ALLIANCE OF

Wound Care Stakeholders

September 11, 2009

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

RE: Comments on LCD for Wound Care GSURG051

Dear Dr Boren:

On behalf of the Alliance of Wound Care Stakeholders "Alliance"), I am submitting the following comments in response to the Wisconsin Physician Services (WPS) 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.

The Alliance originally submitted comments to your draft policy on December 3, 2008 and while some of our comments were adopted, some were not. We did not know if they were overlooked; so respectfully, we are again offering them for your consideration since we understand that the policy will become effective September 15, 2009.

We do applaud your efforts and appreciate your prompt rescission on the non coverage of Negative Pressure Wound Therapy. However, we are still extremely concerned with some provisions within the policy that we believe need to be addressed before this coverage policy can be implemented. As we stated in our August 24, 2009 email to you, we would appreciate the opportunity to discuss these with you in person. Please let me know dates and times that would be convenient for you to do so.

We have provided our continued concerns in the comments below. They include the following categories:

- Inaccurate uses of CPT code definitions
- Comments previously submitted that seem to have been overlooked,
- Corrections (i.e. spelling errors) to the LCD policy
- General comments/concerns. (Our comments regarding the inclusion of palliative care is also included as Addendum 1)

As Addendum 2, we have also placed directly into the LCD in red, some edits/changes in order to assist you (for example, codes that were omitted, areas that were to be deleted

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from the policy that weren't, misspellings, or language that we referred to in our comments below.)

CPT CODES

We continue to be extremely concerned that WPS continues to utilize inaccurate definitions of some of the CPT codes. We believe the liberties taken with these definitions not only makes them inaccurate, but will also cause confusion when submitting claims for the services described in this policy WPS should not be interpreting the CPT code definitions, they should merely be providing the CPT code definitions. The particular areas of concern include:

- The definition of surgical debridement that WPS provided in the policy is inaccurate. The Alliance questions why WPS continues to utilize information that is not part of the CPT code book when defining surgical debridement. The Alliance recommended in our previous comments that WPS utilize the definitions contained in the CPT code book when defining surgical debridement. However, the change was not made in the final policy and no explanations were given on the lack of adherence to the CPT code book. WPS states that they utilized the CPT code book in their response to comments. However, surgical debridement – 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 language is not the definition included in the WPS policy. The Alliance recommends that WPS utilize the definition provided in the CPT code book prior to implementation of this policy.***
- WPS further states that surgical debridement is "*usually carried out in the operating theatre under anesthesia by a surgeon"*. The Alliance maintains that the 11000 codes are not usually carried out in the operating room but rather in wound care centers. This level of surgical debridement can be performed in a hospital outpatient wound clinic or ambulatory surgery center and the CPT codes 11043 and 11044 are included and covered by Medicare in these two settings. As such, the Alliance recommends that WPS not designate a location regarding where this procedure is usually done. Moreover, there is nothing in the CPT codes that addresses where this procedure will take place. WPS states in the response to comments that they addressed this issue however in reviewing the final policy there has been no changes in the language.
- WPS states, that surgical debridement is *"usually used for deep tissue infection, drainage or abscesses or involved tendon sheath, or debridement of bon*e". As the Alliance stated in our previous comments, this sentence is not consistent with the CPT code book. Again, the Alliance is concerned that WPS is adding information into the definitions already established by the CPT code book. We recommend that this sentence be deleted from the policy prior to implementation of this policy.
- Finally, within the juxtaposition discussion, the Alliance believes that WPS is incorrectly interpreting the CPT/AMA definition of when modifier 59 can be

used. The MPFS indicates that the 11040 series of codes are subject to multiple procedure guidelines. These codes have an indicator of "2" which allows the use of a 59 modifier and subjects these codes to multiple procedure reimbursement. In its response, WPS references discreet separate borders but also seems to require that those wounds be of different etiologies. The Alliance believes that the WPS is overstepping its interpretation of CPT/AMA definition of when modifier 59 can be applied.

COMMENTS PREVIOUSLY SUBMITTED AND POSSIBLY OVERLOOKED

In reviewing WPS' document addressing submitted comments, we noted that many of our recommendations were not addressed and did not understand the rationale for the non inclusion of them. That information would be helpful to us in understanding why you decided to exclude most of our recommendations from the final LCD.

We would also recommend that WPS consider follow the example of how First Coast responds to comments that are submitted. The Alliance also submitted comments to First Coast on their recent debridement LCD. While we did not agree with the policy in its entirety, the response to comments was comprehensive which allowed clinicians to better understand why certain provisions in the document were written the way they were. In addition, the document was written clearly which removed ambiguities. We would suggest that WPS provide the same insights when devising a response to comments document in the future.

