



November 10, 2019

Dr. Ryan Holzmacher
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Submitted electronically to policycomments@wpsic.com

Re: WPS Draft Wound Care LCD DL 37228

Dear Dr. Holzmacher,

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”) I am submitting comments on the Draft Local Coverage Determination for Wound Care (DL37228). The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds including diabetic foot, venous stasis, pressure and arterial ulcers. Our clinical specialty societies and organizations not only possess expert knowledge in treating complex chronic wounds, but also in wound care research.

The Alliance has been on the record four times to address our concerns with how WPS is limiting coverage on debridement and not providing adequate scientific evidence to support its coverage policy. We provided comments to the draft LCD in June 2017 and followed it up with both formal letters and emails in June and October 2018 as well as in February 2019 requesting clarification of clinically inaccurate information in the final LCD.

After reading WPS’s decision to not update its wound care LCD, the Alliance once more reiterates our concerns with this flawed policy including:

1. This current LCD as well as the LCD issued in 2017 seem to have no foundation in medical evidence or clinical practice guidelines and are not supported by meaningful citations in the bibliography. This is in violation of CMS’s Program Integrity Manual.
2. The rationale for WPS rejecting the evidence submitted in the APMA reconsideration is not reasonable.
3. WPS eliminated a significant number of CPT codes related to debridement of other chronic non-pressure ulcers when the severity is classified as limited to breakdown of skin without providing adequate evidence for eliminating these codes.

4. WPS eliminated codes related to post-thrombotic syndrome with ulcer and inflammation and chronic venous hypertension without providing adequate evidence for eliminating these codes.
5. WPS has specifically identified a limited number of conditions which must be present in order to provide a debridement, yet left out a significant number of conditions which require it. There is evidence to support that debridement is the standard of care when treating patients with wounds; therefore either WPS should not include a list of conditions or add a rather lengthy list of conditions such as: diabetic foot ulcers, Stage II pressure ulcers, deep tissue injury, osteomyelitis just to name a few.
6. WPS seems to have taken liberties with CPT codes that have already been established by the AMA, accepted by CMS, and utilized verbatim by other contractors and private insurers. WPS does not have the discretion to change CPT code descriptors to suit their purpose and cover certain items within the code while denying others. This is in direct violation of CMS's Program Integrity Manual.
7. WPS included NPWT information within this LCD which conflicts with an already existing DMEMAC NPWT LCD. Therefore, this conflicting information is confusing to providers. It is baffling why WPS needs to provide utilization parameters in this policy when there is a DMEMAC policy already in place.
8. There are clinical errors/inaccuracies contained in the policy, as has been identified previously but ignored by WPS.

Our specific comments follow.

WPS Draft Wound Care LCD Has No Foundation in Medical Evidence or Clinical Practice Guidelines and Is Not Supported By Citations Listed In The Bibliography

In this draft Wound Care LCD, WPS has decreased coverage for debridement, limited the codes accepted for coverage and limited the conditions that are required to be present in order for a debridement to be performed. The evidence that WPS has cited since 2017 in the LCD bibliography to support its decision to decrease coverage is not sufficient nor is it supportive of the language in the policy. We submit that language in the LCD does not have any foundation in medical evidence.

Clinical experts have provided WPS with evidence to support their positions that debridement is a standard of care to treat patients with wounds as well as to reinstate the codes which were eliminated and expand the limited list of conditions which need to be met to perform a debridement (if they need to be listed out at all). However, none of that evidence has been cited in the WPS bibliography.

According to CMS's Program Integrity Manual (PIM) 13.7.1, the evidence supporting an LCD "shall be based on the strongest evidence available". The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. WPS not only did not gather all the evidence that exists when developing this LCD, it used data that is not clinically sound nor comports to the standards of practice based on clinical practice guidelines. The evidence that WPS has cited is not compelling to demonstrate that the debridement procedures which WPS eliminated are either unsafe and/or ineffective. WPS has also not brought forth expert consensus among clinicians and

scientists that debridement for these types of ulcers or conditions are medically unnecessary. Yet, WPS specifically identifies certain procedures which are acceptable for a debridement and do not list others – such as diabetic foot ulcers - without providing evidence to justify its position. Many of the Alliance’s clinical association and physician specialty society members have clinical practice guidelines which very clearly provide evidence that not only is debridement the standard of care for wound care, but also is necessary for appropriate wound healing. However, none of these practice guidelines seem to be reviewed by WPS or they would have been cited in the bibliography for this LCD.

