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Perspective

A Policy Approach to Reducing Low-Value Device-Based Procedure Use

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Policy Points:

- Low-value care is common in clinical practice, leading to patient harm and wasted spending. Much of this low-value care stems from the use of medical device-based procedures.
- We describe here a novel academic-policymaker collaboration in which evidence-based clinical coverage for device-based procedures is implemented through prior authorization-based policies for Louisiana's Medicaid beneficiary population.
- This process involves eight steps: 1) identifying low-value medical device-based procedures based on clinical evidence review, 2) quantifying utilization and reimbursement, 3) reviewing clinical coverage policies to identify opportunities to align coverage with evidence, 4) using a low-value device selection index, 5) developing an evidence synthesis and policy proposal, 6) stakeholder engagement and input, 7) policy implementation, and 8) policy evaluation. This strategy holds significant potential to reduce low-value device-based care.

Keywords: Low-value care, Prior authorization, Medical devices.

IDEALLY, MEDICAL CARE IS BASED ON DIAGNOSTICS and treatments for health conditions that have evidence that their benefits outweigh any potential harms. These considerations would

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be clearly communicated to patients prior to decision-making and care would lead to better quality of life and longer lives.

In actuality, health care is rife with low-value care.[1–3] Patients receive treatments that do not improve clinical outcomes,[4] which can lead to physical, psychological, social, financial, and treatment burden-related harms, as well as overall dissatisfaction with health care.[5] Overtreatment or low-value care costs the United States health care system a significant sum, likely tens of billions of dollars annually.[6]

Role of Device-Based Procedures in Low-Value Care

Medical devices that do not benefit patients represent low-value care and optimizing utilization of device-based procedures represents an underappreciated—but crucial—opportunity to improve the value and quality of care. Many medical devices involve an invasive procedure or even implantation, yet often enter the market without showing clinical outcomes benefit.[7–9] Furthermore, few devices are tested against an active or placebo control.[10,11] Removal of implanted devices when they fail or are recalled can be hazardous or impossible[12] resulting in ongoing risk and anxiety for patients.

Newly approved medical devices often lead to increases in health care expenditures[13] for several reasons. First, device-based procedures often receive higher reimbursement compared with alternatives, such as medical management.[14] For example, although medical therapy has been shown to be equivalent in preventing death and myocardial infarction to percutaneous coronary intervention (PCI) for patients with stable coronary artery disease, PCI adds at least $10,000 to managing this condition and is not cost-effective compared to medical therapy.[15] Second, there may be enthusiasm for new technologies ahead of evidence of benefit, which transmits to patients and the media, and is fueled by recent increases in medical marketing,[16] as well as continuing medical education and hype,[17] leading to rapid adoption.[18] Third, like all health care, medical device prices in the United States are multiples higher than the same devices in other countries.[13] Fourth, no federal agency regulates the practice of medicine and physicians are permitted to use devices for unapproved or unstudied indications.[19] Fifth, devices may be used in patient populations who were not studied in trials, including those with many comorbidities or competing risks.

Current State of Policy Efforts to Reduce Low-Value Care

Many important efforts seek to reduce and de-implement low-value care, including for novel technologies.[3,20,21] These efforts include initiatives to promote shared decision-making,[22] physician incentives and education,[23] Choosing Wisely lists of low-value care,[20] and health care system incentives.

A driver of low-value care is a fee-for-service-based delivery system,[24] where the provision of services leads to greater reimbursement. Strategies to replace fee-for-service with value-based payment, such as global hospital budgets or bundled payment have demonstrated limited success. Accountable care organizations have demonstrated some reductions in low value care,[25] particularly cardiovascular and imaging services that may be overused.[26] Conversely, Maryland's use of global hospital budgets[27] and bundled payments were not found to improve quality of care. While bundled payments have demonstrated cost reductions for some procedures (e.g., lower-extremity joint replacement), they have not reduced costs for other procedures (e.g., spinal fusion and revision joint arthroplasty)[28] and have been associated with increased volume of procedures of questionable appropriateness.[29] Across-the-board payment cuts may control spending, but these cuts are equally likely to reduce high- and low-value care.[30] Requiring greater patient cost sharing, such as high deductible health plans, is also a blunt instrument that reduces both low- and high-value care.[31] Overall, of 54 models tested over the past decade by the Center for Medicare and Medicaid Innovation, only five were shown to reduce costs.[32] Most importantly, even in value-based care arrangements, physician compensation is determined primarily by volume-based compensation.[33] This means robust clinical coverage criteria are still of fundamental importance to ensuring evidence-based care. Overall, there remains an urgent need for further progress in developing strategies to lower cost and improve quality.[34]

By contrast, internationally, health technology assessment agencies assess the safety, effectiveness, and value of specific technologies to inform coverage policy. Prior studies have demonstrated that coverage processes in the United States are often significantly more lax and, thus, more therapies are available in the United States—including some that have no clinical benefits.[35] Internationally, nonpayment of a given health service that had previously been covered has been associated with a reduction in low-value care.[36] Similarly, a New York state policy

that denied reimbursement for inappropriate PCIs was associated with reductions in this procedure.[37]

