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PAYING FOR VALUE:
Improving Outcomes, Costs, and Access through a Condition-based Bundle Payment Model

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Executive Summary

Aortic stenosis (AS) affects around 1.5 million people in the United States and occurs when the heart's aortic valve narrows, potentially causing heart failure, syncope, and sudden cardiac death. Chronically underdiagnosed, AS is often only identified when the severity of the disease has progressed to the point where patients need an aortic valve replacement. Currently, the intervention can either be performed through surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR). While there are benefits and risks associated with either intervention, traditional procedure-based reimbursement may deter provider systems from building capacity to offer both options to appropriately meet patient needs.

In this paper we outline a conceptual design for a bundled payment model agnostic to procedure type, a first step to a condition-based AS model that can reduce or eliminate misaligned incentives around treatment choice. The conceptual model we propose seeks to promote improved long-term outcomes by aligning payment with appropriate choice of procedure (including device), promoting shared decision-making between patients and providers, and coordination of longer-term post-acute care. We developed this proposal in response to the FY2020 President's Budget calling on CMMI to identify more bundled payment arrangements for high-value devices, and incorporate device manufacturers into risk-sharing;[1] evolving label expansion of TAVR devices by the Food and Drug Administration (FDA); and CMS's relaxed procedure volume requirements in their coverage criteria. Ideas presented in this paper are the first steps to identifying an opportunity for CMMI to test an innovative approach to payment for medical device use in the broader health care continuum. We hope to ultimately design, with the input of all stakeholders affected – CMS, commercial payers, physicians, hospital administrators and patients – an analysis of Medicare data, an actionable payment model that expands bundles to encompass longer time horizons, improved condition management, that better account for patient and provider risk factors, gives providers flexibility to choose the treatment that will result in the best long-term outcomes, and involves manufacturers in sharing risk for quality and costs.

Introduction

Aortic Stenosis (AS) is a valvular disease that occurs when the aortic valve narrows, decreasing overall cardiac output. When symptomatic and left untreated, it is a serious condition associated with a 50% mortality rate in the first two years.[2] In the United States, AS affects approximately 1.5 million people, 3% of people over 65.[3] Before a patient reaches severe symptomatic AS, treatments such as guideline directed medical therapy may manage the progression of the disease. Yet, many patients are not diagnosed until the severity of the disease has progressed to the point when an aortic valve replacement (AVR) is required. AVR was historically performed through an open-heart procedure, called surgical aortic valve replacement (SAVR).[4] In 2011, an alternative treatment approach for the AVR procedure was approved, called transcatheter aortic valve replacement (TAVR). TAVR is a minimally invasive

procedure to replace the patient's aortic valve using a catheter-based approach. The TAVR procedure takes less time compared to the traditional surgical approach, requiring a shorter recovery time and hospital stay for the patient, potentially lowering the overall cost of delivering care.

Procedure volumes for TAVR have slowly increased over the years with expanding label indications. TAVR was first approved by the FDA for patients whose clinical condition could not withstand a surgical procedure, and later, for treatment of high, intermediate, and low surgical risk patients. The approval and subsequent label expansions for TAVR significantly expanded the treatable AS population, many of whom would previously have gone untreated. There are now between 50-60,000 TAVR procedures per year in the United States and about another 25,000 isolated SAVR procedures (meaning that only the aortic valve is replaced in the procedure).[5] In 2019, the Food and Drug Administration (FDA) expanded the indication for TAVR to include patients who are at low surgical risk, indicating parity in the effectiveness of AVR for both treatment approaches.[6] The Centers for Medicare and Medicaid Services' (CMS) original coverage criteria for TAVR included procedure volume requirements for provider systems that effectively limited the procedure availability to hospitals that provided more procedures. However in 2019, CMS lowered some volume requirements for providers due to increased evidence of the safety and efficacy of TAVR. As a result, more Medicare patients will likely have access to AVR procedures when clinically appropriate.[7]

