetic does not elevate active wound care management to surgical debridement. Selective debridement includes selective removal of necrotic tissue by sharp dissection including scissors, scalpel, and forceps; and selective removal of necrotic tissue by high-pressure water jet. Selective debridement should only be done under the specific order of a physician.

COMMENT: The Alliance is concerned about the definition provided by WPS for selective debridement. It appears that information is being added to the definition of selective debridement provided by WPS – more information than is appropriate or reflective in the CPT code definitions as developed by the CPT Editorial Panel. Additionally, there is no requirement that a physician order be obtained before performing selective debridement under the Medicare program. According to the Medicare program, the certified plan of care is sufficient evidence of physician involvement as well as the appropriateness of the care being provided.

RECOMMENDATION: The Alliance recommends that WPS directly quote the definitions from the CPT book when defining selective debridement. The Alliance also recommends that the sentence, "selective debridement should only be done under the specific order of a physician" be deleted.

High Pressure Water Jet / Pulsed Lavage: (non-immersion hydrotherapy) is an irrigation device, with or without pulsation used to provide a water jet to administer a shearing effect to loosen debris, within a wound. Some electric pulsatile irrigation devices include suction to remove debris from the wound after irrigation.

COMMENT: As a point of clarification, the Alliance would like to know the rationale for the High Pressure Water Jet/Pulse Lavage information being placed in this section since it is a bit confusing and seems to us to be out of place.

The following Non-Selective Debridement Techniques are not separately billable

• Chemical: necrotic tissue is digested by exogenous proteases in the wound (Enzymes, hypertonic saline). Debridement with topical enzymes is used when the necrotic substances to be removed from a wound are protein, fiber and collagen.

• Whirlpool: 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 therapist may be required to perform an accurate assessment of the patient and the wound to assure the medial 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 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. Note that whirlpool is bundled into 97597 and 97598 and is not separately billable unless applied to a different body part that the wound being treated.

• Blunt debridement: Removal of necrotic tissue by cleansing, scraping, chemical application or wet to dry dressing technique. It may also involve the cleaning and dressing of small or superficial lesions. Generally, this is not a skilled service and does not require the skills of a therapist, nurse, or enterostomal nurse

• Enzymatic Debridement: 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 would be the clinician's responsibility to comply with those guidelines.

Mechanical Debridement: Wet-to-moist dressings may be used with wounds that have a high percentage of necrotic tissue. Hydrotherapy (immersion without jets) and wound irrigation (non-pulsated) are also forms of mechanical debridement used to remove necrotic tissue. They also should be used cautiously as maceration of surrounding tissue may hinder healing. Documentation must support the use of skilled personnel in order to be considered for coverage. While mechanical debridement is a valuable technique for healing ulcers, it does not qualify as debridement services (i.e. CPT 11040-11044 or 97597-97598). It does however qualify for CPT 97602

RECOMMENDATION: The Alliance recommends that WPS add the above language to the last sentence.

The following services are not considered wound debridement:
• Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, and wet-to-dry dressing.

• Scraping the base of the wound bed to induce bleeding, following the removal of devitalized tissue, is not considered to be a separately billable service.
• Washing bacterial or fungal debris from lesions.
• Removal of secretions and coagulation serum from normal skin surrounding an ulcer.
• Dressing of small or superficial lesions.
• Paring or cutting of corns or non-plantar calluses. Skin breakdown under a dorsal corn that begins to heal when the corn is removed and shoe pressure eliminated is not considered an ulcer and does not require debridement unless there is extension into the subcutaneous tissue.
• Incision and drainage of abscess including paronychia, trimming or debridement of mycotic nails, avulsion of nail plates, acne surgery, destruction of warts, or burn debridement. Providers should report these procedures, when they represent covered, reasonable and necessary services, using appropriate CPT or HCPCS codes.

COMMENT: While generally speaking the Alliance agrees with the list of services that are not considered debridement as stated above, we would like to point out that some of these services do fall within CPT code 97602 and as such should not be listed here. For example, when careful scraping and wet to dry dressing are performed in a nursing home they are considered debridement as defined in CPT 97602.

RECOMMENDATION: As such the Alliance recommends that when a service falls within the CPT code definition for 97602 a qualifying statement be provided at the beginning of this section which allows those services to be debridement services when performed as defined in CPT 97602.

