The Society for Vascular Surgery Alternative Payment Model Task Force report on opportunities for value-based reimbursement in care for patients with peripheral artery disease

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ABSTRACT

The Society for Vascular Surgery Alternative Payment Model (APM) Taskforce document explores the drivers and implications for developing objective value-based reimbursement plans for the care of patients with peripheral arterial disease (PAD). The APM is a payment approach that highlights high-quality and cost-efficient care and is a financially incentivized pathway for participation in the Quality Payment Program, which aims to replace the traditional fee-for-service payment method. At present, the participation of vascular specialists in APMs is hampered owing to the absence of dedicated models. The increasing prevalence of PAD diagnosis, technological advances in therapeutic devices, and the increasing cost of care of the affected patients have financial consequences on care delivery models and population health. The document summarizes the existing measurement methods of cost, care processes, and outcomes using payor data, patient-reported outcomes, and registry participation. The document also evaluates the existing challenges in the evaluation of PAD care, including intervention overuse, treatment disparities, varied clinical presentations, and the effects of multiple comorbid conditions on the cost potentially attributable to the vascular interventionalist. Medicare reimbursement data analysis also confirmed the prolonged need for additional healthcare services after vascular interventions. The Society for Vascular Surgery proposes that a PAD APM should provide patients with comprehensive care using a longitudinal approach with integration of multiple key medical and surgical services. It should maintain appropriate access to diagnostic and therapeutic advancements and eliminate unnecessary interventions. It should also decrease the variability in care but must also consider the varying complexity of the presenting PAD conditions. Enhanced quality of care and physician innovation should be rewarded. In addition, provisions should be present within an APM for high-risk patients who carry the risk of exclusion from care because of the naturally associated high costs. Although the document demonstrates clear opportunities for quality improvement and cost savings in PAD care, continued PAD APM development requires the assessment of more granular data for accurate risk adjustment, in addition to largescale testing before public release. Collaboration between payors and physician specialty societies remains key. (J Vasc Surg 2021;73:1404-13.)

Keywords: Alternative payment model; Peripheral arterial disease; Vascular surgery

QUALITY PAYMENT PROGRAM

The Medicare Access and Children's Health Insurance Plan Reauthorization Act (MACRA) was signed into law on April 16, 2015. MACRA is bipartisan legislation that repealed the Sustainable Growth Rate and established the Quality Payment Program (QPP). The QPP requires

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that eligible clinicians who submit claims to the Centers for Medicare and Medicaid Services (CMS) participate in one of two programs: the Merit-based Incentive Payment System (MIPS) or the advanced Alternative Payment Model (APM). MACRA policy mandates that eligible clinicians who do not participate adequately in the QPP will experience financial penalties in their Medicare reimbursements. The requirements for adequate participation in the QPP have increased each year since it was first implemented. Likewise, the proportion of the financial penalty has increased each year from 4% in the first year to 9% in the fourth year and beyond. Providers who participate in the MIPS attain a score based on their reporting in four required domains: quality, improvement activities, promoting interoperability, and cost. The great majority of the quality measures in the QPP have been proposed and maintained by professional organizations, including the Society for Vascular Surgery (SVS). Quality measures can be process measures or outcome measures. The measures are approved by the National Quality Forum and/or the CMS.[1] Improvement activities are activities intended to improve clinical practice or care delivery.[2] Promoting interoperability are requirements that pertain to the electronic health records such as electronic prescribing and providing patients with electronic access to their health information. All available measures can be viewed at the QPP website (available at: https://qpp.cms.gov/).

The final MIPS score is used to determine how the provider's reimbursement will be adjusted. Scores less than the minimum required score will incur a penalty. Scores at or slightly greater than the minimum required score will experience no payment adjustment. Scores significantly greater than the minimum will be rewarded with a positive payment adjustment. Finally, scores greater than a threshold for exceptional performance will be eligible for a portion of the $500 million allocated annually for the first 6 years of MACRA.[3]

The APM is a payment approach that centers on incentive payments for high-quality and cost-efficient care. APMs can apply to a clinical condition, a procedure episode, or population health management. At present, no vascular APMs have been approved. As such, most vascular surgeons who have satisfied the QPP requirement through participation in an APM are a part of a multispecialty accountable care organization (ACO). One of the original ACO models was the Pioneer ACO model, which existed at 32 sites across the United States from 2012 to 2016. The Pioneer ACO models were population-based payment models designed for sharing savings and risk between Medicare and participating providers. Provider incentives were determined by quality improvements and cost reductions.

The current next-generation ACO model builds on the experience derived from the previous ACO model. Typically, the ACO consists of a large hospital system, in addition to several single and multispecialty groups. A board of directors oversees ACO operations. The obligations of the participants include working with the ACO to coordinate the electronic health record interactions, reporting, and enrollment of new patients. The ACO will have the potential for financial benefit or loss determined by performance using quality metrics and the shared savings and loss component. ACO participants would have money at risk if the ACO did not meet financial targets or performed poorly for various clinical measures, most of which will typically be related to primary care and medical therapy. During the first 6 years of QPP, those who successfully participated adequately in an APM received an automatic 5% bonus payment, based on Medicare revenue.

