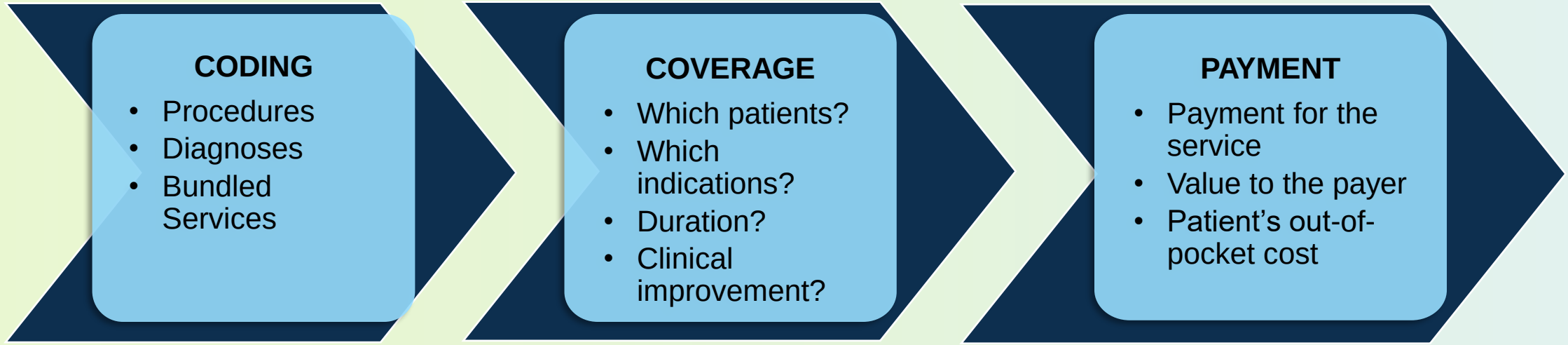
Medical Device Reimbursement Case Study

Athena Med Tech – Athena A-Valve

Reimbursement Overview

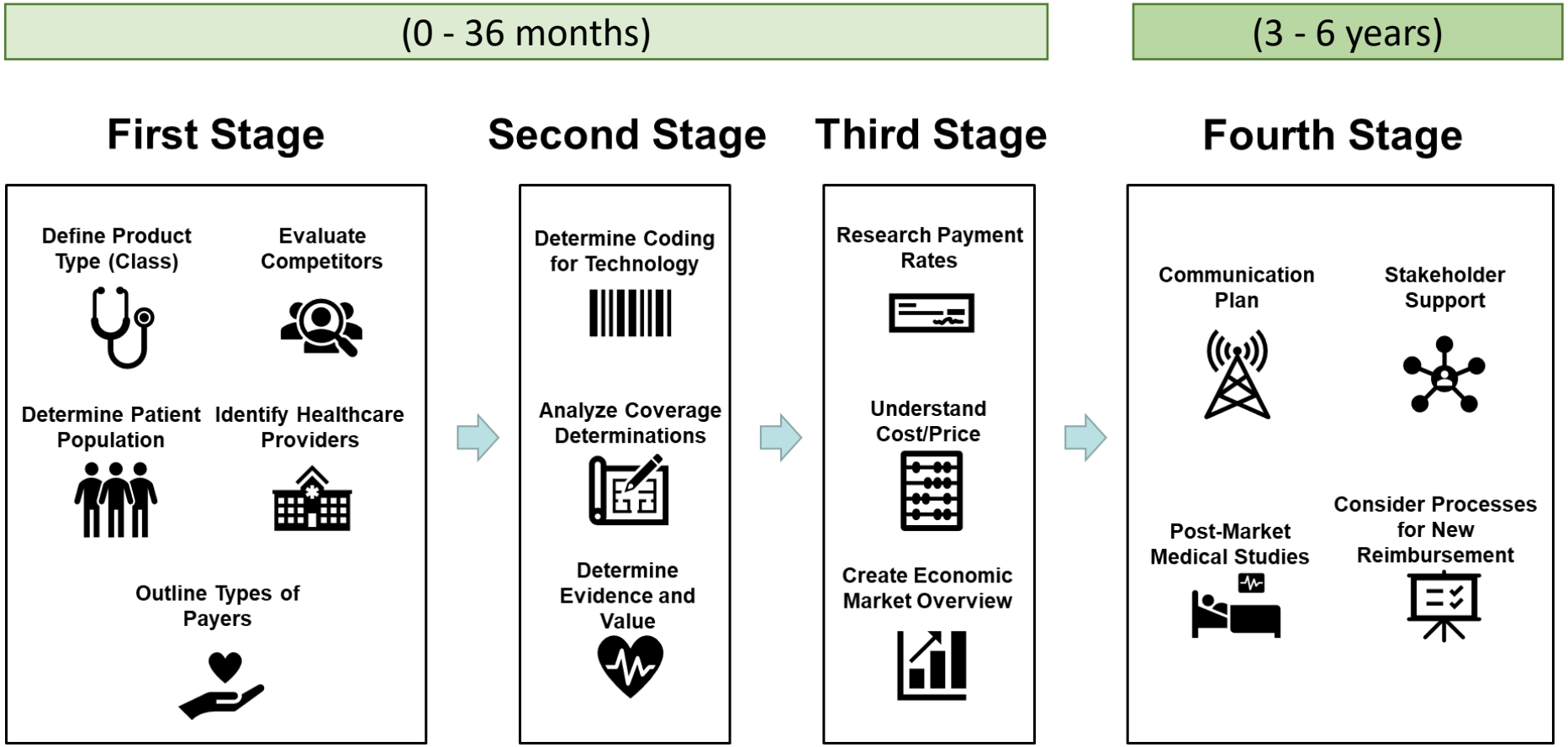
Bringing a medical product to market is a challenge. An academic entrepreneur needs to understand the entire commercialization process and manage multiple tasks related to early-stage research and development, clinical trials, regulations, and reimbursement. The goal of receiving U.S. Food and Drug Administration (FDA) approval is often considered the ultimate endpoint that leads a new technology to commercial success. However, if new products do not obtain the desired amount of reimbursement or, even worse, are not covered by payers, then physicians and hospitals are unlikely to buy and utilize the new products. Therefore, reimbursement for the new product is as important as regulatory approval.

