ASSOCIATION FOR THE ADVANCEMENT OF WOUND CARE

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Novitas Solutions
Medical Policy Department
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Submitted Electronically: DraftLCDComments@novitas-solutions.com

Re: PROPOSED/DRAFT Local Coverage Determination (LCD): Wound Care (DL35125)

Dear Ms. Mandella:

The Association for the Advancement of Wound Care [AAWC] welcomes the opportunity to provide feedback on draft policy *Wound Care (DL35125)*, which we believe is not based on the current and substantial clinical evidence or wound care practice Guidelines. The AAWC is a multi-professional, non-profit organization of nearly 2,500 practicing wound care clinicians and research specialists including multi-specialty physicians, vascular and general surgeons, podiatric surgeons, nurse practitioners, clinical nurse specialists, physical therapists, physician assistants and researchers dedicated to the delivery of evidence-based wound care treatment for beneficiaries that suffer with wounds.

This proposed draft policy is fraught with so many inaccuracies, unsubstantiated assumptions and incorrect language, that we urge Novitas Solutions to retract the draft policy immediately. We suggest that Novitas engage with the AAWC and other wound care related associations or societies to develop an evidence-based, wound care policy that is accurate, evidence-based and in the best interest for the beneficiaries we serve.

We are surprised and concerned by the lack of a thorough and current review of the literature by the MAC. The references cited included:

- 16 papers on maggot therapy
- A 2009 AHRQ report on NPWT
- A 2011 FDA Safety Communication on NPWT
- A 2005 AHRQ Technical Assessment: "Usual care in the Management of Chronic Wounds: A review of the Recent Literature" Technology Assessment.

To support our comments, we have provided Novitas with a list of 485 references (Attachment A) that were recently reviewed by a team of researchers and clinicians at AAWC to support an evidence-based clinical endpoints recommendation to the FDA as part of a collaborative project with them. These address many of the wound care services and treatment methods in this policy. In addition, we are providing the links to the AAWC evidence-based clinical Guidelines for Venous Ulcers and Pressure Ulcers; the

references for the Wound Healing Society's wound related Guidelines for arterial, venous, diabetic and pressure ulcers. There are also recent Guidelines from the Society for Vascular Surgery/ American Venous Forum for Venous Ulcers and the Society for Vascular Surgery, Society for Vascular Medicine, and American Podiatric Medical Association for evaluating and treatment of Diabetic foot Ulcers. We question why only one of these wound care related Guidelines was reviewed or identified by the MAC in preparation of this draft Wound Care LCD. This implies a lack of understanding of wound care by the MAC team who drafted this policy.

Missing guidelines for wounds:
https://aawconline.org/wp-content/uploads/2015/11/AAWCPressureUlcerGuidelineEvidenceTableAug11.pdf

https://aawconline.org/wp-content/uploads/2015/11/AAWC-Venous-Ulcer-EvidenceTable-v33-23Jun13.pdf

Steed, D. L., Attinger, C., Colaizzi, T., Crossland, M., Franz, M., Harkless, L., Johnson, A., Moosa, H., Robson, M., Serena, T., Sheehan, P., Veves, A. and Wiersma-Bryant, L. Guidelines for the treatment of diabetic ulcers. *Wound Rep Regen* 2006;14:680–692. doi:10.1111/j.1524-475X.2006.00176.x

Federman DG, Ladiiznski B, Dardik A, Kelly M, Shapshak D, Ueno, CM, Mostow EN, Richmond NA, Hopf HW. Wound healing society 2014 update on guidelines for arterial. Ulcers. Wound Rep Reg 2016; 24:127–135. DOI:10.1111/wrr.12395

Marston W, Tang J, Kirsner RS, Ennis W. Wound healing society 2015 update on guidelines for venous ulcers. *Wound Rep Reg* 2016; 24:136–144.

Gould L, Stuntz M, Giovannelli M, Ahmad A, Aslam M, Mullen-Fortino M, Whitney JD, Calhoun J, Kirsne RS, Gordillo GM. Wound healing society 2015 update on guidelines for pressure ulcers. *Wound Rep Reg* 2016; 24:145–162.