The MACRA law seeks to incentivize providers to satisfy their QPP participation requirements through APMs rather than through MIPS. Starting in 2026, providers who participate adequately in an APM will receive an automatic 0.75% annual fee schedule increase. In contrast, providers who participate in MIPS will only receive a 0.25% annual fee schedule update.

Owing to the relatively small number of vascular surgeons and vascular procedures recognized in the current ACOs, these have not allowed for effective participation in measurable quality and cost improvement strategies. A dedicated vascular APM model might allow vascular specialists to have more direct control on their measured performance, which might result in a fair financial impact.

ARTICLE HIGHLIGHTS

- The advanced Alternative Payment Model (APM) is a pathway for participation in the Centers for Medicare and Medicaid Services Quality Payment Program associated with value-based financial incentives for providers. Commercial insurers, including Medicare Advantage plans, are also interested in value-based payment arrangements
- Evaluation of the current state of peripheral arterial disease (PAD) management revealed potential improvement opportunities in quality, cost, and patient access. Therefore, continued efforts regarding the possible development of value-based reimbursement structures, including the development of a PAD APM, are needed.
- Creation of a PAD APM will require additional risk-adjusted cost and quality analysis at a granular level to link the PAD severity and clinical characteristics of patients with the available billing information.

SVS APM TASKFORCE

In response to MACRA and in anticipation of a trend toward payor emphasis on value-based

payment reform, the SVS convened an APM Taskforce (TF). The TF's charge was to support the ability of vascular surgeons to participate in value-based vascular care that would qualify as an advanced APM under the QPP and, thus, receive the 5% bonus payments and the higher conversion factor update associated with successful participation. A secondary goal was to develop a more in-depth understanding of the methods and implications of bundled payment in vascular surgery. The TF had broad representation across committees with expertise in various aspects of the project, including the Clinical Practice Council, Government Relations Committee, Coding and Reimbursement Committee, and Quality and Performance Measures Committee. Members reviewed the regulations governing APMs and various examples of proposed physician-focused payment models.

After a review of the general Medicare claims data associated with index vascular surgery procedures, the SVS APM TF selected peripheral artery disease (PAD) as an initial clinical condition for review and APM modeling owing to its prevalence, the increasing cost of interventions and care, and the consequent effects on payors and population health.

PAD INTERVENTIONS

PAD is a global health problem that consumes in excess of $20 billion of healthcare expenditure in the United States annually.[4-6] In 2015, the Sage Group (San Francisco, Calif), a research and consulting company, noted that 20 million people in the United States have PAD and estimated that that number would reach 25 million by 2030.[7] Similar prevalence data have been obtained by other studies, in which PAD could be diagnosed by abnormal ankle-brachial index test results in 20% of patients aged >65 years.[8] The Sage Group report also estimated that chronic limb-threatening ischemia (CLTI), the most severe and deadly form of the disease, afflicts 2 to 3.4 million of those with PAD.[7] A separate analysis of the Nationwide Inpatient Sample across 2003 to 2011 revealed a constant rate of CLTI admissions (150/100,000 U.S. population).[9]

PAD is a systemic illness caused by atherosclerosis and is a marker for other forms of cardiovascular disease. A strong correlation has been reported between PAD and coronary artery disease.[10] Mortality from vascular events has been greatest for those with symptomatic PAD and lowest in the absence of PAD.[8]

The Fontaine and Rutherford classification systems (Table) were developed to stratify the severity of disease in patients with PAD.[11,12] The Global Vascular Guidelines, reported in 2019, focused on the definition, evaluation, and management of CLTI and endorsed the SVS threatened limb classification system (wound, ischemia, foot infection [WIfI]).[13] The WIfI classification system uses the wound grade, degree of ischemia, and extent of infection to stage the disease of patients and predict the likelihood of wound healing and limb loss.[14]

Claudication represents the presence of noncritical ischemia of the limb and should primarily be treated with nonoperative measures. The risk of limb loss in patients with claudication is 1% to 2% annually. The initial treatment of patients with claudication, with few exceptions, should be the correction of contributing comorbidities, initiation of a standardized walking exercise program, statin therapy, aspirin therapy, and, possibly, cilostazol. The SVS guidelines have cited the merits of medical management for patients with claudication and documented the risks of overtreatment with interventions.[15]

The generally agreed on indications for intervention for patients with PAD include debilitating claudication after failed medical management and CLTI (pain at rest and/or tissue loss [ie, ulceration, gangrene]). The incidence of limb loss and mortality for patients with CLTI is significantly greater than that for patients with claudication. A recent meta-analysis of patients with untreated CLTI involving 13 studies and 1527 patients showed that the per-patient amputation and mortality rates were ~22% at a median follow-up of 1 year.[16]