Non-Covered Modalities:
• Ultrasonic Wound Debridement: (CPT code 0183T) a system that uses continuous low frequency ultrasonic energy to atomize a liquid and deliver continuous low frequency ultrasound to the wound bed. The level of scientific evidence is insufficient to validate the efficacy and superiority of this treatment to support it as a proven intervention. Based on the absence of scientific evidence to the contrary, this service will no be considered separately coverable by Medicare. If it is used in conjunction with other methods of sharp debridement, the sharp debridement only would be considered for coverage. In addition, this service does not qualify as a separate, significantly payable service.

COMMENT: The Alliance is seeking clarification on this topic. The CPT code definition for 0183T is “low frequency, NON-CONTACT, non-thermal, ultrasound, including topical application(s) when performed, wound assessment and instruction(s) for ongoing care, per day” and should not be titled “Ultrasonic Wound Debridement.” Moreover, we would like to clarify that CPT 0183T does not include or apply to the low frequency CONTACT ultrasonic wound debridement instruments, which are alternative techniques to perform selective debridement. These instruments are ultrasonically enhanced curettes, scalpels and cutting devices that are fully capable of performing sharp surgical and selective tissue debridement either in the operating room or in the wound care clinic.

The Alliance is also concerned about the statement that "the level of scientific evidence is insufficient to validate the efficacy and superiority of this treatment to support it as a proven intervention." The Alliance is aware of several studies that were not cited in this draft policy that in fact do validate the efficacy of this particular modality. The Alliance believes that the level of evidence that exists for this modality is more sufficient than what was identified in this document.

RECOMMENDATION: The Alliance recommends that WPS provide clarification that the CONTACT ultrasound devices are excluded from this policy. Additionally, the Alliance is aware of several organizations that are submitting specific comments on this particular modality and we urge you to review their comments very closely, along with the entirety of the peer-reviewed published studies containing 460 patients that were submitted with those comments.

• Massage: Massage has not been proven to be effective in wound care and will not be considered for coverage.

• Ultra-sound deep thermal modality (97035): The effectiveness of this modality has not been proven in wound care; and therefore will not be considered for coverage.

COMMENT: We are aware that several organizations are submitting comment on this matter and urge WPS to consider those comments carefully.

RECOMMENDATION: The Alliance recommends that ultrasound should be considered for coverage.

• Infrared (97026): see CMS Pub100-3, Chapter 1, Part 4, Section 270.6
• Noncontact Normothermic Wound Therapy (NNWT): There is insufficient scientific or clinical evidence to consider this device as reasonable and necessary for the treatment of wounds within the meaning of SSA 1862(a)(1)(A), and will not be covered by Medicare. (Pub 100-3, Chp 1, Part 4, Section 270.2)
• Blood-Derived Products for Chronic Non-Healing Wounds. (Pub 100-3, Chp 1, Part 4, Section 270.3)
• Dressing changes not separately payable.
• Phototherapy-ultraviolet (97028) used to promote healing of skin disorders will not be considered for coverage for decubitus ulcers.
• Trimming of callous or fibrinous material from the margins of an ulcer or from feet with no ulcer present is not considered debridement by this Contractor and would not be considered for coverage.
• Nutritional counseling.
• Documentation time
• Administrative tasks

Maintenance wound care is not covered as debridement services.

CPT code 97597 and 97598 require the presence of devitalized tissue (necrotic cellular material). Secretions of any consistency do not meet this definition. The mere removal of secretions (cleansing of a wound) does not represent a debridement service

CPT code 97602 has been assigned a status indicator "B" in the Medicare Physician Fee Schedule Database (MPFSDB), meaning that it is not separately payable under Medicare.

Skin breakdown under a dorsal corn that begins to heal when the corn is removed and shoe pressure eliminated is not considered an ulcer and generally does not require debridement that would be considered necessary and reasonable, unless the breakdown extends into the subcutaneous tissue.

These lesions typically heal without significant surgical intervention beyond removal of the corn and shoe modification. Generally, debridement is not considered reasonable and necessary if pressure reduction and infection control are sufficient to allow the healing of an ulcer. However, some wounds may develop or fail to heal in spite of these measures. Removing a collar of callus (hyperkeratotic tissue) around an ulcer is not debridement of skin or necrotic tissue and should not be billed as debridement.