Key Elements of a Reimbursement Strategy



Reimbursement Strategy Activities Roadmap

This case study breaks down the process described in our *Knowledge Guide for Medical Device Reimbursement*. It will take you step-by-step through a process that innovators may follow to develop a strategy for medical device reimbursement. We'll walk through each step from the innovator's point of view. Aspects of the process may be conducted together, roughly in tandem. Each slide presents one aspect of a particular stage of the process.



Introduction to Athena Med Tech's CEO and Athena A-Valve

Ted is the CEO of Athena Med Tech. He has a novel innovative transcatheter heart valve to address the unmet medical needs of TAVR (Transcatheter Aortic Valve Replacement) procedures. Clinical trials have been initiated.

What does Ted need to do throughout product development to ensure optimal reimbursement?

Here's some background from Athena Med Tech's initial pitch to investors:

Product Description

- Athena Med Tech is developing an innovative transcatheter heart valve called **Athena A-Valve** for TAVR (Transcatheter Aortic Valve Replacement) procedures.
- **Athena A-Valve** is a replacement aortic valve designed to restore proper function to the diseased aortic valve.
- **Athena A-Valve** is made up of a wire valve frame and bovine (cow) animal tissue leaflets.

About TAVR

- TAVR is an emerging less invasive procedure that replaces the aortic valve without opening a patient's chest to reach the heart.
- Patients who undergo a TAVR procedure typically have an easier time recovering and experience less discomfort.
- TAVR is an option for patients previously considered ineligible for open-heart surgery.

First Stage

First Stage

- Define Product Type (Class)
- Evaluate Competitors
- Determine Patient Population
- Identify Healthcare Providers
- Outline Types of Payers

Second Stage

- Determine Coding for Technology
- Analyze Coverage Determinations
- Determine Evidence and Value

Third Stage

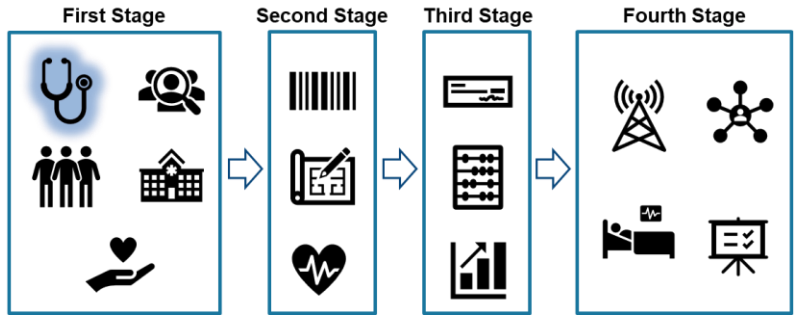
- Research Payment Rates
- Understand Cost/Price
- Create Economic Market Overview

Fourth Stage

- Communication Plan
- Stakeholder Support
- Post-Market Medical Studies
- Consider Processes for New Reimbursement

First Stage: Define Product Type (Class)

Ted needs to understand what medical device regulatory class the Athena A-Valve will fall into and conduct necessary research based on his product type. He will need to research possible existing comparable products and can initiate this search through a landscape analysis of TAVR products. The product type and regulatory class determine the risk of the device and are critical for Ted's regulatory application.



Ted searches through FDA databases for TAVR comparable products.

- Ted identifies four devices on the market for comparison with his device.
- His research on these comparable devices makes Ted realize that Athena A-Valve will be categorized by FDA/CDRH as a **Class III** significant risk device, which requires demonstration of safety and effectiveness for approval.
- Also based on the comparable devices found, Ted acknowledges that the intended use for this product will be patients with valvular heart disease who are at high or extreme risk for open-heart surgery. Typically, patients with the greatest risk are over 65 years of age.

Key questions:

- What will be the specific medical device class for the product?
- What will be the risk category that determines safety and effectiveness?
- What is the intended use for the device?

First Stage: Evaluate Competitors

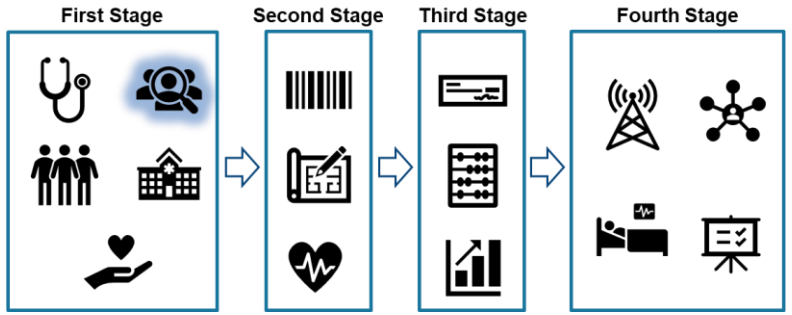
Ted uses the knowledge he learned from his landscape analysis to assess the company's potential competitors, their market share, and product positioning.

Based on his research, Ted has found multiple predominant players/market competitors for TAVR Products:

- Sapien 3™ and Sapien 3 Ultra™ from Edwards Lifesciences
- Evolut R™ and Evolut PRO™ from Medtronic
- Lotus Edge™ by Boston Scientific
- Flexnav™ TAVR System by Abbott

Ted's product will enter the market as an FDA premarket approval (PMA) under the same product code as the competitors. He can elaborate through his marketing positioning the unique features of the product and the intended use for patients with high calcification of bicuspid valves as the product differentiator.