Both endovascular and open surgical procedures have been advocated for patients with PAD who require intervention, as defined. Endovascular interventions can be performed using local anesthesia in an outpatient setting. Open surgical procedures have typically resulted in in better long-term patency rates. Hybrid revascularization procedures combine the benefits of endovascular techniques and open surgery. The commonly performed endovascular interventions include angioplasty, stenting, atherectomy, and combinations of therapy. Open surgical procedures include endarterectomy and bypass operations. The disease extent and location will usually determine the choice among the many variations of these endovascular and open surgical procedures. Frequently, the disease will be amenable to either approach. Several studies have compared the outcomes between endovascular and open revascularization, especially in the critical limb ischemia population. The BEST CLI (best endovascular vs best surgical therapy in patients with critical limb ischemia) is a multicenter, randomized, controlled trial that recently completed enrolling patients with CLTI. The study is intended to address questions about major adverse limb event-free survival, amputation-free survival, all-cause mortality, and a range of secondary clinical end points.[17]

Hospital-based hybrid rooms, which combine the advantages of imaging equipment with a standard operating room, have evolved as ideal locations for treating patients with PAD. However, patients with PAD and CLTI and those with severe comorbidities (eg, atherosclerotic cardiovascular disease, chronic obstructive pulmonary disease, renal disease) will require hospitalization for treatment of their PAD and comorbidities.

Table. Fontaine and Rutherford classification systems for chronic peripheral arterial disease (PAD)

Fontaine stage	Rutherford category	Clinical description	Objective criteria
I	0	Asymptomatic	Can complete standard treadmill exercise
IIa	1	Mild claudication	Can complete standard treadmill exercise; ankle pressure after exercise 20 mm Hg lower than value at rest
IIb	2	Moderate claudication	–
	3	Severe claudication	Cannot complete standard treadmill exercise; ankle pressure after exercise < 50 mm Hg
III	4	Ischemic pain at rest	Ankle pressure at rest < 40 mm Hg or toe pressure < 30 mm Hg
IV	5	Minor tissue loss nonhealing ulcer, focal gangrene with diffuse pedal ischemia	Ankle pressure at rest < 60 mm Hg or toe pressure < 40 mm Hg
	6	Major tissue loss extending above transmetatarsal level, functional foot no longer salvageable	Same as category 5

NA, Not applicable.

The office-based laboratory (OBL) and ambulatory surgery center (ASC) models have been increasing in popularity owing to the inherent built-in efficiencies for patients and providers at decreased costs. Both models can streamline the efficiency of the use of equipment, supplies, staff, treatment, recovery, patient flow, and discharge. Cost efficiencies will result from reduced overhead, flexibility, and productivity. These efficiencies and cost-savings also apply to patients with PAD, especially when using endovascular procedures. Physician-owned OBLs and ASCs offer the obvious advantages of incentivizing physicians to control the process and costs during the treatment phase.

All patients with PAD require optimization of medical management as outlined in the SVS guidelines.[15] Regardless of the treatment modality, long-term surveillance has been recommended for almost all patients undergoing an intervention and for selected patients receiving medical treatment without surgical intervention.

Limb salvage programs have been proposed to decrease the incidence of amputations in patients with CLTI.[18] These programs specialize in treating CLTI to heal wounds and prevent limb loss. The components of these programs include a multidisciplinary team of specialists, protocol-driven care, outcomes monitoring and reporting, and the determination of methods of improvement. The importance of a team approach in the treatment of PAD and reduction of amputations has been consistently reproduced.[19-21] The accreditation criteria for the creation of comprehensive vascular centers of excellence are currently in development. It is expected that these criteria will include further emphasis on guideline compliance and quality monitoring.

Because of the frequent presence of severe comorbid conditions, PAD treatment must be individualized according to many factors, including the severity of the patient's comorbidities, stage of limb ischemia, limb salvage potential, and quality of life expectations. The value proposition of the intimate involvement of vascular surgeons in PAD care is their extensive training in lower extremity vascular disease, the clinical understanding of the effects of different PAD presentations on limb prognosis, the knowledge of when interventions can be appropriately offered, and the ability to expertly perform a wide range of procedures, including endovascular, open surgical, and hybrid revascularization procedures.

MEASUREMENT OF QUALITY IN PAD CARE DELIVERY

Because the design of an APM requires objective measurements of quality and cost, the SVS APM TF reviewed the tools available to measure the quality regarding PAD therapy. As in all healthcare fields, the quality and cost of clinical care provided to patients with PAD are variable. Measurements of quality can be difficult owing to the uneven clinical needs, which are determined by the wide spectrum of presenting symptoms of those with lower extremity ischemia, the severity of comorbid conditions, and the variable and challenging socioeconomic background. Nevertheless, quality and cost evaluations are central elements to APM development. Several reporting tools have become available to the public, payors, and providers. However, the data remain far from perfect owing to the aggregate nature, lack of risk adjustment, and the frequent inability to link quality and cost because patients often use multiple hospital systems during their illnesses.

