Please Note:
Centers for Medicare and Medicaid Services (CMS) has issued a directive that Negative Pressure Wound Therapy (97605-97606) is not covered:

CMS’ preliminary Healthcare Common Procedure Coding System (HCPCS) coding decision and preliminary Medicare Payment decision for negative pressure wound therapy (NPWT) devices is now published in the July 9, 2009 NPWT Public Meeting Agenda. The Medicare Improvements for Patients and Providers Act of 2008 required the Secretary to evaluate existing HCPCS codes for NPWT devices to ensure accurate reporting and billing for the items and services under such codes; use an existing process for the consideration of coding changes; and consider all relevant studies and information furnished through the process.

CMS partnered with Agency of Healthcare Research and Quality (AHRQ) to commission a review of NPWT devices to ensure all relevant studies and information on NPWT were captured. ECRI Institute solicited information from stakeholders and searched literature in conducting this review. A draft report of their findings was published for comment in April 2009. After analysis of comments received, ECRI concluded that the available evidence does not support significant therapeutic distinction of a NPWT system or component of a system. The report informed CMS’ HCPCS workgroup’s decision. The final report may be read at:
http://www.ahrq.gov/clinic/ta/negpresswtd/

Comments: Sometimes a patient’s co morbid condition is such that a wound is considered “unhealable”. In these cases, periodic monitoring and treatment may be necessary in order to prevent worsening, complications, or to prevent amputation.

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.

Response:
WPS agrees that treatment may sometimes be necessary to prevent worsening of wounds or to prevent amputation. Typically, Medicare does not cover maintenance therapies of any type. However, the CPT codes used must reflect the actual services rendered. Documentation would support the medical necessity of these services.

Comment:
The Draft LCD explains the proposed non-coverage due to 1) "...level of scientific evidence is insufficient to validate the efficacy and superiority of this treatment...; and 2) "...the service does not qualify as a separate, significantly payable service." The letter addresses each explanation and includes the full-text for fifteen (15) peer-reviewed, published clinical studies and articles.
Celleration - October 17, 2008

Response:
The information was reviewed and based on this review the LCD has been re-worded to say:
Non-Covered Modalities:
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.

**Comment:**
WPS received several comments stating CPT code 11043 or 11044 does not always require anesthesia or a subspecialty surgeon.

**Comments:** I agree that the 11040 series of codes should be performed in an operating theater in a facility or non-facility setting. However, anesthesia for codes 11040-11042 is not always necessary. In the insensate foot, these debridements are usually carried out without the need for anesthesia. The remaining statement regarding these codes are used for “deep tissue infection, draining of abscess, or debridement of bone” is incorrect. I think the paragraph should perhaps be relabeled to indicate that this paragraph intends its definitions to be applied to 11043-11044.

**Response:**
The Policy states: "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". And "Surgical debridement is excision or wide resection of all dead or devitalized tissue, possibly including excision of the viable wound margin. This is usually carried out in the operating theatre under anesthesia by a surgeon. It is frequently used for deep tissue infection, drainage of abscess or involved tendon sheath, or debridement of bone".

WPS has, upon review of medical records/operative reports, seen inappropriate billing of these codes. This LCD is an attempt to remind providers the correct billing of the services. The statement "Usually" acknowledges that this is not always the case. However, since medical policies respond to the majority of time this statement will stay in the policy.

**Comment:**
WPS received several comments about CPT codes 11040-11042 not meeting admission criteria.

**Response:**
There is nothing in the policy to suggest that in-patient hospital is the appropriate place of service for these codes.

**Comment:**
WPS received comments that patient have different healing rates.

**Response:**
That is correct but documentation should support the medical necessity of all services. Medicare does not pay for maintainance therapy for any disease.

**Comment:**
WPS received several comments saying that juxtaposed wounds are often not a single wound.
“Wounds that are juxtaposition or involve contiguous areas should not have multiple units of service billed, I disagree with the statement of multiple wounds on the same extremity should not have multiple units billed. 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”.