In 2018, approximately 209.3M patients suffered from valvular heart disease globally, which caused about 2.6M deaths that year. Frost & Sullivan forecasts the U.S. TAVR market to grow from $28.7M in 2018 to $956.6M in 2025 with 65% of market growth driven by 1) the expanding use of TAVR, 2) the increasing number of hospitals and physicians eligible for TAVR procedures, and 3) differentiating the patient population for higher risk patients.



Key questions:

- What competitor devices are on the market?
- What is the current market share for each of those products?
- What will differentiate the product from competitors?

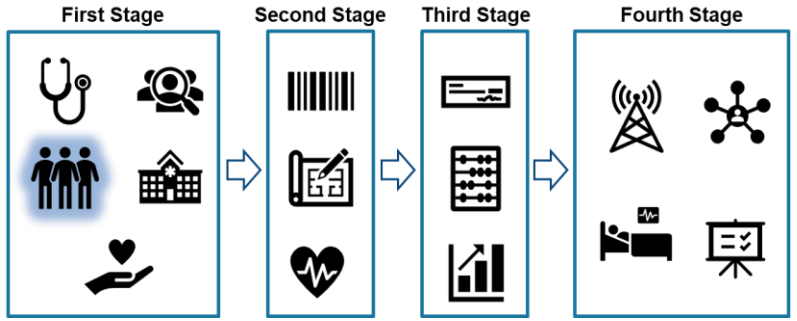
First Stage: Determine Patient Population

Ted knows he also needs to specify the patient population for his product to align with the intended use. He compares his product to his competitors to ensure that he has accurately assessed the patient population needed. This is important, as this information will also inform the clinical study design and data to be collected.

The 2020 American College of Cardiology/American Heart Association Guideline recommends considering TAVR for patients with symptomatic severe aortic stenosis. Age is a key factor in determining eligibility for TAVR.

- Surgical aortic valve replacement (SAVR) or TAVR may be found appropriate for patients aged 65 - 80 years depending on their overall clinical picture
- TAVR is favored for patients over 80 years old
- As a bioprosthetic valve, Athena A Valve is favored for patients older than 65

While SAVR is the favored intervention for patients over 65 years old and for patients of any age at high or extreme risk for open-heart surgery, TAVR is beneficial because it is a less invasive procedure that may result in a shorter hospital stay and a faster return to normal activities.
https://resourcelibrary.edwardsconnect.com/api/v2/view?site=hv&resource=387



Key questions:

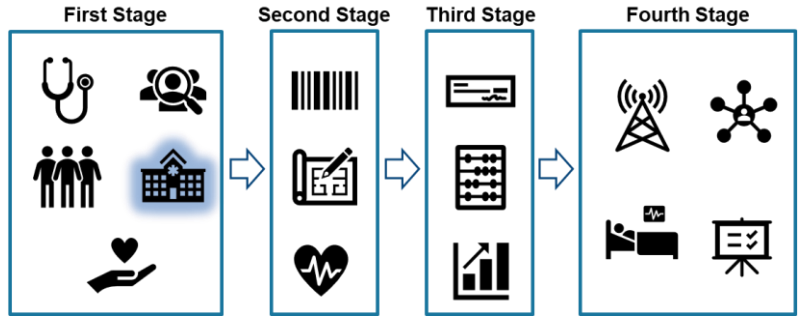
- Which patients would benefit most from this medical device?
- Which patient population offers the largest target market size, and has potentially the highest coverage rates?
- Are there certain socio-economic factors, such as high-risk populations, that should be considered for this patient population?

First Stage: Determine Provider and Site of Service

Ted needs to identify the healthcare provider that will be using the device and site of service where the device will be utilized in order to determine the payer.

In this case, Ted's implantable device will be used during a non-surgical, minimally invasive procedure. The procedure will be performed by a team of healthcare providers including an **interventional cardiologist, cardiac surgeon, imaging specialists, and an anesthesiologist** in an **inpatient setting**.

- The cost of implantable devices are bundled into the facility charge for a procedure. This means that the facility is the direct payer for the device, not the third-party payer (who pays for the procedure).
- Site of service and healthcare providers are important considerations for an innovator. The site will help to determine the payer. The healthcare provider (in this case, surgeon) has input into selection of the type or brand of device.
- Marketing should be targeted toward surgeons and in-patient facilities where the procedure is performed.



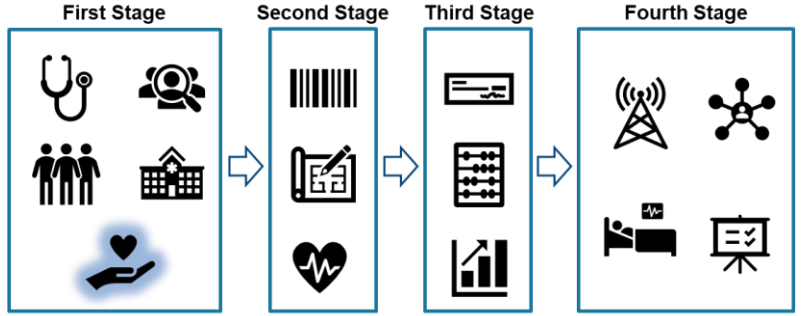
Key questions:

- Based on the intended use and target patient population, which particular group of healthcare providers would use the device (i.e., cardiologist, pediatrician, primary healthcare provider, etc.)?
- Where will the device be used — in an outpatient (doctor's office) or inpatient (hospital) setting, or in the patient's home?
- Why is site of service an important consideration?

First Stage: Outline Third-Party Payers

Ted knows different types of payers – including Medicaid, Medicare, and commercial payers who have Medicare Advantage plans – should be evaluated. Not all payers may be appropriate for the target patient population of the Athena A-Valve.