The Management of Diabetic Foot: A Clinical Practice Guideline by the Society for Vascular Surgery in Collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg 2016*; special supplement published February 2016.

The AAWC Specific Comments and Recommendations

History/Background and/or General Information

1. Policy States: Various methods to promote wound healing have been devised over time. Physicians and health care providers must understand that **many** of these methods are **expensive and unproven by valid scientific literature**, and would be **considered investigational.**

AAWC Comments:
The statement is erroneous & unsubstantiated. None of the treatment methods included in this draft policy are experimental or unproven. There is ample evidence in peer-review journals and clinical guidelines for various methods to achieve wound healing, including:

- NPWT
- Non-contact, low level ultrasound (MIST therapy)
- Debridement Services

Recommendation:

This whole paragraph needs to be removed. The MAC needs to specify which 'method(s)' of healing are unproven by valid scientific literature and which are expensive.

2. Policy States: 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.**

AAWC Comments:
We disagree that patients and/or caregivers can primarily and/or adequately manage the care of their wound(s). This is especially true when the wound is complex or is non-healing and/or may also be managed with negative pressure wound therapy. Frequently these types of wounds occur in elderly patients with several co-morbidities or disabled patients, who do not have the skills or may lack mental acuity to treat their own wound or know how to identify if a problem is occurring. Without skilled qualified professionals assessing the wound, it is easy for contamination and infection to occur in the 'uncontrolled' home environment. Warriner et. al. evaluated care of diabetic foot ulcers and venous ulcers in hospital wound centers and found that more frequent visits under the management of healthcare professionals resulted in faster healing.

- Warriner RA III, Wilcox JR, Carter MJ, Stewart DG. More frequent visits to wound care clinics result in faster times to close diabetic foot and venous leg ulcers. *Adv Skin Wound Care*. 2012;25(11):494-501.

The United States spent 2.9 trillion dollars on Healthcare in 2014 with the largest aggregate spent on treating Diabetes and its complications including cardiovascular disease and ulcers. The healthcare system spends more than 50 billion dollars per year on the treatment of patients with wounds of all types. Current literature documents poor healing rates and lack of following the evidence and this will only worsen if the care is left to patients, families and general practitioners.

3. Policy States: In rare instances, due to severe underlying debility or other factors such as operability, the goal of wound care provided in outpatient settings may be only to **prevent progression** of the wound. Active wound care procedures are performed to remove devitalized tissue promoting healing, and involve selective and non-selective (debridement techniques.

AAWC Comment:
To "prevent progression of the wound" is contradictory.

Recommendation:
The 1st sentence should read… "prevent deterioration of the wound and avoid hospital admissions and readmissions. The second 2nd sentence should read… Active wound care procedures **begin by removing biofilm and** devitalized, **necrotic, or infected** tissue **to** promote healing, and involve **using** selective **(CPT 97597)** and non-selective **(CPT 97602) and surgical (CPT 11042-44)** debridement techniques.

4. Policy States: The provider is required to have direct (one-on-one) patient contact when performing active wound care management.

Recommendation:
Remove sentence. Scope of practice determines the need for 'direct' (one-on-one) patient contact when performing active wound care management.

5. Policy States: The appropriate interval and frequency of debridement depends on the individual clinical

characteristics of patients the extent of the wound. It is highly recommended that the treatment plan forted a patient who requires frequent repeated debridement be reevaluated to ensure that pressure reduction, and infection control have been adequately addressed.

Recommendation:
Revise paragraph: The appropriate interval and frequency of debridement depends on the individual clinical characteristics of patients **and their comorbidities, and the extent of the wound and its' vascular components.** It is highly recommended that the treatment plan forted a patient who requires frequent repeated debridement be reevaluated to ensure that pressure reduction, **compression as appropriate, nutrition status, vascular status** and infection control have been adequately addressed.

Definition of terms for this policy:

Dressing Changes for Wound Debridement

1. Wet dressings: Water and medication can be applied to the skin with dressings (finely woven cotton, linen, or gauze) soaked in solution. Wet compresses, especially with frequent changes, provide gentle debridement.

