Re: Supplemental CMS Episode Groups Posting

Dear Acting Administrator Slavitt:

The CardioVascular Coalition (CVC) is pleased to offer its comments to the Centers for Medicare and Medicaid Services (CMS) request for comments on the Supplemental CMS Episode Groups Posting. The CVC was established to provide policymakers and the public with a greater understanding of the value that freestanding cardiovascular centers (CVCs) bring to their patients, and of the importance of logical, predictable payments to align incentives and ensure patient access to quality vascular care. The CVC is comprised of 255 freestanding centers and affiliated physicians and staff in 32 states, and represents more than one-third of the sector.1 CVC members include providers (Fresenius Vascular Care, Lifeline Vascular Care, National Cardiovascular Partners, and the Outpatient Endovascular and Interventional Society) and manufacturers (Cardiovascular Systems, Inc. and Avinger).

Background

One of the key Medicare patient populations treated in CVCs are those patients with peripheral artery disease (PAD). PAD typically involves “atherosclerosis,” or the build-up of plaque inside the arteries of a patient’s legs. It is estimated that 18 million persons in the United States have PAD.2 Total annual costs associated with the hospitalization of patients with PAD in the United States are estimated to be in excess of $21 billion, and are projected to rise as the population ages.3

CVCs focus on providing revascularization, a proven technique to restore blood flow in a patient’s legs that may, in certain patients, serve as an alternative to amputation of the limb. Improvements in technology have allowed for the migration of revascularization services from the hospital setting to same-day interventions in the office setting.4 Care in community-based, freestanding CVCs focuses on providing revascularization with minimally invasive techniques, and offers a cost-

---

1 For more information about the CVC, please see http://cardiovascularcoalition.com/about/
2 The Sage Group, Critical Limb Ischemia, Volume I, United States Epidemiology, 2010
4 Carr et al., Endovascular Today, May 2016, Vol. 15, No. 5
efficient, patient-preferred alternative site of care for patients.5

Supplemental CMS Episode Groups Posting

As required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS has posted for public comment CMS Episode Groups and supporting technical documentation. CMS seeks comments on the episode groups listed in Appendix A of the Supplemental CMS Episode Groups Posting and described in the supplemental materials and requests feedback on methodologies and other aspects of the episode groups. Included in Appendix A is a new “Leg Revascularization” episode group which was not implemented in 2014 Supplemental Quality and Resource Use Reports for physician groups.

Use of untested episode measures is premature

We agree with other commenters who have expressed concerns that many of the episode-based measures posted by CMS have only recently been developed and/or made widely known to practicing physicians. More time is needed to fine-tune and test the proposed episodes and to consider potential alternatives that relevant specialties believe would be more appropriate and better aligned with episodes being used or developed by other payers. To maintain credibility with the physician community and engender confidence in the measures, CMS must solicit and incorporate input from all practicing physicians, professional organizations and other stakeholders.

Specifically, while some physicians have invested substantial time and effort to help CMS come up with relevant and valid episode groups, we are unaware of stakeholder input during the development process of the leg revascularization episodes. We believe it is inappropriate to begin using leg revascularization episodes for MIPS in ways that could potentially penalize physicians before CMS has provided additional information needed to evaluate their suitability. Although CMS has released lists of the diagnosis and procedure codes used to define these episode measures, to achieve true transparency and facilitate insightful input, additional information must be made available.

Specific concerns relating to the leg revascularization episode

The CVC offers these specific concerns relating to the leg revascularization episode included as part of the Supplemental CMS Episode Groups Posting.

- Revascularization of Second Leg
  - As we understand the episode as it has been presented by CMS, an episode is triggered by one of the listed “trigger codes” in the Supplemental CMS Episode Groups Posting. So, for example, the trigger code 37228 would incorporate all “relevant services” billed for a patient as well as all claims with “relevant

5 Ibid
diagnoses” during the 120 day episode (i.e. 30 days prior to the trigger and 90 days after the trigger). In addition to the concerns we have with respect to “relevant diagnoses” and “relevant services” specifically, we are concerned that the information that has been provided by CMS does not appear to take into account instances when a patient may have a second leg re-vascularized during the 120 episode.

