

# Development of a Content-Validated Venous Ulcer Guideline

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*Evidence-based practice for venous ulcers may improve healing and reduce costs of care. The Association for the Advancement of Wound Care Government and Regulatory Task Force developed a content-validated venous ulcer guideline based on best available evidence supporting each aspect of venous ulcer care. After compiling all-inclusive lists of elements in venous ulcer algorithms published before August 2002, the Task Force objectively rated and summarized up to five best references from MEDLINE, CINAHL, and EMBASE literature searches covering each aspect of care. Sixteen multidisciplinary wound care professionals and educators used judgment quantification to content validate all steps. A 2004 email survey of AAWC members (N = 1,514) clarified effects of under-reimbursement on evidence-based venous practice. The Venous Ulcer Guideline containing all elements with A-level evidence plus those with a Content Validity Index >0.75 now resides on the AAWC and the Agency for Healthcare Research and Quality National Guideline Clearinghouse websites. However, a review of US healthcare environment components, including reimbursement policies, and the results of the survey identified many barriers to implementation of A-level evidence supported steps (sustained graduated high compression, autolytic debridement, and moist wound environments) in practice. Sufficient evidence supports improved venous ulcer care in the US but inadequate and/or inconsistent reimbursement policies impede quality evidence-based venous ulcer practice, delaying healing and increasing the burden of venous ulcers on society.*

**KEYWORDS:** venous ulcer, guideline, evidence, development, reimbursement

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Venous ulcers (VU) profoundly decrease a person's quality of life.<sup>1,2</sup> They affect up to 1% of the population over 60 years of age at any given time<sup>3,4</sup> and cost an estimated \$2.5 to \$3.5 billion US healthcare dollars annually.<sup>5</sup> A MEDLINE literature search revealed that VU patients currently experience an evidence-reimbursement gap for compression modalities and patient education essential for effective, cost-effective VU healing outcomes.<sup>6</sup> To lay the foundation for closing this gap, the Association for the Advancement of Wound Care (AAWC) Government and Regulatory Task Force (henceforth abbreviated "the Task Force") resolved to develop a content-validated VU guideline based on objective summaries of best available evidence supporting each step of VU care.

## Methods

The multidisciplinary, all-volunteer Task Force including 11 Advanced Practice Nurses or Wound Ostomy Continence Nurses (WOCNs), five physicians, four physical therapists, two PhDs, one Doctor of Podiatric Medicine, and a Registered Pharmacist first met on April 29, 2002, at the Symposium for Advanced Wound Care in Baltimore, Md. The Task Force adopted the mission of helping US government and regulatory authorities close gaps between wound care evidence and practice. The Task Force used Total Quality Leadership<sup>7</sup> tools including brainstorming and fishbone diagrams to identify regulatory and reimbursement issues preventing professionals from practicing quality evidence-based VU care. They developed and prioritized strategies for resolving these issues to help close the gap between VU evidence-based care and actual practice.

The Task Force identified eight issues impeding evidence-based, cost-effective VU practice (see Table 1) and resolved to outline the best available evidence supporting each step in VU care. Steps were listed from published algorithms and best evidence supporting each step of care was included to create an evidence-based decision tool for care providers and reimbursement authorities. In addition to including outcome evidence for each step, the Task Force additionally intended to include the reimbursement status of the step to help authorities define and reduce gaps between evidence-based practice and reimbursement policies. However, reimbursement policies are so varied across settings, professions, states, and

regions that reimbursement listings proved impractical. In the end, the Task Force focused on generating an inclusive algorithm annotated with the best available research, hoping to set the stage for reimbursing high quality, evidence-based, cost-effective wound care practice in patients with venous disease.

**Algorithm development.** The steps to algorithm development are summarized in Table 2. The Task Force created a composite of all steps in all algorithms for venous ulcer management based on guidelines, consensus statements, critical pathways, and standards published before August 2002<sup>3,8-21</sup>; this was called the Venous Ulcer Care Initiative (VUCI) algorithm. Next, individual members with experience in each aspect of care searched the literature using MEDLINE, CINAHL, and EMBASE databases to identify and list up to five of the best evidence level references supporting that aspect. Quality of evidence was assessed according to the criteria in Table 3, adapted from prior AHRQ guidelines for pressure ulcer care.<sup>22,23</sup> The resulting guideline was neither a consensus-based document nor a comprehensive or systematic review of all literature supporting each aspect of care. Rather, it was a compendium of objectively rated best currently available evidence that the Task Force could find supporting VU care identified in the combined VU algorithms compiled from the literature. It was intended for use as a continuously improving framework within which to evaluate reimbursement status in light of the evidence supporting each element of VU care and to identify research and reimbursement gaps supporting VU clinical practice.

**Content validity testing.** Establishing validity is crucial for any instrument that affects patient care decisions.<sup>18</sup> The VUCI consisted of 76 aspects of VU care divided into six

### KEY POINTS

- While many guidelines have been developed, the validity and reliability of most remains unknown.
- The authors describe the process of developing the new AAWC venous ulcer (VU) guideline, testing the content validity of each step included in the guideline, and evaluating US healthcare system factors that may present a barrier to providing evidence-based VU care.
- To help healthcare professionals improve the quality of care they provide, the content and prospective validity of practice guidelines must be tested and both regulatory and reimbursement strategies aligned.

**TABLE 1**  
**US HEALTHCARE ENVIRONMENT COMPONENTS DISCOURAGING**  
**EVIDENCE-BASED WOUND CARE PRACTICES**

**Current components that affect practice**

Inconsistent or inaccurate Medicare-required documentation in Minimum Data Set Assessment (MDS) for a skilled nursing facility (SNF) or Outcome and Assessment Information Set (OASIS) assessment for Home Health Care (HHC):

Inaccurate documentation of:

- venous, arterial, pressure, or diabetic ulcer presence or severity
- eschar-covered wounds
- multiple ulcers per patient

Inadequate outpatient Ambulatory Payment Classification (APC) reimbursement for:

- evidence-based, moisture-retentive wound dressings
- innovative wound care
- high-elastic compression bandages and stockings for VU

Wound care education is inconsistent, varying from providers of wound care to payor to consumer. It is rarely supported with *bona fide* evidence of clinical efficacy on wounds

Inconsistent interpretation of federal regulations by state reimbursement authorities causes payment variations for physicians, physical therapists, and advanced practice nurses across settings and geographic regions

There is widespread lack of understanding of what constitutes quality care of complex wounds that become more likely as the population ages. This results in inconsistent or inadequate reimbursement of good quality care for complex wounds

Most private insurers do not reimburse dressing supplies other than gauze. Wound care dressings with evidence of efficacy or safety superior to that of gauze are not adequately reimbursed

Wound care supplies in OASIS and MDS are not appropriately allocated to corresponding Resource Utilization Groups (RUGs) or Home Health Resource Groups (HHRGs) where most wounds are currently classified

**Examples of potential effects on outcomes**

These documents inaccurately determine clinical and overall resource needs of patients with chronic ulcers.

- This may result in insufficient accounting of care costs and in non-reimbursement of necessary orthotics for patients with neuropathic foot ulcers or compression of VU
- It becomes impossible to track ulcer care across settings

More frequently changed, less effective dressings are more favorably reimbursed.