AAWC Comments:
Wet compresses do not debride, and are not used for gentle debridement. Wet dressings are not standard of care for debridement.

2. Dry dressings: Used to provide gentle debridement, protect the skin, hold medications against the skin, keep clothing and sheets from rubbing, or keep dirt and air away. Such dressings may also prevent patients from scratching or rubbing the wound.

AAWC Comments:
Dry dressings are not designed for gentle debridement. Dry dressings are substandard care and do not provide a moist wound healing environment which is accepted standard of care for wound management.

Covered Indications

For this section, we have provided our requested corrected language in **bold.**

Debridement is indicated whenever **necrotic tissue, biofilm, clot, fibrin, slough and** any associated **foreign, non-vital or infected tissue** is present on an open wound. **Debridement may also be indicated in cases of abnormal wound healing or repair.**

Wound Care Selective Debridement (CPT codes 97597, 97598) includes:

- Removal of specific targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by sharp dissection including scissors, scalpel, curettes, and tweezers/forceps. This procedure typically requires no anesthesia and there is generally no bleeding associated with it. **The last sentence is not true as bleeding can be present and local/ regional anesthesia can be provided. Remove this sentence.**

Wound Care Non-Selective Debridement (CPT code 97602) includes:

- Blunt Debridement: 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. **[This sentence is untrue and should be removed.]** Generally this is not a skilled service

and does not require the skills of a physician, podiatrist, therapist, or wound care nurse. **[This sentence is untrue and should be removed.]**

- Enzymatic Debridement: Debridement with topical enzymes is used when the necrotic substances to be removed from a wound are **protein, fiber and collagen. It should not replace mechanical debridement when needed.**

- Mechanical Debridement: Wet-to-dry or dry-to-dry **[remove dry-to-dry… this is substandard care and not acceptable standard of care]** dressings may be used with wounds that have a high percentage of necrotic tissue. Wet-to-dry dressings should be used cautiously as maceration of surrounding tissue may hinder healing. **[Remove wet-to-dry this is not standard of care and, the CMS stopped coverage and reimbursement.]**

- Jet Hydrotherapy and Wound Irrigation: types of mechanical debridement used to remove necrotic tissue. Jet Hydrotherapy and Wound Irrigation should be used cautiously as maceration of surrounding tissue may hinder healing. **[Remove sentence. If used appropriately, these techniques are not associated with maceration.]**

- **Pulse lavage is a selective debridement method and needs to be added to this policy.**

Wound Care Surgical Debridements (CPT codes 11000, 11001, 11004, 11005, 11006, 11008, 11010, 11011, 11012 **(remove all prior codes – these are specific to dermatologic conditions and are not related to wound care]** 11042, 11043, 11044, 11045, 11046, and 11047)

- Conditions that may require surgical debridement of large amounts of skin include: rapidly spreading necrotizing process (sometimes seen with aggressive streptococcal infections), Fasciotomy procedure involving tissue/ muscle /fascia severe eczema, bullous skin diseases, extensive skin trauma (including large abraded areas with ground-in dirt), or autoimmune skin diseases (such as pemphigus). **[Remove this entire section – not related to wounds. These are dermatologic conditions.]**

- Surgical debridement 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 but not limited to **necrosis, eschar, slough, infected tissue, abnormal granulation tissue**, **biofilm, muscle, bone, joint, tendon etc., whatever is involved in keeping the wound in inflammatory state** [**Remove rest of sentence, not correct]** and should be accomplished to the margins of viable tissue. Surgical excision includes going slightly beyond the point of visible necrotic tissue back to **viable tissue. [Removed…until viable bleeding tissue is encountered, as this would not be an appropriate medical approach with patient who have PAD]. Debridement may not be a single event and is really dependent on the patient's wound and comorbidities. We have spent years on encouraging early and aggressive debridement to rid infection and promote wound bed preparation.**

<u>Negative Pressure Wound Care (NPWT), electrically powered (CPT codes 97605, 97606)</u>

- Electrically powered **(Remove this language as it is not part of the CPT code description)** NPWT (CPT codes 97605, 97606) involves the application of controlled or intermittent negative pressure to a properly dressed wound cavity.