We are including below our comments which we would ask for you to consider implementing in your final LCD. These include issues which were included in our previous comments that were not addressed – or were addressed and still raise questions include the following:

- While the Alliance appreciates the list developed by WPS regarding the measures showing evidence of improvement, it is not a complete list. In our comments, the Alliance recommended that WPS add the following measures to the list of evidence of improvement:

  - Odor
  - Increase in granulating tissue
  - Exudates reduction
  - Tunneling and Undermining

  WPS chose not to include these measures stating that "*all practitioners performing wound care will document progress (or lack of progress)"*. While that can be taken into consideration, we would point out that WPS is providing a list of measures that can show evidence of improvement. This is the list of evidence that WPS will be looking for in the documentation when making a determination for coverage. It is therefore questionable as to why WPS would not want to create a list of measures that is accurate and based on current best practices.

If WPS does not choose to add these measures, then the sentence should read, "evidence of improvement includes, but is not limited to, measurable changes (decreases) in at least some of the following". The Alliance recommends that WPS add the four measures to the list of evidence for clarification.

- In our previous comments, the Alliance was very concerned about the following provision as written: '*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"*. The Alliance believes that there are other qualified providers that can and do reassess non healing wounds, yet WPS only identifies physicians – rather than qualified providers – as doing the reassessments. This concern was not addressed in the response to comments issued by WPS.
- We also submitted extensive comments on the 30 day requirement as written by WPS. WPS did not address any of our issues in the response to comments. As such, we are requesting that WPS provide clarification on the following: Does the 30 days begin with the episode of care? Would the clock restart following another event in the patient's care? For example, if there is a setback in the treatment based on the patient's condition such as, but not limited to, severe heart attack, would the 30 day clock restart? We request that WPS address this important issue prior to the implementation of this policy.
- While the Alliance does not have any objections to the expectation that the "*wound volume or surface dimension should decrease by at least 10 percent per month"*, we have been unable to locate any research from where WPS obtained this number. As such, the Alliance would like to request that WPS provide the Alliance with a citation.
- Regarding the issue of selective debridement, the WPS policy states, "*Selective debridement should only be done under the specific order of a physician*". As we stated in our previous comments, 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. As such, the Alliance recommends that the sentence, "selective debridement should only be done under the specific order of a physician" be deleted prior to the implementation of this policy in order to be consistent with Medicare policy.
- Juxtaposition is another issue that was addressed in our previous comments, yet we do not believe that WPS adequately addressed our concerns. The Alliance submitted significant comments on this section and strongly disagrees with the statements made here. As we stated previously, The Alliance does not believe that the information currently contained in the WPS policy 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. Furthermore, in its response to comments and in the final LCD, WPS does not address the argument that "The MPFS indicates that the 11040 series of codes are subject to multiple procedure guidelines. These codes have an indicator of "2" which allows the use of a 59 modifier and subjects these codes to multiple procedure reimbursement. In its response, WPS references discreet separate borders but also seems to require that those wounds be of different etiologies. The Alliance believes that the WPS is overstepping its interpretation of CPT/AMA definition of when modifier 59 can be applied. As previously provided to WPS, 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."

- The surgical debridement section is confusing and leaves a couple of questions open – i.e. what does it mean when WPS states, " *the medical record must reflect the location of the operating room"*? As such, the Alliance has inserted language into the WPS LCD based on another recently issued LCD to make this section less confusing.

CORRECTIONS TO THE LCD

1. The Alliance has noticed that WPS used the word "fiber" throughout the document and perhaps should have used the term "fibrin" instead. We have placed the correction in the LCD attached.
2. Based on the comment and response document WPS issued, several of the changes WPS has stated were made were not actually made in the final LCD document. For example, in the WPS response to comments, there was every indication that reference to 1 mm/wk would be eliminated. The Alliance applauds this decision. However in reviewing the final policy, this language is still included.
3. WPS also stated that they provided the example of CPT codes 11743, 11744 to the surgical debridement section. However, there is no mention of these examples in the final policy.
4. In the ICD-9 section of the policy, WPS stated in your response that it was going to add certain ICD-9 codes to the wound care LCD. Specifically, 707.20-7.25, 998.30 and 998.33 – yet these codes were not added into the final policy.
5. Under ultrasonic wound debridement, the comment and response document indicates that WPS was going to eliminate the statement, "Mist Therapy System 5.0 Wound Treatment Device is not covered". However, this sentence was still in the final policy.

The Alliance urges WPS to review the policy along with the response to comments and ensure that all necessary changes take place and a new LCD be issued prior to implementation.