- For VU patients, reimbursement calculations are based on outdated products that fail to provide sustained, graduated high compression required for optimal healing
- This impedes quality care and rewards substandard care, delaying healing outcomes and increasing care costs

This results in confusion about product use, efficacy, and cost effectiveness. Best evidence-based standards of care and products worthy of reimbursement are poorly understood, used or reimbursed, reducing quality of wound care and outcomes

Evidence-based practices (including high, graduated, sustained VU compression) are reimbursed in one setting or state and denied reimbursement in different settings or states, depriving residents in certain states or settings of optimal care

- Long-term care (LTC) and HHC providers cannot meet care needs for complex wounds under reduced Prospective Payment System (PPS) reimbursement regulations
- Providers are forced to give suboptimal care or use inadequately reimbursed modalities, support surfaces, and supplies, incurring financial risk
- Wounds deteriorate during waiting or documentation periods required before more advanced therapy is reimbursed, adding to expense and delay of healing
- Well-insured or wealthy patients pay out-of-pocket for dressings that improve outcomes
- Many patients settle for reimbursed substandard care with gauze and associated increased pain, infection rates, and healing time

Resulting confusion about appropriate wound care supplies can delay or impede quality evidence-based wound care in HHC or LTC, delaying healing and increasing costs of care

**Continued on next page.**

**Table 1 Continued**

Reimbursement coverage is out of synchrony with government-approved standards of care

Current reimbursement waits for ulceration to trigger action. This spends money on end-of-disease process care instead of a proactive disease management strategy that saves money by preventing skin deterioration

Custom wheelchairs with pressure-reduction seating and tilt features are only reimbursed if a patient is out of bed at least 12 hours/day. However, the standard of care for out-of-bed time for someone with an ulcer on the sacrum or ischium is 1 to 2 hours twice per day with a pressure-reduction surface. Therefore, current reimbursement is in direct conflict with appropriate medical practice for a patient with skin ulceration

Patients lose quality of life and are placed at risk by reimbursement for:

- amputation of a diabetic foot, with no reimbursement for preventive measures
- repeated hospital admissions for cellulitis, with no reimbursement for appropriate compression therapy to manage lymphedema and venous disease in non-hospital settings
- Support surfaces or ulcers. Reimbursement is discontinued after healing despite continued need for pressure relief to prevent ulcer recurrence in high-risk patients – eg, patients with multiple sclerosis or spinal cord injury

LTC or HHC providers are not reimbursed for management of Stage I pressure ulcers to reduce pressure ulcer incidence and costs of care

areas, including diagnosis, alleviating the cause of ulceration, providing local care, care modalities if conservative treatment fails to improve outcomes, surgical options to use if conservative treatment fails, and continuing care until healing or to prevent recurrence. Many of these aspects of care had not undergone content validity testing in prior literature.

To establish content validity of each item of the VUCI Algorithm, the judgment quantification process was used<sup>18,24</sup> by a multidisciplinary convenience sample of volunteer wound care professional respondents from among the 2004 AAWC Board of Directors and the Research, Quality of Care, and Government & Regulatory Task Forces. The Content Validity Index (CVI) was calculated as the percent of respondents rating the clinical relevance or validity of each item as 3 or 4 using a 4-point Likert scale where 1 = not relevant, 2 = unable to assess relevance without further information, 3 = relevant but needs minor attention, and 4 = very relevant and succinct.

**Reimbursement survey.** After completing and validating the algorithm, the Task Force conducted a reimbursement survey distributed by email to 1,514 AAWC members via email in June 2004 to see if the original issues had changed or reimbursement had improved. The eight returned surveys and associated comments were analyzed.

**Data analysis and statistical methods.** Content validity data from respondents were entered into an

EXCEL® (Microsoft, Seattle, Wash) database and analyzed using the program's automatic functions for descriptive statistics. Mean content validity score and the proportion of respondents rating each item a 3 or 4 (CVI) were calculated for each of the aspects of care. A VUCI item remained in the final algorithm, now a content-validated guideline, if it was supported by A-level evidence, if it had a CVI of 0.75 or more, or if it met both criteria. Reimbursement survey responses were analyzed quantitatively (EXCEL database and descriptive statistics) and qualitatively by grouping written responses into thematic categories.

## Results

**Content validation.** Sixteen wound care professionals participated voluntarily in the content validation exercise including one physician, seven WOCNs (three of which were doctorally prepared), three advanced practice nurses, four physical therapists, and one PhD. Several participants engaged in both wound care practice and education or practiced in multiple settings. Respondents had an average of 3.2 (SD = 1.0) years of wound care practice. Of the wounds they treated, 32% were venous ulcers, 31% were pressure ulcers, and 11% were diabetic foot ulcers. Three participants spent an average of 43% of their time in acute care inpatient management. One practiced full time in an acute care outpatient facility. Three spent an average of

## TABLE 2 ALGORITHM DEVELOPMENT PROCESS STEPS

- Step 1: Summarize steps.** Task Force members reviewed published VU algorithms, compiling all steps from each algorithm into the master Venous Ulcer Care Initiative (VUCI) algorithm. Monthly teleconferences maintained communications.
- Step 2: Algorithm review.** Members reviewed final VUCI algorithm to ensure no aspect of care was omitted.
- Step 3: Literature review.** Volunteers conducted MEDLINE, CINAHL, EMBASE searches for every VUCI step and faxed or sent a copy of its best five evidence references to one “shepherd” who kept a hard copy of all references and sent them to volunteer reference reviewers.
- Step 4: Evidence table.** Reference reviewers summarized up to five best references, study design, methods, and results for each step and sent these summaries to the “shepherd,” who compiled them into the master VUCI Evidence Table.
- Step 5: Task Force review.** Task Force members determined whether any algorithms, steps, or references were missed.
- Step 6: AAWC Board of Directors and other task forces review.** Algorithm and evidence tables were reviewed for accuracy and completeness.
- Step 7: Content validation.** A standardized content validation questionnaire was prepared to assess clinical relevance of each step in the algorithm, reviewed by the AAWC Board, and sent to all AAWC members. Responses were entered into an EXCEL© (Microsoft, Seattle, Wash) database and analyzed for content validity.
- Step 8: AAWC Government and Regulatory Task Force final review.** Content validation results were reviewed, deleting steps without Level A evidence that were not content validated by 75% of reviewers as 3 or 4 on the clinical relevance scale. Content then was approved as the final content-validated AAWC Venous Ulcer Guideline.
- Step 9: Dissemination.** The algorithm was disseminated according to the communication plan approved by AAWC Board of Directors, including submission to the AHRQ’s National Guideline Clearinghouse website, placement on the AAWC website, publication, and communications to CMS or other agencies as appropriate to fulfill the goal of improving reimbursement for VU care with A-level evidence of efficacy.

support of A-level controlled clinical studies. Controlled studies are also needed to support venous ulcer cleansing and debridement, filling dead space, and use of silver dressings.

The resulting AAWC VU Guideline containing items with A-level best evidence plus those with a CVI of 0.75 or more was accepted by the Agency for Healthcare Research and Quality National Guideline Clearinghouse and can be viewed or downloaded free of charge at [www.guideline.gov](http://www.guideline.gov) or at the AAWC website [www.aawc.org](http://www.aawc.org).

All 16 respondents believed that a team approach is required for optimal VU management. Most commonly team member suggestions were from a physician, nurse or specialty nurse, physical therapist, and vascular specialist. All believed that evidence-based VU practice would speed healing. Of the respondents, 81% believed evidence-based VU care would reduce the costs of VU care in their environment, 56% felt that it may increase costs now but decrease them in the long run, and 19% believed that it would increase care costs indefinitely. Of the 16 respondents, 10 believed the most important

40% of their time in an extended care setting and three practiced solely in a skilled nursing facility. Five spent an average of 31% of their time in home care. One spent 20% of the time in acute care. Two spent an average of 60% of their time in a separate wound clinic. The physician practiced in acute care and office settings. Two respondents were in government or educational institutions. The items compiled from existing algorithms, level of best available evidence for each item, and corresponding CVI values + standard deviation from the content validation study are presented in Table 4. Items with a CVI  $\geq 0.75$  supported by B- or C-level research present opportunities for further study. For example, items for exercise and elevation of the lower leg above the heart, moisturizing, and protecting or managing periwound inflammation or infection had opinion-based content validity indices  $>0.75$  without the

advantages of an evidence-based approach to VU care would be a systematic and organized approach to treatment, guidelines for novice wound care clinicians, and better outcomes for patients with more satisfied patients, payors, and wound care clinicians. Most respondents listed inadequate reimbursement and difficulty evaluating or finding evidence as disadvantages of evidence-based VU care.