It is very unusual for clinical practice guidelines established by specialty societies and associations, which clearly identify a standard of care, to be ignored by Medicare contractors. Yet, WPS has done just that. For the most part, the clinical evidence that is stated in the reference section of the Wound Care LCD bibliography is not topical or relevant to debridement. The Alliance submits that the language in this policy which limits coverage of debridement by eliminating CPT codes for coverage as well as limiting the conditions that need to be present to perform a debridement flies in the face of standards of care and best practices. Furthermore, WPS does not provide the necessary evidence to support its position to do so. WPS has continuously ignored the clinical community and the evidence provided by them. WPS has continually ignored requests for evidence that was utilized in forming its decisions. While there has been evidence placed in the bibliography, none of it supports the WPS position to decrease coverage OR to eliminate coverage for established CPT codes. Based on the evidence cited in the bibliography, and more importantly the evidence that was omitted, the Alliance submits that WPS has failed to adhere to the above PIM guidelines for limiting and/or decreasing coverage as well as rejecting the APMA reconsideration request.

Alliance recommendation: The Alliance recommends that when developing LCDs WPS ensures that it not only utilizes its experts (CAC members), but also reviews ALL clinical evidence including clinical practice guidelines. This will help to ensure that WPS is meeting their requirements under the PIM. Furthermore, when citing evidence utilized in the policy to support WPS positions, the Alliance recommends creating subheadings to identify what evidence was used to support each section in the policy. This not only helps the reader to better understand whether the evidence cited was used to create policy language for example for ultrasound, maggot therapy or debridement, but will also allow stakeholders to better identify what evidence was not reviewed by WPS. This will assist experts to better be able to provide WPS appropriate evidence to review.

The Rationale for WPS Rejecting the Evidence Submitted in the APMA Reconsideration is Not Reasonable

WPS was dismissive of evidence provided to it not only through the reconsideration request submitted by the American Podiatric Medical Association (APMA), but also of evidence provided by the Alliance as requested by the MAC. One example of the dismissiveness includes the information cited from the Electrical Stimulation NCD. WPS stated that this reference was “not relevant to the request.” Yet, within the CMS NCD, CMS addressed a standard of care and specifically stated within that NCD:

“ Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present ”.

While this national coverage determination recognized a standard of care that has been established over time and through routine clinical practice, we have grave concerns that WPS completely dismissed this evidence citing that the NCD did not address debridement for the types of ulcers specified in the reconsideration request. Again, the point of providing the NCD language was to highlight CMS recognition of debridement as a standard of care. WPS did not find that language to be compelling or on point to accept the NCD evidence submitted.

The manner in which WPS dismissed all the evidence submitted to it follows the same pattern - if the study was not specifically on point, it was dismissed. This is concerning. Debridement is the standard of care. Evidence development when standards of care are clearly established is not typical. WPS would be hard pressed to find studies on point as a result. But, there are studies and clinical practice guidelines that clearly establish debridement is the standard of care. Thus, the rationale that studies need to be specific to a certain type of condition or they will not be accepted is not reasonable. Furthermore, by WPS not accepting the absolute fact that debridement is the standard of care and thereby limiting the debridement that can be performed is not only harmful to patients, it is harmful to clinicians who can be subjected to malpractice for not adhering to their clinical practice guidelines and/or standards of care.

Alliance recommendation: Experts have provided evidence to justify debridement as the standard of care when treating patients with wounds. WPS needs to revise the LCD accordingly.

Chronic Non-Pressure Ulcers When The Severity Is Classified As Limited To Breakdown Of Skin

WPS has removed debridement coverage for chronic non-pressure ulcers when the severity is classified as “limited to breakdown of skin”. The CPT® manual describes 97597 as the appropriate code to utilize when only epidermis and/or dermis are debrided. This WPS policy is contradictory to the definition and goals of debridement that is included in the WPS “Coverage Indication, Limitations and/or Medical Necessity” section of the Wound Care LCD which states: “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.”