GENERAL CONCERNS

It is our belief, the way the WPS policy is currently written, significant opportunities for misunderstandings and confusion exist. Recently, the Alliance submitted comments to First Coast on their recent Wound Debridement services LCD. The Alliance would suggest that WPS review the First Coast document carefully for areas which would help clarify the provisions written in the WPS wound care LCD dealing with debridement. For example, First Coast states, *"Medicare will consider debridement services medically reasonable and necessary when they are provided for the management of wounds and ulcers of the skin and underlying tissue to promote optimal wound healing or to prepare sites for appropriate surgical intervention. The requirements for reasonable and necessary service(s) include safe and effective debridement methods most appropriate to the type of wound, furnished in the appropriate setting, and ordered by/or performed by qualified personnel"*. There is no mention of the setting in which these services take place or the type of clinical personnel that will conduct the service. We have provided a copy of the First Coast Document for your review and have included this language prior to the discussion of the different types of debridement.

In the WPS policy, there is the statement , "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". We submit that this statement is too general since it is only true if the services are provided by a PT or nurse. If the wound care is done by a physician during a home visit, it is a separate billable service. This is an important distinction to be made and should be reflected in this policy prior to implementation.

The Alliance also believes that WPS has confused the issue of when wound care becomes maintenance therapy. We believe that WPS has placed information in this policy from the manual as it relates to physical therapists treating patients and extrapolated that information incorrectly to all clinicians who treat patients with wounds. This is not correct. The benefits manual relating to physical therapy states,

> "*If at any point in the treatment of an illness it is determined that the treatment is not rehabilitative, or does not legitimately require the services of a qualified professional for management of a maintenance program as described below, the services will no longer be considered reasonable and necessary. During the last visits for rehabilitative treatment, the clinician may develop a maintenance program. The goals of a maintenance program would be, for example, to maintain functional status or to prevent decline in function. The specialized skill, knowledge and judgment of a therapist would be required, and services are covered, to design or establish the plan,*

assure patient safety, train the patient, family members and/or unskilled personnel and make infrequent but periodic reevaluations of the plan. The services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances."

This statement does not pertain to wound care patients. Clinicians do not perform maintenance therapy on wounds as they are always trying to get the wound to heal. As such, reference to maintenance therapy in this policy needs to be revised prior to the implementation of this policy.

Finally, as we mentioned in our comments on the WPS draft policy, we believe that there should be a provision for palliative care. Since WPS is placing a measurement in the document for wound progression (10% in 30 days), there must also be provisions to prevent abandonment for patients with wounds that cannot heal. Since this was not addressed in the response to comments document, the Alliance would like to submit this document to you again. We have included our document on palliative care as Addendum 1. We urge you to place some provisions in the final policy which would allow for appropriate care prior to implementation.

CONCLUSION

The Alliance appreciates the opportunity to provide you with our comments and look forward to a continuing dialogue with you as you address our comments and our concerns. If you have any questions, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R. Ph.

Executive Director
Alliance of Wound Care Stakeholders

Addendum 1. Palliative Wound Care

Indications and Limitations of Coverage and/or Medical Necessity

For the purposes of this policy, palliative wound care is defined as care of wounds that are not expected to close (heal). No one specific diagnostic test can currently reliably determine healing potential, and wounds exist in the context of ***patients*** who may themselves be highly compromised. Since there are currently no specific guidelines to quantify when a wound is "un-healable," the point at which a patient enters "palliative wound care" is a clinical decision based on the patient's underlying serious medical condition(s), an unacceptable risk-benefit ratio for aggressive interventions aimed at healing, or be made after the failure of some reasonable period of aggressive wound care. It must also be recognized that a patient may be in palliative care due to life-limiting processes, but not be in palliative ***wound care***. Conversely, the fact that the patient is in palliative wound care does not imply that they are terminally ill. Furthermore, we recognize that patient status may change, thus allowing wounds which were previously considered un-healable to re-enter active therapy.

While the goal of palliative wound care may not be wound ***closure***, there are several legitimate goals which will likely improve patient quality of life with a reasonable expenditure of health care resources.

The primary endpoints of palliative wound care include:

- odor control
- pain management
- quality of life improvements (overall QOL)
- local wound bed stabilization
- control of bioburden
- control of exudate
- limiting infectious complications

In addition to improving quality of life, one other potential beneficial outcome might be that with appropriate palliative care, the need for hospitalization, intravenous antibiotics, and other expensive interventions will be reduced. Furthermore, appropriate palliative care should require a limited number of clinic/physician visits to maintain the wound status. Devices, drugs, advanced wound care technologies, and certain bioactive dressings designed to stimulate wound ***closure*** may not be appropriate for wounds in palliative care although secondary benefits of advanced technologies may in some cases justify their use. Dressings and other interventions focused on reduction of ***infection risk*** may be appropriate. Dressing regimens for palliative care wounds should be effective and chosen if possible to limit the work of care givers. Simplification of dressing regimens will allow, whenever possible, the burden of care to be shifted to the least skilled but competent care-giver available, preferably, a family member.

