Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting
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Typical Patient with CVD and Venous Leg Ulcer Evidence Care and Gaps

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- Podiatrist
- Board member, the Association for the Advancement of Wound Care [AAWC]
- Primary research in regenerative medicine/neonatal stem cells [wound healing & limb preservation]
  - No conflict of interest
  - No financial conflict
    - Consulting associations; Hollister, Inc. [major], Osiris Therapeutics and Vasamed, Inc. [minor]
  - No involvement in federal or nonfederal advisory committee

Typical Patient with Venous Leg Ulcer [VLU]

Evidence-Based Care Venous Ulcers

- Remove devitalized tissue & bioburden[1]
- Assess tissue perfusion[1]
- Manage wound environment across healing process[1]
  - maintain moist healing, control exudate & bacterial proliferation, wound pain, support granulation & epithelialization
- Treat w/sustained, graduate, compression as the first line of treatment[1,2]
  - 30-40mmHg at ankle
    - modify pressure for patients w/arterial component

1. Supported in VU Guidelines: AAWC 2102, WHS 2012, SVS/AVF 2014 [High level]
2. . O'Meara S, Cullum NA, Nelson EA, et al. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. 2012;11:CD000265.

Evidence-Based Care

- IPC therapy: patient non-responding to standard compression or unable to tolerate fixed compression.[1,2]
- Adjunct therapies for non-healing ulcers[1]
- Compression (moderate – high) stockings post-healing to reduce recurrence and support venous return[1]
- Exercise training for calf pump strengthening, walking excercises[1]

1. Supported in VU Guidelines: AAWC 2012, WHS 2012, SVS/AVF 2014 [High Level]
2. O'Meara S, Cullum NA, Nelson EA, et al. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. 2012;11:CD000265.

Guidelines for Evidence-based Care

- Sustained compression therapy for healing a VLU [Level A evidence-based care in VLU Guidelines]
  - AAWC, Wound Healing Society, SVS/ AVF[1]

- Only **17%** of patient w/ venous ulcers received adequate compression therapy.[3]
  - Data 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

1. Supported in VU Guidelines: AAWC 2012, WHS 2012, SVS/AVF 2014 [High Level]

3. Fife CE, Carter, MJ, Walker D. Why is it so hard to do the right thing in wound care? *Wound Rep Reg* 2010;18:154–158.

Issues for Patients with CVD & VLU

- Patients present to multiple specialties
  - not all have expertise recognizing early signs on PVD or pre-ulceration symptoms
  - not all have expertise in wound management
  - not all trained in appropriate compression application
- Non-adherence to VLU Guideline delays appropriate care management & interventions
  - increased in symptoms
  - decreased healing times
  - decreased QOL

Q1: Improve Immediate and Near Term Outcomes Patients w/ Symptoms

- Increase application of appropriate compression[1]
- Increase application of evidence-based[1]wound care pre-post interventions
- Intermittent Pneumatic Compression therapy, when required
- Adjunct therapies for wounds not responding to SOC compression
- Provide exercise training program/ monitoring to increase calf pump function
- Arterial testing [at minimum ABI] for all skin changes in LE, edema, or venous ulcer & annually post healing

1. VU Guidelines [AAWC, 2012, WHS, 2012, SVS/AVF, 2014] support evidence-based care of venous wound

Q1: Improve Immediate & Near Term Outcomes Patients w/Signs but no Symptoms

- Arterial testing for LE w/ skin changes and/or pain[1]
- Exercise assessment/ education/ structured program of calf muscle exercise & range of motion at the ankle[1]
- Compression [stockings] patients w/ skin changes at risk of VLU development[1]
  - AAWC, SVS/AVF/WHS VU Guidelines all support compression to reduce recurrence

1. VU Guidelines [AAWC, 2012, WHS, 2012, SVS/AVF, 2014] support evidence-based care of venous wound

Q1: Improve Long-term Health Outcomes in Patients Presenting w/ or w/o Symptoms?

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

Q3. Important Venous Disease Evidence Gaps

- VLU Guidelines[1] agree post ulcer healing compression therapy to reduce recurrence is evidence-based care
  - AAWC, Wound Healing Society, SVS/ AVF[1]
- **GAP in Practice:**
  - No Medicare coverage for compression therapy after ulcers healed to reduce recurrence
    - Medicare patients w/ diabetic ulcers get therapeutic shoes for reducing recurrence for post- healing
    - Why not VLUs?