The use of CPT codes 11040-11044 is not appropriate for the following services: washing bacterial or fungal debris from lesions, paring or cutting of corns or calluses, incision and drainage of abscess including paronychia, trimming or debridement of nails, avulsion of nail plates, acne surgery, destruction of warts, or burn debridement. Providers should report these procedures, when they represent covered, reasonable and necessary services, using the CPT or CPT codes that describe the service supplied.

Local infiltration, metacarpal/digital block or topical anesthesia are included in the reimbursement for debridement services and are not separately payable.

COMMENT: The Alliance is concerned about these services not being reimbursed under certain circumstances. For example, if a metacarpal block is done in the operating room and an anesthesiologist is monitoring the care, the anesthesiologist should not be precluded from being reimbursed for their services. The Alliance believes that caregivers should not be excluded from billing, and being reimbursed for appropriate monitored anesthesiology care including local infiltration or metacarpal block.

RECOMMENDATION: The Alliance recommends that the language above is modified to reflect these concerns.

Anesthesia administered by or incident to the provider performing the debridement procedure is not separately payable.

Active wound care may not be billed by a Medicare Part B provider when a home health agency (HHA) is seeing the patient as that service is considered to be included in the HHA care.

Active wound care may not be billed by a Medicare Part B provider when a home health agency (HHA) is seeing the patient as that service is considered to be included in the HHA care.

COMMENT: The Alliance would like to seek clarification in this section. Specifically, we do not believe it is the intention of WPS to limit a home care patient from seeking treatment in a wound care center. A home care patient can receive wound dressing changes from a home health nurse and can still go to a wound care center to have services rendered by a physician or physician extender requiring additional dressing changes. The Alliance would like to ensure that a wound care center under this scenario can still bill Medicare and be reimbursed for their services. The Alliance understands that that WPS does not want any duplication in billing, but we do believe under the scenario raised above, the wound care center should be able to provide care to a wound care patient and be reimbursed for their services. The Alliance would also like to clarify that this section is not precluding a home care physician from conducting surgical procedures and/or Evaluation and Management (E//M) services on a patient – as deemed medically necessary.

RECOMMENDATION: The Alliance would like to point out that the sentence is repeated twice and therefore one should be deleted.

Coverage Topic
Ambulatory Surgical Centers
Outpatient Hospital Services
Surgical Services
Bill Type Codes:
12x Hospital-inpatient or home health visits (Part B only)
13x Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
22x SNF-inpatient or home health visits (Part B only)
23x SNF-outpatient (HHA-A also)
71x Clinic-rural health
73x Clinic-independent provider based FQHC (eff 10/91
75x Clinic-CORF
83x Special facility or ASC surgery-ambulatory surgical center (Discontinued for Hospitals Subject to Outpatient PPS; hospitals must use 13X for ASC claims submitted for OPPS payment -- eff. 7/00)
85x Special facility or ASC surgery-rural primary care hospital (eff 10/94)
Revenue Codes:
0360 Operating room services-general classification
0420 Physical therapy-general classification
0421 Physical therapy-visit charge
0422 Physical therapy-hourly charge
0423 Physical therapy-group rate
0429 Physical therapy-other
0430 Occupational therapy-general classification

0431 Occupational therapy-visit charge
0432 Occupational therapy-hourly charge
0433 Occupational therapy-group rate
0434 Occupational therapy-evaluation or re-evaluation
0439 Occupational therapy-other (may include restorative therapy)
0450 Emergency room-general classification
0451 Emergency room-emtala emergency medical screening services (eff 10/96)
0452 Emergency room-ER beyond emtala screening (eff 10/96)
0456 Emergency room-urgent care (eff 10/96)
0459 Emergency room-other
0490 Ambulatory surgical care-general classification
0499 Ambulatory surgical care-other
0510 Clinic-general classification
0511 Clinic-chronic pain center
0512 Clinic-dental center
0513 Clinic-psychiatric
0514 Clinic-OB-GYN
0515 Clinic-pediatric
0516 Clinic-urgent care clinic (eff 10/96)
0517 Clinic-family practice clinic (eff 10/96)
0519 Clinic-other
0520 Free-standing clinic-general classification
0521 Free-standing clinic-rural health clinic
0761 Treatment or observation room-treatment room (eff 9/93)
0977 Professional fees-physical therapy
0978 Professional fees-occupational therapy