Debridement may still be required to achieve the goals outlined above by reducing the burden of devitalized tissue which can serve as a harbor for bacteria. In fact, non healing

wounds may continue to undergo necrosis and thus require periodic debridement to maintain a clean environment.

A palliative care plan should still employ modalities to control pain, unrelieved pressure, infection, uncontrolled metabolic derangement, and/or nutritional deficiency to prevent deterioration of the wound, development of new wounds, or deterioration in overall patient status. These interventions require regular, if infrequent clinic visits. It is anticipated that, in the absence of visits needed to address specific problems, palliative wound care can be accomplished with visits no more frequent than every 30 days.

Documentation Requirements

- Documentation supporting the medical necessity should be legible, maintained in the patient's medical record and made available to Medicare upon request.
- There must be a documented plan of care with documented palliative care goals and documented physician follow-up present in the patient's medical record.
- The patient's medical record must contain clearly documented evidence as to whether the palliative care goals are being met. This documentation at a minimum must include current wound size, wound depth, presence and extent of or absence of obvious signs of infection, presence and extent of or absence of necrotic, and devitalized or non-viable tissue.
- Appropriate evaluation and management of contributory medical conditions or other factors affecting the course of wound management (such as nutritional status or other pre-disposing conditions) should be addressed in the record at intervals consistent with the nature of the condition or factor.

Utilization Guidelines

- 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 180-day period, the patient should be considered for palliative care.
- Palliative wound care is not expected to include advanced wound care technologies such as semi-synthetic human skin, growth factors, or other modalities directed at wound ***closure***, but may include such technologies when secondary benefits of their application are consistent with the goals established for a specific palliative wound care patient.
- The frequency of visits for patients in a palliative care mode is anticipated to be no more often than every 30 days.

ADDENDUM 2

Contractor Name: Wisconsin Physicians Service (WPS)

Contractor Number: 00951, 00952, 00953, 00954, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402, 52280

Contractor Type: Carrier, Fiscal Intermediary A, MAC A, MAC B

LCD Version Number: L28572
LCD Title: Wound Care
Contractor's Determination Number: GSURG-051

Original Determination Effective Date: 09/15/2009
Revision Effective Date: 09/15/2009

Indications and Limitations of Coverage and/or Medical Necessity
For the purposes of this LCD, 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.

This policy does not address metabolically active human skin equivalent/substitute dressings, burns, skin cancer 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. It is not medically reasonable or necessary to continue a given type of WOUND CARE if evidence of wound improvement cannot be shown.

Evidence of improvement includes but is not limited to measurable changes (decreases) of some of the following:

- Drainage
- Inflammation
- Swelling
- Pain
- Wound dimensions (diameter, depth)
- Necrotic tissue/slough
- Odor
- Increase in granulating tissue
- Exudates 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 reassessment by a qualified provider of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment.

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.

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
Medicare expects the wound-care treatment plan to be modified in the event that appropriate healing is not achieved. Medicare will consider debridement services medically reasonable and necessary when they are provided for the management of wounds and ulcers of the skin and underlying tissue to promote optimal wound healing or to prepare sites for appropriate surgical intervention. The requirements for reasonable and necessary service(s) include safe and effective debridement methods most appropriate to the type of wound, furnished in the appropriate setting, and ordered by/or performed by qualified personnel" The types of debridement include:

- **Surgical debridement** is the removal of tissue by surgical means by cutting outside or beyond the wound margin in whole or in part.
- **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.

- **Blunt debridement** is the 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** is debridement with topical enzymes is used when the necrotic
  substances to be removed from a wound are protein, fiber **(should be fibrin)** 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.

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/Disrupted wounds or wounds with exposed hardware or bone;
o Neuropathic ulcers
o Infected wound (The Alliance recommends that an infected wound should be added to the list of conditions that must be present and documented)
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.

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.

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.

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.

"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."

The original debridements typically are true surgical debridements. Repeated debridements are not the same service as the original debridement service. CPT codes 11043 and 11044 are codes that describe deep debridement of the muscle and bone. However, once the initial debridement of muscle and/or bone has been performed, there typically is no true necrotic muscle or bone remaining. Subsequent surgical debridement of muscle or bone is usually not necessary. If the medical record demonstrates complicating factors are present that contribute to further necrosis of muscle or bone, then subsequent staged surgical debridement of muscle and/or bone may be deemed necessary. The medical records should indicate the complicating factor(s) and the medical management used to control these complications. Staged debridement of muscle and/or bone greater than two additional debridements, should raise the question of whether the complicating factors are controlled adequately. Further debridement of muscle and/or bone may not be justified without adequate control of the underlying condition(s) leading to the complicating factors (i.e. infection, abscess, vascular insufficiency, nutritional compromise, etc.).

