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THE ADVANCEMENT
OF WOUND CARE

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Re: Treatment Strategies for Patients with Lower Extremity Chronic
Venous Disease

Dear MEDCAC Panel:

The Association for the Advancement of Wound Care [AAWC] is pleased to provide the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) feedback on lower extremity chronic venous disease with ulceration and the scientific evidence for beneficial “interventions that aim to improve health outcomes in the Medicare population, and address areas where evidence gaps exist.”

The AAWC a non-profit inter-professional association of nearly 2,300 wound care clinical specialists [physicians, surgeons, podiatrists, nurse practitioners, physician assistants, physical therapists and wound care nurses] and researchers, dedicated to the education and delivery of evidence-based care for the patients we serve.

We have focused our remarks on the clinical outcomes related issues and specifically addressing questions #1 and # 3, and 5.

Overall Comments

Patient Complexity

The patient population with chronic venous disease (CVD) of the lower extremity and ulceration are generally older and sicker people that suffer from a wide variety of disease etiologies and comorbidities, including; arterial disease, diabetes, vasculitis, atherosclerosis, renal disease, autoimmune diseases [e.g. RA, Scleroderma, sickle cell, HIV, Lupus, etc.] and effects from post-radiation therapy. As such, many of them are seen by a variety of specialists, which may or may not collaborate in the overall management of the treatment of the patient.

CVD is a common condition that can precipitate development of venous ulcers, which can be debilitating, costly to treat, and reduce the quality of life for the individual. Venous ulcers can recur, even after vascular

intervention, further burdening the patient and the health system. People with CVD with ulceration, and concomitant diabetes are known to have an altered wound microenvironment due to the nature of diabetic vascular disease. In the comorbid CVD population, standardized venous interventions often fail to impact healing.

In a 2015 RCT¹ of patients with venous ulcers, the investigators identified subjects' comorbidities and found 83% had four or more comorbidities. This sick patient profile was previously substantiated in a 2014 retrospective analysis of 897 patients with 1,294 venous ulcers² treated in wound clinics, which showed similar comorbidities. The retrospective data found the comorbidities that delayed healing included; uncontrolled or poorly controlled diabetes mellitus, advanced peripheral artery occlusive disease (PAD), large initial ulcer size and significant depth, active smoking, and use of steroid medications and/or street drugs. These comorbidities complicate the management and treatment of patients with CVD and venous ulcers.

Table 1: Comorbidities Associated with Venous Ulcer

| 2105 RCT Data ¹ : 81 Study patients w/venous leg ulcers | 2014 Wound Clinic Data ² : 897 Treated patients w/1,249 venous ulcers |
|---|---|
| 67% Hypertension | 67% PAD w/ ABI < 0.8 |
| 61% Edema | 74% Edema/ stasis dermatitis |
| 35% Diabetes | 44% Diabetes |
| 25% Arthritis | 59% Varicose veins |
| 14% Anemia | 69% Smokers |
| 7% CAD | 22% CHF |
| 6% Pulmonary Disease | |
| 6% Autoimmune Disease | 35% lipodermatosclerosis |
| 5% Kidney disease | |
| Median BMI 36.5 | 76% Morbidly obese BMI > 45 |
| 56% recurrent ulcers | 24% recurrent ulcers |

Recent data [2016] extracted from a Qualified Clinical Data Registry for meaningful use, the U.S. Wound Registry³ on 19,151 patients with 59,116 venous ulcers treated in 126 outpatient wound clinics showed an average of 3 ulcers per patient and an average initial presenting ulcer size of 34.01cm³. The average wound age on presentation to wound care clinic was 153 days [21.85 weeks]. After comprehensive wound management in the wound care clinic, 78.9% healed during an average of 82.5 days [11.8 weeks], therefore ulcers that healed had an average duration of eight months [mean]. Twenty-one percent [21%] did not heal during treatment time in the wound clinics.

Reducing the time an ulcer is open can dramatically reduce the risk of complications, cost of care and improved the quality of life for people with CVD and ulceration.