The reimbursement mechanisms for AVR procedures may deter newly eligible providers from building capacity to offer both treatment options. With the 2019 National Coverage Determination changes, CMS along with clinical stakeholders expressed the desire to maintain volume requirements as a way to balance broad access for TAVR while still ensuring high quality care and optimal health and safety outcomes. However, the volume requirements may still create barriers to entry for some providers. In addition, certain provider systems[*] face financial barriers from adopting both existing and novel technologies, even with payment that is meant to capture device costs. Depending on certain factors that impact reimbursement amounts (such as geographic wage index, teaching status, and disproportionate share of indigent patients), device-based treatments can result in a net loss, leading hospitals to be less willing to offer TAVR, even if it is the most clinically appropriate treatment option for the patient.

A procedure-agnostic bundled payment model is designed to promote quality of care and outcomes through appropriate treatment choice, while also addressing potentially perverse financial incentives such as inappropriate use of a device due to economics or market interest.[8] Duke-Margolis, with guidance from the [Value-Based Payment for Medical Products Consortium](#) has developed a conceptual bundled payment model for AS that seeks to address the potential

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[*] National Medicare reimbursement amounts for both SAVR and TAVR are based on historic resource utilization data that factors the cost of the procedure, as well as the cost of medical products used in the procedure. Reimbursement amounts are further adjusted by factors unrelated to the procedure such as geographic wage index, teaching status, and disproportionate share of indigent patients, which can increase or decrease the total payment made to the provider.

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limitations of existing payment approaches.[*] Our model builds on components and concepts from CMS' Bundled Payments for Care Improvement Advanced (BPCI-A) Model and moves towards a condition-level bundle that is procedure agnostic. While conceptual, the proposed model is designed to promote improved long-term outcomes by alignment of incentives around shared decision-making with the patient on the appropriate procedure, selection of a device that optimizes outcomes, and coordination of longer-term post-acute care.

This paper represents the first in a series of efforts to conceptualize this payment model. Ultimately, we aim to develop, with stakeholder input and analyses of Medicare fee-for-service claims data, a novel and actionable payment model that:

- Incentivizes patient-centered treatment decision-making based on patient needs, preference, and long-term outcomes,
- Incorporates risk sharing between payers, providers/health systems, and manufacturers (with consideration of what risks each entity may be willing to consider), and
- Expands bundled payment models to encompass longer time horizons, better account for patient risk factors, and involve manufacturers in sharing risk for quality and cost, including device performance as appropriate.

We consider how to appropriately define the episode of care, including episode length, and how to appropriately risk-adjust payments and account for overall outcomes. In addition, we look at various approaches to risk-sharing model(s) between the provider and the payer, the provider and the manufacturer, and potentially even the manufacturer and the payer. While we focus primarily on AS, we aim for our approach to serve as a model for how bundled payments can more broadly shift from procedure-specific to condition-based bundles to improve patient outcomes, optimize costs of care, incorporate longer periods of care, better account for risk factors, involve manufacturers in sharing risk on patient outcomes, and serve as a feasible CMS payment approach to ensure appropriate treatment interventions.

Bundled payments within Medicare

Traditional Medicare operates under fee for service (FFS) contracts whereby providers are paid for each service provided. Table 1 provides the current medical severity – diagnosis related groups[†] (MS-DRGs) for AVR based on treatment approach and their associated reimbursement amounts. Importantly, the MS-DRG groups for both treatment approaches include additional valve procedures, and are not specific to aortic valve interventions. Overall, Medicare reimbursement amounts are similar for both treatment approaches, except for surgical

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[*] The payment model was developed by Duke-Margolis researchers, with input from the Center's Value-Based Payment for Medical Products Consortium. The views of this paper do not necessarily represent the views of the Consortium members nor the organizations that they represent. Consortium members provided feedback on the content of this paper, but the content of the paper was independently determined by the Duke-Margolis Center, which is part of Duke University, and as such honors the tradition of academic independence on the part of its researchers, faculty, and scholars.