Since the WPS LCD states that a debridement is proper for “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”, CPT code 97597 and 97598 would be used to remove devitalized tissue from the dermis or epidermis level. However, WPS is instructing that providers bill an E/M code when the severity is classified “as limited to breakdown of skin”. This is contrary to common coding and billing practices. It is our understanding that physicians and hospitals should code procedures to the most specific 2 codes, which in this case would be 97597 and 97598, if the ulcers are greater than 20 sq.cm. The Alliance urges WPS to comply with CPT coding and allow debridement coverage (CPT code 97597/97598) for chronic non pressure ulcers with a tissue severity of limited to breakdown of skin (this coverage is consistent with all other Medicare Administrative Contractors (MACs) and other 3rd party payers (commercial insurance companies).

Furthermore, the rationale provided to the Alliance for leaving out diagnosis codes with respect to chronic non-pressure ulcers when the severity is classified as “limited to breakdown of skin (ICD- 10 L97.111 – L98.497) was that the main purpose of the policy is to “discuss wound care for 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”.

We have the following concerns with respect to this rationale:

1. First, other jurisdictions, including Novitas and FCSO state the same point in their policies yet still permit these codes to be utilized as they recognize the necessity of debridement for these types of wounds.
2. Second, these codes were included in the WPS policy prior to 2017 when WPS revised its LCD for wound care. The decrease in coverage was not supported by any evidence in the bibliography contained in the LCD. If there is a decrease in coverage, WPS is required to have provided the evidence it used to justify the decreased coverage.
3. Finally, under this policy, WPS is allowing patients to become sicker by not permitting clinicians to appropriately treat their patients by providing a clinically sound procedure - which is not only clinically appropriate - but established in standards of care. Furthermore, WPS is creating a deficiency in the level of care that a patient receives in its jurisdiction compared to others; thereby, creating an imbalance in patient care. A patient in Texas and Florida will get different care than a patient in the WPS jurisdiction. This is not the intent of the program. WPS is creating inequity in the standard of care of patients with the same conditions in other parts of the country who are clinically covered. This is contrary to the integrity and intent of the Medicare program. In addition to creating inequity in the standard of care patients receive, the Alliance would appreciate WPS explaining its intent in creating this disparity.

Alliance recommendation: Once again, the Alliance recommends that the diagnosis codes related to chronic non-pressure ulcers when the severity is classified as “limited to breakdown of skin (ICD- 10 L97.111 – L98.497) be reinstated.

Post-thrombotic Syndrome with Ulcer and Inflammation and Chronic Venous Hypertension

In addition to chronic non-pressure ulcers when the severity is classified as “limited to breakdown of skin (ICD-10 L97.111 – L98.497), WPS has omitted numerous ICD-10 codes that support medical necessity for post-thrombotic syndrome with ulcer and inflammation and chronic venous hypertension.

Alliance recommendation: These codes need to be reinstated for similar reasons as stated above.

Conditions That Need To Be Met In Order To Perform Debridement

WPS identifies conditions which must be present and documented in order for a debridement to be covered. The policy states: “At least ONE of the following conditions must be present and documented:

- Pressure ulcers, Stage III or IV,
- Venous or arterial insufficiency ulcers,
- Dehiscenced wounds,
- Wounds with exposed hardware or bone,
- Neuropathic ulcers,
- Neuroischaemic ulcers,
- Complications of surgically created or traumatic wound where accelerated granulation

The Alliance is very concerned that WPS has decided to list out a limited number of conditions that need to be met in order for a debridement to be performed and covered. There are 1,747 distinct ICD-10 diagnosis codes

of wounds and ulcers that require debridement. To limit the conditions that must be present in order for a clinician to be permitted to perform a debridement is clinically unsound and unreasonable. A patient who requires a debridement of a wound does not always have one of the conditions present that WPS has identified in this LCD. Yet debridement IS the standard of care when treating patients with a chronic wound— whether their condition is listed in this policy or not.