A Path Forward

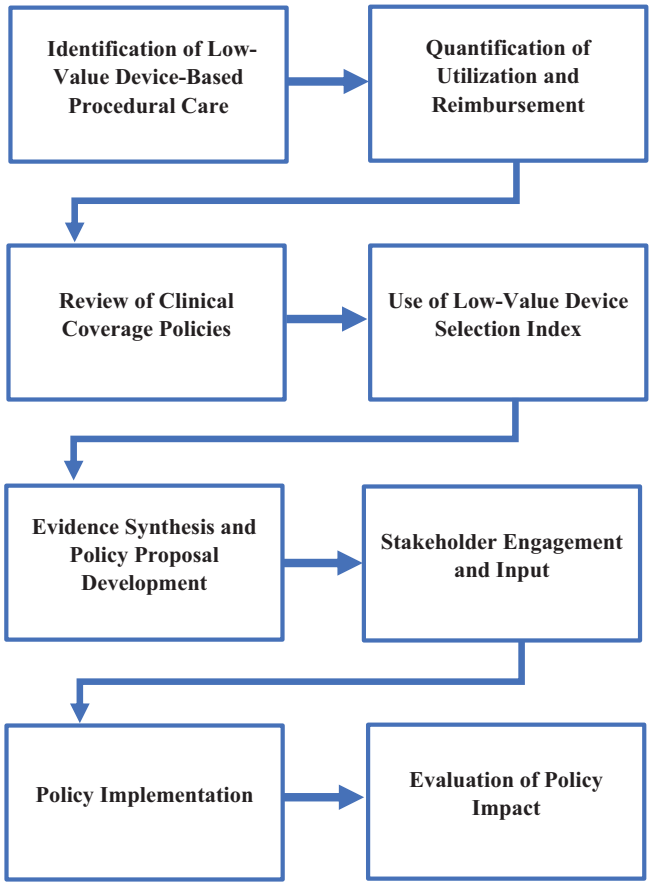
One strategy to meet the widely accepted goal of providing patients with only high-value care is to generate and implement evidence-based clinical coverage policies for specific procedures and to end the coverage of low-value care.[38] Medicaid programs, already subject to state budget limits and high health care needs exacerbated by the COVID-19 pandemic, with an increase of nearly 10 million Americans covered during the pandemic,[39] could particularly benefit from such an approach.

Our team led a unique, scalable collaboration to develop a clinical coverage policy-based implementation strategy to systematically reduce low-value device-based procedural use while ensuring patients have access to appropriate evidence-based therapies. We describe here our implementation strategy as a case study of a partnership between an academic team that brings expertise in technology assessment and health services research methods and a leadership team from Louisiana Medicaid that determines coverage policies. This relationship developed after our academic partners presented the idea of reducing low-value device use to Louisiana Medicaid leadership. As a state with a fixed budget and limited resources, Louisiana Medicaid leadership was receptive to a partnership. The complementary expertise ensures that policymaking is both evidence-based and grounded in the practical implementations of policy change. This process has involved eight steps, which we describe below (Figure 1).

Identifying Low-Value Device-Based Procedural Care

Low-value device-based procedural care is often underrecognized, but it can be identified in one of three categories: 1) a new device used for unapproved or unsupported indication(s) or patient population(s); 2) an established device used beyond its current evidence base; and 3) an established device where the evidence base has shifted to suggest that some current use is low-value. These categories of low-value device-based procedures are often insufficiently and inconsistently addressed through existing coverage criteria.

Figure 1. Flow Diagram of Policymaking and Evaluation Process



The evidence suggesting low-value use can range from either a lack of robust evidence of clinical outcome benefits in the peer-reviewed literature or the presence of robust clinical studies that have definitively shown a given technology does not improve patient outcomes.

We examined evidence from the peer-reviewed literature, with professional society clinical practice guidelines as a key first source because these generally represent overall consensus recommendations created through synthesis of the highest quality evidence available. However,

clinical practice guideline sponsors may have conflicts of interest.[40] Furthermore, guidelines may take time to be updated. Therefore, we examined multiple guidelines, including those from international bodies such as the National Institute for Health and Care Excellence, and those from organizations and authors without conflicts (such as the United States Preventive Services Task Force). We did not screen guidelines because we wanted to obtain a comprehensive view about the evidence for the specific device-based procedures of interest. To strengthen our evidence assessment and best inform our policies, we also closely reviewed the underlying evidence supporting key guideline recommendations, with an emphasis on RCTs, systematic reviews, and meta-analyses.[41] Further, we identified RCTs that had been published since the time of guideline updates. For example, for a policy on PCI for stable coronary artery disease, two landmark RCTs that significantly strengthened the evidence base for medical therapy,[42,43] were not included in the clinical practice guidelines from professional societies based in the United States as the RCTs had not been published at the time of the guideline releases. Finally, because safety events and understanding cascades of downstream care require larger patient populations, we also relied on meta-analyses and large observational studies for additional, complementary information.