Response:
WPS agrees that this is true but when wounds are juxtaposed they must be billed as a single service. Wounds that are on a single extremity, less than an inch apart are still considered to be a single service. When wounds have discrete separate borders and different etiologies they are clearly different services and documentation should support this.

Note: WPS has reviewed medical documentation regarding this for over a year and has almost never found documentation to support billing multiple wounds on a single extremity. There is pattern of providers billing multiple services for juxtaposed wounds - week after week after week without any evidence that their treatment is making a difference.

The following are very recent examples of such claims after documentation was requested and reviewed:
The first chart stated, “the patient’s left ankle ulcers from the left to right position 1.0 x 0.3, 02.x 0.2, 0.5 x 1.0, 0.7 x 0.5, 0.7 x 1.0, 0.6 x 1.4 cm, 0.2 x 0.1 cm, all have a depth of 0.1 cm.” These “seven” are considered juxtaposed wounds and should be billed as one service.

Another claim submitted with “seven” debridement services. Documentation stated, “Partial thickness debridement of skin of right lower leg ulcers (1.0 x 0.3 x 0.1 cm, 0.2 x 0.2 x 0.1 cm, 0.5 x 1.0 x 0.1 cm, .7 x 0.5 x 0.1 cm, 0.7, 1.0 x 0.1 cm, 0.6 x 1.4 x 0.1, 0.2 x 0.1 x 0.1 cm)” Again this would be one service not seven.

Comments: I believe the section on the bottom of Page 5 discussing selective debridement and nonselective debridement should be placed preceding the last paragraph on page 4.

Response
This was done, thank you.

Comment:
The statement that the wound must be free of nonviable or necrotic tissue may be misleading. I may be mistaken, but I believe the indication for the NPWT is that the wound is 75% or more free of nonviable or necrotic tissue.
(Negative Pressure Wound Therapy)

Response:
The LCD stated:
Negative Pressure Wound Therapy Criteria: All of the following must be met:

- Wound is free of active osteomyelitis; and
- Wound is free of nonviable or necrotic tissue and macroscopic contamination; and
- Medical record documents appropriate nutritional assessment(s) and interventions; and
- Wound does not contain exposed arteries or veins.

Since negative pressure wound therapy is no longer covered under Medicare this is not an issue with this LCD and this section has been removed from the policy.
Comment:
The LCD states:
“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.”

Response:
This has been changed to:
“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.”

Comments:
The first paragraph indicates that removing a collar of callus around an ulcer is not debridement of skin or necrotic tissue and should not be billed as debridement. Those of us involved in wound care know that the collar of callus is an interference to wound contraction and healing. I would ask that this statement be revised to indicate that the collar of callus would not be payable unless additional partial or full skin thickness tissue directly deep to the callus is removed as well, to be consistent with CPT 11040-11041.

Response:
The LCD was changed and now reads:
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.

Comments:
This section indicates that nutritional counseling is non-covered. However, your wound care policy indicates that documentation must be present regarding the nutritional status of the patient. Sometimes this requires nutritional counseling by a certified dietician. I would recommend that this non-covered service be considered a covered service if performed by proper credentialed health care professionals.

Non-Covered Modalities:
- Nutritional counseling.

Response:
Since 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 the nutritional counseling would not be a separate identifiable service.

Comment:
The LCD states:
“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.”
I am not clear on what this statement means. Home health care nursing staff are not licensed to perform surgical debridement of a wound. If that patient is receiving HHA care and needs to see a physician for wound monitoring and necessary debridement, it is my opinion that the wound debridement or E&M visit should be considered covered services.

Response:
This is information for providers. Most medical services and supplies for beneficiaries receiving home health care are covered under the consolidated payment given to the health agency. Providers who submit claims to Medicare Part B for services covered under the Home Health agencies services will have their claims automatically denied by CMS’ Common Working File – not WPS. Providers giving active wound care to beneficiary covered under home health they should discuss their payment with the home health agency.