Debridement is a well known and utilized procedure in the treatment of chronic wound care. It is effective and necessary. There is evidence to support its use that both the Alliance and our clinical association members have submitted to WPS. There are numerous review articles on the preparation of the chronic wound bed to support healing and clinical practice guidelines - adopted by professional societies - which address the fundamental importance in debridement in the management of chronic wounds. While all of these guidelines can not address each and every clinical scenario in which debridement should be performed, it is very clear that debridement is the standard of care when treating patients with wounds. Yet, it appears that if a study does not specifically address a specific condition, then WPS will not allow for that condition to be listed as one of the conditions that must be present to be able to perform a debridement – despite every clinical organization stating that it is the standard of care.

In APMA’s reconsideration request, WPS dismissed the evidence submitted because it was not specific enough to include diabetic foot ulcers in the list of conditions. However, not only was the evidence sufficient for WPS to include them in the list of conditions, but it should have also accepted clinical practice guidelines for diabetic foot ulcers which clearly state that debridement is the standard of care when treating this type of ulcer. There certainly is evidence to support diabetic foot ulcers being listed in the conditions which need to be met for a debridement to be performed. But there are many conditions which require debridement which may not have the same level of evidence as diabetic foot ulcers. The Alliance submits that when a standard of care has been established, one may not find studies for every type for every condition that debridement is medically necessary. There are studies to support debridement in the chronic wound care space for more conditions than were listed including diabetic foot ulcers as well as clinical practice guidelines, written by multiple specialty societies which highlight debridement as being the standard of care when treating this patient population for conditions that were not listed in the policy.

The Alliance does not believe that a list of conditions should be spelled out in this policy and question why WPS would limit debridement to a few conditions when so many others are present requiring debridement. We also question why WPS needs to list the conditions when debridement is the standard of care when treating wound care patients. Data exists showing that debridement is successful in helping heal patients with wounds. In fact, there is evidence so suggest that the increased frequency of debridement helps to heal a wound.

The list of evidence that WPS has placed in the bibliography attached to the LCD does not justify the limitation of conditions. It is contrary to good wound care treatment protocols and standards of care. Either WPS needs to remove the list of conditions and provide language consistent with Novitas or FCSO, significantly expand the list of conditions or state the following language in the policy to ensure that the appropriate wounds will be eligible for debridement - “Debridement to be covered for any full thickness wound/site or partial thickness wound that has evidence of progressing to a full thickness wound.”

Alliance recommendation: The Alliance recommends that WPS provide guidance that is consistent with Novitas JL and JH and the FCSO Wound Care LCDs which state the following: “It is the provider’s

responsibility to select codes carried out to the highest level of specificity and select from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted. No procedure code to diagnosis code limitations are being established at this time.” Should WPS not be so inclined to do so, then the Alliance recommends either significantly expanding the list of conditions that need to be present in order for a debridement to be performed or state the following language in the policy to ensure that the appropriate wounds will be eligible for debridement - “Debridement to be covered for any full thickness wound/site or partial thickness wound that has evidence of progressing to a full thickness wound.”

Negative Pressure Wound Therapy

WPS states that “the coverage of traditional Negative Pressure Wound Therapy (NPWT) device/unit/type, or supplies is covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)), and providers should consult their DME LCD for specific coverage, parameters, and guidelines”. However, in the utilization parameters, WPS goes on to limit the utilization of NPWT. Specifically, the language in the policy reads, “Negative pressure wound therapy services should not exceed a 120 day period. There should be no more than 4 dressing changes per wound per month for the majority of wounds.” It is alarming that WPS is providing NPWT utilization parameters in this policy rather than just simply refer to the already well established DMEMAC NPWT LCD. This policy is creating confusion among providers which is unnecessary.

Alliance recommendation: WPS delete information on NPWT and simply refer providers to the DMEMAC NPWT policy as has been done for electrical stimulation and other services referenced in this policy.

