A Policy Approach to Address Appropriate Management of Lower Extremity Peripheral Artery Disease within Louisiana Medicaid

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Background

- Lower extremity peripheral artery disease (LE-PAD) is a vascular disorder caused by atherosclerotic narrowing or blockage of blood vessels within the legs
- LE-PAD affects over 8.5 million Americans every year and is strongly associated with modifiable risk factors such as smoking and obesity
- Intermittent claudication (IC), pain while walking, is a common presenting symptom of LE-PAD
- Endovascular revascularization (ER) is a surgical procedure commonly used to treat LE-PAD
- Multiple national and international guidelines call into question the utility and cost-effectiveness of ER as a first-line therapy for IC and recommend prioritizing conservative management prior to surgical intervention
- Policy does not exist within Louisiana Medicaid to delineate appropriate use criteria for ER

Description

- The goal of our project was to develop a develop a step-wise process that allowed us to identify low-value care targets, engage with stakeholders, and to implement effective policy (Figure 1 and Table 1)
- Through this process we identified ER for treatment of IC as a potential target. Through thorough literature review, we determined that ER has a propensity for overuse in patients with IC when compared to conservative therapies.[1-3]
- Multiple large RCTs have been performed that demonstrate smoking cessation, supervised exercise therapy (SET), and guideline-directed medication therapy (GDMT) provide similar outcomes to ER. National and international guidelines validate these findings with high grade recommendations. Despite this, evidence suggests that EC is commonly performed prior to maximization of these treatments. This improper prioritization can lead to increased morbidity, mortality, and significantly increased spending.[4-7]
- To understand the impact of ER on the Louisiana Medicaid population, we utilized Louisiana Medicaid claims data. We found that in 2019 alone, ER accounted for $7 million in Medicaid spending between 1900 claims. Of those claims, nearly 50% were performed on patients with a primary diagnosis code of IC. Concurrently, over the last three years, a total of 12 supervised exercise therapy claims were filed for patients with LE-PAD. Within Louisiana Medicaid there was no policy available to dictate appropriate use criteria for this procedure and the evidence suggested that one was needed.
- As part of our project, we developed the Low Value Procedure Index as a way to systematically define our target and then delineate the need for policy adjustment. Using this tool, we were able to construct a detailed evidence brief containing the information we had found. The evidence brief was evaluated my many parties involved in ER and policy decisions, including prominent vascular surgeons and the leaders of local Managed Care Organizations (MCO).
- Our policy recommendation was finally developed based on literature evidence, clinical guidelines[6-8], existing policy, and feedback from stakeholders.

Process

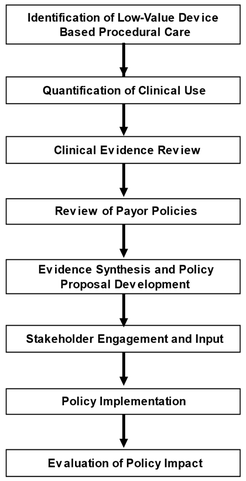

Figure. Flow Diagram of Policymaking and Evaluation Process

Low Value Procedure Index	
Metric	Details and Methods of Quantification
Number of patients affected	Sum of claim recipients (e.g., Medicaid beneficiaries) and number of procedures (as some patients may receive the same low-value procedure multiple times) for whom professional fees were charged in a given year. (Source: claims data)
Cost of low-value device-based procedure	Sum of calendar (or fiscal) year professional fee reimbursement. If possible, facility fees should also be included or estimated. (Source: claims data)
Downstream cascade from low-value device use	Estimated downstream harms and costs. Examples include follow-up outpatient visits or hospitalization days due to complications. (Sources: peer-reviewed literature and claims data)
Severity of adverse events	Low-value procedure use often causes adverse events and devices may be the subject of FDA notifications or recalls because of safety-related concerns. The most severe complications include serious injuries or death. (Sources: peer-reviewed literature, FDA Safety Communications and recalls, FDA Manufacturer and User Facility Device Experience Database)
Frequency of adverse events	Proportion of patients who suffer adverse events associated with device use. (Sources: peer-reviewed literature and claims data)
Quality of evidence showing no effectiveness	Strength of published peer-reviewed evidence demonstrating the device-based procedure is low-value and/or absence of evidence showing benefit. (Sources: clinical practice guidelines and other evidence sources, including peer-reviewed literature)
Ease of policy implementation	Ease of implementing a policy that can distinguish low-value from high-value use.
Urgency of De-implementation	Time-sensitivity of needed policy change, primarily if low-value utilization is increasing with emerging or known harms that are common and/or severe.
Additional policy considerations	These may include meeting state and/or federal legislative requirements, the potential consequences of inaction or action, stakeholder interest in policy changes, anticipated resistance to policy changes and likelihood of surmounting them, and action of other policymakers (who may be implementing criteria to reduce utilization).
Health equity	Policy to reduce low-value use has potential to reduce health disparities.

Policy

Define significant peripheral artery disease

- Moderate to severe ischemic peripheral artery disease with ankle-brachial index (ABI) ≤0.69, OR
- Stenosis in the aortoiliac artery, femoropopliteal artery, or both arteries, with a severity of stenosis greater than or equal to 70% by imaging studies

Delineate necessary conservative management

- 12 weeks of at least 3 times per week at 30 minutes each of either SET or a directed exercise program
- 6 months of optimal pharmacologic therapy including antiplatelet therapy, statin therapy, Cilostazol, and antihypertensive agents with blood pressure goals
- Documented attempt at smoking cessation with utilization of behavioral counseling or pharmacological therapy if necessary

Unproven and not medically necessary cases

- Isolated infra-popliteal disease
- To prevent progression of claudication to chronic limb-threatening ischemia
- Individual is asymptomatic
- Treatment of a non-viable limb

Discussion

- Our policy recommendations were developed in a step-wise process that allowed us to account for many of the different factors that affect policy outcomes
- Our policy defined the appropriate use cases for ER, laid out requirements to perform maximal conservative treatment prior to undergoing ER, and prohibited against improper use cases of ER.
- Our policy was designed to promote good clinical practice without unnecessarily burdening the healthcare system with insurmountable barriers

Future Steps

- Utilizing this process we can identify and address other procedures both within Louisiana Medicaid and in other systems.
- The impact of this policy will need to be evaluated to determine the degree of adherence, effect on cardiovascular outcomes, progression of patients to more severe forms of LE-PAD, and cost savings to Louisiana Medicaid.

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