1. Gibbons GW, Orgill DP, Serena TE, Novoung A, O'Connell JB, Li WW, Driver VR. A Prospective, Randomized, Controlled Trial Comparing the Effects of Noncontact, Low-frequency Ultrasound to Standard Care in Healing Venous Leg Ulcers. *Ostomy Wound Manage* 2015;61(1):16–29.
2. Bongiovanni CM. Effects of Hypochlorous Acid Solutions on Venous Leg Ulcers (VLU): Experience With 1249 VLUs in 897 Patients. *J Am College Clin Wound Specialists* 2014;6(3):32–37.
3. U.S. Wound Registry, [USWR] Venous Ulcer Registry sponsored by the USWR, <https://www.uswoundregistry.com>

Improving Patient Outcomes

To adequately address this high risk, complex patient group, a multi-specialty team approach [e.g., vascular specialists, lower extremity specialists, cardiology, dermatology, podiatry, infectious disease, physical therapy, general practice, wound specialists, nutritionists] is required to assess the entire patient's disease process and associated co-morbidities that impact treatment decisions, timely and appropriate interventions and affect care outcomes.

The biggest challenge for these patients is delivery of appropriate, timely, patient-centered and coordinated care.

During the diagnostic, pre-procedural intervention phase of care and after a surgical intervention, especially when tissue damage is present, the involvement of a wound care specialist team is critical. The multi-specialty team should be engaged to address the overall risk-level of the patient, determine patient specific goals and establish a partnership for healing. Factors critical to healing include functional status, psychosocial and financial aspects, clinical severity, pain assessment, and adherence to lifestyle recommendations. Optimization of the patient, limb and wound prior to intervention procedures include consideration of infection, wound necrosis and other complicating disease factors affecting the wound/ tissue response. Team interventions supplementary to vascular intervention include treatment of the wound microenvironment with evidence-based debridement, compression therapy, dressings and appropriate advanced therapies. The application of multi-specialty interventions enhances the surgical/vascular approach to promote an improved patient outcome.

Warriner et.al.⁴ demonstrated that patients with VUs [215] that had access to Wound Care Specialists/ teams in clinic setting lead to shorter time to healing and greater percent of ulcer healed.¹⁰ Clinical oversight by a wound specialist for the high-risk, complex person with CVD and a wound or tissue infection serves to ensure timely treatments are delivered, especially when the expectation is for immediate intervention. Post-procedure care must involve a coordinated multidisciplinary team, including a wound specialist to ensure management of the limb and/ or wound is optimized for healing and limb preservation. This will support appropriate monitoring, devices, and therapies are delivered, that optimizes the patient outcome of the vascular procedure.

Edwards et.al.⁵ demonstrated that access to wound management expertise can promote streamlined health services and evidence based wound care, leading to efficient use of health resources and improved health.

In consideration of this large Medicare population, with risk of tissue and limb viability due to their CVD with and without a wound, the MEDCAC Panel must ensure in their recommendations that these individuals have access to receive all evidence-based interventions, supported in VU Guidelines for optimal outcomes, better quality of life and preservation of their limbs.

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

5. Edwards H, Finlayson K, Courtney M, Graves N, Gibb M, Parker C. Health service pathways for patients with chronic leg ulcers: identifying effective pathways for facilitation of evidence based wound care. *BMC Health Services Research* 2013, 13:86

Questions – MEDCAC Meeting

To address the specific questions posed for the MEDCAC meeting; in our responses we have provided tables that identify specific interventions, confidence levels and the supporting evidence.

Q1. For adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency, how confident are you that there is sufficient evidence for an intervention that improves:

A. Immediate/near-term health outcomes in patients presenting with symptoms?

Medicare individuals that present with signs and symptoms of CVI with ulceration of the lower extremity require local skin and wound treatment, assessment of vascular status and healing potential and ongoing management of their wounds with appropriate evidence-based standard of care [SOC] supported in clinical guidelines.