Public, nonprofit, and for-profit hospital rating systems have generated increased attention and scrutiny, owing to their easy accessibility by the general public via the Internet. The main criticisms of these programs has been the lack of validation mechanisms and the limitation of measurement to the index hospitalization alone. Examples of these consumer-oriented programs that pertain to PAD care include Hospital Compare and Healthgrades, both using Medicare data. Hospital Compare also includes data from the American College of Surgeons National Surgical Quality Improvement Program, and Healthgrades uses consumer feedback.[22]

To facilitate quality benchmarking of PAD healthcare delivery, process and outcome measures are available for use in an APM. Process measurement aims to eliminate treatment disparity by evaluating whether standard care is being offered. Some process measures include ankle-brachial index measurement, optimal medical therapy initiation, smoking cessation, and measurement of diabetes markers.[23] Outcome measures, in contrast, evaluate the treatment results. For patients with PAD, meaningful outcomes include amputation rates, mortality rates, hospitalization duration, and readmission rates. Although these outcome measures provide powerful metrics, they might not reflect the adequacy of care delivered, especially if evaluated in isolation.

Although the QPP has dedicated a large portion of the MIPS-related payment formula to quality measures, PAD-specific quality measurements have not been clearly delineated. PAD care can be graded using other, more general, CMS measures such as quality measure 438 (statin therapy for the prevention and treatment of cardiovascular disease), quality measure 236 (controlling high blood pressure), and quality measure 357 (surgical site infection). New quality measures can be proposed to the CMS for approval every year. These are evaluated according to the importance, measurability, and existing disparity. Medical organizations, such as the SVS, participate in this process on behalf of their members.[1]

Cost measures are more sophisticated than quality measures owing to the variability of the treatment modalities, patient characteristics, and demographic factors. Because the cost disparities in PAD care are very evident, a critical limb ischemia revascularization cost measure was adopted by the CMS in 2017 to be used in the MIPS program. Using this measure, the cost reflects the payment by the payors. The measurement is, therefore, based purely on the reimbursement by Medicare. The cost calculation is triggered by the revascularization intervention and holds the provider accountable for costs extending for 90 days postoperatively. The measurement algorithm, including attributing some of the subsequent healthcare costs to the index vascular procedure, was designed by a CMS contractor with involvement of physician representatives. These costs include clinical services such as imaging studies, readmission, and home health services.[24,25] Because APMs aim to decrease payment variations, provider reimbursement will rely heavily on the financial component of their delivered care within the APM. Therefore, the cost measurements in any proposed PAD APM must be accurate and adjusted for risk to maintain fairness.

Patient-reported outcomes (PROs) refer to the patients' perceived disease burden on quality of life. PROs are obtained through questionnaires completed only by patients to report the patients' evaluation of their psychological and physical impairments after medical or surgical interventions. PROs can also be completed by interview if the responses are those of the patient and not a clinical interpretation by the interviewer. Several PRO measurement tools are available that have been validated for PAD. Some tools measure the general quality of life perceptions, including as the Medical Outcomes Study short-form 36-item health survey and Medical Outcomes Study short-form 12-item health survey.[26] Others measure the functional PAD-related quality of life perceptions such as VascuQoL (Vascular Quality of Life), WIQ (Walking Impairment Questionnaire), and PAQ (Peripheral Artery Questionnaire).[26-28]

PROs have become increasingly important in the drug and device approval process. In addition, a recent report by the Government Accountability Office opined that PROs could be the best method to define risk adjustment payments for Medicare advantage plans.

OVERUSE AND UNDERUSE IN PAD CARE

The underlying concept of the APMs is to maximize value in healthcare. Therefore, APMs could potentially be effective in the PAD field owing to the high prevalence, increasing costs, and variable treatment options. Furthermore, the healthcare-related expenditures for patients with PAD is almost three times the average rate of expenditure for adults in the United States ($12,702 vs $4433).[29] The combination of the high prevalence and increased expense has resulted in an annual estimated cost >$21 billion dollars.[6] Thus, the potential for improvement in value is related to the wide variation in the accepted treatment modalities, which ranges from medical treatment for patients with claudication to bypass for patients with CLTI.