Comment
I noticed that ulcers 707.10-15, 707.19, 707.8, 707.9 are not listed as covered under the debridement codes (only under codes G0281 and G0329. I would recommend that they be added to the covered ICD-9 codes for debridement.

Response:
The debridement codes the ICD-9 range includes these codes:

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>707.00-707.9</td>
<td>Decubitus ulcer, unspecified site - chronic ulcer of unspecified site</td>
</tr>
</tbody>
</table>

Comment:
The requirement for photographic documentation, in my opinion, is an unnecessary requirement for wound care. Many physicians do not have the capability of photography (digital or standard) or the EMR in an office situation to allow storage of this type of data. With the extensive description/documentation required in this policy, there should be no necessity for photographic documentation, since this would be redundant. The additional expense involved in obtaining digital photography or the storage of these images is an unnecessary financial burden to the provider which will provide no additional benefit to documentation over and beyond the description in the medical records. I believe, in my opinion, that this requirement should be omitted from the policy.

“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.”

Response:
Photography documentation is not a requirement. However, if a provider provides wound care for a large number of beneficiaries for extensive periods of time they are going to be required to provide documentation that the services are medically necessary.

Comment:
The initial statement under this heading regarding “multiple units” should be removed as mentioned previously.

“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.”
Response:
This is repeated under the Utilization section of the LCD because abuse has been identified and is still an on-going issue.

Comment:
“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”

This paragraph does not make clinical sense. The statements are placing a maximum service per patient per year. Patients may develop more than one ulcer in the same or different locations over the course of one year. Each wound could possibly require several deep debridements. This limitation would preclude the patient from receiving necessary medical care for these additional wounds. I believe the rewritten paragraphs on Page 4 should adequately address the concerns in Paragraph 2 under Utilization Guidelines. In my opinion, this paragraph should be omitted from this policy.

Response:
This paragraph is intended to inform providers that claims submitted for CPT codes 11043 and /or 11044 are, on prepayment, being manually reviewed by WPS medical staff. This has been done for over two years and a large percentage of the claims are not coded correctly. Covered services that are medically necessary and documented are always allowed.

Comment:
In statement #3, it states that 11043-11044 may only be billed in place of service inpatient hospital, outpatient hospital, or ASC. This statement should be amended to allow an in-office surgical suit. CMS allows these procedures in both “facility” and “non-facility” settings. 3. CPT codes 11043-11044 may only be billed in place of service inpatient hospital, outpatient hospital or ambulatory care center (ASC).

Response:
Providers who bill these services in place of service 11 will have to submit the claims for reconsideration with an operative report.

Comment:
In statement #1, it states that a claim will be denied if deep debridement in POS other than inpatient hospital, outpatient hospital, or ASC. I believe the previous statement I made adequately explains the viability of performing 11043-11044 in an office surgical suite. Also, the CMS MPFS indicates that these two codes are payable in a non-facility setting. The non-facility settings would include an office or other outpatient facilities. The statement in the LCD contradicts allowance by CMS for these codes to be performed in a non-facility setting. I believe the statement must be amended to comply with CMS policy/allowance.

1. Performing deep debridement in POS other than inpatient hospital, outpatient hospital or ASC

Response:
WPS medical staff has reviewed claims submitted with CPT codes 11043 and 11044 for more than two years. The greatest majority were mis-coded and either denied, or paid at the correct CPT code documented in the medical record. Providers will have to submit the claims for reconsideration with an operative report and the services will be reviewed by medical staff. It is
WPS goal to pay claims timely and correctly. In this situation, the way to pay the claims correctly is to review all operative reports.

Comments:
This statement indicating necessity for “pretreatment wound management” does not make clinical sense. Wound debridement of necrotic tissue is a part of initial wound care. This is the precursor for more advanced wound therapies. These advanced wound therapies require failure of a wound to respond to the type of care indicated in this policy. I do not understand what other pretreatment wound management failure needs to occur prior to utilization of basic wound debridement, which is often necessary for wound healing.

Response:
While it is expected that documentation will include the history of the ulcer, this sentence was removed from the LCD.