<u>Application of Paste Boot (Unna Boot) or Application of Multi-Layer Compression System (CPT codes 29580 or 29581)</u>

- Unna boot is a type of compression **therapy used to treat the vascular system problem to** promote return of blood from the peripheral veins back into the central circulation. When both a debridement is done and

an Unna boot is applied only the debridement will be reimbursed. **This is incorrect – These are separate and independent procedures; debridement addresses the skin organ (wound) and compression addresses the vascular system. These are two different organ systems. The current NCCI edits do allow debridement and Unna Boot and or Multi-layer compression applications (CPT 29580 & 29581) at the same visit with use of modified (-59). These procedures treat two different organ systems and by definition are separate billable procedures.**

Limitations

Debridement will be considered not reasonable and necessary for a wound that is clean and free of necrotic tissue, **fibrin, slough, biofilm** or in the absence of abnormal wound healing.

Since the overall goal of care is healing and not palliation, it is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement as outlined in this LCD cannot be shown. **[Contradictory to earlier language and statement is not correct. In some cases, healing may not be possible and maintaining the wound free of infection or preventing further deterioration is the goal of the wound care. This is especially true for older, non-ambulatory patients with limited life span.]**

- It would not be expected that an individual wound would be repeatedly debrided of skin and subcutaneous tissue because these tissues typically do not regrow very quickly. Coverage for prolonged, repetitive debridement services will be considered through the redetermination process. **[Need to define what is considered prolonged debridement and repeatedly debrided]**

- The use of a sharp instrument does not necessarily substantiate the performance of surgical excisional debridement. **[The term 'incisional' is inappropriate and not part of definition of these codes – later in the policy it states that a scalpel or blade is appropriate]**

- Wound debridement utilizing experimental or investigational methods is considered not reasonable and necessary. Therefore, it would not be reasonable and necessary to report these services with any CPT code. **[We do not agree with this statement. Novitas needs to specify what is defined as experimental or investigational methods and provide examples]**

- Disposable non-powered mechanical or single use non-electrically powered NPWT (CPT codes 97607, 97608) for any indication is considered not medically reasonable and necessary. **[Statement needs to be removed. There is no evidence provided in the policy references to support this statement. Disposable NPWT has been covered by Novitas since 2014 and there is no justification to remove coverage in this draft policy. Armstrong et. al.[1] conducted a RCT comparing disposable NPWT to DME-NPWT and found similar and equivalent outcomes, with no significant difference in complete wound closure at all study time points. Marston et. al.[2] also demonstrated equivalency of both devices for pressure ulcers. Disposable NPWT needs to be a covered treatment method in the final policy. As a matter of fact Patient satisfaction and compliance was statistically significant for the disposable mechanically powered NPWT.]**

1. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: A multicenter randomized controlled trial. *Wound Repair Regen* 2012;20:332-341.
2. Marston WA, Armstrong DG, Reyzelman AM, Kirsner RS. A multicenter randomized controlled trial comparing treatment of venous leg ulcers using mechanically versus electrically powered negative pressure wound therapy. *Adv Wound Care* 2015;4:75-82.

- When both an Unna boot is applied and a wound debridement is performed, the debridement will be

reimbursed, if the medical record supports that the service is reasonable and necessary as outlined in this LCD, and the Unna boot application will be denied. **[We have already addressed this issue above. This is incorrect and not consistent with the NCCI edits. Statement needs to be removed.]**

- Continuing MIST treatments for wounds demonstrating no improvement after six treatments is considered not reasonable and necessary. Observable, documented improvements in the wound(s) should be evident after 2 weeks or 4-6 MIST treatments. Improvements would include documented reduction in pain, necrotic tissue, or wound size or improved granulation tissue. **[There is no evidence supporting limiting MIST therapy to just six treatments to demonstrate improvement for all wounds, regardless of complexity.]**

- The following services are considered to be not reasonable and necessary wound debridement services:
  - 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. **[Breakdown under a dorsal corn is no longer a corn, it is then an ulcer, and does qualify for wound care treatments]**