Multi-specialty involvement in care is often required, not only to manage the CVD with an ulcer, but also the many comorbidities seen in this population. Wound care specialists serve to ensure the timeliest and appropriate treatment(s) are initiated and monitored to optimize ongoing management of the tissue and limb viability. The table below includes Interventions rated with moderate-high confidence levels for Immediate/near-term improved health outcomes in patients presenting with symptoms.

| Intervention | Level of Confidence | Improved Benefit | Evidence Level |
|--|----------------------------|--|---|
| Compression [Multi-layer/ Unna/ Duke boots, elastic/ non-elastic, short stretch/ long stretch, compression boot] | 5 | Edema reduction Improved venous return Promote faster healing Cost-effective Improve QoL | Level A AAWC Guideline ⁶ Cochrane review ⁷ GRADE - 1; LEVEL-A, SVS/AVF Guideline ⁸ WHS Guideline ⁹ |
| Intermittent pneumatic compression [Intermittent/ sequential] Promote healing, reduce pain | 4 | Alleviate symptoms of chronic VI Assist healing longstanding chronic ulcerations Use w/ or w/o compression in patients unable to wear adequate compression system Improves outcomes | Cochrane Syst Rev 2014 ¹⁰ Level A WHS Guideline ⁸ Lullove/Alvarez 2104 ¹¹ |
| Compression and/ or compression stockings – immediately post healing | 4 | Maintain venous return Support new tissue maturation Reduce risk of recurrence | GRADE - 2; LEVEL – B SVS/AVF Guideline ⁸ AAWC Guideline ⁶ CVI=0.905 |
| Advance dressings to manage exudate, maintain moist healing environment, reduce bacterial proliferation, protect fragile skin] | 4 | Optimal healing environment Manage exudate Cost-effective Reduce pain Reduce infection incidence | AAWC Guideline ⁶ CVI= 0.955 |
| Exercise assessments/ education/ for calf pump effectiveness | 3.5 | Improve hemodynamic performance & prevent ulcer recurrence ¹² | SVS/AVF Guideline ⁸ J Vasc Surg ¹² |

| | | | |
|--|---|--|--|
| <p>Structured program of calf muscle exercise & range of motion at the ankle.</p> <p>Patient-appropriate program of walking, leg elevation and/or appropriate ankle exercise</p> | | <p>Enhance venous emptying in the calf.¹³</p> <p>Improve venous return</p> <p>Improve venous hemodynamics or calf muscle pump function</p> <p>Increase calf muscle pump function demonstrated helpful in long-term maintenance and venous ulcer prevention</p> <p>Improved ulcer healing time</p> | <p>J Vasc Resr¹³</p> <p>AAWC Guideline⁶: (Jull et al., 2009¹⁴; Meagher et al., 2012¹⁵; O'Brien et al., 2013¹⁶; Padberg et al.¹², 2004; Szewczyk et al., 2010¹⁷; Yim 2015¹⁸), CVI=0.955</p> <p>WHS Guideline⁹ Heinen et. al. 2011¹⁹</p> |
| Arterial testing for venous ulcer [at minimum ABI] on all patient w/ ulcers & post healing | 4 | Early detection | <p>SVS/AVF Guideline⁸</p> <p>AAWC Guideline⁶</p> <p>WHS Guideline⁹</p> |
| <p>Nutrition evaluation for pts. w/ VLU, assess potential for healing. Treatment as indicated</p> | 3 | <p>Sufficient protein supports growth of granulation tissue</p> <p>Reduce deficiency in vitamins A and E, carotene, proteins, and zinc found in patients with VLUs</p> <p>Reduce risk for elderly susceptible to development of ulcers w/ insufficient intake of proteins, vitamins, and minerals</p> | <p>Level B AAWC Guideline⁶</p> <p>SVS/AVF Guideline⁸</p> <p>SVS/AVF Guideline⁸</p> <p>Geria Nurs, 2015²⁰</p> |
| <p>Debridement necrotic & devitalized tissue [sharp, enzymatic, autolytic, mechanical, biologic]</p> | 5 | <p>Remove obvious necrotic tissue, excessive bacterial burden, and cellular burden of dead and senescent cells.</p> <p>Maintenance debridement to maintain the appearance and readiness of the wound bed for healing.</p> <p>More than one debridement method may be appropriate.</p> | <p>GRADE 1; LEVEL - B SVS/AVF Guideline⁸ AAWC Guideline⁶ WHS Guideline⁹</p> <p>GRADE - 2; LEVEL - B SVS/AVF Guideline⁸ AAWC Guideline⁶ WHS Guideline⁹</p> <p>GRADE - 2; LEVEL -B SVS/AVF Guideline⁸</p> |
| <p>Skin replacement or surgical grafting as an adjunct to appropriate compression & Tx of underlying pathology if less than 40% VU area reduction is seen in 3 weeks [after assuring blood supply to VU is adequate].</p> <p>Natural tissue constructs [amniotic membrane or cryopreserved skin], or swine</p> | 4 | <p>Supports VU healing</p> <p>Support VU healing compared to standardized compression alone</p> | <p>A Level AAWC Guideline⁶ (Jones & Nelson, 2013²¹; Serena 2014²², Gibbons 2015¹, Valle 2014²³), CVI=0.765, High</p> <p>A Level AAWC Guideline⁶ (Mostow 2005²⁴; Romanelli et al., 2010²⁵;</p> |