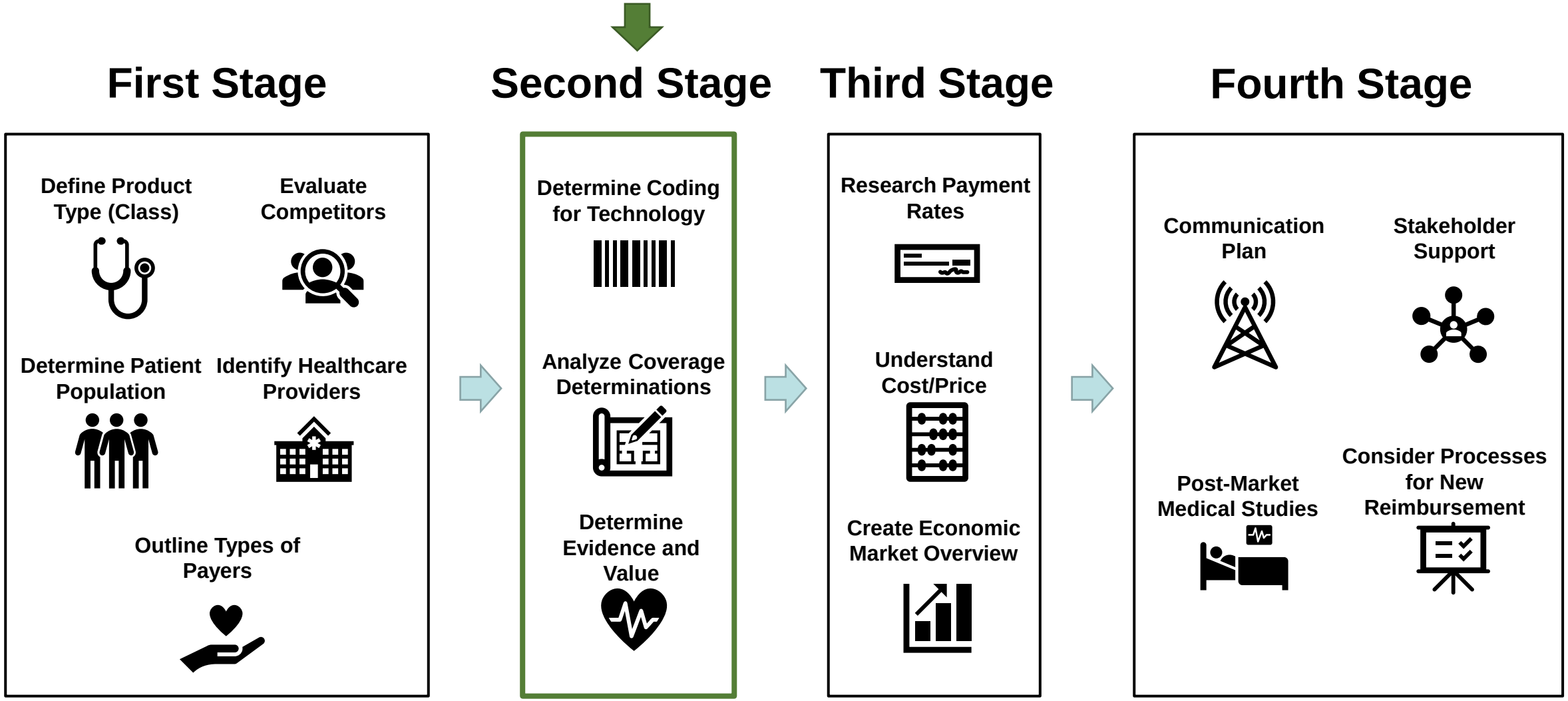
The third-party payer will reimburse the inpatient facility and the surgeon for performance of the TAVR procedure. As the target patient population is individuals over 65, the likely payers are traditional Medicare, Medicare Advantage, and other Federal programs such as the Federal Employee Program and the Veterans Health Administration (VHA). However, it will be important to be remain cognizant of any clinical studies conducted that support the performance of the procedure on a younger population which would broaden the payer landscape to include commercial payers.



Key Questions:

- Based on the age of your target patient population, should any payers be excluded from the analysis?
- Would the device be predominantly used by a patient population with a specific payer, i.e., commercial payers only?

Second Stage



Second Stage: Determine Coding for Technology

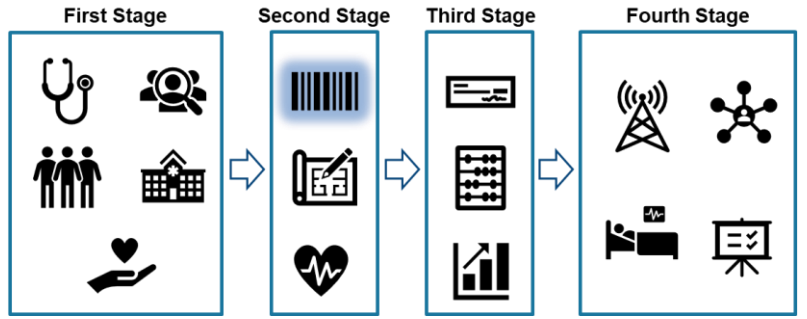
Ted knows he needs to determine if there is existing coding for his product. Google searches on "TAVR" may yield some information. However, the best place to find an existing Current Procedure Terminology Codes® (CPT®) code that meets the description of the service for his tool or device is a CPT book or an eBook. The American Medical Association (AMA) maintains CPT codes.

Billing for any medical procedure involves using codes that are assigned to identify every medical procedure, item, or service. Surgical procedures performed in an inpatient facility will require the submission of two bills:

- a bill for the professional services of the surgeon who performs the surgery will be submitted by the surgeon
- a bill for the use of the facility and its equipment will be submitted by the facility

Codes for the professional services performed by healthcare providers are known as CPT codes and are assigned and maintained by the AMA. The AMA publishes a new CPT manual yearly that can be purchased online.