  - 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. **[Integrated fibrin, crusts and biofilms cannot be removed without some measure of tissue included. This statement needs to be removed, it is incorrect]**

- Medicare expects that with appropriate care:
  - Wound volume or surface dimension should decrease by at least 10 percent per month or wounds will demonstrate granulation tissue advancement of no less than 1 mm/week. **[There is no evidence in the literature to substantiate the 10% per month or the 1 mm granulation tissue per week statements. No specific standard of care or Guidelines support these statements. Both the 1mm/ week and the 10% per month criteria are within the margin for error for measurement of a wound. Remove these statements. What is documented is that reduction of less than 40% for venous and less than 50% for diabetic ulcers at 4 weeks is an overall predictor of outcome.]**

<u>Documentation Requirements</u>

- Identification of the wound location, size, depth and stage by description and may be supported by a drawing or photograph. 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. **[There is no data to support the #5 for debridements. It is important for the MAC to understand that a lot of EHR systems cannot accept a photo digitally, therefore this needs revision]**

- A pathology report substantiating depth of debridement shall be submitted when billing for the debridement procedure described by CPT code 11044. **[While we agree the initial debrided bone sample should have a pathology report, subsequent bone removal would not necessitate additional pathology, which is increasing costs without a medical benefit. Only initial pathology is required]**

- In addition, except for patients with compromised healing due to severe underlying debility or other factors, documentation in the medical record must show:
  - The status of the wound is such that the treatment is expected to make a significant practical improvement in the wound in a reasonable and generally predictable period of time. **[What is**

considered 'significant practical improvement' and what references support this statement? Who can predict and what is considered a 'generally predictable' period of time? These are vague, unreliable criteria with no means to measure and no evidence to support use in any particular wound type and by complexity of wound.]

- The medical record must include a plan of care containing treatment goals and physician or **other qualified professional** 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. A wound that shows no improvement after 30 days **requires re-evaluation**. Documentation of such cases may include a physician **or other qualified professional** reassessment of underlying infection, metabolic, nutritional, **vascular** problems, **cardiac, renal and any auto-immune conditions** inhibiting wound healing, or a new treatment approach.

Utilization Guidelines

This entire section is incorrect. There is no evidence provided by the MAC in this policy to support this statement. The current literature does not support the limitations included below. These are all inconsistent with clinical practice Guidelines. This section needs to be removed as it is harmful for patient care and outcomes. Wounds debrided frequently as needed have better healing than those not debrided-Steed article. This is most important for diabetic wounds as diabetic patients mask signs and symptoms of infection and limiting # of debridements will increase major amputation rates and death by sepsis. It should be done by clinicians who have expertise in the art of debridement and speaks again to the need for wound providers and not relying on PCP's etc. who don't have the training or expertise.

- Debridements will be limited to eight total services per year for any of the debridement codes listed in this LCD (CPT codes 11000,11004-11006,11010-11044, 97597 and 97598). Of the eight debridements, no more than five debridements involving removal of muscle and/or bone (CPT codes 11043, 11044) per year will be considered reasonable and necessary. Services beyond these limits may be considered through the redetermination process when supported in the medical record.

  Wilcox, Carter and Covington conducted a retrospective study of 154 644 patients with 312 744 wounds of all etiologies to evaluate the effect of debridement at different frequencies. They found unequivocally that the more frequent the debridements, the better the healing outcome. They stated…"Standard care for the treatment of chronic wounds includes debridement, with best evidence existing for diabetic foot ulcers, where secondary analysis of randomized trials suggests centers with higher frequency of debridement have superior healing rates. The rationale for debridement is to remove tissue and debris that inhibit healing, which at times is obvious, for example, when necrotic eschar or excessive callus is present, but at other times is less obvious, for example, when trying to remove bacterial biofilms or abnormal host cells that may also contribute to slow healing. For example, keratinocytes adjacent to chronic wounds have a diminished ability to migrate and respond to growth factors and contribute to a pathogenic phenotype that inhibits healing."

  Wilcox JR, Carter MJ, Covington S. Frequency of Debridements and Time to Heal; A Retrospective Cohort Study of 312 744 Wounds. *JAMA Dermatol.* 2013;149(9):1050-1058.