| | | | |
|---|---|---|--|
| small intestine submucosa support VU healing compared to standardized compression alone. | | | Serena et al., 2014) ²² , CVI=0.727, Moderate SOR |
| Tx limb cellulitis w/ systemic gram-positive antibiotics | 4 | | GRADE - 1; LEVEL – B SVS/AVF Guideline ⁸ |
| Tx wound infection <i>[ulcers with $>1 \times 10^6$ CFU/g of tissue & clinical evidence of infection]</i> w/ antimicrobial therapy. Antimicrobial therapy for virulent or difficult to eradicate bacteria (such as beta-hemolytic streptococci, pseudomonas, and resistant staphylococcal species) at lower levels of colony-forming units per gram of tissue. Combination of mechanical disruption and antibiotic therapy | 4 | Eradicate bacteria that impede healing Most likely to be successful in eradicating venous leg ulcer infection. | GRADE - 2; LEVEL - C SVS/AVF Guideline ⁸ GRADE- 2; LEVEL – C SVS/AVF Guideline ⁸ GRADE - 2; LEVEL – C SVS/AVF Guideline ⁸ |

B. Immediate/near-term health outcomes in patients presenting without symptoms but with physical signs

Patients with lower limb physical changes to their skin [thickening, pigmentation, dermatitis, edema, varicose veins] have signs diagnostic of CVI and a risk of venous ulceration, Interventions that should be considered which have shown evidence of impacting outcomes **in patients presenting without symptoms but with physical signs** include:

| Intervention | Confidence Level | Benefit | Evidence |
|--|------------------|---|---|
| Arterial testing for LE w/ skin changes and/ or pain: [e.g. minimum ABI] | 4 | | SVS/AVF Guideline ⁸ AAWC Guideline ⁶ WHS Guideline ⁹ |
| Exercise assessment/ education/ structured program of calf muscle exercise & range of motion at the ankle. | 3.5 | Improve hemodynamic performance & prevent ulcer recurrence ¹² Enhance venous emptying in the calf. ¹³ Improve venous return Improve venous hemodynamics or calf muscle pump function | SVS/AVF Guideline ⁸ J Vasc Surg ¹² J Vasc Resr ¹³ AAWC Guideline ⁶ WHS Guideline ⁹ |
| Compression [stockings] patients w/ skin changes @ risk of VU development | 4 | Prevent development of VU | GRADE - 2; LEVEL C SVS/AVF Guideline ⁸ |