For most payers, whether government or commercial, Medicare Severity-Diagnostic Related Group (MS-DRG) codes are used to bill facility charges. ICD-10 surgical codes are also reflected on inpatient claims



Key questions:

- What are billing codes and how are they used?
- Where can I find CPT codes?
- What reimbursement codes are used by facilities?
- Where is the best place to search for existing CPT codes?

Second Stage: CPT Code Descriptions*

CPT Code	CPT Code Description
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)
+ 33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)
+ 33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
+ 33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

*CPT codes and descriptions were retrieved from the 2022 Current Procedural Terminology (CPT) codebook. The most recent CPT codebook is available for purchase here.

Second Stage: Determine a Code for the Technology

A MS-DRG is a payment category that is used to classify patients into "like" groups for the purpose of hospital reimbursement. A set fee is assigned to each MS-DRG code and is the basis of reimbursement rather than actual costs incurred.

DRG classifications are based on:

- Principal diagnosis code
- Surgical procedure code
- Age of patient
- Expected length of stay in the hospital

This information is fed into a software system known as a "Grouper" which will assign the MS-DRG code.

These codes are used by Medicare and many commercial payers as the basis for reimbursement of inpatient hospital stays.

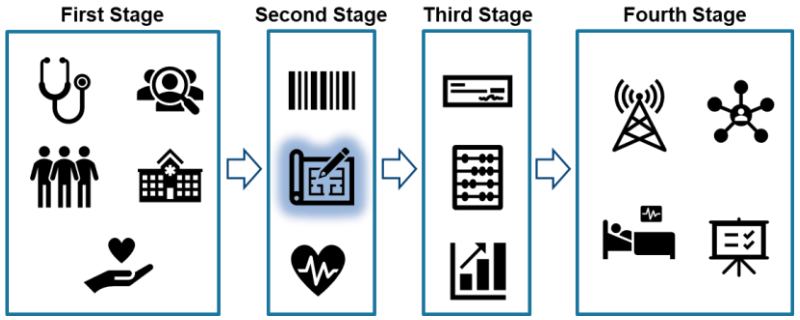
Ted learns that the following MS-DRG codes are most commonly assigned for inpatient hospital reimbursement for TAVR:

MS-DRG	Description of Procedure
266	Endovascular cardiac valve replacement and supplement procedures with MCC
267	Endovascular cardiac valve replacement and supplement procedures without MCC

Second Stage: Analyze Coverage Determinations

Ted needs to know if third-party payers are reimbursing the TAVR Procedure:

- To ensure that it is a covered service and not a service that patients would be required to pay for out-of-pocket
- To understand coverage indications and limitations



CMS and other payers have coverage determinations and medical policies that provide information on the indications and limitations of coverage of medical services. Notably, CMS does not include coding information in coverage determinations but separates this information into Billing & Coding Articles.

Ted searches through medical journal databases, the CMS Medicare Coverage Determinations Database, and commercial Medicare Advantage Plan sites to learn more about payer coverage of TAVR.

Key questions:

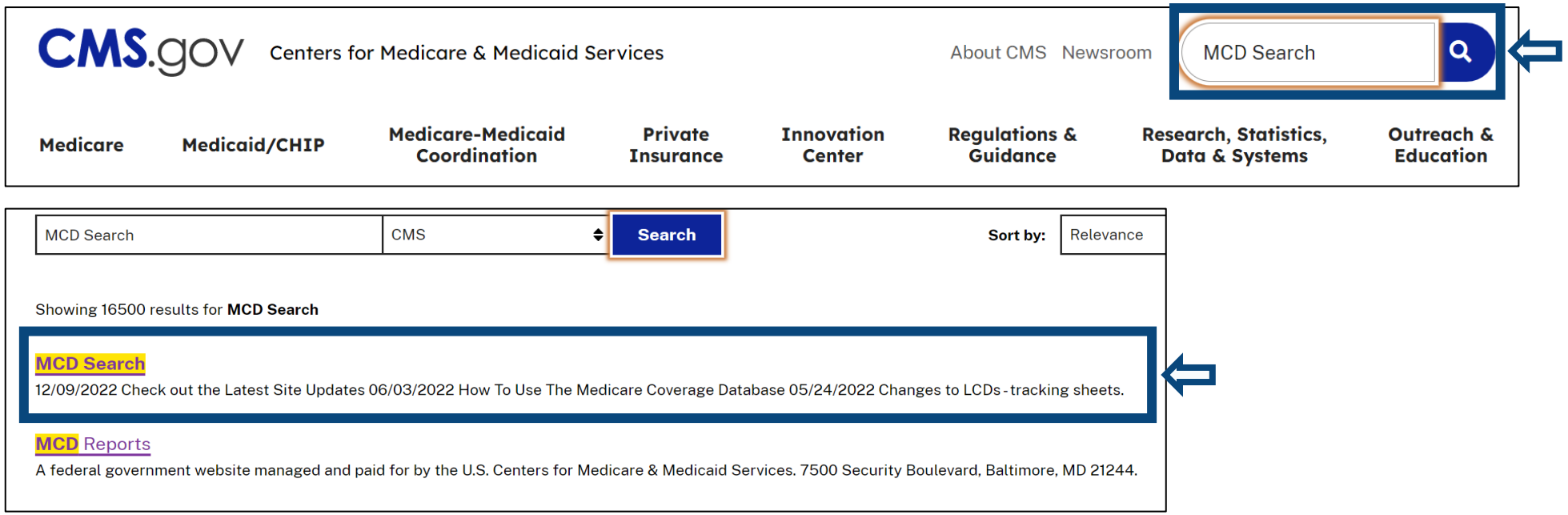
- Where can you find coverage information on your device?
- What are the coverage indications for this type of procedure?
- What are the limitations of coverage for this type of procedure?