- Relevant Services
  - Upon review of the “relevant services” included in the Leg Revascularization Episode in the Supplemental CMS Episode Groups Posting, we have found that many of these “relevant services” are rarely, if ever, provided as part of an actual leg revascularization episode. For example, services that should be reconsidered or removed from the list of “relevant services” include the following:

  - Anesthesia for procedures on heart, pericardial sac, and great vessels of chest; without pump oxygenator;
  - Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; not otherwise specified;
  - Therapeutic apheresis; for plasma pheresis;
  - Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance;
  - Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck;
  - Ligation or banding of angioaccess arteriovenous fistula;
  - Cochlear device implantation, with or without mastoidectomy;
  - Radiologic examination, chest; single view, frontal;
  - Radiologic examination, chest, 2 views, frontal and lateral;
  - Transluminal balloon angioplasty, venous (eg, subclavian stenosis), radiological supervision and interpretation;
  - Duplex scan of extracranial arteries; complete bilateral study;
  - Injection, darbepoetin alfa, 1 microgram (non-esrd use);
  - Injection, alteplase recombinant, 1 mg;
  - Injection, vancomycin hcl, 500 mg; and
  - Mycophenolic acid, oral, 180 mg

In addition to the aforementioned services, many other services on the “relevant services” list are generally questionable as well or may be questionable depending on the indication. Furthermore, we are concerned about a dozen additional services on the list that appear to be part of a larger treatment strategy that includes
revascularization (some of which are done before revascularization and some of
which are done after revascularization), including:

- Debridement, subcutaneous tissue (includes epidermis and dermis, if
  performed); first 20 sq cm or less;
- Debridement, muscle and/or fascia (includes epidermis, dermis, and
  subcutaneous tissue, if performed); first 20 sq cm or less;
- Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of
  body area of infants and children (except 15050);
- Muscle, myocutaneous, or fasciocutaneous flap; lower extremity;
- Debridement (eg, high pressure waterjet with/without suction, sharp
  selective debridement with scissors, scalpel and forceps), open wound, (eg,
  fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm),
  including topical application(s), wound;
- Physician or other qualified health care professional attendance and
  supervision of hyperbaric oxygen therapy, per session;
- Wound care set, for negative pressure wound therapy electrical pump,
  includes all supplies and accessories;
- Hyperbaric oxygen under pressure, full body chamber, per 30 minute
  interval;
- Oxygen concentrator, single delivery port, capable of delivering 85 percent
  or greater oxygen concentration at the prescribed flow rate;
- Negative pressure wound therapy electrical pump, stationary or portable; and
- Apligraf, per square centimeter.

• Relevant Diagnoses
  - Relevant diagnoses listed in the proposed Leg Revascularization Episode include
    over 40 ICD-9 diagnosis codes for symptoms, signs, and other non-trigger
    diagnoses that describe manifestations of the condition. According to CMS, the
    presence of one of these codes can be used to qualify a service for assignment to an
    open episode of the condition and “steer claims to an episode.” However, as CMS
    noted in a recent FAQ, “Medicare claims with a date of service on or after October
    1, 2015, will be rejected if they do not contain a valid ICD-10 code.”6 The CVC is
    very concerned that the “relevant diagnoses” listed in the Leg Revascularization
    Episode in fact are not relevant to current required billing and claims procedures.

• Risk Adjustments
  - We understand that CMS also is developing episode-specific covariate coefficients
    for risk-adjustment based on beneficiary (e.g. gender, age, medical conditions).
    Unfortunately, these risk-adjustment variables, which could have significant impacts

---

6 Clarifying Questions and Answers Related to the July 6, 2015, CMS/AMA Joint Announcement and Guidance Regarding ICD-10 Flexibilities
on reimbursement for a leg revascularization episode, are not available for comment.

- We believe that risk adjustment should also include considerations for higher risk patients (Critical Limb Ischemia or CLI) and higher risk lesion morphologies (calcified lesions) and higher risk procedures (treating above the knee or ATK and below the knee or BTK) in the same procedure.

**Conclusion**

The CVC recognizes that Congress directed CMS to move to episode measurement, and we support this approach if it is done right. We strongly urge CMS to use this opportunity to work with stakeholders to identify and refine those episodes that seem most promising and then pilot them with groups or individual physicians who volunteer to have their MIPS score tied to performance under applicable episodes. Exact details of this approach could vary. No resource use measures should be mandated until Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories have been developed and gained support from the physician stakeholders who treat the majority of patients falling into a particular episode.

CVC’s comments on the CMS Supplemental Episode Groups Posting seek to ensure ongoing access to high-quality, state-of-the-art freestanding centers. CVCs provide an integral service in the overall healthcare continuum. These places of service are an important part of patient access to care and their survival depends on a balanced approach to reimbursement for their services. We hope that our comments highlight our sincere interest in continuing to provide cost-avoiding CVC services that are fairly reimbursed and readily accessible to Medicare patients. We look forward to continuing to work with CMS to guarantee quality cardiovascular services are provided by our centers to every Medicare patient. If you have additional questions regarding these matters and the views of the CVC, please contact Jason McKitrick at (202) 442-3710.