Lack of Adherence to CPT Code Descriptors

According to the Program Integrity Manual, the MAC “*shall ensure that all LCDs do not conflict with statutes, rulings, regulations, and national coverage, payment and coding practices.*” Yet throughout this LCD, WPS seems to take great liberties with CPT codes that have already been established by the AMA, accepted by CMS and used verbatim by all other contractors and private payers. WPS does not have the authority or the discretion to change CPT code descriptors and cover certain items within the code while denying others. This is in direct violation of CMS’s Program Integrity Manual. There are several areas in which WPS is in error.

The Alliance has already pointed out one instance of WPS containing language contrary to CPT code descriptors in its policy in our discussion above on debridement coverage for chronic non-pressure ulcers when the severity is classified as “limited to breakdown of skin”. However, there are several more instances in the LCD where WPS has violated the PIM and altering CPT.

Specifically, the LCD states the following:

The following services may be done during wound care services and can be medically necessary, but they are not considered wound debridement services and wound debridement CPT codes should not be used.

- ***Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, or wet to dry or dry to dry dressing.*** Generally, dressing changes are not considered a skilled service. The prior dressings are different and distinct from wet to moist dressings that are used for removal of devitalized tissue from wound(s) for non-selective debridement

- ***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***

The Alliance is concerned that WPS has stated that certain procedures are not considered wound debridement services and therefore wound debridement CPT codes should not be used when the CPT descriptor clearly lists those items.

CPT 97597 states, “Debridement (e.g. high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel, and forceps), open wound (e.g. fibrin, devitalized epidermis and/or dermis exudate, debris, biofilm) including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq. cm or less.”

WPS states that fibrin is not covered for a debridement when it is clearly listed in the 97597 code descriptor.

Similarly, 97597 clearly lists scissors and forceps when selective debridement is performed, yet WPS limits the removal of necrotic tissue to a scalpel or curette.

The Alliance has requested on multiple occasions for WPS to adhere to the CPT code descriptor language, but two years later, we are still making that recommendation. The Alliance again recommends that WPS needs to revise this policy so that it is consistent with the CPT code descriptors and not be in violation of the Program Integrity Manual.

Finally, the policy states, “While mechanical debridement is a valuable technique for healing ulcers, it does not qualify as debridement services”. Again, WPS is taking liberties with CPT. Mechanical debridement IS classified as a non-selective debridement within CPT code 97602.

As a reminder, there are surgical debridement codes (11042 – 11047). These codes are defined by the type of tissue removed – i.e., subcutaneous, muscle, bone. There are also medical debridement codes 97597, 97598 and 97602 that are defined as open wounds. The type of instrument used does NOT define these codes.

Alliance recommendations: WPS must make the above changes to the LCD in order to adhere to CPT code descriptor language as stated above.

Clinical Errors/Inaccuracies

There are several areas in which WPS clinically incorrect information contained in the policy. The Alliance has highlighted these areas multiple times. One of the most significant is that WPS states that debridement is categorized as selective or non selective debridement and then goes on to state that non-selective debridement includes surgical, sharp, enzymatic and wet to moist dressings. WPS states, “selective debridement includes selective removal of necrotic tissue by sharp dissection including scissors and forceps”. WPS then identifies that non selective debridement is surgical or sharp debridement. Not only is this contradictory, it is clinically incorrect.

As other MACs have correctly stated, “**Selective Debridement** includes the removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by **sharp dissection utilizing scissors, scalpel, curettes, and/or tweezers/forceps**. This procedure typically requires no anesthesia and generally has no or minimal associated bleeding.” Whereas **Non-Selective Debridement** may include any of the following:

- **Mechanical Debridement:** This type of debridement is the removal of necrotic tissue by cleansing, or application of a wet-to-dry or dry-to-dry dressing technique. Wet-to-dry dressings should be used judiciously as maceration of surrounding tissue may hinder healing. Generally, dressing changes are not considered a skilled service.
- **Enzymatic Debridement:** Debridement with topical enzymes is used when the necrotic substances to be removed from a wound are protein, fiber and collagen. The manufacturer’s product insert contains indications, contraindications, precautions, dosage and administration guidelines; it is the clinician’s responsibility to comply with those guidelines.
- **Autolytic Debridement:** This type of debridement is indicated where manageable amounts of necrotic tissue are present, and there is no infection. Autolytic debridement occurs when the enzymes that are naturally found in wound fluids are sequestered under synthetic dressings.
- **Maggot / larvae therapy:** Debridement with medical-grade maggots.

