MEDICARE EVIDENCE DEVELOPMENT AND COVERAGE ADVISORY COMMITTEE (MEDCAC) MEETING JULY 22, 2015

Association for the Advancement of Wound Care [AAWC]

Dr. Gary Gibbons, MD, FACS

- Medical Director, South Shore Hospital, Center for Wound Healing
- Professor of Surgery, Boston University School of Medicine
- Vascular Surgeon
- Representing the Association for the Advancement of Wound Care [AAWC]
  - Multi-professional clinical association of over 2,400 clinicians and researchers specialized in wound care
  - No conflict of interest or financial conflict
  - No involvement in federal or nonfederal advisory committee

PAD Under-diagnosed

- PAD of LE can be present in diabetic and non-diabetic individuals:
  - venous disease w/ ulceration or vasculitis
  - general CAD
  - atherosclerosis
  - renal dialysis patients
  - persons with autoimmune diseases [e.g. RA, Scleroderma, sickle cell, HIV, Lupus, etc.]
  - people post-radiation therapy

PAD Under-diagnosed

- Need early, consistent identification of PAD
  - ABI can help identify asymptomatic patients
    - ABI as routine annual test - all diabetic patients age 50 or >
    - ABI standard - all diabetic patients with a wound
    - ABI standard - all tissue infection in the LE
  - For diabetic w/ LE wound and/or infections - a normal ABI should be evaluated further with skin perfusion pressures/ toe pressures/ TcO_2M before any treatment procedure and drainage of acute sepsis

PAD and LE Wounds

- PAD is a common complicating condition affecting wounds and very much under appreciated both in diagnostics and treatment.
  - **“ One size does not fit all especially in the Diabetic”**
- Diabetics have a different biology especially affecting the wound microenvironment
- One diabetic’s PAD affecting the wound may be different from another

Question #4 *Evidence gaps that have not been previously or sufficiently addressed*

- **Gap in Practice:** Patients w/ PAD are seen by multiple specialties [e.g. podiatry, cardiology, vascular specialists, endocrinologists, wound specialists, etc.]
  - Not all specialties have expertise in wound management
    - Inconsistent application of evidence-based treatment/ management of wound pre-post interventions
  - No common core clinical guideline that defines the <u>quantitative</u> value of PAD
    - Collaboration across specialties is critical

Question #4

- **Gap in Practice:** To maximize outcomes in suspected PAD, IC or CLI, especially w/ tissue damage or infection present, **requires** involvement of WC specialist /multi-professional team prior to any vascular procedure
  - Should be integral part of diagnosis phase & treatment
  - Understand complexities of PAD and micro-wound environment
  - Ensure continued, appropriate progression to healing is optimized after revascularization

Question #4

- **Gap in Practice:** Wound specialists need to be involved with creating & following algorithms for wound patients with non-reconstructible PAD
  - Help answer if these patients benefit from HBO or other modalities

- **Gap in Practice:** Need one set of guidelines for the prevention, treatment, education and research of patients with PAD and wounds
  - AAWC & WHS + other international wound healing societies collaborating on consolidating validated guidelines VU, DFU, PU, and Infection

Question #4

- **Gap in Practice:** Wound healing RCTs for advanced treatment and devices exclude patients w/PAD
  - Results - no advanced wound care therapies currently approved through FDA or covered by the CMS for treating a patient w/ PAD with a wound
  - Research needs to be funded and approved that includes at least mild to moderate PAD patients to identify effective treatments going forward

Question #4

- **Gap in Practice:** Process to determine which patients are candidates for vascular procedures needs to be consistently applied
  - Some guidelines from the SVS, SCIR, ACC/AHA but they need some common agreement

Question #4

- **Gap in Practice:** 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 PAD
  - Measures must be evidence based, include the wound care aspects such as offloading and compression, etc. to be able to evaluate optimal approaches for the person with PAD

Question #5: *PAD treatment disparities and how they may affect the health outcomes of Medicare beneficiaries*

- Beneficiaries w/ PAD often have venous disease-**must** be considered & treated along w/PAD related issues
  - Increases risk for complications, ulcer recurrence and infection threatening limb viability
  - Issue: Compression therapy, essential Tx for venous disease of LE and wound healing, **not** consistently addressed & applied by all specialties
  - Issue: Medicare only covered until wound epithelializes
    - Evidence-based care w/ compression to support venous flow or lymphadema to reduce recurrence after healing is **not covered**

Question #5

- Individuals w/ PAD who are not candidates for vascular interventions may benefit from exercise training, walker devices or arterial compression devices to mimic the effects of exercise and / or treat small vessel disease
  - Issue: No coverage for arterial pump devices
  - Issue: No coverage for ongoing physical therapy [PT] services to periodically evaluate and assess the effectiveness or compliance to exercise management
  - Issue: Walkers for PAD management not covered

Question #5

- Optimal outcomes & function for patients w/PAD of LE after a vascular intervention, if wound/tissue damage is present, depends on application of evidence-based wound care to address the specific condition of the wound and/or limb
  - Issue: Beneficiaries w/diabetes + wound are eligible for continued off-loading shoes/devices for healing/ healed wound area. Beneficiaries w/o diabetes are <u>not</u> eligible
    - All Medicare recipients require same Tx approaches
    - Not received consistently due to non-coverage

Overall

- WC specialist/team is critical in diagnosis, pre-procedural intervention phase & post intervention, when infection and/ or a wound is present:
  - Understand overall risk-level of patient
  - Integral part in determining medical need for appropriate interventions
  - Clinical oversight ensures timely Tx delivered, especially if immediate intervention expected
  - Ensures appropriate treatment for better outcomes of interventions – most cost-effective approach

Conclusions

- We urge MEDCAC to consider the complexity of the Medicare individual w/ PAD of LE and a wound or or infection

- When considering cost to the health system – imperative these beneficiaries have been adequately diagnosed for the degree of their disease including venous disease involvement

- Beneficiaries need access to services, devices, therapies and vascular interventions that can help mange their disease better and salvage limbs

Conclusion

- Can have the greatest revascularization performed by any of the specialties and all for not, if there is not offloading in the treatment algorithm for a diabetic patient with a foot wound

- Appropriately Tx of wound microenvironment w/ appropriate dressings, debridement, and advance therapies, appropriately used, is as important as the vascular treatment, which is one aspect of the total plan.

This is a concert not a solo!