July 16, 2014

**Via Electronic Mail Only**

AHRQ  
Scientific Resource Center, Oregon EPC  
Mail code: BICC  
3181 S.W. Sam Jackson Park Road  
Portland, Oregon 97239-3098

**Re: Draft Technology Assessment – Negative Pressure Wound Therapy Technologies (WNDT0913)**

Dear Scientific Resource Center Review Team:

AdvaMed appreciates the opportunity to offer comments in response to the draft Technology Assessment on Negative Pressure Wound Therapy (NPWT) Technologies. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

We are encouraged by AHRQ’s review of NPWT technologies and the focus the assessment places on this important component of patient care work in this area. We are pleased to provide comments, which were developed in conjunction with our member companies who manufacture NPWT technologies, and encourage AHRQ to continue to seek stakeholder input and feedback as similar documents are drafted in the future. Our comments focus primarily on issues raised in the draft Technology Assessment’s Introduction, Methodology, Discussion, and Conclusion sections and raise concerns about the exclusion of certain research criteria regarding the use of NPWT to treat chronic and acute wounds in the home setting.
AdvaMed has been engaged in efforts over the past several years to increase understanding and awareness as it relates to the development, types, treatment, and healing of chronic and acute wounds. In an effort to raise awareness we have commented on the various types of technologies, including NPWT, and the fact that frequently a variety of wound technologies are used adjunctively to treat a patient’s chronic or acute wound. With respect to research, a number of wound therapies do not lend themselves to randomized controlled trials because of the significance of the wounds in the varying patient populations. We have also been very diligent in explaining the stages of wound healing and in suggesting that complete wound closure, while ideal, is not the standard that should be applied in many cases. We were therefore pleased that the draft technology assessment includes a range of study comparators as well as a range of clinical wound outcomes.

Introduction Section

A. The Technology Assessment Incorrectly Suggests that the NPWT Mechanism of Promoting Wound Healing Is Not Evidence-Based.

The introduction states that, “The exact mechanism by which these devices may promote wound healing is not known.” AdvaMed is concerned that the inclusion of this statement, as written, may leave the non-scientific reader with the impression that there is limited understanding of the use of NPWT in treating wounds and that the therapy has not been investigated adequately. This, however, is not the case, as is demonstrated by the number of articles referenced throughout the technology assessment document. Since 1993, there have been over 900 Negative Pressure Wound Therapy-related peer-reviewed articles published, including 41 articles on randomized clinical trials (RCTs). Furthermore, there has been over 900 NPWT abstracts, 650 NPWT-related articles and over 70 NPWT book references published. Additionally, there are numerous articles specifically discussing the mechanism of action of NPWT.\(^1,2,3,4,5,6\) AdvaMed encourages AHRQ to clarify or to revisit inclusion of this paragraph.

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B. The Technology Assessment Fails to Consider the Use of NPWT in the Treatment of Surgical Wounds in the Home Setting

AdvaMed is concerned about the reference to the use of NPWT to treat acute surgical wounds in only acute care settings. NPWT is frequently used to treat surgical wounds, especially dehisced wounds, in the home.\(^7\) A large number of surgical wounds will become dehisced wounds and will take on chronic-wound characteristics in a home setting — resulting in the need to address their treatment through the use of NPWT. For this reason, AdvaMed believes that the authors should include references and evidence that speak to the use of NPWT in the treatment of dehisced surgical wounds in the home setting. This population of wound patients accounts for a very large percentage of those receiving NPWT in the home. Failure to include this subset of wounds does not enable a full evaluation of the usefulness or impact of these technologies in the home and misrepresents the burden of this type of wound being treated in the home setting and utilizing NPWT. Unless a separate review is planned to evaluate the impact of NPWT on dehisced surgical wounds, AdvaMed recommends including treatment for these types of wounds in the technology assessment.

Methods Section

A. The Technology Assessment Methodology Applies Inclusion/Exclusion Criteria that are Overly Restrictive and Inconsistent with Effective Wound Care Practices

The methods section of the Technology Assessment sets out the specific inclusion and exclusion criteria for the selection of studies that were reviewed. Regarding wound healing outcomes, studies were only included if they dealt with one of the following parameters:

- Complete Wound Healing;
- Time to Complete Wound Healing;
- Time to Surgical Readiness of the Wound Bed;
- Mortality; or
- Wound Healing Rate for Healed Wounds

By excluding studies that do not specifically address the endpoint of complete wound healing, the authors of the Draft Assessment are missing a substantial volume of evidence regarding the usefulness of NPWT’s role as an adjuvant therapy in wound care at various stages during the lifecycle of a wound.

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Using the incidence of complete wound healing or the time to complete wound healing as the main outcome measure of a study is not always a feasible or desirable goal due to patient characteristics, comorbidity and the type of ulcer. In addition, some technologies for the treatment of chronic wounds are not always appropriately evaluated by measuring wound closure, since wound closure may not be their intended goal. Examples of alternate endpoints include control of exudate, reduction of odor, stimulation of tissue growth to decrease wound volume and/or surface area, alleviation of pain and protection of the periwound skin.