Quantifying Utilization and Reimbursement

After identifying low-value device-based procedures, we examined utilization among Louisiana Medicaid beneficiaries. The demographics and health needs of Louisiana Medicaid beneficiaries inform what procedures are performed.

Reviewing Clinical Coverage Policies

After we identified a potentially low-value device-based procedure used in Medicaid beneficiaries, our next step was to determine if current clinical coverage policies were aligned with the evidence. Within Louisiana, there are five Medicaid managed care organizations (MCOs), in addition to fee-for-service Medicaid. We found that clinical coverage policies across these Louisiana Medicaid plans had some heterogeneity, including even the existence of a written policy on a given procedure as well as the contents of the policy. Although the purpose of multiple MCOs in

a single state is to foster competition and innovation, Medicaid MCOs cover a beneficiary population with more similarities than differences. If there was consensus on appropriateness of a certain procedure, there would not necessarily need to be significant variation in coverage policies for that procedure. The variation provided an opportunity to identify aspects of policies that are most aligned with evidence, which could also help providers by increasing consistency across Medicaid plans within the state. Additionally, examining clinical coverage policies across the United States can be informative.

Using a Low-Value Device Selection Index

Once payor policies were determined to leave opportunity to reduce low-value care, the next step was to prioritize the procedure for policy implementation compared with other procedures. We created a low-value device selection index to inform this prioritization process (Table 1). These factors, which were weighted differently depending on the procedure, include the number of patients affected by the procedure, the direct financial cost, downstream cascade and costs from low-value device use, severity and frequency of adverse events suffered by patients, quality of evidence showing no effectiveness, ease and urgency of de-implementation, potential to further health equity, and additional policy considerations. Cost-effectiveness analyses were not used because the process was centered primarily on the clinical factors most important to patients and physicians (safety and effectiveness) and an emphasis on cost would have obscured those primary factors. However, we recognize that cost-effectiveness analyses play an important role in addressing low-value care, and the use of cost-effectiveness analyses in future policy-based efforts could hold great potential to identify and reduce low-value device-based procedure use.

Evidence Synthesis and Policy Proposal Development

The next step was to generate a formal evidence synthesis and policy proposal to close gaps in current payor policies. Our policy proposals have followed a PICOS format (Population, Intervention/Technology, Comparators, Outcomes, and Settings).

Table 1. Low-Value Device 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 communications 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.

Continued

Table 1. (Continued)

Metric	Details and Methods of Quantification
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.

For beneficiaries 21 years of age and older, state Medicaid programs have broad discretion on what specific services are covered within the mandatory and optional service categories[44] and termination of coverage (or continuing to not cover), when consistent with federal and state law, can be one option to address low-value care. For covered services, two common policy levers in Medicaid programs for nonemergency procedures are prior authorization and post-payment review. For prior authorization, providers must satisfy certain criteria prior to receiving reimbursement. In post-payment review, clinical criteria are established and then used in medical record reviews after payment is made. This can occur either on a broad sample or, if there are outliers in procedural volume, in a targeted manner. We focused on prior authorization because, relative to post-payment review, it represents a stronger approach to ensuring coverage criteria are followed because a coverage decision is made up front. Further, in Louisiana Medicaid, the MCO contracts require that MCOs not rescind authorizations or reduce payment after authorization approval, unless there was a material omission or misrepresentation. In other words, an approved prior authorization gives providers a reasonable assurance of reimbursement, which may not be

the case for other payors. In contrast, post-payment reviews do not have the initial abrasion of prior authorization; however, providers may not be aware of relevant coverage policies and, because a coverage decision is not made up front, post-payment reviews and recoupments, if made, may come as a surprise. The strengths and weaknesses of both approaches are specific to the disease state, intervention, plan, and provider contexts. Increasing beneficiary cost sharing beyond nominal amounts is generally not possible under federal regulations and not advisable because it would shift the burden of low value care onto vulnerable patients.[45]

Stakeholder Engagement and Input

Successful policy implementation requires stakeholder engagement. Because most Louisiana Medicaid beneficiaries are covered by MCOs, our first step has been to share the policy and engage MCO physician and operations leadership, both for written feedback and through a videoconference meeting. In videoconference meetings, these leaders have shared their awareness about low-value use of the specific device-based procedures, challenges in ensuring use of conservative therapies, and conveyed an interest in developing a common policy to reduce low-value use. MCO leadership also requested, if available, evidence specific to Medicaid beneficiaries.

Additionally, to increase buy-in, we engaged local practicing physicians who would be affected by the policy proposal, both through written feedback and meetings. These physicians have requested rigorous discussions of the evidence supporting our policy proposals (which we have engaged in), conveyed the challenges of prior authorization, and provided suggestions for modification (which we have incorporated when supported by robust evidence and based on barriers specific to local clinical practice contexts). These physicians have also conveyed appreciation for our engaging with them, answering their questions, and incorporating their feedback to ensure that policy aligns with the local clinical context.