CPT/HCPCS Codes

11040 Debride skin, partial
11041 Debride skin, full
11042 Debride skin/tissue
11043 Debride tissue/muscle
11044 Debride tissue/muscle/bone
97597 Removal of devitalized tissue from wound(s), selective debridement, without anesthesia (eg,high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), with or without topical application(s), wound assessment, and instruction(s) for ongoing care, may include use of a whirlpool, per session; total wound(s) surface area less than or equal to 20 square centimeters
97598 Removal of devitalized tissue from wound(s), selective debridement, without anesthesia (eg,high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), with or without topical application(s), wound assessment, and instruction(s) for ongoing care, may include use of a whirlpool, per session; total wound(s) surface area greater than 20 square centimeters
97602 Wound(s) care non-selective
97605 Neg press wound tx, < 50 cm
97606 Neg press wound tx, > 50 cm

G0281 Electrical stimulation, (unattended), to one or more areas, for chronic stage iii and stage iv pressure ulcers, arterial ulcers, diabetic ulcers, and venous statsis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
G0329 Electromagnetic therapy, to one or more areas for chronic stage iii and stage iv pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

Does the CPT 30% Rule Apply
No

ICD-9 Codes that Support Medical Necessity

COMMENT: The Alliance would like to point out that several codes were left out from this list.

RECOMMENDATION: The Alliance would like to recommend that WPS add the following ICD-9 codes:

707.20-707.25: Pressure ulcers, stages I-IV and unstageable (new ICD-9 codes effective 10/1/2008)
729.90-729.99: Disorders of soft tissue (new ICD-9 codes effective 10/1/2008)
998.30: Disruption of wound, unspecified (new ICD-9 code effective 10/1/2008)
998.33 Disruption of traumatic injury wound repair (new ICD-9 code effective 10/1/2008)

Note: ICD-9 codes must be coded to the highest level of specificity.
Medicare is establishing the following limited coverage for CPT/HCPCS codes 11040, 11401, 11042,11043, 11044, 97597, 97598, 97602, 97605 and 97606.
040.0 GAS GANGRENE
440.23 Atherosclerosis of native arteries of the extremities with ulceration
440.24 Atherosclerosis of native arteries of the extremities with gangrene
443.9 Peripheral vascular disease
454.0 Varicose veins of lower extremities with ulcer
454.1 Varicose veins of lower extremities with inflammation
454.2 Varicose veins of lower extremities with ulcer and inflammation
680.0 - 680.9 Carbuncle and furuncle of face - carbuncle and furuncle of unspecified
681.0 - 681.9 Unspecified cellulitis and abscess of finger - cellulitis and abscess of unspecified digit
682.0 - 682.9Cellulitis and abscess of face - cellulitis and abscess of unspecified sites
686.09 Other pyoderma
686.8 Other specified local infections of skin and subcutaneous tissue
686.9 Unspecified local infection of skin and subcutaneous tissue
707.00- 707.9 Decubitus ulcer, unspecified site - chronic ulcer of unspecified site
709.4 Foreign body granuloma of skin and subcutaneous tissue