Some recent studies have demonstrated the potential for overusage of imaging studies and intervention for patients with early or mild symptoms of claudication.[30,31] In addition to the increased healthcare expenditures, patients undergoing intervention for claudication might have a greater risk of complications.[32,33] The concern over the increased risk of complications and cost has led the SVS to emphasize the importance of risk factor modification, medical management, and physical exercise for patients with claudication in its practice guidelines.[15] The assumption of the overuse of interventions for PAD has also been reported in the mainstream media.[34] The disproportionate reimbursement for

outpatient procedures such as atherectomy has been postulated as a potential contributing factor for such growth in the number of procedures.[35-37] Given the concern for the overuse of interventions for patients with nondisabling claudication or asymptomatic PAD, it is important that appropriateness criteria be included in the PAD APM. The use of appropriate use criteria (AUC) will give clinicians and payors guidelines by which to determine whether an intervention meets the accepted clinical indications. Although some appropriateness criteria have been created by other medical societies, we found that they do not address the overuse phenomenon, including overly aggressive interventional treatment of patients with claudication.[38] Therefore, comprehensive PAD AUC are currently being developed by the SVS to guide appropriate care, in particular, prioritizing medical management over interventions for minimally symptomatic patients.

Overuse has not been limited to interventional procedures. It has also included unnecessary diagnostic imaging tests for patients who should receive medical therapy alone. Comprehensive AUC should also address this issue, along the same lines as the Protecting Access to Medicare Act (PAMA) of 2014, which established a new program to increase the rate of AUC for advanced diagnostic imaging services provided to Medicare beneficiaries.

In addition to the standardization of practices, a robust APM should provide a mechanism for disease severity documentation, using objective methods such as the WIfI scoring system and PROs. These methods can facilitate cost-risk adjustment. One of the primary challenges encountered in the cost assessment of current PAD care can be attributed to the difficulty in determining the severity of the preoperative condition solely using the billing codes. At present, generic billing codes have been used most often, such as I73.9 in the International Classification of Diseases, 10th revision, which indicates unspecified peripheral vascular disease. The large degree of heterogeneity within the unspecified billing code has made it difficult to differentiate the severity of PAD when using an administrative database. Without more specificity regarding the underlying disease process, it becomes difficult to pinpoint the value improvement opportunities. It is, therefore, important to incorporate within the APM accurate medical record documentation to indicate the presenting symptoms along the PAD severity spectrum of asymptomatic disease to CLTI.

Unlike the concern for the overuse of interventions, evidence has also shown the underuse of guideline-recommended medical therapies for patients with PAD.[39] In a recent study, only one third of patients with PAD were receiving antiplatelet or statin medication and only 20% of patients had received lifestyle counseling.[40] In addition to the concern regarding the low rate of medical therapy usage, significant geographic variations were found in the perioperative and long-term outcomes for patients with PAD, indicating the potential for improved value through periprocedural standardization.[41] APMs should recognize the difference in regional rates and encourage outreach to standardize the care of patients with PAD.

PRELIMINARY ANALYSIS OF PAD CMS CLAIMS DATA

To understand the costs associated with PAD care and the potential for savings under an APM, the SVS APM TF performed an analysis of patients undergoing surgical treatment of PAD. The financial analysis used the CMS claims data and included Medicare fee-for-service beneficiaries, including dual eligible beneficiaries, undergoing nonemergent procedures from a list of Healthcare Common Procedure Coding System (HCPCS) procedure codes related to lower extremity revascularization procedures.[42] Because these procedures can be performed for a variety of conditions, all inpatients procedures were included if they mapped to one of three diagnosis-related group (DRG) families consistent with the PAD patient population (codes 252-254, 268-269, and 270-272). All patients undergoing outpatient or office-based procedures were included if the claims data were inclusive of the HCPCS procedure codes (Supplementary Table I, online only).

The analysis retrieved all claims data starting 90 days before the index procedure through 90 days after the index claim (fiscal year 2016 through the third quarter of 2017). We excluded patients from the final analysis if they had experienced a PAD event of interest in the proceeding 30 days before the index procedure. Patients with end-stage renal disease were also excluded owing to the potential overlap with other CMS APMs.

The claims were reviewed for all postdischarge events (PDEs) occurring ≤90 days after the index procedure. PDEs included all return visits to the emergency department, observation stays, inpatient admissions, and deaths within 90 days of the index procedure. Postprocedural admissions are not uncommon for this patient population, with a significant proportion admitted for subsequent staged or expected procedures. These cases were deemed postprocedure events (PDEs) and included in the Medicare cost for the index procedure.

In the 123,186 cases included in the final analysis, a shift from the inpatient to outpatient setting was noted, with 82% of cases performed in the outpatient or office-based setting. The Medicare-allowed payment for all index cases showed that inpatient procedures were costlier than were outpatient and office-based procedures. The average Medicare payment per index case for DRG other vascular procedures (codes 252-254) was $18,755, for DRG aortic and heart assist procedures (codes 268, 269) was $34,600, and for DRG aortic and heart assist procedures

(codes 270-272) was $25,245. Outpatient facility interventions had an average Medicare cost of $11,458 and office-based index procedures an average cost of $11,533.

Postacute care services, including rehabilitation, skilled nursing facility, and home health aides, were commonly used, with inpatient index procedures requiring more services than outpatient or office-based cases. Postacute care service usage exceeded 50% after inpatient procedures compared with 15% after outpatient interventions. PDEs at 30 and 90 days were similar in incidence across all sites of service and had similar cost characteristics. PDEs represented greater expenditure than did the index procedure in some situations. Postintervention outpatient and office-based services resulted in higher costs when the index procedures had been performed in the outpatient and office-based settings (Supplementary Table II, online only).