As an independent check on the content validation VU practice data, Caroline Fife, MD, provided an analysis of the US-based Intellicure Clinical Documentation and Facility Management Software (ICDFMS) database<sup>25</sup> containing 622 VU patients with 1,377 VU for a perspective of VU practice in the US. Approximately one third of identifiable VUs in this database did not receive compression of any sort. The

**TABLE 3  
EVIDENCE CRITERIA FOR SUPPORT OF  
EACH STEP IN THE ALGORITHM**

Evidence Level	Standardized Criteria
Level A	Results of two or more randomized controlled trials (RCTs) in humans provide support (or for diagnostics or risk analysis: cohort [CO] studies)
Level B	Results of two or more historically controlled trials (HCTs) or convenience or non-randomized controlled trials (CCTs) or a CCT and a RCT in humans provide support or when appropriate, results of two or more controlled trials in an animal model provide indirect support
Level C	This rating requires one or more of the following: <ol style="list-style-type: none"> <li>1. Results of one controlled trial – eg, RCT, CCT, or HCT</li> <li>2. Results of at least two case series (CS) or descriptive studies or a cohort study in humans</li> <li>3. Expert opinion (EO)</li> </ol>

*Adapted from AHRQ (formerly AHCPR) Pressure Ulcer Treatment Guidelines*

most common form of compression used was a four-layer bandage (21%), followed by double-layer elastic tubular bandage (18%), compression stockings (9%), or short-stretch compression (4%).

**Reimbursement survey.** The 2005 Reimbursement Survey was returned by eight clinicians: two physicians, three physical therapists, one advanced practice nurse/CWOCN, one RN, and one anonymous respondent, together experiencing a total of 10,000 patient visits per year for wound care. Aspects of practice supported by A-level best evidence with inadequate reimbursement or reimbursement that had been refused based on respondent experience included patient education and elastic compression bandages as well as stockings needed both to heal venous ulcers and to prevent their recurrence.

Venous ulcer patients remained in their professional care for an average of 14 (8 to 30) weeks and were seen once or twice per week. Compression was performed on 94% of

visits, requiring an average of 16 minutes per visit. Venous ulcer evaluation (eg, measuring wound dimensions or percent or area of necrotic tissue) was performed during 67% of visits, taking an average of 13 (2 to 45) minutes per initial visit and 6 (2 to 15) minutes on later visits. Management (eg, cleansing or topical care) was performed during 92% of visits with initial visits taking an average of 11 (4 to 20) minutes and later visits taking 9 (4 to 15) minutes. Debridement was performed during 46% of visits, taking an average of 12 (4 to 20) minutes per initial visit or 7 (0 to 20) minutes on later visits. Compression, performed on an average of 94% of visits, took an average of 16 (7 to 30) minutes on the first visit and 20 (5 to 60) minutes on later visits. Percent of procedural or supply costs billed separately varied between 0% and 100% for all aspects of care, as did percents of billing normally paid. Procedural payment by different payors was reported to differ. Respondents emphasized that VU patients are never cured and that once healed, a VU patient requires graduated compression of the lower leg adequate to aid venous return for the rest of his or her life.

Survey respondents and Task Force members reported that their facilities were cited and forced to pay fines for using evidence-based sustained, graduated, high elastic compression modalities to manage VU patients because they coded these procedures with the only existing Common Procedural Terminology (CPT) code for compression, CPT 29580. Reimbursement varied widely among payors and was usually insufficient for and/or inconsistent with evidence-based VU care. Supplies were generally not reimbursed, placing the economic burden of VU care on the provider and/or patient. Four of the five respondents who provided comments said they may have to close their facility due to lost revenue while providing high quality evidence-based VU care. One of these four has now closed its leg ulcer clinic.

Scenarios (see Appendix I) were written by qualified wound care professionals in relevant settings of care to illustrate the reimbursement inadequacy of items in the algorithm typically used for VU care. These example scenarios illustrate the impact of current reimbursement methodologies on real-world care. They may or may not match the reader's experience due to expense and reimbursement variability according to setting and location of service, professional specialist

**TABLE 4**  
**VUCI CONTENT VALIDATION QUESTIONNAIRE AND RESULTS**

**I. Venous Ulcer Diagnosis**

**Questions regarding aspects of care**

Question: If the goal of the VUCI is to facilitate obtaining an evidence-based venous ulcer patient assessment and history, how relevant is it to ask about a history of or record/obtain:	Level of Best Available Evidence	Content Validity Index (Mean +/- Standard Deviation of Ratings)
1. Phlebitis present	C	0.94 (3.6±0.5)
2. Lower leg swelling or edema	A	1.00 (3.8±0.0)
3. Experiencing aching or tiredness in the affected leg	C	0.63 (2.8±1.1)
4. Injury to or surgery of affected leg vasculature	C	1.00 (3.8±0.2)
5. Lower leg ulcer or venous ulcer history in patient's mother	C	0.63 (2.3±1.1)
6. Engaging in vigorous exercise	C	0.69 (2.5±1.0)
7. Hypercoagulation	B	1.00 (3.5±0.48)
8. Multiple pregnancies (female patients only)	C	1.00 (3.1±0.58)
9. Measure Doppler Ankle/Brachial Index	A	0.88 (3.7±0.86)
10. Conduct plethysmography testing	A	1.00 (3.5±0.48)
10.1 Conduct duplex scanning ultrasound testing	B	1.00 (3.4±0.34)
11. Conduct ambulatory venous flow or refill time testing	B	0.88 (3.2±0.72)
12. Measure transcutaneous oxygen pressure (TcPO <sub>2</sub> )	A	1.00 (3.4±0.51)
13. Check for elevated temperature in the lower leg	C	0.69 (2.8±1.02)
13.1 Test blood for Factor VIII-related antigen	C	0.50 (2.3±1.08)
<b>Question: If the goal of the VUCI is to facilitate an evidence-based physical exam of a venous ulcer patient, how relevant is it to:</b>		
14. Measure all CEAP <sup>a</sup> variables below in items 14.1 to 14.4	A	1.00 (3.6±0.32)
14.1. Clinical: C0 = no visible venous disease; C1= telangiectatic or reticular veins; C2 = varicose veins; C3 = edema; C4 = skin changes with no ulceration; C5 = skin changes with healed ulceration; C6 = skin changes with active ulceration	A	1.00 (3.8±0.00)
14.2. Etiology: c = congenital; p = primary disease; s = secondary venous disease, usually due to prior deep venous thrombosis	A	1.00 (3.8±0.26)
14.3. Anatomy: As = superficial; Ad = deep; Ap = perforating veins	A	1.00 (3.7±0.35)
14.4.1. Pathophysiology: Add "r" for reflux and/or "o" for obstruction	A	0.93 (3.6±0.56)
14.4.2. Pathophysiology: 0 = asymptomatic	A	0.73 (3.2±1.06)
15. Check for lower leg edema	A	1.00 (3.8±0.37)
16. Evaluate lower leg skin for stasis dermatitis	C	0.94 (3.6±0.77)
17. Evaluate lower leg skin for hemosiderin discoloration	C	0.94 (3.7±0.50)
18. Evaluate lower leg skin for lipodermatosclerosis?	C	0.88 (3.5±0.87)
19. Note that the ulcer is located on the medial lower leg	A	0.81 (3.2±1.08)
20. Note presence of varicosities on the affected leg	C	0.81 (3.2±1.09)
21. Measure ulcer dimensions	A	1.00 (3.8±0.00)
<b>Question: If the goal of the VUCI is to facilitate evidence-based, venous ulcer care practices to remove the cause of the venous ulcer, how relevant is it to:</b>		
22. Include patient education in the protocol of care	A	1.00 (3.8±0.00)
23. Include in the protocol of care regular, consistent elevation of the affected lower limb above the heart	C	0.94 (3.6±0.77)
24. Include regular exercise of the lower limb, such as ankle flexes or walking if feasible	C	1.00 (3.7±0.34)
25. Include at least one of the options below for compression of the lower limb in the protocol of care to aid venous ulcer healing? Please rate clinical relevance of all options below relative to the option of not using any compression		
a. Multilayer, high compression elastic bandages	A	1.00 (3.8±0.34)
b. Single-layer, high elastic compression bandages	A	0.80 (3.2±1.12)
c. Elastic, one-layer, high compression stockings	A	0.93 (3.5±0.82)