Alliance recommendation: The language in the WPS policy is not clinically correct and needs to be revised as stated above.

Conclusion

The Alliance represents almost every physician specialty society and clinical association whose members treat patients with wounds¹ and are the experts in their fields. Many of these organizations also have clinical practice guidelines which support debridement as the standard of care when treating patients with chronic wounds. The Alliance has provided links to these guidelines in Attachment A as well as additional evidence for WPS to consider (some of which we have provided in our comments in the past which was completely ignored). While WPS has provided some evidence in its LCD, our members have informed us that none of the evidence is compelling to demonstrate that the debridement procedures which WPS has eliminated are either unsafe and/or ineffective. WPS has also not brought forth expert consensus among clinicians and scientists that debridement of these types of ulcers is not medically necessary. These are the standards that WPS must prove when citing evidence for a reduction in coverage for a certain item or procedure. However, WPS specifically identifies certain procedures which are acceptable for a debridement yet does not list others – such as for diabetic foot ulcers without providing evidence to justify its decision to include some and exclude others, despite debridement being considered the standard of care. The Alliance has requested this information in our emails and letters, yet it has not been provided to us or in the draft LCD. Our members are appalled at this policy. Simply stated, this policy does not uphold the standard of care and is unacceptable.

¹ A list of our clinical members include: Academy of Nutrition and Dietetics, American Association of Nurse Practitioners, American Board of Wound Medicine and Surgery, American College of Foot and Ankle Surgeons, American College of Hyperbaric Medicine, American Diabetes Association interest Group on foot care, American Physical Therapy Association, American Podiatric Medical Association, American Professional Wound Care association, American Society of Plastic Surgeons, American Vein and Lymphatic Society, American Venous Forum, Amputee Coalition, Association for the advancement of Wound Care, National Lymphedema Network, Society for Vascular Medicine, Society for Vascular Surgery, Undersea & Hyperbaric Medical Society, Visiting Nurse Association of America, Wound, Ostomy and Continence Nurses Society, Wound Healing Society.

We request that WPS listens to the experts who treat these patients everyday – this policy is negatively impacting the care that our members provide to their patients in the WPS jurisdiction. Chronic non-pressure ulcers when the severity is classified as limited to breakdown of skin must be covered under this policy. We request that the codes that were contained in the WPS LCD prior to the Wound Care policy being finalized in 2018 be reinstated. If WPS finds a need to list out the conditions that must be present in order to receive a debridement, then we request that diabetic foot ulcers and many other conditions be added to the list of conditions that need to be present for debridement to be covered.

We appreciate the opportunity to provide you with our comments and hope that WPS will use us as a resource to ensure that the wound care policy in its jurisdiction is clinically accurate, is not in violation of CMS policy on CPT coding and is not providing disparate coverage to the patients our members serve.

Sincerely,



Marcia Nusgart R.Ph.
Executive Director

c.c. Tamara Syrek-Jensen
Susan Miller M.D.

ATTACHMENT A

EVIDENCE FOR WPS REVIEW

Diabetic Foot Ulcer References

1. Caputo GM, Cavanaugh PR, Ulbrecht JS, Gibbons GW, Karchmer AW. Current Concepts: Assessment and Management of Foot Disease in Patients With Diabetes. N. Eng. Journal Med. 1995; 13:854-860.