C. Long-term health outcomes in patients presenting with symptoms?

| Intervention | Confidence Level | Benefit | Evidence |
|--|------------------|--|---|
| <p>Compression stockings – 20 to 30 mm Hg, post healed VLU</p> <p>Patients with healed or surgically repaired ulcers should use compression stockings constantly and forever</p> | 4 | <p>Minimize ulcer recurrence</p> <p>Most treatments do not eliminate the underlying increased ambulatory venous pressure (venous hypertension).</p> <p>A degree of compression is necessary long-term.</p> | <p>AAWC Guideline⁶ CVI=0.905</p> <p>WHS Guideline⁹</p> <p>WHS Guideline⁹</p> |
| <p>Compression, 20 to 30 mm Hg, knee or thigh high - patients with clinical CEAP C3-4 disease due to primary valvular reflux</p> | 4 | <p>Prevent risk of ulceration</p> | <p>GRADE - 2; LEVEL - C SVS/AVF Guideline⁸</p> |
| <p>Exercise therapy, structured program of calf muscle exercise</p> <p>Range of motion at the ankle</p> <p>Supervised active exercise to improve muscle pump function</p> | 3.5 | <p>Improve hemodynamic performance & Prevent ulcer recurrence¹²</p> <p>Enhance venous emptying in the calf.¹³</p> <p>Improve muscle pump function, reduce pain and edema⁷</p> <p>Improved time to healing</p> | <p>Level C. J of VS¹²</p> <p>J Vas Res¹³</p> <p>GRADE - 2; - Level B] SVS/AVF Guideline⁸</p> <p>Heinen et. al. 2011¹⁹</p> |
| <p>ABI for all pts. w/ diagnosed CVD or prior ulceration or DVT</p> | 4 | <p>Early detection vascular issues Prevent complications, such as VU, DVT</p> | <p>SVS/AVF Guideline⁸ AAWC Guideline⁶ WHS Guideline⁹</p> |
| <p>Nutrition/ Weight loss plan</p> | 3 | <p>Improve mobility – improve calf pump muscle function and venous hypertension.</p> | <p>Geria Nurs, 2015²⁰</p> |

D. Long-term health outcomes in patients presenting without symptoms but with signs?

| Intervention | Confidence Level | Benefit | Evidence |
|--|------------------|---|--|
| <p>Exercise education & structured program of calf muscle exercise and ankle flexion</p> | 4 | <p>Improve hemodynamic performance¹²</p> <p>Enhance venous emptying in the calf.¹³</p> <p>Improve muscle pump function and to reduce pain and edema in patients with venous leg ulcers.</p> | <p>J of VS¹²</p> <p>J Vas Res¹³</p> <p>GRADE - 2; - Level B] SVS/AVF Guideline⁸</p> |
| <p>ABI in patients w/ physical changes to their skin [thickening, pigmentation, dermatitis, edema, varicose veins]</p> | 4 | <p>Early detection vascular issues Prevent complications, such as VU or DVT</p> | <p>SVS/AVF Guideline⁸</p> |

Q1 Discussion: Considering the heterogeneity of the Medicare population, discuss for which subgroups of the Medicare population the evidence demonstrates likely benefit or which subgroups are not likely to benefit from intervention.

To our knowledge, clinical studies and QCDR data of venous ulcer treatments includes age ranges from early 40's to eight-plus without an indication that age or sex is negatively associated with treatment effectiveness. Even with multiple comorbidities, there has not been evidence that a specific condition would not respond to the evidence-based modalities included above. Compression, when adjusted for an arterial component [0.8 – 0.6] also has not been associated with negative response to treatment.

Conclusion:

To Improve Immediate and Near Term Outcomes Patients with Symptoms:

- Increase application of appropriate compression^{5,7,8}
- Increase application of evidence-based¹ wound care pre-post interventions^{6,8,9}
- Ensure Intermittent Pneumatic Compression therapy, is available when required ^{6,8,9}
- Ensure adjunct therapies for wounds not responding to SOC compression are available^{6,8,9}
- Provide exercise training program/ monitoring to increase calf pump function^{6,8,9}
- Provide arterial testing [at minimum ABI] for all skin changes in LE, edema, or venous ulcer & annually post healing^{6,8,9}

To Improve Immediate and Near Term Outcomes Patients with Symptoms:

- Arterial testing for LE w/ skin changes and/ or pain^{6,8,9}
- Exercise assessment/ education/ structured program of calf muscle exercise & range of motion at the ankle^{6,8,9}
- Compression [stockings] patients w/ skin changes at risk of VU development^{6,8,9}

To Improve Long-term Health Outcomes in Patients Presenting with or without Symptoms?