**Table 4 Continued**

d. Elastic, multilayer, high compression stockings	A	0.93 (3.5±0.82)
e. Unna Boot and elastic high compression (Duke Boot)	A	1.00 (3.6±0.46)
f. Short stretch	A	1.00 (3.6±0.41)
g. Unna boot zinc paste impregnated bandage	A	0.87 (3.2±1.06)
h. Non-elastic compression	C	0.73 (2.6±1.16)
i. Intermittent pneumatic compression	B	0.80 (2.9±1.13)
j. Sequential-gradient pneumatic compression	B	0.81 (3.1±1.05)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based venous ulcer care practices to remove the cause of the venous ulcer, how relevant is it to:		
26. Include moisturizing the skin of the affected area in the protocol of care?	C	0.88 (3.4±0.89)
27. Protect the peri-ulcer skin as part of the protocol of care?	C	0.94 (3.6±0.58)
28. Manage peri-ulcer inflammation/circulation as part of protocol of care?	C	0.88 (3.5±0.89)
29. Manage periwound skin infection as part of the protocol of care?	C	0.94 (3.6±0.59)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based local venous ulcer care practices, how relevant is it to:		
30. Cleanse a venous ulcer		
a. with a safe wound cleanser	C	0.88 (3.5±0.72)
b. at an irrigation pressure of 8 to 15 ps	C	0.80 (3.1±0.96)
31. Debride necrotic tissue using sharp debridement	C	0.81 (3.1±1.05)
32. Debride necrotic tissue using enzymatic debridement	B	0.88 (3.2±0.72)
33. Debride necrotic tissue using autolytic debridement	A	0.94 (3.5±0.60)
34. Debride necrotic tissue with mechanical debridement (wet-to-dry gauze)	C	0.19 (1.7±1.17)
35. Fill deep venous ulcers to reduce dead space	C	0.75 (3.1±1.13)
36. Manage excess exudate	A	1.00 (3.8±0.00)
37. Apply dressings that maintain a moist wound environment	A	1.00 (0.34)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based local venous ulcer care practices and the ulcer did not heal in 30 days using principles described in items 29 to 36, how relevant is it to apply:		
38. Topical antimicrobial wound care		
a. Iodine-containing dressings	A	0.88 (3.5±0.89)
b. Silver-containing dressings	C	0.94 (3.4±0.81)
39. Biologic dressings		
a. Containing collagen or its combinations	C	0.67 (2.9±1.25)
b. Containing hyaluronic acid or its combinations	C	0.67 (3.0±1.06)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based local venous ulcer care practices and the ulcer did not heal in 30 days using principles described in items 29 to 36, how relevant is it to use the surgical coverings below?		
40. Split-thickness or cultured autografts (epidermal and dermal)?	B	0.88 (3.9±2.78)
41. Pinch grafts	B	0.75 (3.2±1.14)
42. Cultured epidermal autografts (eg, culture cells from epidermal biopsy)	C	0.63 (2.8±1.12)
43. Allografts (eg, swine skin)	C	0.63 (2.7±1.20)
44. Bioengineered skin (eg, Apligraf [Organogenesis, Canton, Mass])	B	0.88 (3.4±0.89)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based venous ulcer care practices and no progress has been seen during 30 days of the best available evidence-based care, how relevant is it to use the following biophysical modalities?:		
45. Electrical stimulation	A	0.81 (3.5±0.81)
46. Vacuum (negative pressure wound therapy)	B	0.75 (3.1±1.00)
47. Warming therapy	C	0.44 (2.3±1.26)
48. Electromagnetic or radiofrequency stimulation	A	0.63 (2.8±1.12)
49. Laser stimulation	C	0.19 (2.0±1.06)

**Table 4 Continued**

50.	Infrared stimulation (eg, monochromatic light)	C	0.56 (2.6±1.06)
51.	Hyperbaric oxygen	C	0.38 (2.3±1.21)
52.	Ultrasound stimulation	A	0.47 (2.5±1.30)
53.	Whirlpool	C	0.44 (2.2±1.35)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based venous ulcer care practices and no progress has been seen during 30 days of the best available evidence-based care, how relevant is it to use the following pharmaceutical modalities?:			
54.	Topical growth factors (eg, becaplermin)	C	0.56 (2.7±1.22)
55.	Hemorrhheologic agents (eg, pentoxifylline or stanozolol)	C	0.69 (2.9±1.00)
56.	Acetyl salicylic acid (aspirin)	C	0.56 (2.6±1.06)
57.	Obliteration or closure of veins using laser surgery	C	0.44 (2.3±1.20)
58.	Obliteration or closure of veins using sclerotherapy	C	0.56 (2.7±1.22)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based venous ulcer care practices and conservative treatment fails, how relevant is it to use the following surgical options?:			
59.	Subfascial endoscopic perforating vein surgery with ligation and stripping (SEPS)	C	0.50 (2.6±1.13)
60.	Venous valve repair		
	a. Valve reconstruction	B	0.69 (2.9±1.12)
	b. Transplant or graft valve	C	0.42 (2.3±1.09)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based venous ulcer care practices, how relevant is it to recommend the protocols in Sections 1 to 5 :			
61.	Until the venous ulcer is healed?	A	0.94 (3.7±0.50)
<b>Question:</b> If the goal of the VUCI is to facilitate evidence-based venous ulcer care practices, how relevant is it to recommend the following regimens after healing to reduce edema and prevent the 70% to 90% venous ulcer recurrence?:			
62.	Elastic high compression	A	1.00 (3.8±0.00)
63.	Elevation of the affected limb	A	1.00 (3.8±0.00)
64.	Walking or exercise such as ankle flexes	A	1.00 (3.8±0.00)

*This table was preceded by sections describing goals and methods of derivation of the VUCI algorithm and participants' role. Instructions in completing the Questionnaire and evidence level (A= highest – eg, randomized controlled trials, C = lowest – eg, opinion-based) followed each item and rating values described below were repeated at the top of each page. The algorithm and evidence table with detailed descriptions of evidence ratings were appended for participant information. Items were deleted from the final VU Guideline unless supported by A-level evidence. <sup>a</sup>Eklof B, Rutherford RB, Bergan JJ, et al. Revision of the CEAP classification for chronic ulcer disorders: consensus statement. *J Vasc Surg.* 2004;40(6):1248–1252.*

delivering the care, type of relative value unit (RVU), complexity of service (Evaluation and Management codes), code modifiers such as unintended additional assessment or care, and procedural codes and diagnoses attached to such codes.