Our claims data analysis revealed several limitations in using this method for APM creation. Given the complexity of coding, a fail-safe manner to identify the vascular patient population is challenging. Initial attempts to base the analysis on diagnosis codes instead of procedure codes proved suboptimal because several disciplines use similar codes that do not reflect any attempts at revascularization. Thus, it was decided to proceed with procedural coding as defined by the predetermined HCPCS codes. The use of HCPCS codes has its own limitations because it might not be inclusive of all patients.

The Medicare expenditures for inpatient care were all inclusive and did not stratify by the type of facility. This does not allow for the determination and impact of indirect medical expenses, as determined by resident staff support, or outlier payments and disproportionate share hospital payments, all of which can significantly affect Medicare expenditure. Although the postacute care services were a significant expenditure, skilled nursing facility usage before the index procedure was not evaluated. Therefore, we are uncertain of the proportion of postacute care services that were new vs a continuation of baseline care. PDEs were common given this patient population and in line with previously reported studies. The CMS has used different methods to reduce and even penalize for these events. In this analysis, we attempted to incorporate this process as related to previous CMS guidelines but the results were not definitive. Another limitation for PDE incidence and cost determination is the inability to identify purposely staged procedures. We were also unable to differentiate PDEs in the same or contralateral limb.

Addressing these limitations will be essential in the creation of a PAD APM. Although this claims-based evaluation revealed sizeable additional healthcare expenditure beyond the index PAD procedures, risk adjustment using more accurate clinical data linkage is required to create a fair APM that will account for the variable costs of PAD care in variable clinical presentations ranging from claudication to gangrene.

COST MINIMIZATION AND QUALITY IMPROVEMENT STRATEGIES IN PAD CARE

A key component of a PAD-based APM is to properly select the trigger event that enrolls the patient into the APM and the period before and after enrollment that defines the PAD APM episode. A second critical component of any PAD-based APM is to develop an understanding of the actual cost structure to apply cost minimization strategies that will maximize the benefits to the APM-defined episode. Finally, the broad application of societal guidelines on PAD and decision support tools that use predictive indexes and modeling within the electronic medical record can increase confidence in decision making for all providers and furnish well-sourced information.

PAD is a systemic disease that is accompanied by other conditions such as hypertension, hyperlipidemia, diabetes, coronary artery disease, and tobacco use. Therefore, a focused procedural APM model is unlikely to be a good template for PAD.[43] A blend between the procedural templates and the population APM templates, such as the ACO and oncology APMs, might be more suitable, but additional analysis is needed. Management of comorbid conditions should be heavily weighted in the APM because that could lead to better disease management at a population level. Screening for current disease states at the primary care level is equally important. The adoption of preventive strategies and enhanced medical therapies for systemic atherosclerosis can increase upfront costs owing to the need for nurse navigators, health coaches, vascular rehabilitation centers, and smoking cessation programs. These costs will eventually be offset because the intensity of interventional therapies will be reduced but would require upfront investment in the setting of cost control expectations.

The PAD APM could promote cross-disciplinary efforts to ensure uniform approaches to all aspects of the disease. Advancing an APM design limited to the vascular interventionalist might not be successful in controlling perioperative health care costs that do not directly result from the PAD intervention. Therefore, APMs will need to recruit other important specialty stakeholders such as podiatry, cardiology, interventional radiology, primary care, endocrinology, and ancillary care providers (ie, home health agencies, rehabilitation centers, wound centers). A widely perceived uniform approach will reduce leakage from integrated systems and vested physician groups and, thus, increase compliance.

Within a PAD APM, surgeons and interventionalists should be empowered to control the costs of their interventions with consideration for the optimal therapeutic needs of their patients. This could include triaging patients to suitable sites of service for percutaneous or open interventions. Many endovascular procedures are

suitable for placement in office-based procedure laboratories and ambulatory surgery centers, allowing for more cost-efficient care, and are appropriate for patients who do not require hospitalization. However, some patients will require hospitalization. Maximal use of outpatient preparation and enhanced recovery pathways after surgery should be implemented to allow for cost containment and enhanced quality. A well-designed PAD APM should recognize the spectrum of clinical needs and variable costs based on the PAD condition stage. The APM should promote appropriate documentation such as the use of the SVS WIfI classification system to help stage patients with critical limb ischemia as they progress through treatment.[14] Similarly, the appropriate use of primary amputation therapy and enhanced use of palliative care concepts should be encouraged for selected patients for whom limb salvage interventions have a greater degree of risk than benefit. A three-step integrated approach has been proposed in the SVS CLTI guidelines to include patient risk estimation, limb staging, and the anatomic pattern of disease. This useful paradigm was designed to improve decision-making and cost-effectiveness.[13]