[†] Under the Medicare Inpatient Payment System, medical and surgical services are grouped into MS-DRGs, service bundles based on diagnosis, the procedures, complicating conditions, age, and discharge status. Payment rates for MS-DRGs are meant to cover all costs attributable to care, from inpatient admission to discharge.

procedures with Major Complications and Comorbidities (MCC). The reimbursement rates are similar despite TAVR patients' shorter average length of time in the hospital because of the higher cost of the TAVR device.

Table 1: Payment Categories for AVR Procedures by MS-DRG*

Treatment approach	MS-DRG	Description	Length of Stay	FY2020 Reimbursement*
Surgical valve replacement	216	Cardiac Valve & Oth Maj Cardiothoracic Proc w Card Cath w MCC	13.7	$ 62,855
	217	Cardiac Valve & Oth Maj Cardiothoracic Proc w Card Cath w CC	8.5	$ 41,632
	218	Cardiac Valve & Oth Maj Cardiothoracic Proc w Card Cath w/o CC/MCC	5.9	$ 33,807
	219	Cardiac Valve & Oth Maj Cardiothoracic Proc w/o Card Cath w MCC	9.0	$ 49,071
	220	Cardiac Valve & Oth Maj Cardiothoracic Proc w/o Card Cath w CC	6.0	$ 33,209
	221	Cardiac Valve & Oth Maj Cardiothoracic Proc w/o Card Cath w/o CC/MCC	4.1	$ 28,767
Transcatheter valve replacement	266	Endovascular Cardiac Valve Replacement & Supplement Procedures w MCC	3.5	$ 44,573
	267	Endovascular Cardiac Valve Replacement & Supplement Procedures w/o MCC	1.9	$ 35,523

As part of a broader effort to improve quality and reduce expenditures, CMMI created bundled payment models that hold providers accountable for costs and outcomes over pre-defined periods of time.[9] Most bundle models are built on the FFS chassis; providers are paid for each service provided and then those total payments are reconciled retrospectively against a pre-defined target price or expenditure amount. This target price is calculated based on the average historical and regional costs of all items and services. The participating health care provider or provider system assumes the financial risk for their attributed patients; if expenditures are lower than the target price, the participants share in the savings based on quality performance data; however, if their expenditures are above the target amounts, CMS recoups some of that overage. The goal of the bundle is to encourage the participating provider or health system to carefully coordinate patients' care and recovery to ensure good outcomes, while discouraging low value care during and after the procedure.[10]

An example of a procedure-based bundled payment program is CMS's Bundled Payments for Care Improvement Advanced (BPCI-A) Model, which allows participants to select from thirty

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three inpatient and four outpatient clinical episodes.[*] The clinical episode begins either at the start of an inpatient stay ("Anchor Stay"), as identified by a diagnostic related group (MS-DRG) code, or at the start of an outpatient procedure ("Anchor Procedure"), as identified by a Healthcare Common Procedure Coding System (HCPCS) code. The BPCI-A Model includes the Anchor Stay or Procedure plus 90 days post-discharge covering the initial period of recovery and rehabilitation for patients. All providers and supplies are paid under the usual FFS payment system and the episode includes all related items and services[†] paid under Medicare Part A and Part B.[11] At the end of the model performance year, actual Medicare spending during the episode of care is compared to the Medicare target episode price for the responsible provider. The target price is established using regression models that consider regional and historic spending, adjust for patient risk adjustment and spending trends at peer hospitals. Every six months, CMS compares Medicare FFS expenditures to determine whether the participant is eligible to receive a payment from CMS or owe a portion of the episode spending to Medicare.[12] The total reconciliation payment or owed amount is further adjusted based on quality performance against specific measures.

While these models have had a modest impact on costs, there are challenges with the current bundled payment models.[13] Current methodologies around risk adjustment do not always adequately account for pertinent clinical factors and may therefore be inadequate. Collecting outcomes and quality measures can add to administrative burden of providers and current measures do not sufficiently focus on outcomes of interest such as patient functional status and procedure-specific complications. The participating entity is required to take on risk for the overall health of a patient, which may include conditions outside of their expertise and control. Finally, the target price may not account for care coordination and other administrative services that create the efficiencies and improved outcomes seen with successful bundles. As these efficiencies cause the target price to decrease, the shared savings used to pay for those services also decrease, and may no longer cover the costs involved.