Second Stage: Analyze Coverage Determinations

CMS maintains a database of local and national coverage determinations (NCD). CMS national Medicare coverage determinations supersede CMS local coverage determinations. However, 90% of Medicare coverage determinations are local. It is important to be aware of CMS and commercial payer coverage determinations. (Commercial payers may refer to such determinations as medical policies or reimbursement policies.)

Ted wants to search the CMS coverage database:

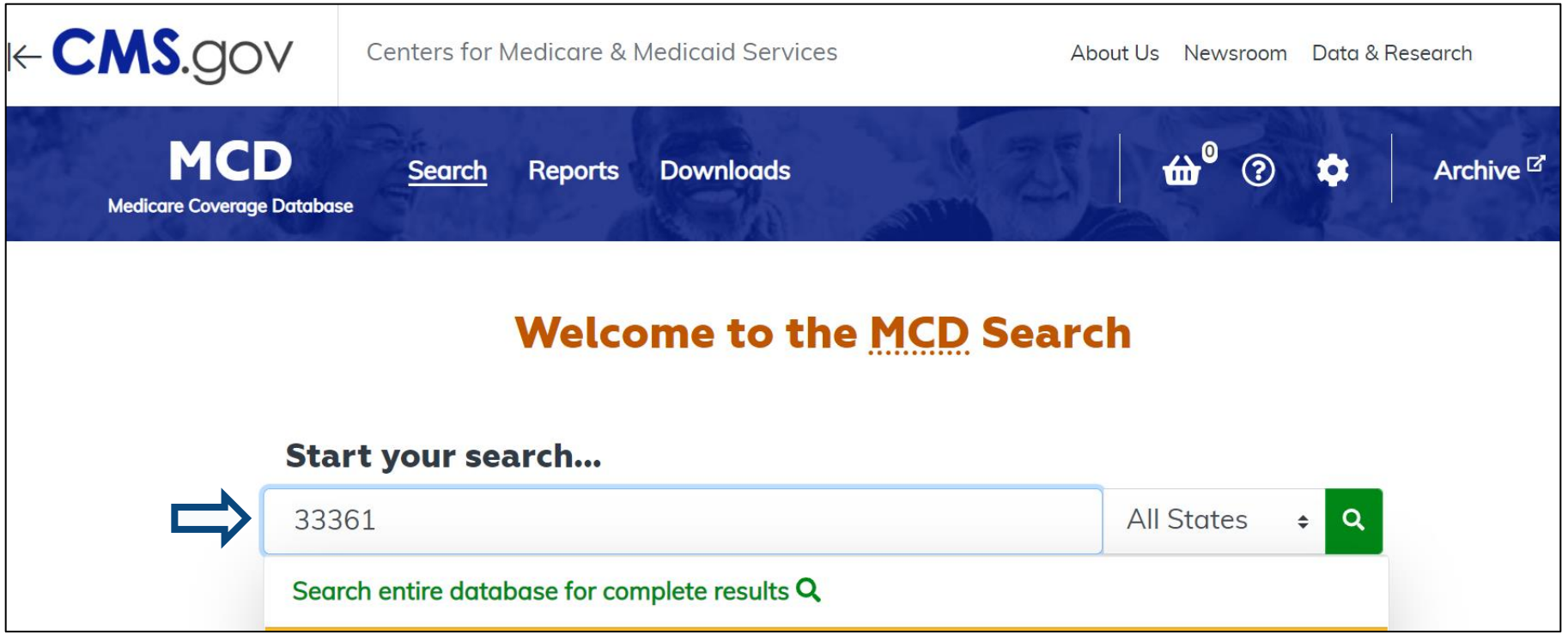
- He searches for "MCD search" on the CMS website and selects "MCD Search."