Importantly, when combination or sequential interventions are necessary to achieve wound closure, relevant intermediate endpoints short of healing can be appropriate measures for product efficacy and effectiveness. It is well accepted that wound healing is a multi-phase process, thus endpoints other than wound closure are valid in research design. AdvaMed believes that the authors of the Draft Technology Assessment should reevaluate their data and analysis after they have included studies that are not limited solely to those that consider complete wound healing.

In addition, the following types of studies were excluded from analysis in the Draft Assessment:

- Studies of Patients with Surgical or Traumatic Wounds;
- Studies that did not have a Comparison Group;
- Studies that Reported Wound Healing Rates Without Also Reporting Complete Wound Healing;
- Studies Without Original Data (e.g., reviews, editorials and commentaries); and
- Studies Conducted in the Hospital, Inpatient or Long-Term Care Setting

The comments above regarding studies concerning surgical wounds and those related to complete wound healing apply here as well. In addition, it appears that many studies that contained significant data regarding NPWT treatment in the home setting were excluded.

Wounds are often treated in a number of different settings (hospital, nursing facility, home health service, outpatient clinic, doctor’s office, etc.) during the course of healing. In fact, the initiation of wound therapy often begins in the inpatient setting with care continuing in the patient’s home following discharge. The likelihood of having a wound that is solely treated in the home setting, from inception to final healing without occasional consultations by professionals in other settings, such as outpatient/ambulatory or others is highly unlikely.

Appendix C of the Draft Technology Assessment lists over 150 excluded studies; many based on not being conducted in home or outpatient settings. Several of these studies were conducted predominately (approximately 90%) in the home setting. For example,

in the randomized study in 342 diabetic foot ulcer patients by Blume, et al which was conducted across 37 centers, the proportion of home care therapy days to total therapy days was 9,471 of 10,579 (89.5%) for NPWT and 12,210 of 12,810 (95.3%) for AMWT (the controls). In a population consisting of diabetic foot ulcers or patients receiving amputations for foot ulcers, it is inconceivable that some inpatient care would not be experienced, given the need for urgency for responses to those patients who did experience issues with suspected infection, in either control or treatment arms. To exclude patients from access to acute care if necessary would, of course, be unethical. It seems perverse to exclude such studies as not being “sufficiently” homecare based. **AdvaMed believes that the authors of the Draft Technology Assessment should modify their exclusion criteria to include NPWT studies that were not conducted solely in the home care setting and provide a reassessment of the evidence, after these studies are included.**

**Discussion Section**

The discussion section of the draft technology assessment refers to the “paucity” of well-designed and well-conducted studies of NPWT technologies. As noted in our comments to the methodology, AdvaMed is concerned that the authors may have excluded from consideration a number of studies that examined randomized comparative studies related to the use of NPWT in the home setting. It is typical for patients with certain conditions treated with NPWT in the home setting (i.e. diabetic foot ulcers) to also receive some inpatient care for their condition especially since preventing them from having access to acute care when needed would be unethical. Therefore, AdvaMed questions the author’s definition of “sufficiently” homecare based and their subsequent decision to exclude many studies on those grounds. AdvaMed urges the authors to re-evaluate and to consider inclusion of those studies as they work towards finalization of the draft document.

**Conclusion Section**

The authors conclude that there is a need to develop consensus on study methods and that efforts should be made to standardize the conduct and reporting of NPWT studies. **AdvaMed is concerned that this finding does not take into account the complex nature of chronic and acute wounds and the resulting need to employ a range of methodologies to treat the patients who have them — including patients who participate in studies.** The lack of similarities in terms of patient symptoms, co-morbidities, and stages of healing require that all wound patients receiving NPWT and other technologies be treated in a manner specific to their condition and their care needs in order to promote the best care outcomes. These same factors also impact the rate of healing. Therefore, it is important to consider varying endpoints when evaluating

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these patients and the efficacy of various technologies, in this instance NPWT, in healing their wounds.

Wound care also poses significant challenges to the selection of comparator groups, in that most wounds require a number of different therapies or therapeutic approaches to take a wound from an early phase of healing to complete closure. If, in good clinical practice, treatment modifications are made to ensure healing, the active control arm of a study should allow for such modifications to ensure acceptable standard of care. In addition to the selection of the primary wound therapy within the control arm, other factors (i.e. offloading of pressure-related wounds, debridement and treatment of wound-related complications) should be discussed clearly in the protocol, with an approach for handling of the subject and subject’s data. Data should be collected to understand the impact of these factors on overall outcome.

AdvaMed appreciates your consideration of our comments. Please contact me at 202-434-7207 or sbrotman@advamed.org if you have questions or concerns about our comments. Thank you and we look forward to your feedback.

Sincerely,

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