Surgical debridement

Surgical Debridement (CPT 11040-11044) occurs only if material has been excised and is typically reported for the treatment of a wound to clear and maintain the site free of devitalized tissue including necrosis, eschar, slough, infected tissue, abnormal granulation tissue, etc., to the margins of viable tissue. Surgical incision includes going slightly beyond the point of visible necrotic tissue until viable bleeding tissue is encountered in some cases. The use of a sharp instrument does not necessarily substantiate the performance of surgical excisional debridement. Unless the medical record shows that a surgical excisional debridement has been performed, debridements should be coded with either selective or non selective codes (97597, 97598, or 97602).

Surgical debridement codes (11040-11044), as performed by physicians and qualified non physician practitioners licensed by the state to perform those services, must be based on the type of tissue removed, not on the depth or grade of the ulcer or wound. These codes can be very effective but represent extensive debridement, often painful to the patient, and could require complex, surgical procedures and sometimes require the use of general anesthesia. Surgical debridement will be considered as not medically necessary when documentation indicates the wound is without infection, necrosis, or nonviable tissues and has pink to red granulated tissue.

Documentation for surgical debridement procedures should include the indications for the procedure, the type of anesthesia if and when used, and the narrative of the procedure that describes the wounds, as well as the details of the debridement procedure itself. The CPT code selected should reflect the level of debrided tissue (ie partial thickness skin, full thickness skin, subcutaneous tissue, miscle and /or bone), not the extent, depth, or grade of the ulcer or wound. For example, CPT code 11042 defined as "Debridement; skin, and subcutaneous tissue" should be used if only nectoric skin and subcutaneous tissue are debrided, even though the ulcer or wound might extend to the bone. In addition, if only fibrin is removed, this code would not be billed.

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. The Alliance recommends that you add the following CPT codes to the list in order to more accurately reflect all the codes for recurrent debridements: CPT codes **11041 and 11042.**

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

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.

The following services are not considered debridement:
▪ **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 (nonpulsated) 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)

▪ 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 the shoe pressure eliminated may be a small ulcer but generally does not require true debridement unless the breakdown extends significantly into the subcutaneous tissue and that tissue is removed as well.

▪ 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.

▪ 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 unless additional partial for full skin thickness tissue directly deep to the callus is removed as well.

Non-Covered Modalities:

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 **(should be fibrin)** 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.

Ultrasonic Wound Debridement: (CPT code 0183T) is a system that uses continuous low frequency ultrasonic energy to atomize a liquid and deliver

continuous low frequency ultrasound to the wound bed. This cleansing method is not considered a significantly separately payable coverable service by Medicare. Therefore Mist Therapy (CPT code 0813T) is included in the payment for the E&M or wound care services.

- **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.

- **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.

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. 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.

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
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

Revenue Codes:
0360 Operating room services-general classification
042X Physical therapy-general classification
043X Occupational therapy-general classification
045X Emergency room-general classification
049X Ambulatory surgical care-general classification
051X Clinic-general classification
052X Free-standing clinic-general classification
0761 Treatment or observation room-treatment room
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
G0281 Electrical stimulation, (unattended), to one or more areas, for chronic stage III and stage
IVpressure 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 The Alliance would like to point out that additional codes should have been included in this section. The Alliance has provided those codes and their description. These codes should be added into the policy prior to implementation
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 - 440.24 Atherosclerosis of native arteries of the extremities with ulceration - atherosclerosis of native arteries of the extremities with gangrene
443.9 Peripheral vascular disease
459.31 Chronic venous hypertension with ulcer
459.33 Chronic venous hypertension with ulcer and inflammation

454.0 Varicose veins of lower extremities with ulcer
454.0 – 454.2 Varicose veins of lower extremities with ulcer - 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 - 682.9 Cellulitis 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
707.01 - 707.07 Pressure ulcer, elbow - pressure ulcer, heel
707.10 – 707.19 Unspecified ulcer of lower limb - ulcer of other part of foot
707.8 – 707.9 Chronic ulcer of other specified sites - chronic ulcer of unspecified site
707.20-7.25 – Pressure Ulcers, stages I-IV and unstageable
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 - 873.1 Open wound of scalp without complication - open wound of scalp complicated
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
998.30 Disruption of wound, unspecified – disruption of traumatic injury wound repair
998.31 Disruption of internal operation wound
998.32 Disruption of external operation wound
998.33 Traumatic injury wound repair
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

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

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.

Wound care provided by Physical therapist, for both in and outpatient wound care the following is expected:
▪ Physician order(s) for physical therapy (PT)/wound care services
▪ Initial evaluation of PT/wound care services
▪ Wound characteristics such as diameter, depth, color, presence of exudates or necrotic tissue
▪ Previous wound care services administered to include date and modalities of treatment
▪ Plan of treatment for PT/wound care services
▪ Weekly progress notes to include current wound status, measurements (including size and depth), and the treatment provided
▪ Description of instrument used for selective or sharp debridement (i.e. forceps, scalpel, scissors, tweezers, high-pressure water jet, etc.)
▪ Treatment grid/log reflecting PT HCPCS billed
▪ Certification/recertification for PT/wound care services
▪ Detailed itemization for any 27X (Supplies) or 62X (Supplies) charges
▪ Actual minutes provided to support each timed service/HCPCS provided

Note: If patient is continued from one billing period to another, include initial evaluation and progress notes/summary of wound progress prior to the service dates billed.