Building a Bundled Payment Model in Medicare
Overall Structure
The payment model we describe below builds upon the BPCI-A Model while moving towards a condition-level bundle. Components of our conceptual model are summarized in Table 2.

Episode Trigger
We note that a fully condition-based bundle would begin when a patient has a confirmed diagnosis of a condition. Starting the bundle at diagnosis encourages coordination across providers, as well as appropriate diagnostic testing and management of the condition that can improve outcomes and reduce costs over the long-term.[14] However, as mentioned earlier, AS patients are generally not diagnosed until they are symptomatic and therefore may require

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[*] The inpatient clinical episodes include both TAVR and SAVR but each is its own model rather than being procedure-agnostic.
[†] Less payments for services billed under a list of "excluded DRGs" for certain high cost services and treatments for conditions unrelated to the procedure.

treatment soon after diagnosis.[15] Because clinical guidelines suggest there should be a short period between diagnosis and treatment, the payment model will initially continue using the replacement procedure as the episode trigger to enable ease of implementation. However, the model could potentially include an additional "look back" period, which accounts for costs prior to the replacement procedure or move up the start of the bundle to the time of diagnosis.

By initially keeping the aortic valve replacement procedure as the episode trigger, the eligible participating entities would be the hospital systems that perform the procedure. These systems are likely better equipped to successfully implement the model and have more control over the clinical decisions most likely to affect overall outcomes. Initially, eligible entities should be restricted to provider systems offering both surgical and the transcatheter procedures as one of the goals of the bundle is to ensure appropriate patient-centered choice of treatment.

Patient Population

The target population for the model will be FFS Medicare patients with severe symptomatic AS for whom an aortic valve replacement is an appropriate intervention. Surgical and transcatheter valve replacement procedures are mapped to DRGs that do not offer specificity on the intervened valve. However, the International Classification of Diseases (ICD-10) codes can be used in addition to the DRG to provide the needed specificity to identify that a patient had an aortic valve replacement. [16] In the BPCI-A program, CMMI has already defined a cardiac valve replacement bundle using a combination of DRGs and ICD-9/ICD-10 codes which could serve as a potential foundation for this bundled payment model. However, the model described in this proposal would be triggered by codes that are specific to aortic valve, indicating either a TAVR or a SAVR procedure was performed, and the target price would not be affected by which procedure was used.

A subset of AVR patients will have multiple planned cardiac procedures performed during the same inpatient hospital stay or during the episode of care. At least in the initial phase, this bundle will not include those patients, but could potentially be expanded to include them later.

Bundle Components and Duration

The majority of current CMS bundled payment models are 90 days or less, although there are examples, such as the Oncology Care Model, that are longer-term. The length of the episode of care is intended to allow for initial recovery from the procedure, including any required follow up care.

For the AS bundle, a longer-term episode that extends 180 days from the Anchor Stay will allow for inclusion of full treatment and recovery, including any procedure-related complications (e.g., major vascular / bleeding events, acute kidney injury, new permanent pacemaker implantation, heart failure-related hospital admissions, paravalvular leak repair, sepsis/infection, and stroke) in the payment. [17] This longer time horizon or episode length will also serve as an incentive to coordinate any required ongoing cardiac care for patients who may still have other major factors exacerbating their heart failure that were previously not prioritized in order to treat the AS.

However, due to this longer time frame and the older age of the patient population, many of whom have multiple comorbidities, there is a higher risk of unanticipated expenditures unrelated to cardiac care or procedure-related complications. Eligible hospital systems may be unwilling to take on risks associated with subsequent care unrelated to the procedure or follow-up cardiac care. The level of risk is increased for lower-volume hospitals where one or two unexpectedly high-cost patients could deplete any potential shared savings.