Policy Implementation

Our next step was finalizing and implementing the policy. While the state Medicaid agency only directly reimburses clinicians rendering services to beneficiaries in the fee-for-service program, the state's

policies set the coverage minimums for the whole program. As the stakeholder engagement process should have addressed any concerns from the MCOs, MCOs are likely to adopt the new policy. Further, a new policy may trigger a prospective reduction in capitation rates paid to the MCOs, which can create a stronger incentive to consistently align with the new evidence-based policy. To date, we have pursued 15 low value medical device-based procedures, and three have had policies implemented.

Evaluating Policy Impact

Coverage criteria are rarely evaluated to determine if they improve quality of care and clinical outcomes based on the highest quality available evidence.[46] However, as with any health care interventions, studying the impact of a policy change is essential. There are multiple possible strategies for evaluating the policies. An RCT, such as using a stepped-wedge design of the implementation across different payors, would theoretically provide the most robust evidence. However, coordination of payors who operate in the same market (i.e., are competitors) and possible spillover effects make this strategy challenging. Another option to study the effect of policy implementation is an interrupted time series approach. The most robust, and preferred, is a quasi-randomized option, determining the effect using a difference-in-difference approach with a comparator group of similar patients, such as Medicaid beneficiaries in nearby states. Our primary outcome will focus on quantifying changes in utilization, while secondary outcomes will include costs of care, use of medical therapy, and clinical events.

Case Example: Endovascular Intervention for Lower Extremity Peripheral Artery Disease

Our academic-policymaker collaboration developed and implemented a policy for endovascular intervention among patients with lower extremity peripheral arterial disease and intermittent claudication. There has been widespread and increasing adoption of endovascular intervention among patients with peripheral arterial disease, with the

intended goal of treating intermittent claudication and reducing progression to more severe, limb-threatening disease.[47]

To better understand the evidence base, we first examined professional society clinical practice guidelines from the Society for Vascular Surgery for Atherosclerotic Occlusive Disease of the Lower Extremities.[48] The guideline-recommended treatments (with a Class 1, Level of Evidence A— strongest recommendation) are a combination of smoking cessation, supervised exercise therapy, and medication therapy (such as blood pressure control)[48] because these non-invasive therapies have demonstrated comparable quality-of-life as well as functional and long-term outcomes to endovascular intervention in RCTs.[49] These recommendations were consistent with those from other professional societies, the National Institute for Health and Care Excellence,[50] and the Agency for Healthcare Research and Quality.[51]

However, there is significant underutilization of these guideline-based approaches in clinical practice.[52] Endovascular intervention is among the procedures with the highest aggregate expenditures by Louisiana Medicaid (approximately $7 million in professional fees paid in 2019 alone). Of the few thousand patients who received endovascular revascularization in Louisiana Medicaid, less than one percent had received supervised exercise therapy. In addition, there is concern that the use of paclitaxel-coated devices during endovascular intervention procedures is associated with an increase in mortality, demonstrated in multiple meta-analyses,[53] including one based on formal discussions with the FDA.[54] These safety concerns coupled with underuse of medical therapy and supervised exercise therapy indicate that patients with intermittent claudication have not been receiving high-value, evidence-based care. We reviewed clinical coverage policies in Louisiana Medicaid and found that they had opportunity for greater alignment with evidence.

After reviewing clinical practice guidelines and the underlying evidence (primarily RCTs) as well as a Medicare National Coverage Determination providing reimbursement for supervised exercise therapy, we developed a policy using prior authorization to reduce low-value procedural use. We engaged Medicaid MCO medical directors and both local and prominent national vascular surgeons for feedback, which we incorporated into a final policy proposal that has been implemented (available upon request from authors). This policy focuses on ensuring that only patients who meet objective criteria for peripheral arterial disease and have claudication symptoms that limit their work and/or activities of daily living qualify for the procedure. We have emphasized the

importance of evidence-based conservative therapies as first-line therapy. Specifically, patients are required to have a trial of an exercise program for a minimum of 12 weeks at least three times weekly as well as at least six months of optimal pharmacologic therapy (including an antiplatelet medication, statin, and cilostazol, unless contraindicated). Further, patients must achieve adequate blood pressure control and, if they smoke, receive at least one documented attempt for smoking cessation. As local physicians explained that there was a paucity of available programs for supervised exercise therapy, the policy allowed flexibility for a directed, home-based exercise program. A concurrently implemented policy also explicitly covers supervised exercise therapy for symptomatic peripheral arterial disease; this was implemented after feedback from local vascular surgeons about prior lack of coverage being a factor preventing use.

Strengths of Using Clinical Coverage Policy to Reduce Low-Value Procedure Use

Designing and implementing evidence-based policies for coverage of device-based procedures represents a significant opportunity to reduce low-value care, thereby improving patient outcomes and reducing unnecessary spending. Payors often employ utilization management strategies by assessing appropriateness of care for specific clinical scenarios.[46] Managed care is commonly used, including by 39 of 50 state Medicaid programs in 2019, covering more than 53 million beneficiaries.[55] However, state agencies and Medicaid MCOs typically focus on adding restrictions to high-cost procedures to reduce costs. MCOs often use coverage policies based on commercial packages, to which providers may not have access. Further, even customized criteria may lack a transparent process for development. There is also sometimes heterogeneity in coverage of device-based procedures across payors, consistent with prior research.[56] Variation means that different factors may inform decision-making across payors.