https://www.cms.gov/medicare-coverage-database/search.aspx

Second Stage: Analyze Coverage With A MCD Search

Ted enters “33361” (one of the CPT codes for TAVR) into the search box

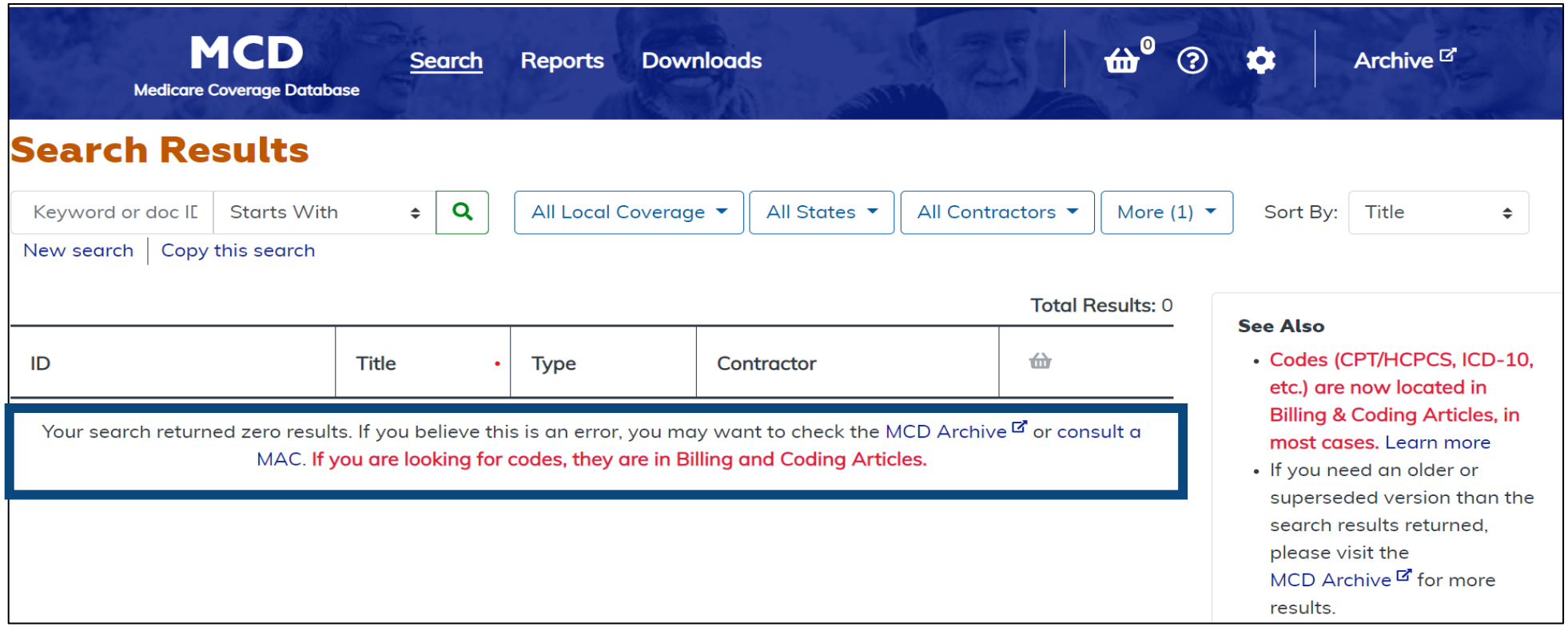


https://www.cms.gov/medicare-coverage-database/search.aspx

Note that your search may be by keyword, code, or document ID. It make take multiple searches to be certain that all possibilities have been exhausted.

Second Stage: Analyze Coverage Determinations MCD Results

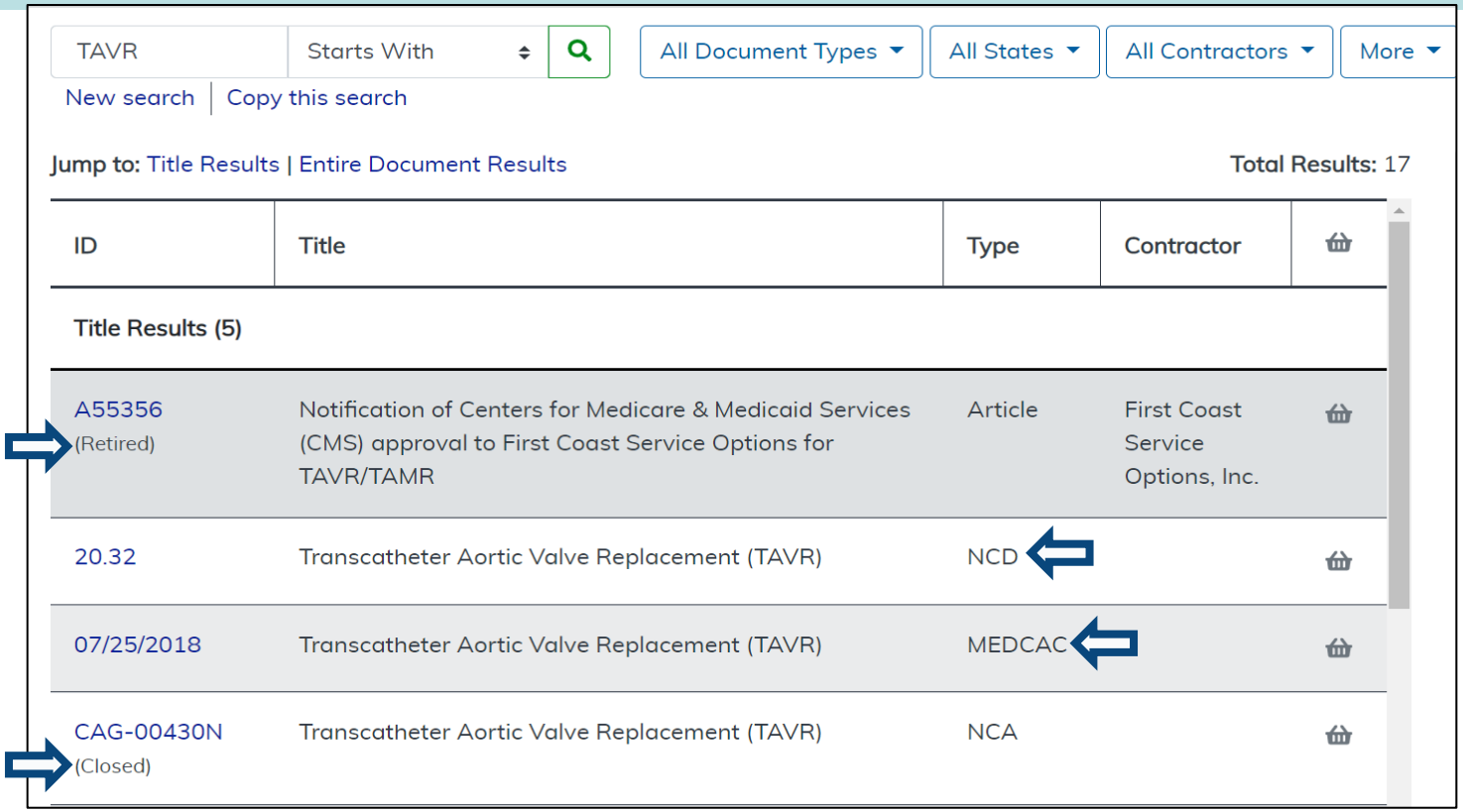
Unfortunately, this search returned zero results and included a message indicating that codes are in Billing & Coding Articles. Ted tries again.



Second Stage: Continue to Analyze Coverage Determinations

Ted tries searching for “TAVR” instead.