Innovation aiming at value improvement should be encouraged and continuously evaluated in a PAD APM. The use of telemedicine and remote real-time monitoring might decrease the incidence of readmissions and reintervention; however, these lack a universally accepted process and reimbursement for clinicians and medical centers. The efficiency of inpatient PAD care can also be improved by more careful attention to discharge disposition tracking, postoperative lengths of stay, clinical documentation, and continuous team education. PAD care redesign initiatives incorporating these items have successfully improved hospital costs without negatively affecting the quality of care.[44]

Quality reporting using a recognized PAD registry should allow for continuous outcome tracking within an APM. Participation in quality improvement activities, longitudinal outcome monitoring, and feedback reporting are essential aspects of value-based care.

PAD APM ADVANTAGES FOR PARTICIPANTS

APM models offer advantages to patients within the defined APM episode. APMs provide the prospect of consistent all-encompassing PAD care driven by a longitudinal approach with horizontal integration of multiple key services with an emphasis on disease screening and prevention and evidence-based medical and surgical interventions. This could lead to a multidisciplinary approach to a complex patient population with less variation in care and superior outcomes and allow for the development of advanced techniques and technology supported by a rigorous systematic approach focused on improved clinical outcomes, patient satisfaction, and cost containment. The PAD APM could benefit the providers by increasing their integration in the care of patients with PAD. APMs decrease the variation in care and result in greater uniformity of care across the continuum. Greater multidisciplinary and cross-disciplinary interactions result in more effective and more coherent care.

For payors, the decreased variation in care within the APM allows for better cost management. The additional data on quality and outcomes will allow for more efficient improvement processes that can affect costs. Although additional payments are needed to reward quality, the total cost of care is reduced, with greater emphasis on primary and secondary prevention measures. The elimination of prior authorization and fee-for-service billing processing will decrease the administrative burden.

For the healthcare system, the introduction of an APM that emphasizes quality and evidence-based care will improve the image of the participating hospitals. APM participation can also improve the interactions between multiple specialties within the healthcare system as emphasis moves toward improved quality rather than procedure volume.

PAD APM RISKS FOR PARTICIPANTS

Although much has been advocated in terms of benefits, all APM models do present a variable risk environment to the participants within the APM-defined episode. Patients have the risk of decreased access to care that can manifest as longer wait times and travel distances owing to centralization of care and the development of narrower networks. High-risk patients risk exclusion from the APM and diversion to alternative and, perhaps, inferior care. Decreased provider choice can lead to patient dissatisfaction and leakage from the APM ecosystem, especially if patients seek interventions not recommended within the APM.

Providers participating in the APM face an upside risk and a downside risk regarding reimbursements. Positive outcomes and adherence to guidelines should mitigate these issues; however, the goals set by the APM could be difficult to achieve in some environments in which healthcare systems are less integrated. The decision to participate in the APM could be derived from historical data that might be inaccurate or incomplete. Misunderstandings regarding the continuum of care, poor preparation of the providers, and/or inaccurate estimates will exaggerate the downside and blunt the upside risks for participants. Similarly, changes in CMS policy can influence the longevity of any APM. Risk tolerance will need to be defined before APM participation because investments in personnel, telemedicine, quality registries, and financial data analysts could be required. The financial penalties will affect the providers' revenue stream. Because APMs emphasize guideline implementation and intervention appropriateness, some providers will risk exclusion from APM participation for nonadherence.

Also, the volume-to-quality relationship for advanced PAD interventions could redirect patients from some centers and could lead to skill exclusions.

Healthcare institutions could face changes in the profile of interventions, with more focus on outpatient medical therapy, a greater emphasis on OBLs and ASCs, and reduced usage of inpatient beds. This change in practice will result in a change in payment profiles and potential decreases in DRG mix, case mix indexes, and service line profitability. Therefore, facilities will need to develop adaptive and supportive strategies in a PAD APM.

CONCLUSIONS

Quality improvement and cost-saving opportunities in PAD care are vast owing to the prevalence of the disease, costly treatment modalities, and varied treatment approaches. In addition, delayed diagnosis and poor access to care have been recognized as real problems that increase the risks of limb loss in some segments of society. The complexities of PAD conditions and subsequent cost assessments were demonstrated in the SVS APM TF Medicare claims data analysis. Although general conclusions could be made from the analyzed data, detailed APM design recommendations could not be made owing to the imprecision of the used diagnosis codes, the absence of a limb risk stratification mechanism within the administrative data source, and the difficulties in attribution of the postprocedural events. An advanced alternative payment model focused on PAD treatment has the potential to curb spending by reducing unnecessary interventions, postoperative hospitalization, and complications. However, continued development of the APM design for PAD requires significant resources to quantify the benefits using granular data and larger scale testing before public release.