## Discussion

This research established a content-validated VU algorithm supported by best available evidence that met US Department of Health and Human Services AHRQ criteria for acceptance as a venous ulcer guideline. Other content-validated algorithms have been published for general wound care<sup>21,26</sup> and for

nursing education to prevent pressure ulcers.<sup>27</sup> To the authors' knowledge, this is the first formally content-validated VU guideline in the literature. This guideline will be updated every 2 years to incorporate new evidence, offering a benchmark for professional VU care and reimbursement.

The reimbursement survey findings and low incidence of compression use on VU patients in the independent analysis of the ICDFMS database reflect a disturbing trend in US healthcare. By limiting reimbursement of care based on the best available evidence, reimbursement authorities may be unintentionally limiting economic access to quality wound care.<sup>28</sup> The AAWC Survey and the real wound

care scenarios illustrate how government and private reimbursement policies are short-changing patients with venous disease as well as those trying to provide these patients with high quality care. Substandard care has the potential to delay healing and increase the risk of poor outcomes. This increases the economic, clinical, and humanistic burdens of chronic wound care at a time when the elderly population at risk of chronic wounds is growing, along with the US budget deficit. If the current reimbursement system's stated goal is to improve the quality of care,<sup>29</sup> now is the time to do so before spiraling costs of caring for chronic wounds consume the resources that should be spent healing and preventing them.

The content-validated AAWC VU Guideline and its associated Evidence Table have been placed on the National Guideline Clearinghouse and AAWC websites to enable use by professionals managing VU patients and to encourage appropriate reimbursement of VU practice based on the best evidence the Task Force could find at the time of the literature search.

This project identified several opportunities for future research. Items with high content validity and C-level evidence signal the need for controlled clinical research in the areas of leg elevation or exercise, management of venous ulcer periwound skin, necrotic tissue, and inflammation or infection.

## Limitations

A limitation of this guideline is that some steps lack Level A support. Content validation is a powerful tool for quantifying expert opinion consensus but it is not a substitute for prospective, randomized controlled studies of safety or efficacy of each aspect of VU care. The evidence supporting each aspect of care will improve as Level A studies are conducted for those steps currently lacking sufficient evidence to qualify for Level A support. The steps with B or C level evidence suggest future research focused on areas of venous ulcer practice needing a more respectable research base.

Another limitation is the sample size and potential response bias of respondents to the Reimbursement Survey. Less than 1% of the AAWC members receiving the survey completed and returned it. Despite the limited number of respondents, these clinicians represented care delivered to a significant number of patients. At the time of the survey (2004), reimbursement was an emerging

concern among clinicians, many not even aware of clinical impact. Over the subsequent 2 years, this issue has moved to the forefront and reimbursement has surfaced as a powerful factor limiting care decisions.

As the multidisciplinary Task Force, comprised of members of a variety of specialist physician, nursing and physical therapist societies, worked together to compile and validate this evidence-based algorithm, they realized the value each professional brings to VU patient care and the power with which reimbursement can encourage or discourage quality care. The Task Force recommended developing a recognized wound care subspecialty that links reimbursement to expertise — eg, a subspecialty in venous ulcer care for experts who know and practice evidence-based management of patients with venous disorders. Before this can happen, wound care professionals would need to agree on objectively standardized, reliable, validated documentation and patient-centered, evidence-based protocols of care. This requires rigorous operational definitions for procedures and consensus on care across disciplines. Professional societies and government agencies would need to speak with one voice, sharing a unified, coordinated approach to deliver and reimburse quality wound care. The Task Force offers the AAWC VU Guideline as a first step toward unifying venous ulcer care supported by adequate reimbursement.

The authors plan to update the Guideline annually with new evidence and successive review and validation by other societies so it can continually improve as a multidisciplinary resource for professionals and payors serving patients with venous disorders. While availability of a guideline based on best available evidence is a step toward improving the quality of venous ulcer care, US clinics continue to lose revenue if they provide optimal care for venous ulcers. Without improvements in reimbursement of evidence-based venous ulcer care, patients, providers, and payors will continue to pay the price of suboptimal VU practices.

## Conclusion

The AAWC Government and Regulatory Task Force established a content-validated venous ulcer guideline supported with a summary of best available evidence for each element of VU practice. This dynamic document is a first step toward aligning the language, practice, and reimbursement of venous ulcer care. - OWM

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## References

1. Phillips T, Stanton B, Provan A, Lew R. A study of the impact of leg ulcers on quality of life: financial, social and psychological implications. *J Am Acad Dermatol*. 1994;31:49–53.
2. Abbade LP, Lastoria S. Venous ulcer: epidemiology, physiopathology, diagnosis and treatment. *Int J Dermatol*. 2005;44(6):449–456.
3. Heit JA, Rooke TW, Silverstein MD, et al. Trends in the incidence of venous stasis syndrome and venous ulcer: a 25-year population-based study. *J Vasc Surg*. 2001;33:1022–1027.
4. Cornwall JV, Dore CJ, Lewis JD. Leg ulcers: epidemiology and aetiology. *Br J Surg*. 1986;73:693–696.
5. McGuckin M, Kerstein M. Venous ulcers and family physicians. *Adv Skin Wound Care*. 1998;11:344–346.
6. Korn P, Patel ST, Heller JA, et al. Why insurers should reimburse for compression stockings in patients with chronic venous stasis. *J Vasc Surg*. 2002;35(5):950–957.
7. Hourani LL, Hurtado SL. Total quality leadership in the US Navy: effective for health promotion activities? *Prev Med*. 2000;30(6):478–484.
8. Alguire PC, Mathes BM. Chronic venous insufficiency and venous ulceration. *J Gen Internal Med*. 1997;12:374–383.
9. Alexanderhouse Group. Consensus paper on venous leg ulcers. *Phlebology*. 1992;7:48–58.
10. Black SR. Venous stasis ulcers: a review. *Ostomy Wound Manage*. 1995;41(8):20–29.
11. Burton CS. Venous ulcers. *Amer J Surg*. 1994;167(suppl 1A):37S–39S.
12. Cherry GW, Cameron J, Ryan TJ. Blueprint for the treatment of leg ulcers and the prevention of recurrence. *WOUNDS*. 1993;3:2–5.
13. Falanga V. Venous ulceration: assessment, classification and management. In: Krasner D, Kane D. *Chronic Wound Care, 2nd ed*. Wayne, Pa: Health Management Publications, Inc;1997:165–171.
14. Kerstein MD. The non-healing leg ulcer: peripheral vascular disease, chronic venous insufficiency and ischemic vasculitis. *Ostomy Wound Manage*. 1996;42(10 suppl A):19S–35S.
15. McGuckin M, Waterman R, Brooks J, et al. Validation of venous leg ulcer guidelines in the United States and United Kingdom. *Amer J Surg*. 2002;183:132–137.
16. Nelson EA, Dale J. The management of leg ulcers. *J Wound Care*. 1996;5(2):73–76.
17. Morrison M, Moffatt C, Bridel-Nixon J, Bale S. Leg ulcers. In: Morrison M, et al. *Color Guide to the Nursing Management of Chronic Wounds*. 2nd Ed. London, UK: Mosby;1997:177–220.
18. Phillips T. Successful methods of treating leg ulcers. *Postgrad Med*. 1999;105(5):159–180.
19. Royal College of Nursing. The management of patients with venous leg ulcers: *Clinical Practice Guideline*. 1998; The RCN Institute, Center for Evidence-based Nursing, University of York and School of Nursing, Midwifery and Health Visiting, University of Manchester. Available at: [www.rcn.org.uk/resources/guidelines](http://www.rcn.org.uk/resources/guidelines). Accessed October 24, 2006.
20. Stacey M, Falanga V, Marston W, et al. The use of compression therapy in the treatment of venous leg ulcers: a recommended management pathway. *EWMA J*. 2002;2(1):3–7.
21. Beitz J, van Rijswijk L. Using wound care algorithms: a content validation study. *JWOCN*. 1999;26:238–249.
22. Panel for the Prediction and Prevention of Pressure Ulcers in Adults. *Pressure Ulcers in Adults: Prediction and Prevention. Clinical Practice Guideline, Number 3*. AHCPR Publication No. 92-0047. Rockville, Md: US Department of Health and Human Services;1992.
23. Bergstrom N, Bennett MA, Carlson CE, et al. *Pressure Ulcer Treatment. Clinical Practice Guideline, Number 15*. AHCPR Publication No. 95-0653. Rockville, Md: US Department of Health and Human Services;1992.
24. Yaghmaie F. Content validity and its estimation. *J Med Education*. Spring 2003. Available at: <http://www.sbm.ac.ir/Journal/MedEdu/jm>. Accessed September 2, 2003.
25. Fife C. First pass analysis of the Intellicure Clinical Documentation and Facility Management Software (ICDFMS). E-mail communication to L. Bolton. July 25, 2006.
26. Bolton L, McNees P, van Rijswijk L, et al. Wound healing outcomes using standardized care. *JWOCN*. 2004;31(3):65–71.
27. Sinclair I, Berwiczek II, Thurston N, et al. Evaluation of an evidence-based education program for pressure ulcer prevention. *JWOCN*. 2004;31(1):43–50.
28. Eaton MK. The influence of a change in Medicare reimbursement on the effectiveness of Stage III or greater decubitus ulcer home health nursing care. *Policy Politics Nurs Pract*. 2005;6(1):39–50.
29. Rewarding superior quality care: the Premier Hospital quality incentive demonstration. Centers for Medicare and Medicaid Services Fact Sheet. Updated January 2006. Available at: <http://www.cms.hhs.gov/HospitalQualityInits/>. Accessed March 21, 2006.