One method to address this concern is to create an "inclusive" bundle, in which only expenditures related to overall cardiac care and known complications of the procedure are included when calculating a target price. This could be accomplished through historical models of costs and clinical understanding of complications. Using this method, a participating entity would not be held accountable for billing codes outside of that care, allowing them to focus on the costs within their control. The bundled payment model could also employ techniques used by current models to mitigate the impact of outliers and allow more predictability, such as stop-loss and stop-gain mechanisms.[18]

Quality and Outcome Measures

Current CMS bundled payment models are defined using a pay-for-performance methodology, which ties reimbursement to outcomes. In the BPCI-A Cardiac Valve model, for example, the model is adjusted based on All-cause Hospital Measures, Advance Care Plan, the CMS Patient Safety Indicators and Perioperative Care: Selection of Prophylactic Antibiotic 1st or 2nd Generation Cephalosporin measure.[19, 20, 21, 22]

A procedure-agnostic aortic valve replacement bundle should also include outcome and quality measures, with an emphasis on clinical outcomes that are not sufficiently incentivized by simply bundling payment, such as mortality and new onset atrial fibrillation. In addition, to assess improvement in quality of life and incorporate patient's goals into choice of intervention, the bundle should also include patient reported outcome instruments such as the Kansas City Cardiomyopathy Questionnaire or Short Form-36, and additional measures such as maintaining independence and reducing pain symptoms.[23, 24]

While some of these outcomes can be assessed through administrative data, others may not be adequately captured in claims. Additional data infrastructure might be required to collect these types of data (described in greater detail below). In addition, while patients are already given the KCCQ-12 to assess how their valve disease and treatment influences their quality of life, this data is not normally collected at 6 months, which would mark the end of the episode. Also, at present, CMS has not mandated the use of the KCCQ-12 for SAVR (it has been mandated as part of the National Coverage Determination for TAVR). More work is needed to determine the most useful measures, for both patients and clinicians, to assess improvement from baseline.

Setting a Target Price

Bundled payment target prices are typically set based on historic utilization rates and expenses for the target population, recalculated semi-annually.[25] The American Hospital Association

recommends that CMS consider policies that ensure a hospital does not have to compete against its own best performance which facilitates efforts in continued improvement and investments in future innovations.[26]

Patient-level risk adjustment is critical to ensure appropriate payment given variability in procedural volume across hospitals and case-mix of patients.[27] In the current BPCI-A model, target prices are risk adjusted by DRG codes that differentiate patients with and without complications and comorbidity and by Hierarchical Condition Category (HCC) identifiers. The current MS-DRGs for the TAVR and SAVR procedures do not segment patient risk the same way. DRGs for SAVR have a three-way split between procedures with co-morbidities and complications (CC), with MCCs and those without CCs or MCCs. TAVR DRGs, on the other hand, only have a two-way split between those that include MCCs and those that do not. Meaning, a procedure-agnostic bundle cannot directly use the current DRG codes to risk adjust.

Risk adjustment methods that allow more gradations in risk as well as potentially considering factors other than comorbidities (e.g. frailty) may be more desirable. For example, one potential metric that captures many of these nuances is the Society for Thoracic Surgeons (STS) risk score -it is regularly collected as part of standard of care and is commonly reported in surgical registries, although not generally available to CMS.[28, 29, 30] Given some of the recent changes in the STS risk score after adoption of the TAVR, it might be appropriate to develop a novel claims-based risk assessment that approximates the STS risk score. While the ideal measure for risk adjustment in the condition-based bundle has yet to be identified, it is imperative to assess the reliability, validity and accuracy of the risk score before implementation.

Manufacturer-Shared Risk

The President's HHS budget for FY 2021 encourages manufacturers to take on some risk for bundled payments for the adoption of high-value technologies. However, manufacturers are limited by the current legal and regulatory landscape from being financially accountable for patient outcomes. While simple warranties related to mechanical failures of medical devices can be offered, arrangements that allow the manufacturer to share risk in the overall outcomes are more complex to implement. First, it is challenging to appropriately allocate risk between manufacturers and providers. Adverse or poor outcomes can result from the device itself, the operator, or the infrastructure in which the care takes place, but are generally the result of a combination of these factors and are often difficult to attribute to any one actor or product.[31] Current regulations related to the Anti-Kickback Statute (AKS) require that warranties and associated remuneration are only given for the purposes of the cost of the product itself and limit manufacturers from paying for anything else apart from the cost of the device, such as assuming additional financial risk for overall patient outcomes. Second, while regulations do allow manufacturers to contract with provider systems to provide products, services, and infrastructure supports that may improve overall patient outcomes, the warranties and rebates related to those products, services, and supports may not exceed the cost of the provided items, which may be significantly less than the overall cost of care.