Utilization Guidelines
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, unless that single wound heals and reoccurs in that same 12 month timeframe"

Sources of Information and Basis for Decision
Agency for Health Care Policy and Research, Clinical Practice Guide, Number 15, Publication No. 95- 0652, December 1994.
American Physical Therapy Association, Guide to Physical Therapist Practice, Second Edition, 2001.
CMS RAI Version 2.0 Manual, Chapter 3, MDS Items (L/M).
Healthcare Common Procedure Coding System (HCPCS), Level II, 2008.
Medicare Coverage Policy – Decisions, Warm-Up Wound Therapy a/k/a Noncontact Normothermic Wound Therapy, HCFA.gov/coverage.
Physical Agents in Rehabilitation, From Research to Practice; Michelle H. Cameron, Section 2, page 204.
Advances in Skin and Wound Care; Vol 17, No.2, Debridement: Controlling the Necrotic/Cellular Burden
Pulsavac III Wound Debridement System, Zimmer Inc, Wound protocol Information.
Wound Care Information Network, www.medicaledu.com.
Mist Therapy System marketing information
KCI The Clinical Advantage. (May 2007) V.A.C. Therapy Clinical Guidelines: A reference source for clinicians.

Almodovar L.F., Canas A., Candas P.P., Hernandez M.C. (2005). Vacuum-assisted therapy with a handcrafted system for the treatment of wound infection after median sternotomy. Interactive
Cardio Vascular and Thoracic Surgery 2005; 4:412-414 Retrieved on February 7, 2007 from
http://proquest.waldenu.edu
Anderson I., (February 28, 2006) Debridement methods in wound care. Nursing Standard Volume 20 Issue 24 pages 65, 5 pgs. Retrieved on March 9, 2007 from
http://proquest.waldenu.edu
Blunt J. (2001) wound cleansing Ritualistic or research-based practice. Online Journal Nursing standard.
Harrow –on-the-hill: September 19-September 25, 2001, Vol. 16, Iss.1; pg. 33, 4 pg. Retrieved February 131, 2007 from http://proguest.waldenu.edu/pqdweb?index
Burke T.J. (2006).The Effect of Monochromatic Infrared Energy on Sensation in Subjects with Diabetic Peripheral Neuropathy: A Double-Blind, Placebo-Controlled Study. Diabetes Care 29:1186 A response to Clifft et al. Retrieved on March 15, 2007 from
http://care.diabetesjournals.org/cgi/content/full/29/51186
Bryant R. A, Nix D. P., (2007). Acute & chronic Wounds Current Management Concepts: Third Edition, Chapter 10 Wound Debridement. Mosby St Louis Missouri.
Bryant R. A, Nix D. P., (2007). Acute & chronic Wounds Current Management Concepts: Third Edition, Chapter 19, Principles of Wound Management. Mosby St Louis Missouri.
Carson S.N., Overall K. Lee-Jahshan S., Travis E. (March 2004) Vaccum-Assisted Closure Used for Healing Chronic Wounds and Skin Grafts in the Lower Extremities. Ostomy Wound Management Volume 50 Issue 3 pages 52-58 Retrieved on March 15, 2007 from http://www.o-wm.com/article/2386
Clifft J. K., Newton T. S., Bush A. J. (2005). The Effect of Monochromatic Infrared Energy on Sensation in Patients with Diabetic Peripheral Neuropathy. Online Journal American Diabetes
Association. Diabetes Care (28) 2896-2900, 2005. Retrieved January 15, 2007 from
http://care.diabetesjournals.org/cgi/content/full/28/12/2896
Clifft J.K., Kasser R.J., Newton T.S.S, Bush A.J., (2006). The Effect of Monochromatic Infrared Energy
on Sensation in Subjects with Diabetic Peripheral Neuropathy: A Double-Blind, Placebo-Controlled
Study. Diabetes Care 29:1186-1187. A response to Burke Retrieved on March 15, 2007 from
http://care.diabetesjournals.org/cgi/content/full/29/5/1186-a
Clifft J. K., Newton T. S., Bush A. J. (2005). The Effect of Monochromatic Infrared Energy on Sensation
in Patients with Diabetic Peripheral Neuropathy: A Double-Blind, Placebo-Controlled Study Diabetes.
Online Journal American Diabetes Association. Diabetes Care (28) 2896-2900, 2005. Retrieved January
15, 2007 from http://care.diabetesjournals.org/cgi/content/full/28/12/2896