- ABI for all diagnosed CVD or prior ulcer or DVT^{6,8,9}
- Nutrition/ weight loss programs^{6,8,9}
- Structured exercise program of calf muscle, range of motion at the ankle^{6,8,9}
- Compression stockings - reduce risk of recurrence^{6,8,9}
 - monitor compliance and stockings effect every 6 months
- Patient training on venous disease and need for compliance to compression
- Monitor skin of patients with known CVD at least every 6 months

6. Association for the Advancement of Wound Care Venous Ulcer Guideline. Malvern, PA, USA: Association for the Advancement of Wound Care; 2012. Available from: <http://aawconline.org/wp-content/uploads/2012/03/AAWC-Venous-Ulcer-Guideline-Update+Algorithm-v28.pdf>. Accessed November 27, 2013. [2015 update in submission phase]

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Additional Discussion Topics:

Q3. Discuss important venous disease evidence gaps that have not been previously or sufficiently addressed.

- A. Sustained compression therapy for healing a VU has ample evidence and support in VU Guidelines AAWC⁶, WHS⁹, SVS/AVF⁸ [High Level]. Patients with CVD are being seen by multiple specialties that do not all have expertise in recognizing early signs on CVD or pre-ulceration or have expertise in wound management or are trained in compression application. Adherence to wound care VU Guideline treatment while active ulcers are present and /or post-vascular intervention is critical to healing & success of procedures.

Data that was extracted from the Intellicure Research Consortium (IRC) registry of 108,000 de-identified patient visits to 18 hospital based outpatient wound centers in 16 states, identified only 17% of the patients with venous ulcers received adequate compression therapy.³ This low application rate of adequate compression, the cornerstone of evidence-based therapy for the treatment of venous ulcers is alarming. It suggests for a majority of patients with venous ulcer from these sites, substandard care is being provide and may be responsible for prolonged healing times. This raises concerns as to why there is of lack of evidence-based care being provided.

- 1) Is there a gap in understanding the importance of this treatment modality?
 - 2) Is there an issue related to a lack of training/ skill to appropriate apply sustained compression?
 - 3) Is there a less time consuming approach selected?
 - 4) Are there patient issues causing the clinicians to avoid application of appropriate compression?
- Compliance to adequate compression therapy, both during active ulceration and post healing, has resulted in higher healing rates and lower recurrence rates¹. If the Medicare population with venous ulcer achieved and 85-90% compliance to application of adequate compression, what would the healing rates, recurrence rates and overall cost of care for venous ulcers be for the Medicare population?
 - Can a proactive approach to requiring a wound care specialist to be engaged in the manage CVD patients with venous ulcers within 30 days of diagnosis rapidly impact the outcomes for Medicare patient?
- B. Structured exercise/walking programs are beneficial for patient with CVD and / or venous ulcers. Data has shown^{6,8,9,12,13,15,19}
- a. Deficiency of the calf muscle pump is significant with regard to the severity of venous ulceration.
 - b. Active ulcers associated with greater impairment of calf muscle pump
 - c. Impaired calf muscle pumps have significantly lower ejection volumes and fractions
 - d. Links between reduced range of motion at the ankle in individuals with VI and severity of the disease
 - e. Structured program of calf muscle exercise may improve hemodynamic performance and prevent ulcer recurrence
 - f. Higher levels of muscle activity & greater muscle mass may enhance venous emptying in the calf
 - g. Exercise has been shown to moderate the detrimental effects associated with impaired calf muscle function. A structured program of calf muscle exercise may improve hemodynamic performance and prevent ulcer recurrence.