We, along with others are actively working to address the legal and regulatory challenges to the implementation of value-based payment (VBP) arrangements and outline the potential role for device manufacturers in this approach. [32] There are a variety of ways that medical device manufacturers could partner with providers to manage and share risk, such as providing long-term patient monitoring or offering consulting services. [33, 34]

At its core, the decision to use a particular medical device is made between a clinician and a patient. The condition-based bundle provides additional autonomy to the clinician and patient regarding choice of device best suited for the patient. While it is important to the implementation of this type of bundled payment to bring the device manufacturer to the table, their exact role has yet to be defined.

In 2019, Health and Human Services' Office of the Inspector General proposed new AKS safe harbors related to value-based arrangements and sought comments on whether to exclude medical device manufacturers from the definition of value-based enterprise (VBE) participants, eligible for safe harbor protection.[35] Provided that device manufacturers remain part of the new AKS VBE safe harbors, they would be able to contract with value-based entities, like hospital systems, to assume some risk for the AS bundled payment model outlined here. Additionally, as proposed, the Warranties safe harbor would permit device manufacturers to apply a warranty to one or more items and related services, provided that the warranty covers at least one item, potentially allowing them to assume risk for outcomes beyond device malfunction. However, it is unclear what services would be allowed to be covered by a warranty and to whom the warranty would be paid. There is no direct authority for the warranty to be sent to CMS directly and it is unclear if the warranty could be paid to the hospital that replaces the device if it wasn't the same hospital that performed the original procedure.

The payment model conceptualized in this white paper is designed to be agnostic to the treatment approach, in order to incentivize providers and patients to select the intervention that is the most appropriate for the patient's particular case and clinical preference. Safe harbors that only apply when a specific product is used, and will not cover services provided alongside a competitor's device or if a decision is made to not use a device at all, may prevent providers from being able to effectively engage with manufacturers to share risk in a condition-based payment model. However, as more entities are pulled into risk-sharing models, these payment models must respect patient privacy expectations and desires. This includes how patient-level data can be used outside of that patient's direct care decision-making and payment calculations.

In the case of AS, given the deep clinical expertise of providers as well as device manufacturers, it may be most impactful to grant flexibility to providers, device manufacturers, and payers to enter into outcomes-based contracts around the episodes and subcontract financial accountability for particular outcomes within the episode. Unfortunately, the current legal framework limits manufacturers and providers from entering into shared-risk contracts. However, this level of flexibility, to craft contracts around outcomes within the episode payment model, is similar to the flexibility CMMI awards participants in some of the current

programs such as BPCI-A. If the final rule on the new value-based arrangements AKS safe harbor excludes device manufacturers, the model outlined in this paper should include a new waiver that would allow device manufacturers to participate as risk-bearing partners.

Data Infrastructure

Information required to administer bundled payment models is generally collected through administrative claims data. However, this conceptual model suggests that clinical and patient-reported data not normally collected through claims could be useful for both risk adjustment and outcome and quality assessment. Currently, CMS does not have infrastructure in place to receive this type of clinical data directly from provider systems. While some of these data would be available for TAVR patients through the TVT Registry, SAVR patients are not included in this registry.[36]

A complimentary module could be created to support data collection on SAVR patients, analogous to the American Joint Replacement Registry, for purposes of bundle payments.[37] Alternatively, data from the STS Adult Cardiac Surgery Database could also be used. However, this general registry is voluntary (though it covers ~ 95% of all adult cardiac surgery in the United States) and does not include all of the data that might be required, such as KCCQ-12 results. Pay-for-reporting could also be implemented to collect these measures and develop the necessary data infrastructure. In this case, developing the systems in ways that could pull data directly from EHRs or other electronic record systems could ease workflow and reduce the costs of reporting requirements. This lack of infrastructure and access to clinical data is a critical obstacle to developing more outcomes-based bundled payment models, especially for medical devices.