In contrast, our approach relies on the highest-quality peer-reviewed evidence to inform decision-making. Because published evidence should be the hallmark of coverage, this strategy enables the possibility of more homogenous policies where appropriate (in our case, across Louisiana's Medicaid program, including fee-for-service and managed care members). Greater predictability in policies could also be more widely

accepted by physicians, who may be glad to see consistency when requesting authorization. Because we rely on widely-accepted high-quality peer-reviewed evidence—a universal goal among payors—our work focused on Louisiana's Medicaid population can also inform the policies of other payors and other states; however, generalizability and scalability will need to be addressed in the future as policymaking may also need to be adapted to local contexts.

Identifying low-value devices is of growing importance because medical devices are more frequently reaching market without evidence of clinical outcome benefit. Curtailing low-value care improves health care value by minimizing the number of patients receiving non-beneficial procedures and realizing cost savings accrued from reduced procedural spending and downstream cascades of additional testing and procedures. Our approach could be complemented by other value-based initiatives that seek to reduce low-value care, with the goal of synergistically improving quality of care while reducing costs. Our current approach is limited in that we did not change incentives for either physicians or patients to reduce low-value care. Physicians are still financially incentivized to perform device-based procedures that are highly reimbursed, even when they are low value. Similarly, patients are not often aware that they are receiving low-value care. In our mostly third-party coverage system, patients also generally lack financial incentives to avoid unnecessary care, despite its cascades of risk and high costs. Modifying our delivery system structure for both physicians and patients could help propel reductions in low value device-based procedure use. Limited resources could then be redirected toward strategies that provide the greatest benefit to patient outcomes, thereby potentially reducing health care disparities.[57] Since increased health care costs are shouldered by taxpayers, reducing costs of low-value care for publicly insured individuals ultimately benefits the greater public.

Challenges in Implementing Clinical Coverage Policy to Reduce Low-Value Procedure Use

There are also important challenges and limitations of clinical coverage policy-based approaches to reducing low-value medical device use. First, new restrictions on coverage may engender negative attitudes among

clinicians.[58] Clinicians often express exasperation with paperwork burden for intended cost control;[59] a recent American Medical Association survey found that 85% of physicians described the burden from prior authorization as high or extremely high.[60] Specifically in Medicaid, clinicians may already be concerned about low reimbursement rates and perceived high administrative burden. Research has demonstrated that of all payors, denial rates are the highest in fee-for-service Medicaid[61] and physicians lose more than one-sixth of Medicaid revenue to billing issues.[62] Further coverage restrictions may compound those concerns and, for Medicaid plans, reduce clinician willingness to participate and therefore reduce Medicaid beneficiary access. Medicaid beneficiaries often lack access to specialists (one-third of specialists do not accept publicly-insured patients).[63] Although we have used prior authorization, our approach is distinct given the clinically-initiated focus and engagement with local, practicing physicians and consideration of the administrative realities of medical care. Regardless, we determined it was not prudent to pursue policymaking for select low-value procedures, such as tonsillectomy and adenoidectomy and knee arthroscopy because previous MCO experience found that prior authorization led to significant provider abrasion, usually due to administrative issues. Additionally, prior authorization policies can also be administratively complex and have their own associated costs, which can be prohibitive to widespread implementation. For some payors, there may also be a role for retrospective denials for unnecessary care in specific circumstances; many common claim denials are device-based procedures.[64]

Second, some low-value device-based procedures were determined infeasible for policy implementation given the significant difficulty of adjusting reimbursement for patients hospitalized for emergency services. Other device-based procedures have low utilization in the Medicaid beneficiary population and, thus, revised clinical coverage policies would not have a significant impact.

Third, certain device-based procedures, such as colonoscopy, may be low value in certain circumstances, such as when performed more frequently than recommended or in specific patient populations;[65] on the other hand, these procedures may have high, or at least reasonable, value in other circumstances. Robust policies that require appropriate level of documentation to clearly distinguish appropriate and inappropriate indications can help to reduce low-value care while providing sufficient flexibility for an appropriate procedure to be authorized. However, there may be circumstances where demarcating such care remains challenging

and reducing low-value care may not be possible. Additionally, underuse of recommended services may limit the ability to reduce low value use; for example, we did not develop any policy aimed at overuse of screening colonoscopy to avoid lowering any appropriate use of colorectal cancer screening, as Louisiana Medicaid wishes to encourage such screening.

Unknowns and Next Steps

Although we focus on device-based procedures with robust evidence demonstrating lack of clinical benefit for specific indications, payors must also make coverage decisions for therapies with uncertain evidence (i.e., the data have not been generated). Because the Food and Drug Administration (FDA) is focused on shortening pre-market review for medical devices with greater reliance on post-approval evidence generation,[66,67] there are often important gaps in evidence for safety and effectiveness at the time of FDA approval. Unfortunately, post-approval evidence may not be generated because trials are not initiated, progress slowly, or are terminated early,[9,68,69] leaving uncertainty about any patient benefit. However, when such evidence is generated, coverage criteria should be updated in a timely manner.