Individuals with CVD with or without and ulcers who are not candidates for vascular interventions may benefit from structure exercise training for calf muscle pump strengthening and ankle range of motion, walker devices or mobile compression devices to mimic the effects of exercise and / or treat small vessel disease. However, these therapy choices are not provide to the Medicare patient with CVD. No coverage for ongoing physical therapy [PT] services to periodically evaluate and assess the effectiveness or compliance to exercise management could help reduce the incidence of ulceration, decrease the severity of ulceration and help reduce recurrence of venous ulcers.

- C. VU Guidelines^{6,8,9} agree that post ulcer healing compression therapy to reduce recurrence is evidence-based care. With the high recurrence rates for venous ulceration, Medicare is not providing for a therapy that has been documented efficacy and is supported in VU Guidelines as beneficial for reducing recurrence. This is not consistent with providing evidence-based, patient-centered quality care and cost-effective health delivery. Medicare provides therapeutic shoes for reducing recurrence for post-healed diabetic ulcers but not for patient with venous ulcers.

Q4. Discuss any current venous disease treatment disparities and how they may affect the health outcomes of Medicare beneficiaries.

Compression therapy is an important part of treatment for their venous disease and for the wound to heal. Currently Medicare individuals only have access to compression therapy until the wound epithelializes. Evidence-based care management with compression stockings to support venous flow and reduce recurrence is not provided or covered. For patients that have CVD and venous ulcers, the risk for ulcer recurrence and infection is heightened, increasing risk for complications, threatening limb viability and decreases patient quality of life.

Currently, the Medicare recipient with diabetes and a wound is provided devices for continued off-loading protection of their healed wound area. Medicare patients with venous ulcers, with high recurrence rates who also need these compression stockings or devices to reduce the risk for deterioration or re-ulceration have no coverage. Medicare patients with diabetes and a wound are afforded more benefits in the Medicare program than beneficiaries with CVD and a wound.

Medicare individuals with CVD that are not candidates for vascular interventions or who have healed ulcers may benefit from exercise training, walker devices or portable compression devices to mimic the effects of exercise and / or treat small vessel disease. However, there is no coverage for portable devices, or coverage for ongoing physical therapy [PT] services to periodically evaluate and assess the effectiveness or compliance to exercise management. Those beneficiaries that can be best managed with non-vascular interventions need the ongoing monitoring and evaluation by PT or access to walkers and arterial compression pumps to keep them mobile and/ or help reduce pain and sustain a quality of life.

Accurate and early diagnosis of CVD and potential for ulceration can later impact wound healing response. Diagnosed early or correctly, threatening limb viability and increasing amputation risk long range. At a minimum, an ABI should be a routine annual test for all persons presenting with skin changes of the lower extremity, pain in the lower extremity, edema or tissue infection of the limb and any wound presenting. All presenting diabetic patients with a wound and/ or should also have an ABI. In these cases, a normal ABI should be evaluated further with skin perfusion pressures/ toe pressures/ TcO₂M before any treatment procedure and drainage of acute sepsis.

Q5. Discuss any mechanisms that might be supported by CMS that would more quickly generate an improved evidence base that would underpin improved care for the Medicare population affected by lower extremity chronic venous diseases.

Achieving optimal outcomes and functionality for beneficiaries with CVD of the lower extremity with a wound / tissue damage after a vascular intervention is dependent on the application of evidence-based wound care management post-procedure that addresses the specific condition of the wound and / or limb.

Maximizing outcomes requires establishing a 'partnership for healing' with involvement of a WC specialist /multi-professional team prior to any vascular procedure. Implementing a required evaluation wound care specials as an integral part of the diagnosis phase and treatment of CVD with ulceration brings professional who are trained and understand the complexities of CVD and wound micro-wound environment. This ensures continued appropriate progression to healing is optimized prior to and after revascularization, as necessary.

All specialties involved in the prevention, care, education and research should be using the same outcome and quality measures for wound healing especially in patients with VUs. Need to be captured evidence based measures for wound care aspects such as debridement, compression, ABI, etc. to be able to evaluate optimal approaches for the person with VU. There are evidence-based QCDR reported wound care measure is available, but these QCDR measures are not included in future MIPS payment system.