728.86 Necrotizing fasciitis
729.6 Residual foreign body in soft tissue
730.10 - 730.19 Chronic osteomyelitis site unspecified - chronic osteomyelitis involving multiple sites
730.20 -730.29 Unspecified osteomyelitis site unspecified - unspecified osteomyelitis involving multiple sites
758.4 Balanced autosomal translocation in normal individual
785.4 Gangrene
872.0 –872.01 OPEN WOUND OF EXTERNAL EAR UNSPECIFIED SITE COMPLICATED – Auricle, ear
872.8 - 872.9 Open wound of ear part unspecified without complication - open wound of ear part unspecified complicated
873.30 - Open wound of scalp without complication - open wound of scalp complicated 873.1
873.2 –873.21 OPEN WOUND OF NOSE - UNSPECIFIED SITE WITHOUT MENTION of COMPLICATION
873.40 - 873.59 Open wound of face unspecified site uncomplicated - open wound of other and multiple sites complicated
873.8 Other and unspecified open wound of head without complication
875.0 - 875.1 Open wound of chest (wall) without complication - open wound of chest (wall) complicated
876.0 - 876.1 Open wound of back without complication - open wound of back complicated
877.0 - 877.1 Open wound of buttock without complication - open wound of buttock complicated
878.0 - 878.9 Open wound of penis without complication - open wound of other and unspecified parts of genital organs complicated
879.0 - 879.9 Open wound of breast without complication - open wound(s) (multiple) of unspecified site(s) complicated
880.00 - 887.7 Open wound of shoulder region without complication - traumatic amputation of arm and hand (complete) (partial) bilateral (any level) complicated
890.0 - 897.7 Open wound of hip and thigh without complication - traumatic amputation of leg(s) (complete) (partial) bilateral (any level) complicated
906.0 Late effect of open wound of head neck and trunk
906.1 Late effect of open wound of extremities without tendon injury
906.2 Late effect of superficial injury
919.0 - 919.9 Abrasion or friction burn of other multiple and unspecified sites without infection - other and unspecified superficial injury of other multiple and unspecified
958.3 Posttraumatic wound infection not elsewhere classified
991.6 Hypothermia
997.60 Unspecified late complication of amputation stump
997.62 Infection (chronic) of amputation stump
997.69 Other late amputation stump complication
998.31 Disruption of internal operation wound
998.32 Disruption of external operation wound
998.51 Infected postoperative seroma

998.59 Other postoperative infection
998.6 Persistent postoperative fistula not elsewhere classified
998.83 Non-healing surgical wound

CPT/HCPCS codes G0281 and G0329:
Covered
707.01 - 707.07 Decubitus ulcer, elbow - decubitus ulcer, heel
707.09 Decubitus ulcer, other site
707.10 - 707.15 Unspecified ulcer of lower limb - ulcer of other part of foot
707.19 Ulcer of other part of lower limb
707.8 - 707.9 Chronic ulcer of other specified sites - chronic ulcer of unspecified site

Diagnoses that Support Medical Necessity
See above

ICD-9 Codes that DO NOT Support Medical Necessity
Codes not listed above

Diagnoses that DO NOT Support Medical Necessity
Contiguous and juxtaposition in utilization guidelines.

COMMENT: As stated above and in the utilization guidelines below, the Alliance disagrees with the assertion made by WPS that wounds or ulcers that are juxtaposition, involve contiguous areas, or on the same extremity are considered to reflect only one debridement service. Thus multiple units of service for these are not separately billable – and therefore not medically necessary. Wounds that are located on the same extremity may require separate evaluation, decision-making and procedures resulting in different plans of care and can be billed separately as provided by the Medicare modifier 59. These wounds do support medical necessity.

RECOMMENDATION: The Alliance recommends that this diagnosis be deleted from this section.

Documentation Requirements
The medical record must include a Certified Plan of Care containing treatment goals and physician follow-up.

COMMENT: As mentioned earlier, the Alliance would like to restate that the Medicare program does not require a physician visit unless required by state law or a national coverage determination. A certified plan of care however is required and something that the Alliance supports.

RECOMMENDATION: The Alliance recommends that WPS delete "and physician follow up" from the sentence above in order to be consistent with Medicare policy.

The record must document complicating factors for wound healing as well as measures taken to control complicating factors when debridement is part of the plan. Appropriate modification of treatment plans, when necessitated by failure of wounds to heal, must be demonstrated. The patient's medical record must contain clearly documented evidence of the progress of the wound's response to treatment at each visit. This documentation must include, at a minimum:

- 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.

When debridements are reported, the debridement procedure notes should demonstrate tissue removal (i.e., skin, full or partial thickness; subcutaneous tissue; muscle and/or bone), the method used to debride (i.e., hydrostatic, sharp, abrasion, etc.) and the character of the wound (including dimensions, description of necrotic material present, description of tissue removed, degree of epithelialization, etc.) before and after debridement.

Appropriate evaluation and management of contributory medical conditions or other factors affecting the course of wound healing (such as nutritional status or other predisposing conditions) should be addressed in the record at intervals consistent with the nature of the condition or factor.