There is also a need to monitor for unintended consequences, such as provider actions that may circumvent policies, especially if they have purchased equipment and established practice patterns, which may be hard to change.[70] For example, patients may be documented as having more advanced symptoms to justify PCI, which is likely to represent upcoding and not changes in patient status.[71] Growth in other low-value procedures may occur to offset potential revenue loss; for example, if fewer PCIs are performed because of our policies, it is possible that mechanical circulatory support devices may be used in the PCIs that are performed, because these devices lead to higher reimbursement. Another issue to be monitored is if procedures are shifted to other payors, such as commercial insurers or Medicare.

Conclusion

Current approaches to reducing low-value medical device use have significant gaps. Academic-policymaker collaborations focused on

generating evidence-based coverage policies hold significant potential and promise for curtailing low value device-based procedural care and helping to ensure that plan beneficiaries receive only treatments that are likely to improve their health care outcomes, while also reducing health care costs. While there are challenges and practical considerations that must be balanced, as well as a need for further evaluations of the outcomes of such collaborations and possible unintended consequences, we believe they can help improve outcomes for all patients and the financial sustainability of public as well as private insurance.

References

1. Morgan DJ, Wright SM, Dhruva S. Update on medical overuse. *JAMA Intern Med*. 2015;175(1):120-124.
2. Brownlee S, Chalkidou K, Doust J, et al. Evidence for overuse of medical services around the world. *The Lancet*. 2017;390(10090):156-168.
3. Grady D, Redberg RF. Less is more: how less health care can result in better health. *Arch Intern Med*. 2010;170(9):749-750.
4. Schwartz AL, Landon BE, Elshaug AG, Chernew ME, McWilliams JM. Measuring low-value care in Medicare. *JAMA Intern Med*. 2014;174(7):1067-1076.
5. Korenstein D, Chimonas S, Barrow B, Keyhani S, Troy A, Lipitz-Snyderman A. Development of a conceptual map of negative consequences for patients of overuse of medical tests and treatments. *JAMA Intern Med*. 2018;178(10):1401-1407.
6. Shrank WH, Rogstad TL, Parekh N. Waste in the US health care system: Estimated costs and potential for savings. *JAMA*. 2019;322(15):1501-1509.
7. Dhruva SS, Bero LA, Redberg RF. Strength of study evidence examined by the FDA in premarket approval of cardiovascular devices. *JAMA*. 2009;302(24):2679-2685.
8. Johnston JL, Dhruva SS, Ross JS, Rathi VK. Clinical evidence supporting US Food and Drug Administration clearance of novel therapeutic devices via the de novo pathway between 2011 and 2019. *JAMA Intern Med*. 2020;180(12):1701-1703.
9. Rathi VK, Krumholz HM, Masoudi FA, Ross JS. Characteristics of clinical studies conducted over the total product life cycle of high-risk therapeutic medical devices receiving FDA premarket approval in 2010 and 2011. *JAMA*. 2015;314(6):604-612.

10. Chen CE, Dhruva SS, Redberg RF. Inclusion of comparative effectiveness data in high-risk cardiovascular device studies at the time of premarket approval. *JAMA*. 2012;308(17):1740-1742.
11. Redberg RF. Sham controls in medical device trials. *N Engl J Med*. 2014;371(10):892-893.
12. Parkash R, Crystal E, Bashir J, et al. Complications associated with revision of Sprint Fidelis leads: report from the Canadian Heart Rhythm Society Device Advisory Committee. *Circulation*. 2010;121(22):2384-2387.
13. Wenzl M, Mossialos E. Prices for cardiac implant devices may be up to six times higher in the US than in some European countries. *Health Aff (Millwood)*. 2018;37(10):1570-1577.
14. Institute of Medicine Committee on Conflict of Interest in Medical Research E, Practice. The National Academies Collection: Reports funded by National Institutes of Health. In: Lo B, Field MJ, eds. *Conflict of Interest in Medical Research, Education, and Practice*. Washington (DC): National Academies Press; 2009.
15. Weintraub WS, Boden WE, Zhang Z, et al. Cost-effectiveness of percutaneous coronary intervention in optimally treated stable coronary patients. *Circ Cardiovasc Qual Outcomes*. 2008;1(1):12-20.
16. Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. *JAMA*. 2019;321(1):80-96.
17. Holtzman JN, Dhruva SS. Media portrayals of extracorporeal membrane oxygenation: The unforeseen harm of unfounded optimism. *JAMA Intern Med*. 2021;181(3):394-395.
18. Redberg RF. ORBITA: Implications For Regulatory Review And Coverage Processes. https://www.healthaffairs.org/do/10.1377/hblog20181004.266389/full/. Accessed February 13, 2022.
19. Hira RS, Vemulapalli S, Li Z, et al. Trends and outcomes of off-label use of transcatheter aortic valve replacement: Insights from the NCDR STS/ACC TVT Registry. *JAMA Cardiol*. 2017;2(8):846-854.
20. Cassel CK, Guest JA. Choosing wisely: helping physicians and patients make smart decisions about their care. *JAMA*. 2012;307(17):1801-1802.
21. Lopez MH, Daniel GW, Fiore NC, Higgins A, McClellan MB. Paying for value from costly medical technologies: A framework for applying value-based payment reforms. *Health Aff (Millwood)*. 2020;39(6):1018-1025.
22. Hess EP, Hollander JE, Schaffer JT, et al. Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial. *BMJ (Clinical research ed)*. 2016;355:i6165.