## APPENDIX 1 CLINICAL SCENARIOS

### Scenario A: Home Venous Ulcer Care

A 76 year-old woman with type 2 diabetes and a non-healing venous ulcer of 1-year duration was referred to Home Health Services following hospital admission for acute cellulitis. As part of the cellulitis, the patient presented with large ulcer measuring 6 cm x 5 cm x 0.2 cm of the right lower extremity. The wound base was covered 100% with yellow adherent fibrin slough, periwound erythema was significant, and a large amount of exudate, palpable pulses, +3 pitting edema, and significant pain with hospital treatment of daily topical enzymatic debridement ointment and gauze dressing were noted. After OASIS assessment was completed, the patient was classified into HHRG C2F2S0 with a corresponding payment rate of \$2,404 for the episode.

In addition to oral antibiotics, glucose control, leg elevation, and patient education, the home care treatment plan included 2 weeks of three nursing visits per week for autolytic debridement and application of compression with the use of Versiva® 5" x 5" foam composite dressing (ConvaTec, a Bristol-Myers Squibb Company, Princeton, NJ) wrapped with gauze and reusable high compression wrap (SurePress®, ConvaTec, a Bristol-Myers Squibb Company, Princeton, NJ) applied over the dressing.

After 2 weeks, the acute cellulitis, edema, pain, and erythema were resolving but the wound was not debriding with current treatment and wound dimensions had not changed. Pulsatile lavage therapy followed by serial sharp debridement treatments performed by Outpatient Physical Therapy (PT) were instituted to continue debridement efforts. Outpatient PT services were contracted by the Home Health Agency (HHA) and treatments were continued three times per week for 3 weeks with an additional nursing reassessment visit once per week for those 3 weeks.

Pulsatile lavage therapy followed by serial sharp debridement treatments performed at a nearby hospital outpatient PT department was instituted to continue debridement efforts. Outpatient PT services are contracted by HHAs. Treatments were continued three times per week for 3 weeks until the patient could no longer arrange transportation to PT appointments. Subsequently, home skilled nursing visits resumed three times per week for 3

weeks with shower irrigation, hypertonic saline gauze dressing (Mesalt®, Molnlycke Health Care, Norcross, Ga), and compression, progressing to shower irrigation, use of an alginate dressing (Algisite®, Smith and Nephew, Largo, Fla), and compression. At the conclusion of the 60-day episode, the wound was 90% debrided, granulation tissue formation was progressing, and ulcer size was reduced 20%. Exudate levels had diminished, which allowed for twice weekly skilled nursing visits. The ulcer healed in another 8 weeks and the patient required compression stockings for life.

**Problem with current Medicare reimbursement system.** Typically, up to 77% of venous ulcers (using non-adherent gauze primary dressings) or 57% (using hydrocolloid primary dressings) can be expected to remain unhealed after 12 weeks of standardized care.<sup>1</sup> The initial OASIS assessment of the patient resulted in placement into HHRG C2F2S0. This patient required physical therapy (PT) services. In the current Prospective Payment System (PPS), fewer than 10 PT sessions delivered for appropriate care do not trigger any reimbursement for those services in the OASIS score under the service domain; therefore, no additional payment was provided to the HHA for the cost of the PT care provided. This resulted in substantial provider underpayment for the patient's cost of care.

Additionally, medical supply allocation for a 60-day episode of care is approximately \$50, regardless of HHRG or the clinical requirements. Wound care, particularly ulcers of the leg or wounds with complications — eg, infection, cellulitis, presence of necrotic tissues, depth, heavy exudate, delayed closure, undermining of the edges, and tunneling into deeper tissue — all require more skilled visits and supplies than allocated for a simple surgical wound management. In OASIS, clinical need by ulcer difficulty factor is only scored for pressure ulcers and uses a staging methodology — no variation of scoring for venous ulcers, arterial leg ulcers, or diabetic foot ulcers based on their complexity exists despite evidence that deeper ulcers take longer to heal.<sup>2</sup> These wounds are all considered the same regardless of wound depth, complications, history, or clinical need.

In this actual case, both the allocation of skilled care payment and supply payment are grossly underpaid. The HHA will sustain a loss on this episode.

Chronic wounds, by their nature, heal more slowly than acute or surgical wounds, often requiring removal of necrotic tissue; management of infection or high bioburden counts, undermined areas, and exudate; or promotion of closure of the deeper tissues before epithelialization. In some cases, the use of pressure relief, offloading, irrigation, enzymes, growth factors, sharp debridement, electrical stimulation, and/or compression therapy will be required to assist the healing process.

The current Home Health PPS system has fundamental flaws concerning the utilization of services (PT, occupational therapy [OT], and speech language therapy [SLP]) and supplies). The PPS provision of appropriate reimbursement for care of patients with chronic wounds that usually need various types of supplies, PT services, pressure-relief devices, compression therapy, and debridement agents is inadequate, which encourages the substitution of less effective supplies that lead to poor clinical outcomes. An example of this is the frequent substitution of ineffective ace wraps in place of high compression garments.

Only pressure-relief devices, negative pressure wound therapy, and offloading devices are covered and

reimbursed separately to the PPS rate as durable medical equipment (DME) under the DME benefit. The remaining supplies and modalities for care are included under the approximately \$50.00 per 60 days supply allocation. As identified in this actual case, supply costs alone were \$912.90; personnel (PT) were not accounted for in the PPS system because fewer than 10 sessions were prescribed for this patient. This patient required daily nursing visits and nine PT sessions for management of this complicated venous ulcer following cellulitis and hospitalization. Clearly, a need exists to account for lesser amounts of required therapy in the PPS system. Without an adequate clinical scoring mechanism for venous, arterial, and diabetic ulcers and tiered scoring for utilization of PT services, HHAs will continue to incur severe losses with this type of patient.