Mechanisms to quickly impact improved care for patients with CVD and ulceration:

- Develop baseline of real life VU patient data from QCDR WC Registries to understand current 'real world' practice and adherence to adequate compression.
- Educate general practice / other specialties on early signs & symptoms venous disease and venous ulcers.
- Require WC specialist evaluation at earliest indication of CVD and prior to any intervention.
- Use QCDR WC databases to compare pre and post education effect on patient care, outcomes and value of WC specialist involvement.
 - Measure impact on compression compliance, healing, recurrence
 - Measure compliance thru QCDR WC Registries to Guidelines^{6,8,9} utilizing QMs related to wound care [20 measures available in USWR], as well as other measures available.
 - A collective pool of wound care measures needs to be made available to physicians as soon as possible to provide a vehicle to track progress during any research of the improved care effects and for implementation in the MIPS program.
- Having many specialties involved in care of the patient with can lead to a lack of standardized implementation of evidence-based management of the wound and limb. Evidence confirms practice guidelines are not followed across specialties especially in terms of compression for venous +/- arterial combination disease. You can have the greatest revascularization performed by any of the specialties and all for not if there is appropriate care of the wound in the treatment algorithm. Revascularization and well-perfused venous wounds will not heal if not properly managed, wasting healthcare dollars for fragmented care.
- To maximize the potential for improved outcomes, when a wound is present with suspected CVD a full evaluation by a wound care specialist / multi-professional wound care team needs to be conducted prior to any vascular procedure. After revascularization follow-up management by wound care specialist/team is also required to ensure continued, appropriate progression to healing is optimized and maintained.
- There needs to be agreement in evidence-based guidelines for the prevention, treatment, education and research of patients with CVD and wounds. The AAWC and the Wound Healing Society, along with other interested international wound healing societies are already engaged in collaborating on consolidated, validated guidelines for Venous Ulcers, Diabetic Foot Ulcers, Infection, and Pressure Ulcers that can be utilized by all specialties when dealing with the wounds. More work is needed to incorporate these into all specialties' management of a wound/ limb.
- All specialties involved in the prevention, care, education and research should be using the same outcome and quality measures for wound healing especially in patients with CVD. Those measures must be evidence based, include the wound care aspects such as compression, etc. to be able to evaluate optimal approaches for the person with CVD.
 - At the current time there are no available wound care specific measurers identified in MIPS to assess treatment improvements / compliance. Validated measures are available as part of QCDR approved for CMS and need to be accessible and included in MIPS access.

We support the development of standardized quality initiatives across all specialties as the only way to reduce and eliminate variation and fragmented care. We urge the MEDCAC to consider the complexity of the Medicare individual with CVD of the lower extremity who has a wound or tissue damage and/or infection. When considering the cost to the health system it is imperative that these beneficiaries have been adequately diagnosed for the degree of their disease. The beneficiaries also need access to services, devices, therapies and vascular interventions that can help manage their disease better and salvage limbs.

We encourage the consistent use of evidence-based wound care guidelines in treating the wound/infection by all specialties to save limbs, preserve function and reduce the care burdens and costs for patients and the Medicare program.

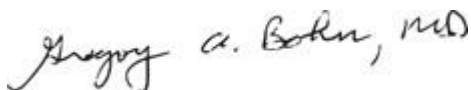
We support the collaboration of all societies involved in CVD to work towards common standardized wound and perfusion diagnostics for CVD crossing all specialties.

Further, we support addressing a common process to determine which patients are candidates for vascular procedures. There are some guidelines from the SVS, SCIR, ACC/AHA but they need some common agreement.

We suggest the CMS provide funding to better capture data through collaborative quality measures that include the management of wounds to evaluate the overall improvement in outcomes with care practices and interventions for patients w/ CVD.

The AAWC is thankful for the opportunity to provide feedback to the MEDCAC.

Sincerely:

A handwritten signature in black ink that reads "Gregory A. Bohn, MD". The signature is written in a cursive, flowing style.

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