- No more than 6 NPWT (CPT codes 97605-97606) services in a four month period will be considered reasonable and necessary. NPWT services exceeding this frequency may be covered upon redetermination only when medical necessity continues to be met as previously outlined and there is documented evidence

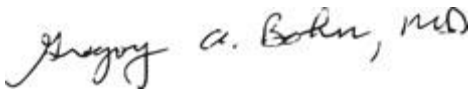
of clear benefit from the NPWT treatment already provided. [**There is no evidence to support this limitation]**

- No more than 18 services of low frequency, non-contact, non-thermal ultrasound (MIST Therapy) within a six week period will be considered reasonable and necessary.

- Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided 2-3 times per week to be considered reasonable and necessary. [**There is no evidence to support this limitation]**

Again, the AAWC requests the immediate removal of this draft policy from review and requests that Novitas convene a working group, which includes wound care specialists and clinicians to help draft a meaningful, accurate and evidence-based Wound Care policy. The AAWC stands ready and willing to provide help and expertise to support such efforts. This is the only way to ensure patients get evidence-based quality care and the only way to reduce costs. The policy as written lacks data to support many of the assumptions and will harm patients and increase costs for care of wound patients. The evidence is clear that adherence to wound care Guidelines and involvement of wound specialist is necessary, similar to the need for cancer specialists being involved and following guidelines for cancer care. For diabetic patients with neuro-ischemic ulcers the 5-year mortality is worse than some very common cancers and requires aggressive wound specialty management.

Sincerely:



Dr. Greg Bohn, MD, FACS, ABPM/UHM, CWSP, FACHM
President, Association for the Advancement of Wound Care
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Please see Attachment A below.

Attachment A:
AAWC 2016 Literature Review for Wound Care Related Clinical Endpoints
[485 related articles from peer-reviewed journals]

1. Adeolu AA, Olabanji JK, Komolafe EO, Ademuyiwa AO, Awe AO, Oladele AO. A prospective study of two methods of closing surgical scalp wounds. Br J Neurosurg. 2012 Feb;26(1):75-7.
2. Ahmad M, Arifi AA, Onselen Rv, Alkodami AA, Zaibag M, Khaldi AA, Najm HK. Gender differences in the surgical management and early clinical outcome of coronary artery disease: Single centre experience. J Saudi Heart Assoc. 2010;22(2):47-53.
3. Akan M, Misirlioğlu A, Yildirim S, Cakir B, Taylan G, Aköz T. Ice application to minimize pain in the split-thickness skin graft donor site. Aesthetic Plast Surg. 2003;27(4):305-7.
4. Akkaya N, Ardic F, Ozgen M, Akkaya S, Sahin F, Kilic Efficacy of electromyographic biofeedback and electrical stimulation following arthroscopic partial meniscectomy: a randomized controlled trial. Clin Rehabil 2012; 26(3):224-36.
5. Albert NM, Rock R, Sammon MA, Bena JF, Morrison SL, Whitman A, Kato I, Landis-Erdman JC. Do patient and nurse outcome differences exist between 2 negative pressure wound therapy systems? J Wound Ostomy Continence Nurs 2012;39(3):259-66.
6. Alexandrescu V, Vincent G, Azdad K, Hubermont G, Ledent G, Ngongang C, Filimon AM. A reliable approach to diabetic neuroischemic foot wounds: below-the-knee angiosome-oriented angioplasty. J Endovasc Ther. 2011;18(3):376-87. doi:
7. Allen L, McGarrah B, Barrett D, Stenson B, Turpin PG, Vangilder C. Air-fluidized therapy in patients with suspected deep tissue injury: a case series. J Wound Ostomy Continence Nurs 2012;39(5):555-61.
8. Al-Waili NS, Saloom KY. Effects of topical honey on post-operative wound infections due to gram positive and gram negative bacteria following caesarean sections and hysterectomies. European J Medical Research 1999;4(3):126–30.
9. Amann B, Luedemann C, Ratei R, Schmidt-Lucke JA. Autologous bone marrow cell transplantation increases leg perfusion and reduces amputations in patients with advanced critical limb ischemia due to peripheral artery disease. Cell Transplant 2009;18(3):371-80.
10. Amer-Alshiek J, Alshiek T, Almog B, Lessing JB, Satel A, Many A, Levin I. Can we reduce the surgical site infection rate in cesarean sections using a chlorhexidine-based antisepsis protocol? J Matern Fetal Neonatal Med 2013;26(17):1749-52.
11. Amr YM. Multi-day low dose ketamine infusion as adjuvant to oral gabapentin in spinal cord injury related chronic pain: a prospective, randomized, double blind trial. Pain Physician 2010;13(3):245-9.
12. Andriessen PA, Polignano R, Abel M. Development and implementation of a clinical pathway to improve venous leg ulcer treatment. Wounds 2009;21(5):127-33.
13. Anglen JO. Comparison of soap and antibiotic solutions for irrigation of lower-limb open fracture wounds. A prospective, randomized study. J Bone Joint Surg Am 2005;87(7):1415-22.
14. Archer KR, Castillo RC, Mackenzie EJ, Bosse MJ. Gait symmetry and walking speed analysis following lower-extremity trauma. Phys Ther 2006;86(12):1630-40.
15. Armstrong SH, Ruckley CV. Use of a fibrous dressing in exuding leg ulcers. J Wound Care 1997;6(7):322-324.
16. Ashby RL, Gabe R, Ali S, Adderley U, Martin Bland J, Cullum NA, Dumville JC, Iglesias CP, Kang'ombe AR, Soares MO, Stubbs NC, TOrgerson DJ. Clinical and cost-effectiveness of compression hosiery versus compression bandages in treatment of venous leg ulcers (Venous Leg Ulcer Study IV, VenUS IV); a randomized controlled trial. Lancet 2014; 383:871-79.
17. Arnold TE, Stanley JC, Fellows EP, Moncada GA, Allen R, Hutchinson JJ, Swartz WM, Bolton LL, Vickers CF, Kerstein MD. Prospective, multicenter study of managing lower extremity venous ulcers. Ann Vasc Surg. 1994;8(4):356-62.