#### References

1. Burton CS. Venous ulcers. *Amer J Surg.* 1994;167(suppl 1A):37S–39S.
2. Bolton L, McNees P, van Rijswijk L, et al. Wound healing outcomes using standardized care. *JWOCN.* 2004; 31(3):65–71.
3. Kerstein MD, Gemmen E, van Rijswijk L, et al. Cost and cost effectiveness of venous and pressure ulcer protocols of care. *Dis Manage Health Outcomes.* 2001;9(11):651–636.

#### Scenario B: Venous Ulcer Management in a Physician's Office

A 69-year-old man with a history of leg ulcers presented to his primary care physician with a full-thickness venous ulcer of 5 months' duration on his right leg. Wound assessment found moderate pitting edema, adequate palpable pedal pulses, 80% of the wound covered with necrotic tissue, moderate exudate, and dimensions of 3.2 cm x 4.5 cm x 0.2 cm. Doppler evaluation confirmed no arterial disease involvement.

The physician performed a full history and physical, examined the ulcer, conducted a Doppler exam/ABI to eliminate arterial involvement, debrided some of the necrotic tissue, cleansed the wound with sterile saline, applied an alginate dressing to manage the exudate, and covered this with a foam dressing without border. He then applied ProFore® (Smith & Nephew, Inc, Largo, Fla) high compression bandage system to promote venous return. The patient was shown how to care for his bandages, taught the signs of circulation problems,

and instructed to return to the office in 4 days for removal of the bandages and reassessment of the ulcer, further debridement as needed, and reapplication of the compression system. The physician spent more than 1 hour with this patient.

The patient had two office visits per week for 3 weeks while the wound was in the exudative phase of healing. Each visit involved examination of the ulcer, cleansing, application of alginate and foam wound site dressings, and application of a high compression bandage, requiring 35 minutes of the physician's time. After week 3, the physician saw the patient once per week for an additional 5 weeks until healing was complete. At each visit, the physician removed the compression wrap, examined the wound, assessed healing, checked pulses, cleansed the wound, and reapplied appropriate dressings and the high compression bandage, which required 25 minutes per visit. During weeks 4, 5, and 6,

the wound was treated with once-per-week alginate dressing and foam composite cover dressing plus the high compression bandage. During weeks 7 and 8, the wound was treated with a hydrocolloid dressing plus the compression bandage. After healing, the patient was given a prescription for medical compression leg wear (30 to 40 mm Hg).

#### **Problem with current Medicare Payment System.**

In the physician's office, provision of appropriate, clinically proven standard of care for the treatment of venous ulcers included sustained high compression therapy, moist-healing wound dressings, debridement of necrotic tissue, and reduction of wound bioburden to reduce the risk of infection. Most non-complicated venous ulcers will heal within 12 to 17 weeks<sup>1-3</sup> with appropriate wound care and compression management. Without this approach, venous ulcer healing rates have been reported to last from 52 to 62 weeks<sup>2</sup> for an uncomplicated venous ulcer. Longer healing times are associated with greater risk of infection, more complications, and increased cost to the health system to treat these patients.<sup>2,4</sup>

The cost of the high compression bandages and moist-healing dressings that can reduce the number of office visits, reduce the risk of infection, and improve healing rates are not accounted for adequately in the practice expense in the physician fee schedule for Medicare. This creates a situation where the physician is penalized for the use of clinically proven, best practice care for venous ulcers. In this case, the venous ulcer treatment was relatively

uncomplicated; it utilized a minimal amount of dressing supplies and healed in a reasonable timeframe. Unfortunately, even with a low complexity venous ulcer in the physician office setting, the reimbursement does not cover the use of evidence-based wound care. The physician had been paid \$970.26 for an 8-week episode of wound healing; from this, the physician paid more than half the fee (\$568.00) for un-reimbursed supplies. The net payment for 11 visits and more than 6 hours of direct care was \$402.26. Given this scenario, most clinicians choose low-cost gauze dressings instead of more expensive dressings with clinically proven efficacy that reduce the overall burden of care costs<sup>3</sup> to Medicare for treatment of venous ulcers.

#### **References**

1. Lyon RT, Veith FJ, Bolton L, Machado F, and the Venous Ulcer Study Collaborators. Clinical benchmark for healing of chronic venous ulcers. *Am J Surg*. 1998;176:172-175.
2. Kerstein MD, Gemmen E, van Rijswijk L, et al. Cost and cost effectiveness of venous and pressure ulcer protocols of care. *Dis Manage Health Outcomes*. 2001;9(11):651-636.
3. van Rijswijk L, Multi Center Leg Ulcer Study Group. Full-thickness leg ulcers: patient demographics and predictors of healing. *J Fam Pract*. 1993;36(6):625-632.
4. Hill DB, Poore S, Wilson J, Robson MC, Cherry GW. Initial healing rates of venous ulcers. Are they useful as predictors and comparators of healing? *Wound Rep Regen*. 2000;8(suppl A):417.

#### **Scenario C: Venous Ulcer Management in Long-Term Care/Skilled Nursing Facility**

A 72-year-old woman with a complicated postoperative recovery following venous ulcer skin grafting was admitted to a skilled nursing facility for wound care. She presented with bilateral lower extremity wounds and 3 to 4+ pitting edema, toe to thigh. Her left lower extremity (LLE) had cellulitis, an infected donor site on the left anterior thigh measured 15 cm x 18 cm x 0.1 cm, and the wound was highly exudative and painful. The right lower extremity (RLE) had a partial-take skin graft site of the anterior and lateral calf regions; open ulcerations on medial RLE and lateral RLE measured 3 cm x 7 cm x 1.5 cm and 3 cm x 9 cm x 2 cm, respectively, and drainage was evident. The patient's comorbidities included insulin-dependent type 2 diabetes,

neuropathy, morbid obesity, Stage I bilateral heel and posterior calf pressure ulcers, and fungal infection of the perineal region; the patient was bedbound. She required an 8-week rehabilitation stay including twice-daily complex wound care; IV therapy; medications; nutritional therapy; bariatric-sized bed with a low-air-loss, pressure-reduction surface; bariatric chair, commode, and lift; incontinence care and supplies; custom compression garments; laboratory tests; PT; OT; and psychiatric consult services.

#### **Problem with current Medicare Payment System.**

Reimbursement under the Medicare Skilled Nursing Facility PPS is intended to provide coverage of all services and goods that comprise the resident's daily skilled

care including skilled nursing, medications, equipment, medical-surgical supplies, rehabilitation, laboratory testing, and room and board.

This patient's 8-week period of care resulted in closure of the wounds but the facility sustained a revenue loss of \$3,344.26. The calculations in the PPS rate for room and board did not accurately reflect the cost of the extensive manpower this individual required for daily care. Furthermore, her size necessitated procurement of bariatric equipment at significant un-reimbursed cost to the facility. Edema management was achieved with custom compression garments that were not reimbursed because the venous ulcers were not open wounds.

Venous ulcers may present in a manner that precludes the need for debridement or surgical intervention; thus, eliminating a beneficiary's option to use Medicare Part B coverage for wound dressings. Furthermore, without ongoing, lifelong compression therapy, ulcers reoccur.<sup>1</sup> Neither Medicare nor Medicaid currently provides for coverage of preventa-

tive maintenance compression garments to avoid costly ulcerations or to prevent recurrence. In addition, individuals with complex health issues and abnormal posturing require custom seating systems that support quality of life and health maintenance, yet no reimbursement allowance is extended to those confined to long-term care settings. If Medicaid denies this appeal for specialty equipment, resources are nonexistent to cover such extensive cost, increasing the risk for complications, the need for medications, diagnostic services, and further hospitalization. Venous ulcer patients with significant comorbidities require numerous services, products, and equipment in the skilled nursing setting; large gaps exist between evidence-based care needs and reimbursement.