2. Cavanaugh PR, Buse JB, Frykberg RG, Gibbons GW, Lipsky BA, Pogach L, Reiber GE, Sheehan P. Consensus Development Conference on Diabetic Foot Wound Care. *Diabetes Care* 1999; 22:1354-1360.
3. Gibbons GW, Diabetic Foot Sepsis. *Seminars in Vasc Surg.* December 1992; 5 (4): 1-3.
4. Gibbons GW. The Diabetic Foot: Amputations and Drainage of Infection. *J. Vasc Surg.* 1987; 5:791-793; 800-802.
5. Gibbons GW, Habershaw GM, Marcaccio EJ. Management of the Diabetic Foot. In: Callow AD, Ernest C, eds. *Vascular Surgery: Theory and Practice*, Norwich, CT: Appleton and Lang. 1995; 167:167-179.
6. Gibbons GW. The Diabetic Foot. In: Becker KL, Khan RC, eds. *Principles and Practice of Endocrinology and Metabolism*. 2nd ed. Philadelphia: JB Lippincott Co. 1995; Chapter 148; 1313-1316.
7. Gibbons GW, Habershaw GM. The Septic Diabetic Foot “Foot Sparing Surgery”. In: Ernst CB ed. *Advances in Vascular Surgery*, Chicago, IL Mosby-Yearbook, Inc. 1996; 4:211-226.
8. Gupta S, Andersen C, Black J, et al. Management of chronic wounds: Diagnosis, preparation, treatment, and follow-up. *Wounds*. 2017; 29(9 Suppl):S19-S36.
9. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clinical Infectious Diseases*. 2012; 54:132-173.
10. Steed DL, et al, Effect of extensive debridement and treatment on the healing of diabetic foot ulcers. *J Amer Coll Surgeons* 1996; 183:61-64.
11. Sapp LJ, Falanga V. Debridement performances index and its correlation with complete closure of diabetic foot ulcers. *Wound Rep Reg* 2002; 10:354-359.

References Supporting Debridement

1. Armstrong DG, de Asia RJ. Management of diabetic foot ulcers. Eidt JF, Mills JL, Nathan DM, eds. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on October 11, 2019.)
2. Attinger CE, Bulan EJ. Debridement: The key initial first step in wound healing. *Foot Ankle Clin N Am* 2001; 6:627- 660.
3. Cardinal M, Eisenbud DE, Armstrong DG, et al. Serial surgical debridement: a retrospective study on clinical outcomes in chronic lower extremity wounds. *Wound Repair Regen*. 2009;17(3):306-311.
4. Dowsett C and Newton H. Wound bed preparation: TIME in practice. *Wounds UK*. 2005; 1(3):58-70.
5. Game FL, Apelqvist J, Attinger C, et al. for the International Working Group on the Diabetic Foot (IWGDF). IWGDF Guidance on use of interventions to enhance the healing of chronic ulcers of the foot in diabetes. International Working Group on the Diabetic Foot. 2015.
6. Gupta S, Andersen C, Black J, et al. Management of chronic wounds: Diagnosis, preparation, treatment, and follow-up. *Wounds*. 2017; 29(9 Suppl):S19-S36.
7. Halim AS, Khoo TL, Mat Saad AZ. Wound bed preparation from a clinical perspective. *Indian Journal of Plastic Surgery*. 2012; 45:193-202.
8. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *Journal of Vascular Surgery* 2016; 63(2S): 3S-21S.
9. Hunt N. Debridement of foot wounds in patients with diabetes mellitus. *Diabetic Foot Journal*. 2019. 22(3):18-23.