Leonard D.R., Farooqi M.H., Myers S., (2004). Restoration of Sensation, Reduced Pain, and Improved
Balance in Subjects with Diabetic Peripheral Neuropathy. Diabetes Care 27:168-172 Retrieved on March
15, 2007 from
http://care.diabetesjournals.org/cgi/content/full/27/1/168?maxtoshow=HITS=10hits
The Guide to Physical Therapist Practice; Second Edition 2001, The Journal of the American Physical
Therapy Association January 2001 Volume 81 Number 1
The Guide to Occupational Therapy Practice, The American Occupational Therapy Association, Inc,
(1999).
Cowan K., Teague L., Sue S.C., Mahoney J.L. (April 4, 2005). Vacuum-Assisted Wound Closure of Deep
Sternal Infections in High-Risk Patients after Cardiac Surgery. The Annals of Thoracic Surgery (80) p.
2205-2212 Retrieved on February 6, 2007 from http://proquest.waldenu.edu
Department of Health and Human Services. (2006). Food and Drug Administration Regarding Kinetic
Concepts, Inc Re: K062227
Ennis, W. J., Valdes, W., Gainer, M., Meneses, P., (2006) Evaluation of clinical effectiveness of mist
ultrasound therapy for the healing of chronic wounds. Advances in skin & wound care. Wound Care
journal October 2006, Retrieved March 1, 2007 from www.woundcarejournal.com
Ennis, W.J., Formann, P., Mozen N., Massey, J., Conner-Kerr, T., Meneses, P., Ultrasound therapy for
recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study.
(2005) Ostomy/Wound Management, 2005; 51 (8); 24-39. Retrieved March 1, 2007 from www.o-wm.com/article/4532 - 67k
Fleck T.M., Fleck M., Moidl R., Czerny M., Koller R., Giovanoli P., Hiesmayer M.J., Zimpfer D.,
Wolner E., Grabenwoger M., (2002) The vacuum-assisted closure system for the treatment of deep sternal
wound infections after cardiac surgery. The Annals of Thoracic Surgery 2002;74:1596-1600 Retrieved on
March 3, 2007 from http://proquest.waldenu.edu
Lefevre S. D., Aronson N., (2004). Wound-healing technologies: low-level laser and vacuum-assisted
closure: December 2004. Evidence report/technology assessment. Agency for healthcare research and
quality. Number 11. Retrieved March 1, 2007 from www.ahrq.gov
Luedtke-Hoffmann K. A., Schafer S. D., (2000) Pulsed lavage in Wound cleansing: Physical therapy
14

March 2005 Vol. 80, No. 3, pp. 292-300 Retrieved March 1, 2007 from http://www.ptjournal.org/cgi/content/full/80/3/292
McCulloch J. (2004). The integumentary system-repair and management: an overview. Alexandrai:
February 2004. Vol. 12, Iss. 2; pg. 52, 18 pgs. Retrieved February 1, 2007 from http://proquest.waldenu.edu/pqdweb?
Milne C.T. (2003). Wound, Ostomy, and Continence Nursing Secrets. Questions and Answers Reveal the
Secrets to Successful WOC Care.
Morris S., Brueilly E., Hanzelka H., (January 2007). Negative Pressure Wound Therapy Achieved by
Vaccum-Assisted Closure: Evaluating the Assumptions. Ostomy Wound Management. Volume 53 Issue
1 pages 52-57 Retrieved on March 15. 2007 from http://www.o-wm.com/article/6655
Rakel A. Ekoe J.M. (2006) Canadian Diabets Association Technical Review: The Diabetic Foot and
Hyperbaric Oxygen Therapy. Canadian Journal of Diabetes, 2006; 30 (4);pages 411-421.
Rayman G, Rayman A, Baker N.R., Jurgeviciene. (2005). Sustained silver-releasing dressing in the
treatment of diabetic foot. Online Journal British Journal of Nursing. London January 27-February 9,
2005. Vol. 14, Iss. 2; pg. 109, 5 pg. Retrieved February 1, 2007 from http://proquest.waldenu.edu/pqdweb?index
Sibbald G. R., Mahoney J., Therapy Canadian Consensus Group. (November 2003). A consensus Report
on the Use of Vaccum-Assisted Closure in Chronic, Difficult-to-Heal Wounds. Ostomy Wound
Management Volume 49 issue 11 pages: 52 – 66 Retrieved on March 15, 2007 from http://www.owm.
com/article/2209
Technology Evaluation Center Evidence-based Practice Center. (2004) Wound-Healing Technologies:
Low-level Laser and Vaccum-Assisted Closure. Number 11, Chicago, Illinois.
Technology Assessment (March 8, 2005) Usual Care in the Management of Chronic Wounds: A Review
of the Recent Literature. Rockville, Maryland
Wolvos T., (November 2004). Wound Installation-The Next Step in Negative Pressure Wound Therapy.
Lessons Learned from Initial Experiences. Ostomy Wound Management Volume 50 Issue 11 pages 56-
66. Retrieved on March 15, 2007 from http://www.o-wm.com/article/3261
Zamboni W.A., (January 2003) Hyperbaric oxygen and wound healing. Clinics in Plastic Surgery Volume
30 Issue 1 pages 67-75. Retrieved on February 12, 2007 from http://www,plasticsurgery.theclinics.com/article/PIIS009412980200688/fulltext