1. VU Guidelines [AAWC, 2012, WHS, 2012, SVS/AVF, 2014] support evidence-based care of venous wound

Q3. Important Venous Disease Evidence Gaps

- Structured exercise/walking programs beneficial:
  - active ulcers assoc. w/> impairment of calf muscle pump [CMP]
  - impaired CMP - significantly lower ejection volumes and fractions
  - links between reduced range of motion at the ankle in individuals with VI and severity of the disease
  - structured program of calf muscle exercise may improve hemodynamic performance and prevent ulcer recurrence
  - higher levels of muscle activity & greater muscle mass may enhance venous emptying in the calf

4. Heinen M, Borm G, van der Vleuten C, Evers A, Oostendorp R, van Achterberg T. The Lively Legs self-management programme increased physical activity and reduced wound days in leg ulcer patients: Results from a randomized controlled trial. *Int J Nurs Stud*. 2011 Sep 28
5. Padberg FT, Johnston MV, Sisto SA._ Structured exercise improves calf muscle function in chronic venous insufficiency: a randomized trial. *J Vas Surg* 2004;39:79-87.
6. Kugler C, Strunk M, Rudofsky G. Venous pressure dynamics of the healthy human leg. Role of muscle activity, joint mobility and anthropometric factors. *J Vasc Res* 2001;38:20-29.

Q3. Important Venous Disease Evidence Gaps

- Individuals w/ CVD and ulcers who are not candidates for vascular interventions or have healed VLU
  - may benefit from exercise training, walker devices or mobile compression devices to mimic the effects of the calf muscle function
- **GAP in Practice**
  - no coverage for ongoing physical therapy [PT] services to periodically evaluate and assess the effectiveness or compliance to exercise management
  - no coverage for mobile compression devices

Q3. Important Venous Disease Evidence Gaps

- Patient QOL issues can be improved with compliance to treatment that:
  - reduces edema, odor, drainage, pain, time to heal ulcers
  - increase mobility, feelings of well being
- **GAP in Practice:**
  - no quality measures included MIPS related to VLU treatment for CMS to track QOL & compliance to evidence-based care

Q3. Important Venous Disease Evidence Gaps

- Maximizing outcomes requires involvement of inter-disciplinary wound care team overall & prior to any vascular intervention
- **Gap in Practice:**
  - WC specialist not engaged as integral part of any interventional Tx of PVD or VLUs
    - understand complexities of CVD and wound micro-wound environment
    - ensure continued, appropriate progression to healing w/ evidence-based wound management

Q3. Important Venous Disease Evidence Gaps

- Evidence-based algorithms for prevention & Tx of patients w/ wounds improves healing rates, reduces overall cost of care
- **Gap in Practice:** Need agreed guidelines for the prevention, treatment, education and research of patients with VLUs
  - Currently AAWC, WHS, SVS/AVF support major conservative care
  - AAWC & WHS w/ other international wound healing societies collaborating on consolidating & validating VLU management guidelines

Q3. Important Venous Disease Evidence Gaps

- All specialties involved in VLU prevention, care, education and research should use same outcome & quality measures for wound healing
- **Gap in Practice:**
  - Evidence based measures for wound care [e.g. debridement, compression, ABI, etc.] must be captured to evaluate optimal Tx
  - A QCDR wound care registry w/ 20 measure is available[7], but QCDR measures not included in future MIPS payment system.

7. Venous Ulcer Registry [sponsored by US Wound Registry, /www.uswoundregistry.com/

Q5: Mechanisms CMS can support to more quickly generate improved evidence base for improved care

- Develop VLU baseline data from QCDR WC Registries
- Require WC specialists evaluation at earliest indication of CVD and prior to any intervention
- Educate general practice / other specialties on early signs & symptoms venous disease and ulcers
- Use QCDR WC databases to compare impact of pre-post education & WC specialists involvement
  - measure impact on compression compliance, healing, recurrence
  - Measure QMs related to wound care [20 measures available thru QCDR WC Registry - USWR][7] & other registries

7. Venous Ulcer Registry [sponsored by US Wound Registry, /www.uswoundregistry.com/

Conclusions

- Beneficiaries need access to services, devices, therapies, vascular interventions and education that can help mange their disease better, heal ulcers, salvage limbs, and reduce recurrence rates.