23. Meeker D, Linder JA, Fox CR, et al. Effect of behavioral interventions on inappropriate antibiotic prescribing among primary care practices: A randomized clinical trial. *JAMA*. 2016;315(6):562-570.
24. Erickson SM, Outland B, Joy S, et al. Envisioning a better U.S. health care system for all: Health care delivery and payment system reforms. *Ann Intern Med*. 2020;172(2 Suppl):S33-S49.
25. Schwartz AL, Chernew ME, Landon BE, McWilliams JM. Changes in low-value services in year 1 of the Medicare Pioneer Accountable Care Organization Program. *JAMA Intern Med*. 2015;175(11):1815-1825.
26. Song Z, Fendrick AM, Safran DG, Landon B, Chernew ME. Global budgets and technology-intensive medical services. *Healthc (Amst)*. 2013;1(1-2):15-21.
27. Oakes AH, Sen AP, Segal JB. The impact of global budget payment reform on systemic overuse in Maryland. *Healthc (Amst)*. 2020;8(4):100475.
28. Agarwal R, Liao JM, Gupta A, Navathe AS. The impact of bundled payment on health care spending, utilization, and quality: A systematic review. *Health Aff (Millwood)*. 2020;39(1):50-57.
29. Navathe AS, Liao JM, Emanuel EJ. Volume increases and shared decision-making in joint replacement bundles. *Ann Surg*. 2018;267(1):35-36.
30. Berwick DM, Hackbarth AD. Eliminating waste in US health care. *JAMA*. 2012;307(14):1513-1516.
31. Colla CH. Swimming against the current–what might work to reduce low-value care? *N Engl J Med*. 2014;371(14):1280-1283.
32. Smith B. CMS Innovation Center at 10 Years - Progress and Lessons Learned. *N Engl J Med*. 2021;384(8):759-764.
33. Reid RO, Tom AK, Ross RM, Duffy EL, Damberg CL. Physician compensation arrangements and financial performance incentives in US health systems. *JAMA Health Forum*. 2022;3(1).
34. Mafi JN, Reid RO, Baseman LH, et al. Trends in low-value health service use and spending in the US Medicare Fee-for-Service Program, 2014-2018. *JAMA Netw Open*. 2021;4(2):e2037328.
35. Egilman AC, Wallach JD, Dhruva SS, Gonsalves GS, Ross JS. Medicare spending on drugs and biologics not recommended for coverage by international health technology assessment agencies. *J Gen Intern Med*. 2019;34(11):2319-2321.
36. Henderson J, Bouck Z, Holleman R, et al. Comparison of payment changes and Choosing Wisely recommendations for use of low-value laboratory tests in the United States and Canada. *JAMA Intern Med*. 2020;180(4):524-531.

37. Hannan EL, Samadashvili Z, Cozzens K, et al. Changes in percutaneous coronary interventions deemed "inappropriate" by appropriate use criteria. *J Am Coll Cardiol*. 2017;69(10):1234-1242.
38. Dhruva SS, Redberg RF. A successful but underused strategy for reducing low-value care: Stop paying for it. *JAMA Intern Med*. 2020;180(4):532.
39. Center for Medicare & Medicaid Services. New Medicaid and CHIP Enrollment Snapshot Shows Almost 10 million Americans Enrolled in Coverage During the COVID-19 Public Health Emergency.
40. Sox HC. Conflict of interest in practice guidelines panels. *JAMA*. 2017;317(17):1739-1740.
41. Alper BS, Haynes RB. EBHC pyramid 5.0 for accessing preappraised evidence and guidance. *Evid Based Med*. 2016;21(4):123-125.
42. Maron DJ, Hochman JS, Reynolds HR, et al. Initial invasive or conservative strategy for stable coronary disease. *N Engl J Med*. 2020;382(15):1395-1407.
43. Al-Lamee R, Thompson D, Dehbi HM, et al. Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial. *Lancet*. 2018;391(10115):31-40.
44. Medicaid and CHIP Payment and Access Commission. Mandatory and Optional Benefits. https://www.macpac.gov/subtopic/mandatory-and-optional-benefits/. Accessed February 13, 2022.
45. Medicaid. Cost Sharing. https://www.medicaid.gov/medicaid/cost-sharing/index.html. Accessed February 13, 2022.
46. Bailit HL, Sennett C. Utilization management as a cost-containment strategy. *Health Care Financ Rev*. 1992;1991(Suppl):87-93.
47. Conte MS. Data, guidelines, and practice of revascularization for claudication. *J Vasc Surg*. 2017;66(3):911-915.
48. Society for Vascular Surgery Lower Extremity Guidelines Writing G, Conte MS, Pomposelli FB, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. *J Vasc Surg*. 2015;61(3 Suppl):2S-41S.
49. Murphy TP, Cutlip DE, Regensteiner JG, et al. Supervised exercise, stent revascularization, or medical therapy for claudication due to aortoiliac peripheral artery disease: the CLEVER study. *J Am Coll Cardiol*. 2015;65(10):999-1009.
50. National Institute for Health and Care Excellence. Peripheral Arterial Disease: Diagnosis and Management. https://www.nice.org.uk/guidance/cg147. Accessed November 20, 2022.