2008 Additional Information and Basis for Decision

Acute & Chronic wounds – Current Management Concepts, Third Addition, Chapter 10 – Wound
Debridement, Chapter 19 – Principles in Wound Management, Mosby –Elsevier Copyright 2007, 200, 1992.
Boulton, A.J.M., Kirsner, R.S., and Vileikyte, L. (July 2004) Neuropathic Diabetic Foot Ulcers. The New
England Journal of Medicine, Volume 351:48-55, Number 1. Retrieved February 20, 2008 from
http://content.nejm.org/cgi/content/full/351/11/787.
Huttenlocher, A., Horwitz, A.R. (January 2007) Wound Healing with Electric Potential. The New
England Journal of Medicine, Volume 356:303-304, Number 3. Retrieved February 20, 2008 from
http://content.nejm.org/cgi/content/full/356/3/303.
Journal of the American Academy of Dermatology. Treating the chronic wound: A practical approach to
the care of nonhealing wounds and wound care dressings. Volume 58, Issue 2(February 2008) –
Copyright 2008 American Academy of Dermatology, Inc. Retrieved on February 20, 2008 from
http://www.mdconsult.com/das/article/body/88398184-3/jorg
Other Contractor policies: Wisconsin Physicians Service; National Government Services; Highmark
Medicare Services; Cahaba Government Benefit Administrators; TrailBlazer Health Enterprises;
15
Riverbend Government Benefits Administrator; Palmetto Government Benefit Administrators; CIGNA
Government Services.
Sumpio, B.E. (September 2000) Foot Ulcers. The New England Journal of Medicine, Volume 343:787-
793, Number 11. Retrieved February 20, 2008 from
http://content.nejm.org/cgi/content/full/343/11/787
Singer, A.J., Clark, R.A.F., (September 1999) Cutaneous Wound Healing. The New England Journal of
Medicine, Volume 341: 738-746, Number 10. Retrieved February 20, 2008 from
http://content.nejm.org/cgi/content/full/341/10/738.
Stillman, R.M., (January 2007) Wound Care. Emedicine from WebMD, Last Updated January 4, 2007.
Retrieved February 20, 2008 from http://www.emedicine.com/MED/topic2754.htm.
Swartz, M.N.(February 2004) Cellulitis. The New England Journal of Medicine, Volume 350:904-912.
Retrieved on February 20, 2008 from http://content.nejm.org/cgi/content/full/350/9/904.
Wound Care Information Network, http://www.medicaledu.com.
The Clinical Relevance of Microbiology in Acute and Chronic Wounds. McGuckin M, Goldman R,

Bolton L, Salcido R. Adv Skin Wound Care. 2003 Jan-Feb;16(1):12-23;
Vanscheidt W, Sadjadi Z, Lillieborg S. EMLA Anaesthetic Cream For Sharp Leg Ulcer Debridement: A
Review of the Clinical Evidence For Analgesic Efficacy and Tolerability. Eur J Dermatol. 2001 Mar-
Apr;11(2):90-6
Leaper, David Sharp Technique for Wound Debridement.http:
//www.worldwidewounds.com/2002/december/Leaper/Sharp-Debridement.html

Advisory Committee Meeting Notes
Meeting Date:
Wisconsin 09/26/2008
Illinois 09/17/2008
Michigan 09/24/2008
Minnesota 09/11/2008
Iowa 10/16/2008
Kansas 10/16/2008
Missouri 10/17/2008
Nebraska 10/16/2008

This policy does not reflect the sole opinion of the contractor or the Contractor Medical Director(s).
Although the final decision rests with the contractor, this policy was developed in cooperation with the Carrier Advisory Committee(s), which include representatives of various medical specialty societies.

Start Date of Comment Period
10/18/2008
End Date of Comment Period
12/03/2008
Start Date of Notice Period
(Published)
16
08/01/2009
Revision History Number/Explanation
08/01/2009, one, new LCD replaces L15700 Wound Care, L26653 GSURG-551 – Chronic Wound Care
that are retired as of 9/15/2009;
Last Reviewed On: 08/01/2009
Notes
* - An asterisk indicates a revision to that section of the policy.
Does this LCD contain a "Least Costly Alternative" Provision?
No