ASSOCIATION FOR THE ADVANCEMENT OF WOUND CARE

Business Office
83 General Warren Blvd.
Suite 100
Malvern, PA 19355
866-AAWC-999
610-560-0484
www.aawconline.org

Vickie R. Driver, MS, DPM, FACFAS
President
drvdriver@aol.com

Tina Thomas
Executive Director
tthomas@aawconline.org
267-664-9946

June 15, 2015

Maria Ellis, Executive Secretary for MEDCAC
Centers for Medicare & Medicaid Services
Center for Clinical Standards and Quality, Coverage and Analysis Group, S3–02–01
7500 Security Boulevard
Baltimore, MD 21244

Electronically submitted via: MedCACpresentations@cms.hhs.gov

Dear MEDCAC Panel:

The Association for the Advancement of Wound Care [AAWC], a non-profit multi-professional association of nearly 2,400 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 are pleased to provide the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) feedback on lower extremity peripheral artery disease (PAD), on "interventions that aim to improve health outcomes in the Medicare population, and address areas where evidence gaps exist."

We have focused our remarks on the clinical outcomes related issues, wound healing and specifically are addressing questions #4 and #5.

Overall Comments:

The Medicare population with PAD of the lower extremity involves a wide variety of disease etiologies and not just the diabetic patient with foot ulceration and / or infection. The Medicare patients with PAD seen by wound specialists can include persons with venous disease and an ulceration or vasculitis, general CAD, atherosclerosis, renal dialysis patients, persons with autoimmune diseases [e.g. RA, Scleroderma, sickle cell, HIV, Lupus, etc.] and people post-radiation therapy. MEDCAC needs to consider this larger Medicare population that have ischemic risk of tissue and limb viability due to their PAD with and without a wound as these individuals also require intervention to provide quality of life and limb salvage.

This complex, high-risk patient group requires a multidisciplinary team approach [e.g. podiatrists, vascular specialists, lower extremity specialists, infectious disease, physical therapy] to assess the entire patient's disease process and associated co-morbidities that impact

treatment decisions, timely and appropriate interventions and affect care outcomes. 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 people with diabetes. Diabetics have a different biology especially affecting the wound microenvironment and one diabetic's PAD affecting the wound may be different from another. In this PAD population, one intervention may not be a cure especially for diabetics due to the nature of diabetic vascular disease.

During the diagnostic, pre-procedural intervention phase of care and after a surgical intervention, especially when infection and/ tissue damage is present, the involvement of a wound care specialist team is critical. They should be engaged to understand the overall risk-level of the patient and to manage the wound/ tissue /limb before any procedure is performed and be an integral part of determining the medical need for appropriate interventions. While addressing infection, wound necrosis and other complicating disease factors affecting the wound/ tissue response and limb viability, their involvement ensures appropriate treatment of the wound microenvironment with evidence-based dressings, debridement, and advance therapies, appropriately selected and used, for better outcomes of interventions. This is as important as the vascular treatment, which is one aspect of the total plan.

Clinical oversight by a wound specialist for the high-risk, complex person with PAD and a wound / infection serves to ensure timely treatments are delivered, especially when the expectation is for immediate intervention.

Post procedure care must involve a multidisciplinary team, including a wound specialist to ensure management of the limb and/ or wound is optimized for healing and limb preservation. This supports that appropriate monitoring, devices, and therapies are delivered, depending on the disease process that optimize the patient outcome of the vascular procedure.

Q4: Discuss the important evidence gaps that have not been previously or sufficiently addressed.

Gaps in Practice**:**

- Patients presenting with associated PAD are seen by multiple specialties [e.g. podiatry, cardiology, vascular specialists, endocrinologists, wound specialists, etc.] and as such there is no common core clinical guideline that defines the quantitative value of PAD. Collaboration in identifying PAD with the various specialties is critical for these patients.

- Having many specialties involved in care of the patient with PAD 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 or offloading of a diabetic foot ulcer. You can have the greatest revascularization performed by any of the specialties and all for not if there is not offloading in the treatment algorithm. Revascularization and well-perfused plantar diabetic foot wound will not heal if not properly off-loaded, wasting healthcare dollars for fragmented care.

- To maximize the potential for improved outcomes, when a wound is present with suspected PAD, IC or CLI, 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 one set of guidelines not many for the prevention, treatment, education and research of patients with PAD and wounds. The AAWC and the Wound Healing Society [WHS], 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.

- Wound healing randomized controlled studies [RCTs] for advanced treatment and device modalities for wounds exclude the patient population discussed above because of their PAD status. This has resulted in no advanced wound care therapies currently approved through FDA and 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.

- 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. Those 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.

- The process to determine which patients are candidates for vascular procedures needs to be consistently applied. There are some guidelines from the SVS, SCIR, ACC/AHA but they need some common agreement.

- Wound specialists need to be involved with creating and following algorithms for wound patients with non-constructible PAD. This would help answer if these patients benefit from HBO or other modalities.

Q5: Discuss any apparent lower extremity PAD treatment disparities and how they may affect the health outcomes of Medicare beneficiaries.

Achieving optimal outcomes and functionality for beneficiaries with PAD 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.

Currently, only the Medicare recipient with diabetes and a wound is provided devices for continued off-loading of their healing/ healed wound area. For example diabetic shoes and off-loading devices are approved for Medicare beneficiaries with diabetes, for the management of their foot ulceration and post-healing management yet other beneficiaries with PAD who also need these devices to ensure healing outcomes or reduction of risk for deterioration or amputation, are not covered. Medicare patients with PAD and diabetes are afforded more benefits in the Medicare program than beneficiaries without diabetes.

Another example is people with PAD and venous disease involvement. Commonly Medicare individuals with PAD may also have venous involvement, which must be considered and treated along with the PAD related issues. 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 PAD and venous disease, the risk for ulcer recurrence and infection is heightened, increasing risk for complications, threatening limb viability and decreases patient quality of life.

Medicare individuals with PAD that 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. However, there is no coverage for arterial 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 kept them mobile and/ or help reduce pain and sustain a quality of life.

Those with diabetes have unique complicating factors that impact their accurate and early diagnosis of PAD and their wound healing response. Diabetic patients with PAD and wounds frequently have neuropathy with reduced pain sensation or have minimal pain marker making appropriate diagnosis the PAD, IC or CLI problematic. This can result in many patients not being 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 diabetic patients age 50 or older. All presenting diabetic patients with a wound and/ or tissue infection should also have an ABI. In these cases, a normal ABI should be evaluated further with skin perfusion pressures/ toe pressures/ TcO_2M before any treatment procedure and drainage of acute sepsis.

Conclusions

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 PAD 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 including venous disease involvement. The beneficiaries also need to be provided 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.

We support the collaboration of all societies involved in PAD to work towards common standardized wound/ ischemia/ infection diagnostics for PAD crossing all specialties such as the SVS-Wound, Ischemia, and Foot Infection (WIfI) scale, instead of the inconsistent use of other scales [Ruthford, Wagner, Fontaine, etc.] by those involved in PAD treatment.

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/ PAD.

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

Sincerely,

Dr. Vickie R. Driver
President, Association for the Advancement of Wound Care

CC: Dr. Gary Gibbons, MD, FACS
AAWC Physician Member, Speaker to represent AAWC at MEDCAC Meeting
Medical Director, South Shore Hospital, Center for Wound Healing
Professor of Surgery, Boston University School of Medicine