Photographic documentation of wounds immediately before and after debridement is recommended for prolonged or repetitive debridement services (especially those that exceed five debridements per wound). Photographic documentation is required for payment of more than five extensive debridements (beyond skin and subcutaneous tissue) per wound.

When ES or ET is used, wounds must be evaluated periodically (no less than every 30 days) by the treating provider. Clear documentation of this must be present in the patient's medical record.

Active debridement must be performed under a treatment plan as any other therapy service outlining specific goals, duration, frequency, modalities, an anticipated endpoint, and other pertinent factors as they may apply. Departure from this plan must be documented.

COMMENT: It appears from the information provided above WPS is describing active wound care management and not active debridement. Since this is the first time that active debridement is being utilized/mentioned in this document, a definition of active debridement would be helpful. Moreover, it is unclear to Alliance organizations whether this is selective or non selective, surgical or sharp debridement.

RECOMMENDATION: The Alliance recommends that WPS provide a definition of this type of debridement based on the CPT codes. We also recommend that WPS change the terminology used to reflect more accurately what is being conveyed above. The term should be "active wound care management" as noted in the CPT manual.

Documentation for debridement exceeding Utilization Guidelines must include a complete description of the wound, progress towards healing, complications that have delayed healing and a projected number of additional treatments necessary.

When hydrotherapy (whirlpool) is billed by a physical therapist with CPT codes 97597 or 97598, the documentation must reflect that the skill set of a physical therapist was required to perform this service in the given situation.

When hydrotherapy (whirlpool) is billed by a therapist with CPT codes 97597 or 97598, the documentation must reflect the clinical reasoning why hydrotherapy was a necessary component of the total wound care treatment. Separate billing of whirlpool (97022) is not permitted with 97597-97598 unless it is provided for a different body part that the wound care treatment.

Utilization Guidelines

Wounds or ulcers that are juxtaposition, involve contiguous areas, or on the same extremity are considered to reflect only one debridement service. Thus multiple units of service for these should not be billed.

COMMENT: As stated above, the Alliance does not believe that the information contained in these two sentences is correct or reflective of current practice. Wounds that are located on the same extremity may require separate evaluation, decision-making and procedures resulting in different plans of care. Medicare recognizes this situation exists and has approved the use of modifier 59 for such instances. Since this vehicle already exists for the billing of this service, it is our position that the statement as provided by the Alliance below is more reflective of current practice and guidelines for wound care.

RECOMMENDATION: The Alliance would like to recommend that the language above be changed to read as follows: "Wounds or ulcers that are in juxtaposition or involve contiguous areas are considered to reflect only one debridement service. Wounds significantly separated or of different etiologies may require different levels of debridement and should be able to be described and billed separately as appropriate when utilizing modifier 59."

Services beyond the fifth surgical debridement, CPT code 11043 and/or 11044, per patient, per year, will be payable only upon medical review of records that demonstrate the medical reasonableness and necessity (appeal). This guideline is not applicable to wound care services for burn wounds.

COMMENT: The Alliance agrees with the language provided above as it applies to a patient with a chronic wound being treated in an outpatient setting.

RECOMMENDATION: The Alliance recommends that the language above be modified to read as follows, " For patients with chronic wounds being treated in an outpatient setting, services beyond the fifth surgical debridement, CPT code 11043 and/or 11044, per patient, per year, will be payable only upon medical review of records that demonstrate the medical reasonableness and necessity (appeal)."

Payment for prolonged, repetitive debridement services requires adequate documentation of complicating circumstances that reasonably necessitated additional services. It is expected only one debridement involving true removal of muscle and/or bone to be required for management of most wounds within a 12 (twelve) month period.

COMMENT: This sentence contradicts the utilization guidelines provided in the paragraph above.

RECOMMENDATION: The Alliance recommends that this sentence be deleted.

Conclusion

The Alliance appreciates the opportunity to provide WPS with our comments on the draft LCD for wound care. As stated earlier in our comments, due to the diversity of organizations with wound care knowledge and experience who comprise the Alliance, we would be pleased to serve as a resource to you now or in the future. We look forward to working with you as you finalize this policy. If you have any questions or would like additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director
www.woundcarestakeholders.org