18. Assouline M, Renard G, Arne JL, David T, Lasmolles C, Malecaze F, Pouliquen YJ. A prospective randomized trial of topical soluble 0.1% indomethacin versus 0.1% diclofenac versus placebo for the control of pain following excimer laser photorefractive keratectomy. Ophthalmic Surg Lasers 1998;29(5):365-74.
19. Attenberger C, Amsler F, Gross T. Clinical evaluation of the Trauma Outcome Profile (TOP) in the longer-term follow-up of polytrauma patients. Injury 2012;43(9):1566-74.
20. Avery PP, Baker RP, Walton MJ, Rooker JC, Squires B, Gargan MF, Bannister GC. Total hip replacement and hemiarthroplasty in mobile, independent patients with a displaced intracapsular fracture of the femoral neck: a seven- to ten-year follow-up report of a prospective randomised controlled trial. J Bone Joint Surg Br 2011; 93(8):1045-8.
21. Baghel PS, Shukla S, Mathur RK, Randa R. A comparative study to evaluate the effect of honey dressing and silver sulfadiazene dressing on wound healing in burn patients. Indian J Plastic Surgery 2009;42(2):176–81.
22. Bale S, Hagelstein S, Banks V, Harding KG. Costs of dressings in the community. J Wound Care 1998a;7(7):327-30.
23. Bale S, Banks V, Haglestein S, Harding KG. A comparison of two amorphous hydrogels in the debridement of pressure sores. J Wound Care 1998b;7(2):65-8.
24. Bale S, Tebbie N, Price P. A topical metronidazole gel used to treat malodorous wounds. Br J Nurs 2004; 13(11):S4-11.
25. Balingit PP, Armstrong DG, Reyzelman AM, Bolton L, Verco SJ, Rodgers KE, Nigh KA, diZerega GS. NorLeu(3) -A(1-7) stimulation of diabetic foot ulcer healing: Results of a randomized, parallel-group, double-blind, placebo-controlled phase 2 clinical trial. Wound Repair Regen 2012;20(4):482-90.
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