10. Johani K, Malone M, Jensen S, Gosbell I, Dickson H, Hu H, Vickery K; Microscopy visualisation confirms multispecies biofilms are ubiquitous in diabetic foot ulcers. *Int Wound J.* 2017 Dec;14(6):1160-1169. <https://onlinelibrary.wiley.com/doi/pdf/10.1111/iwj.12777> . Epub 2017 Jun 23.
11. Lavery LA, Davis KE, Berriman SJ, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. *Wound Rep Reg* 2016; 24:112-126.
12. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clinical Infectious Diseases.* 2012; 54:132-173.
13. Malone M and Swanson T. Biofilm-based wound care: the importance of debridement in biofilm treatment strategies. *Community Wound Care.* 2017; Jun 2;22(Sup6):S20-S25.
14. Marston W, Tang J, Kisner R, et al. Wound Healing Society 2015 update to guidelines for venous ulcers. *Wound Rep Reg* (2016) 24:136-144.
15. Milne J. Wound-bed preparation: the importance of rapid and effective desloughing to promote healing. *British Journal of Nursing,* 2015. 24: S52-S58.
16. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers: Quick Reference Guide.* Emily Haesler (Ed.). Cambridge Media: Osborne Park, Australia; 2014.
17. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers: Wound Care and Pain Management – an Extract from the Clinical Practice Guideline.* Emily Haesler (Ed.). Cambridge Media: Osborne Park, Australia; 2014.
18. National Coverage Determination 270.1: Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds. Downloaded from <https://www.cms.gov/medicare-coverage-database/details/nccdetails.aspx?NCDId=131&ncdver=3&DocID=270.1> on November 28, 2018.
19. Ndip A, Jude EB. Emerging evidence for neuroischemic diabetic foot ulcers: model of care and how to adapt practice. *Int J Low Ext Wounds* 2009: 82-94.
20. O'Donnell Jr TF, Passman MA, Marston WA, et al. Clinical practice guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF)—management of venous leg ulcers. Introduction. *J Vasc Surg* 60.2 suppl (2014): 1S-2S.
21. O'Donnell Jr TF, Passman MA, Marston WA, et al., op cit., at 6S. GRADE – 1 = “strong (we recommend). LEVEL OF EVIDENCE B = moderate quality evidence.
22. Püllen R, Popp R, Volkers P, Füsigen I. Prospective randomized double-blind study of the wound-debriding effects of collagenase and fibrinolysin/deoxyribonuclease in pressure ulcers. *Age and Aging.* 2002; 31:126-130.
23. PubMed search for randomized controlled trials using the search terms “wound debridement”, “venous ulcer, diabetic foot ulcer, pressure ulcer, or decubitus ulcer debridement” and separately for those items under “rate of closure.” The search period was January 1, 2000 through January 1, 2017.
24. Schultz G, Bjarnsholt T, James GA, et al. Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. *Wound Rep Reg.* 2017; 25:744-757.
25. Schultz G.S., Sibbald R.G., Falanga V., Ayello E.A., Dowsett C., Harding K., Romanelli M., Stacey M.C., Teot L., Vanscheidt W.; Wound bed preparation: a systematic approach to wound management. *Wound Repair Regen.* 2003 Mar;11: Suppl 1:S1-28.
26. Sibbald RG, Orsted H, Schultz GS, et al. for the International Wound Bed Preparation Advisory Board and the Canadian Chronic Wound Advisory Board. Preparing the wound bed 2003: Focus on infection and inflammation. *Ostomy/Wound Management* 2003; 49:24-51.

27. Snyder RJ, Applewhite AJ, Joseph WS, and Serena TE. A standardized approach to evaluating lower extremity chronic wounds using a checklist. *Wounds*. 2019; 31 (5 Suppl):S29-S45.
28. Steed DL, Donohoe D, Webster MW, Lindsley L. Diabetic Ulcer Study Group. Effect of extensive debridement and treatment on the healing of diabetic foot ulcers. *J Am Coll Surg*. 1996;183(1):61-64.
29. Steed DL, Attinger C, Colaizzi T, et al. Guidelines for the treatment of diabetic ulcers. *Wound Rep Reg*. 2006; 15:680-692.
30. Wilcox JR, Carter MJ, Covington S. Frequency of debridements and time to heal: a retrospective cohort study of 312 744 wounds. *JAMA Dermatology* 149.9 (2013): 1050-1058.
31. Wolcott RD, Rumbaugh KP, James G, et al. Biofilm maturity studies indicate sharp debridement opens a time-dependent therapeutic window. *Journal of Wound Care*. 2010; 19(8):320-328.
32. Wolcott RD, Kennedy JP, Dowd SE. Regular debridement is the main tool for maintaining a healthy wound bed in most chronic wounds. *Journal of Wound Care*. 2009; 18(2):S4-S6.
33. Wounds International. *International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers*. Wounds International. 2013.

Clinical Practice Guideline Reference links

[IDSA DFI Guidelines](#)

[IWGDF Wound Healing Intervention Guidelines](#)

[SVS, SVM and APMA Clinical Practice Guideline for Diabetic Foot Ulcer](#)

[Wound Healing Society Diabetic Foot Ulcer Guideline](#)

[Wounds International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers](#)

Other references supporting debridement that are attached to this comment letter including studies by: Doerler , Granck, Harries, Oreilly, Schultz, Tentolouri, Trostrup