AUTHOR CONTRIBUTIONS

Conception and design: YD, KW, RZ
Analysis and interpretation: YD, KW, FA, JA, PR, MT, JH, MD, WS, DM, YL, MS, RZ
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Supplementary Table I (online only). Healthcare Common Procedure Coding System (*HCPCS*) code distribution across inpatient diagnosis-related group (DRG) groups, outpatient facilities, and office-based laboratories

	Inpatient, %				
HCPCS code	Other vascular procedures	Aortic and heart assist procedures	Other major vascular procedures	Outpatient facility procedures, %	Office-based procedures, %
34201: Removal of artery clot	1.3	7.6	4.2	0.1	NC
35302: Rechanneling of artery	4.3	5.3	5.8	0.0	–
35303: Rechanneling of artery	0.9	NC	0.4	NC	–
35304: Rechanneling of artery	0.2	NC	NC	NC	–
35305: Rechanneling of artery	NC	–	NC	NC	–
35331: Rechanneling of artery	–	2.0	NC	–	–
35361: Rechanneling of artery	NC	NC	NC	–	–
35371: Rechanneling of artery	14.4	37.6	9.8	0.0	–
35372: Rechanneling of artery	4.4	5.2	5.9	NC	–
35537: Art byp grft aortoiliac	NC	NC	–	–	–
35538: Art byp grft aortobi-iliac	NC	NC	NC	–	–
35539: Art byp grft aortofemoral	NC	–	NC	–	–
35540: Art byp grft aortbifemoral	NC	NC	0.5	–	–
35556: Art byp grft fem-popliteal	9.0	NC	2.6	NC	–
35566: Art byp fem-ant-post tib/peroneal	6.8	NC	2.4	NC	–
35570: Art byp tibial-tib/peroneal	0.1	–	NC	–	–
35571: Art byp pop-tibl-peroneall-other	2.1	NC	0.3	NC	–
35583: Vein byp grft fem-popliteal	2.7	–	1.0	–	NC
35585: Vein byp fem-tibl peroneal	2.2	–	0.7	–	–
35587: Vein byp pop-tibl peroneal	0.2	–	NC	–	–
35637: Art byp aortoiliac	NC	1.1	0.4	–	–
35638: Art byp aortobi-iliac	NC	4.8	1.7	–	–
35646: Art byp aortobifemoral	0.2	7	11.6	–	–
35647: Art byp aortofemoral	NC	1.7	1.4	–	–
35656: Art byp femoral-popliteal	16.4	1.5	5.4	NC	–
35666: Art byp fem-ant-post tib/peroneal	3.9	NC	1.4	NC	–
35671: Art byp pop-tibl-peroneal-other	0.3	–	NC	–	–
37224: Fem/popl revas w/tla	8.0	3.6	5.0	22.8	5.9
37225: Fem/popl revas w/ather	2.6	NC	10.9	22.1	40.7
37226: Fem/popl revasc w/stent	7.0	3.8	7.1	20.2	5.9
37227: Fem/popl revasc stnt & ather	1.8	NC	7.1	9.5	27.2
37228: Tib/per revasc w/tla	8.0	NC	4.4	13.9	4.3
37229: Tib/per revasc w/ather	1.7	–	7.8	8.9	14.5
37230: Tib/per revasc w/stent	1.0	–	0.6	1.8	0.2
37231: Tib/per revasc stent & ather	0.3	–	1.0	0.6	1.3

ant, Anterior; *Art,* arterial; *ather,* atherectomy; *byp,* bypass; *fem,* femoral; *grft,* graft; *NC,* not calculated because index case count was <11; *per,* peroneal; *pop, popl,* popliteal; *post,* posterior; *revasc,* revascularization; *stnt,* stent; *tib, tibl,* tibial; *tla,* transluminal angioplasty; *w/,* with.

Supplementary Table II (online only). Frequency of postdischarge events[a] and noninpatient vascular procedures during the 30-, 60-, and 90-day periods after discharge from index revascularization interventions

	Inpatient				
Episode group	Other vascular procedures	Aortic and heart assist procedures	Other major vascular procedures	Outpatient facility	Office-based
Cases	17,405	977	4295	63,572	36,931
Cases with ≥1 PDE					
30-Day	5289 (30.4)	232 (31.1)	1297 (30.2)	18,796 (29.6)	9359 (25.3)
60-Day	7380 (42.4)	324 (33.2)	1757 (40.9)	26,700 (42.0)	13,443 (36.4)
90-Day	8735 (50.2)	380 (38.9)	2072 (48.2)	31,265 (49.2)	15,979 (43.4)
Noninpatient vascular procedures					
30-Day	1899 (10.9)	24 (2.5)	348 (8.1)	12,471 (19.6)	5812 (15.7)
90-Day	4123 (23.7)	102 (10.4)	896 (20.9)	21,844 (34.4)	10,160 (27.5)

PDE, Postdischarge event.
Data presented as number of index cases with the event (%).
[a]Emergency department visits, observation stays, inpatient readmissions, and inpatient reintervention.