51. Agency for Healthcare Research and Quality. Treatment Strategies for Patients With Peripheral Artery Disease. https://effectivehealthcare.ahrq.gov/products/peripheral-artery-disease-treatment/research. Accessed May 11, 2022.
52. Saxon JT, Safley DM, Mena-Hurtado C, et al. Adherence to guideline-recommended therapy-including supervised exercise therapy referral-across peripheral artery disease specialty clinics: Insights from the International PORTRAIT Registry. *J Am Heart Assoc*. 2020;9(3):e012541.
53. Katsanos K, Spiliopoulos S, Kitrou P, Krokidis M, Karnabatidis D. Risk of death following application of Paclitaxel-coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *J Am Heart Assoc*. 2018;7(24):e011245.
54. Rocha-Singh KJ, Duval S, Jaff MR, et al. Mortality and Paclitaxel-coated devices: An individual patient data meta-analysis. *Circulation*. 2020;141(23):1859-1869.
55. Kaiser Family Foundation. Medicaid managed care penetration rates by eligibility group. https://www.kff.org/medicaid/state-indicator/managed-care-penetration-rates-by-eligibility-group/. Published 2019. Accessed February 13, 2022.
56. Chambers JD, Chenoweth M, Thorat T, Neumann PJ. Private payers disagree with Medicare over medical device coverage about half the time. *Health Aff (Millwood)*. 2015;34(8):1376-1382.
57. Helfrich CD, Hartmann CW, Parikh TJ, Au DH. Promoting health equity through de-implementation research. *Ethnicity & disease*. 2019;29(Suppl 1):93-96.
58. Buck JA, Silverman HA. Use of utilization management methods in State Medicaid programs. *Health Care Financ Rev*. 1996;17(4):77-86.
59. Shams MR, Winokur M, Meadows JA. Prior authorization frustration: How can we ease the pain. *Ann Allergy Asthma Immunol*. 2020;124(6):548-549.
60. American Medical Association. 2020 AMA Prior Authorization Physician Survey. 2020.
61. Gottlieb JD, Shapiro AH, Dunn A. The complexity of billing and paying for physician care. *Health Aff (Millwood)*. 2018;37(4):619-626.
62. Dunn A, Gottlieb JD, Shapiro AH, Sonnestuhl DJ. A denial a day keeps the doctor away. *National Bureau of Economic Research Working Paper Series*. 2021.
63. Decker SL. In 2011 nearly one-third of physicians said they would not accept new Medicaid patients, but rising fees may help. *Health Aff (Millwood)*. 2012;31(8):1673-1679.

64. Schwartz AL, Chen Y, Jagmin CL, et al. Coverage denials: Government and private insurer policies for medical necessity in Medicare. *Health Aff (Millwood)*. 2022;41(1):120-128.
65. Goodwin JS, Singh A, Reddy N, Riall TS, Kuo YF. Overuse of screening colonoscopy in the Medicare population. *Arch Intern Med*. 2011;171(15):1335-1343.
66. Jones LC, Dhruva SS, Redberg RF. Assessment of clinical trial evidence for high-risk cardiovascular devices approved under the Food and Drug Administration Priority Review Program. *JAMA Intern Med*. 2018;178(10):1418-1420.
67. Johnston JL, Dhruva SS, Ross JS, Rathi VK. Early experience with the FDA's Breakthrough Devices Program. *Nat Biotechnol*. 2020;38(8):933-938.
68. Reynolds IS, Rising JP, Coukell AJ, Paulson KH, Redberg RF. Assessing the safety and effectiveness of devices after US Food and Drug Administration approval: FDA-mandated postapproval studies. *JAMA Intern Med*. 2014;174(11):1773-1779.
69. Rathi VK, Krumholz HM, Masoudi FA, Ross JS. Postmarket clinical evidence for high-risk therapeutic medical devices receiving Food and Drug Administration premarket approval in 2010 and 2011. *JAMA Netw Open*. 2020;3(8):e2014496.
70. Redberg RF. Evidence, appropriateness, and technology assessment in cardiology: a case study of computed tomography. *Health Aff (Millwood)*. 2007;26(1):86-95.
71. Wadhera RK, Sukul D, Secemsky EA, et al. Temporal trends in unstable angina diagnosis codes for outpatient percutaneous coronary interventions. *JAMA Intern Med*. 2019;179(2):259-261.

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