Table 2: Components of a Payment Model

Component	Details of VBP Component
Payment Approach	A longer-term bundled payment that is procedure-agnostic, with the goal of incorporating patient preference and access, incentivizing care coordination post-procedure, and improving outcomes
Triggers to Enter the Model	A combination of CPT and ICD codes indicating an aortic valve replacement
Patient Population	Traditional Medicare patients with severe AS in whom an aortic valve replacement is an appropriate intervention.
Episode Length	Anchor Stay + 180 days following discharge.
Care Delivery Model	The hospital that performed the procedure would assume financial liability for episode spending. The longer time frame would encourage care coordination with the patient's physicians who are related to their other cardiac care. A unique attribute of this proposal is that it would not include all care within the episode. Instead, the model focuses on cardiac care and care relevant to the procedure, including the procedure hospitalization, all cardiac care within the model period, and treatment for procedure-related complications such as: - Major vascular events / bleeding - Acute kidney injury - New permanent pacemaker implantation - Heart failure-related hospital admissions - Paravalvular leak repair - Sepsis/infection - Stroke
Risk Adjustment	The bundled payment would be risk adjusted to account for the heterogeneity of the patient population with AS.
Performance Measures	Outcomes and quality measures will also be used to adjust payment. This could include outcomes such as mortality, new onset AF, and patient-reported quality of life or physical function.
Risk Sharing	There is also interest in how manufacturers may be able to share risk, however there are legal and regulatory barriers to this. This risk-sharing could involve warranties that cover early failure of a device, or separate provider-manufacturer contracts that allow alignment on some of the outcomes that the provider would be at risk for in this bundle, with the manufacturer providing additional services such as remote monitoring or training.
Data Sources	Much of the data that would be required for risk adjustment and performance measures would not be available through traditional claims. Some of this data is potentially available through current registries, although new infrastructure would likely be required.

Conclusion: Next Steps for Design and Implementation

In this paper, we posit that condition-based episode bundles that tie payments to outcomes can encourage the adoption of disruptive novel technologies in a resource constrained environment. We explore how device manufacturers might further promote care coordination and along with providers, share risk on outcomes within this payment model. In this initial work, we outline the main components of the payment model, within an example use case, including a novel bundle approach, condition of interest, target patient population, triggers to initiate the episode, risk adjustment approaches, outcome and performance measures, risk sharing, and data infrastructure. Importantly, the condition-based bundle provides additional autonomy to the clinician and patient regarding choice of device best suited for the patient – another step towards patient-centered care.

While we have presented here the main components, further analysis is needed to propose and implement an appropriate and actionable model within the current policy and infrastructure ecosystem. We aim to design, with the input of multiple stakeholders, a payment model that incentivizes patient-centered treatment decision-making, incorporates risk sharing, and expands bundled payment models to encompass longer time horizons. To meet these goals, and finalize the payment model, we are undertaking the following steps:

1. Engaging feedback from payers including CMS and Medicare Advantage plans, and provider systems.
2. Conducting quantitative and qualitative analyses to inform and substantiate each component of the model.
3. Identifying the quality measures and outcomes of interest used to evaluate provider performance.
4. Conducting a budget impact analysis to determine if the proposed model will result in savings to the Medicare program.
5. Assessing how to structure upstream risk for bundled payments by addressing the root cause of the disease before the patient undergoes surgery and calculating the risk of needing any intervention at all.

Furthermore, while we use aortic stenosis as a case study and are responding to the recent policies from the FDA and CMS, we are also considering broader efforts to seek coverage solutions for innovative medical technologies.[38] Ultimately, the key aspects of this model, such as the shift away from procedure-specific; the incorporation of longer periods of care; the involvement of manufacturers in sharing risk on patient outcomes, can serve as a feasible CMS payment approach for other innovative medical technologies.

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