## References

1. McGuckin M, Waterman R, Brooks J, et al. Validation of venous leg ulcer guidelines in the United States and United Kingdom. *Am J Surg.* 2002;183:132–137.

### **Scenario D: Hospital-Owned Outpatient Wound Departments (HOPD) – Advanced Practice Registered Nurse (APRN) Care Provider**

A 73-year-old woman with a history of recurrent lower extremity ulcerations presented with multiple full-thickness wounds over an 8 cm x 20 cm circumferential area of her right lower extremity; the wounds had been present for an indeterminate time. The wounds were covered with fibrinous necrotic slough and exhibited significant odor, purulent drainage, erythema, and dermatitis. Pedal pulses were palpable with an ABI of 0.9; pitting edema was present. The patient had a history of prior aortic valve replacement, rheumatoid arthritis, and multiple drug allergies and reported a 35-lb weight loss.

Her first visit to the clinic included history and physical examination, Doppler exam, partial-thickness debridement, wound irrigation, tissue biopsy for culture and pathology, and serum laboratory tests; topical treatment was applied to the periwound skin. A primary absorptive hydrofiber dressing with ionic silver (AQUACEL® Ag, ConvaTec, a Bristol-Myers Squibb Company, Princeton, NJ) was used to manage excess exudate and limit bacterial access to the wound. This dressing was covered by another layer of the absorptive hydrofiber wrapped with cast padding and a re-usable

Setopress® (ConvaTec, a Bristol-Myers Squibb Company, Princeton, NJ) high compression wrap. A referral was written for Home Skilled Nursing Services for three-times-per-week wound assessment and dressing and compression reapplication as needed. Arrangements were made for follow-up in 1 week to the Wound Center to include a nutritional consult. A social worker was called to evaluate financial and social stresses (a widow, she cared for her adult son with Down's syndrome and requested help with her fuel bills). Patient teaching and written instructions were provided. Subsequent weekly and biweekly visits over 8 weeks included a podiatric evaluation of bony foot deformity and onychomycosis, Infectious Disease consult for resistant bacterial infection, and frequent collaboration with home health services and social work services regarding the ongoing plan of care. The patient was subsequently hospitalized for exacerbation of leg ulcers but she went on to heal in 24 weeks with complex coordinated multidisciplinary care.

**Problem with current Medicare Payment System.** This scenario depicts a real-life situation where interventions by a multidisciplinary care team

were necessary to adequately address all the patient needs impacting wound healing. Substantial qualitative research studies demonstrate positive outcomes and the value of comprehensive multidisciplinary wound care (AAWC 2005).

A total of eight APRN professional fees (CPT 99205, 99214) and eight Ambulatory Payment Classification (APC) (levels 2 to 5) visits were billed for a total reimbursement of \$1,119.62. Supply costs for the eight visits were \$508.32, consuming approximately 45% of payments to the clinic. Multidisciplinary coordination of the care plan for complex wounds in patients with multiple comorbidities takes considerable time. In this scenario, the direct APRN time was 11.5 hours with nearly six additional hours of professional staff phone time and team coordination over 8 weeks. Support staff

**(see Appendix 1 Table 1 for economic summaries of each scenario)**

time, documentation, billing functions, overhead, supplies, and liability are all expenses to the facility.

Ambulatory Payment Classification payments do not offset costs associated with management of complex wounds that ideally are treated by a multidisciplinary team. Inadequate reimbursement for comprehensive wound care services and supplies delivered in an HOPD forces clinics to choose less effective treatment options, cut services, reduce expertise, and cost shift to other care settings. The rapid healing rates associated with evidence-based venous ulcer care along with multidisciplinary care delivery in HOPD reduces the overall costs for Medicare.

# APPENDIX I TABLE 1 COST SUMMARY FOR VENOUS ULCER CASE SCENARIOS APPLYING “A” LEVEL EVIDENCE\*

Site of Care	Episode/A-level Interventions	Payor	Professional Fees	Supply Costs	Reimbursement	Revenue +/-	Comments
Scenario A: Home Care	<b>8 weeks:</b> Dressings: <ul style="list-style-type: none"> <li>• autolytic debridement</li> <li>• exudate management</li> <li>• moisture-retentive</li> <li>• elastic compression</li> </ul> Patient education Pulsatile lavage	Medicare	Skilled nursing visits: 18 @ \$131.45 = \$2,366.10  PT visits: 9 @ 121.29 = \$1,091.61	\$912.90	HHRG payment = \$2,404.00	-\$1,966.61	* Adjunctive use of PT modalities may hasten debridement phase but <10 PT sessions does not trigger additional reimbursement and adds to loss. * Medical supply allocation inadequate for complex chronic wounds. * Outlier payments yield little compensation
Scenario B: Physician Office	<b>8 weeks:</b> H & P Doppler exam <ul style="list-style-type: none"> <li>• Sharp debridement</li> </ul> Dressings: <ul style="list-style-type: none"> <li>• exudate management</li> <li>• moisture-retentive</li> <li>• compression wraps</li> </ul> Patient education	Medicare	CPT 99204 x 1 CPT 99214 x 10 CPT 11041 x 1  Total = \$970.26	\$568.00	\$970.26	\$402.26	* Supply expenses are not reimbursed in the office setting * Physician is penalized for best practice care for venous ulcers * Less effective gauze dressings lead to poor healing and higher overall Medicare burden
Scenario C: Skilled Nursing Facility	<b>8 weeks:</b> Dressings: <ul style="list-style-type: none"> <li>• exudate management</li> <li>• moisture-retentive</li> </ul> Patient education Bariatric equipment IV Therapy	Medicare PPS	Skilled nursing twice daily Dressing changes PT  Specialty bed Dressings Medications Lab tests Room and board	Total costs = \$17,096	\$13,751.74	-\$3,344.26	* Reimbursement under Medicare SNF PPS is intended to provide coverage of all services, supplies, and care that comprise the resident's daily skilled care * Manpower costs are extensive and not adequately reimbursed for complex wound care * No incentive to provide more expensive best practice dressings
Scenario D: Wound Clinic (HOPD) Care delivered by multidisciplinary wound team	<b>8 weeks:</b> H & P Doppler exam Serial sharp debridement Dressings: <ul style="list-style-type: none"> <li>• antimicrobial exudate management</li> </ul> Multilayer elastic compression	Medicare + APC	CPT 99205 x 1 CPT 99214 x 10 APC (level 2-4) x 8	\$508.32	Professional = \$497.68 APC = \$621.94 Total for episode = \$1,119.62	\$611.30	* APC payments do not offset increased expenses associated with complex wound requiring multidisciplinary care * Supplies consume approximately 40% of payment to clinic * Payments do not cover professional salaries, liability, overhead, documentation, billing functions * Little incentive to utilize expensive best practice dressing supplies and treatments

\* Note: Clinical scenarios are actual cost computations taken from the care of venous ulcer patients in various care settings across the US 2005-2006. All patients were cared for by members of the AAWC Government and Regulatory Task Force and are genuine case scenarios with actual fiscal data.

SNV = skilled nursing visit; PT = physical therapy; H & P = history and physical exam; PPS = Prospective Payment System  
 APC = Ambulatory Payment Classification; HOPD = Hospital-Owned Outpatient Wound Care Department