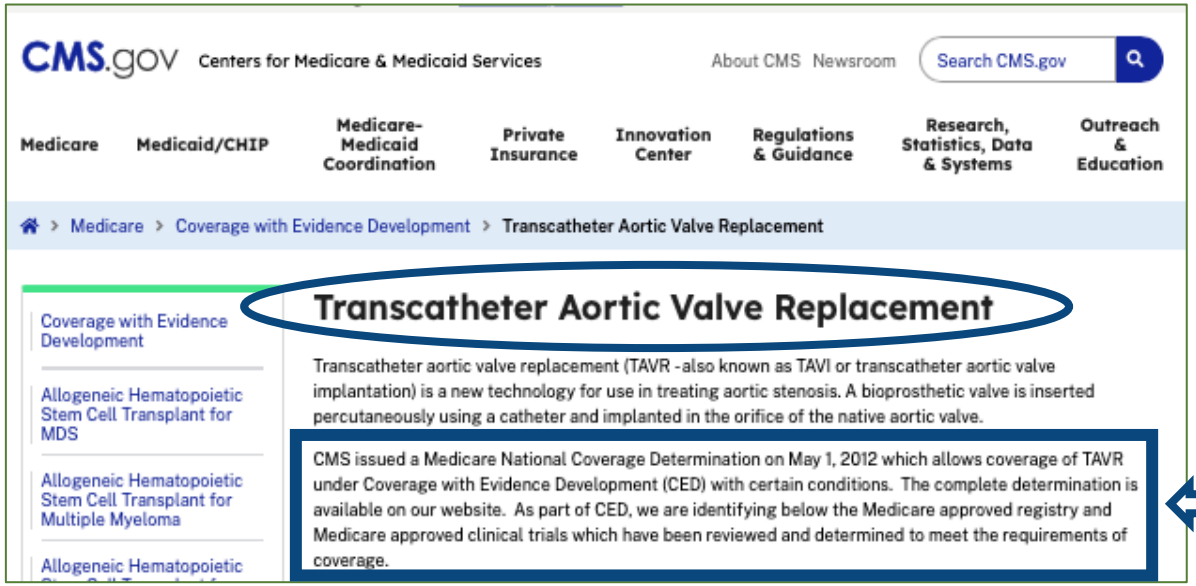
Several documents are returned. The first is a retired article that it is no longer applicable, the second is an active NCD, the third is a MEDCAC notice, and the last is a closed National Coverage Analysis. Ted should read both the retired and closed items to find out why they are not active.

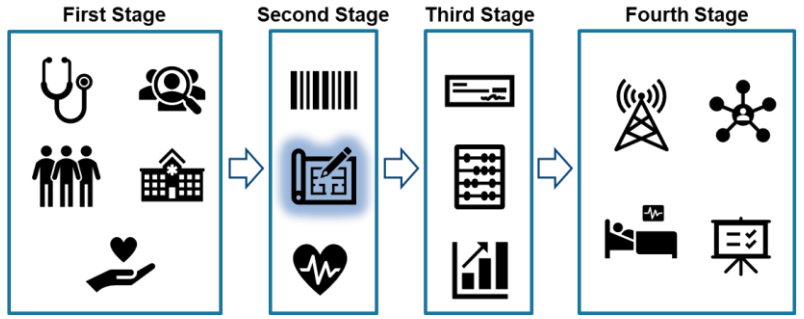


Second Stage: Refine Results

Ted finds that the Centers for Medicare & Medicaid Services (CMS) cover TAVR under Coverage with Evidence Development (CED) and it is considered inpatient hospital services.

- TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to an FDA-approved indication.
- TAVR is covered for use in clinical studies with a device that is not expressly listed as FDA-approved but must adhere to the standards of scientific integrity and relevance to the Medicare population.
- TAVR is not covered for patients with existing co-morbidities that would preclude the expected benefit from correction of the aortic stenosis.





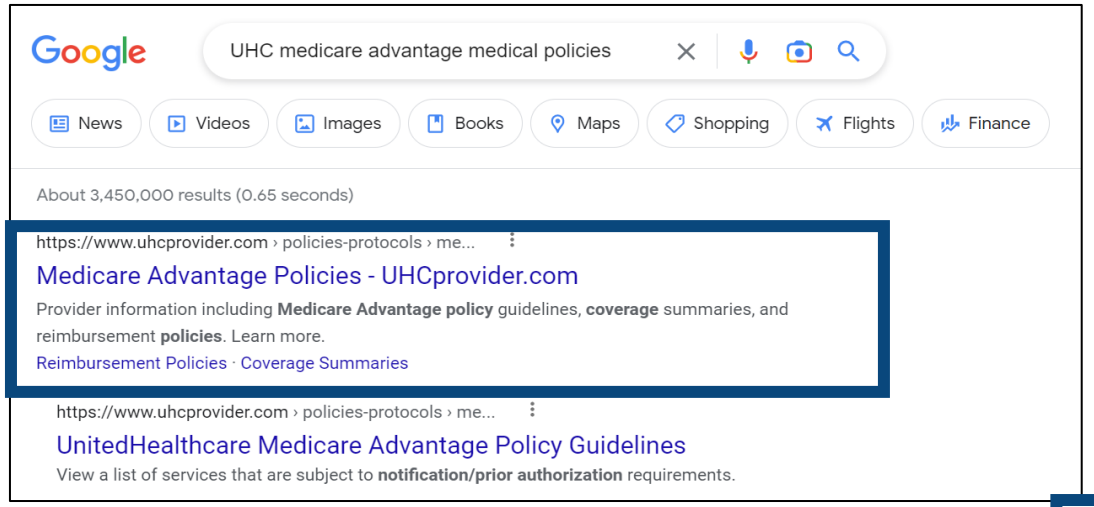
Key questions:

- What are the coverage indications for this type of procedure?
- What are the limitations of coverage for this type of procedure?

Second Stage: Analyze Medical Policies

It is also important to research commercial payer coverage information. There are many commercial payers and each one is a bit different. Their policies may be similar to CMS, or completely different. It's easiest to start with a Google search.

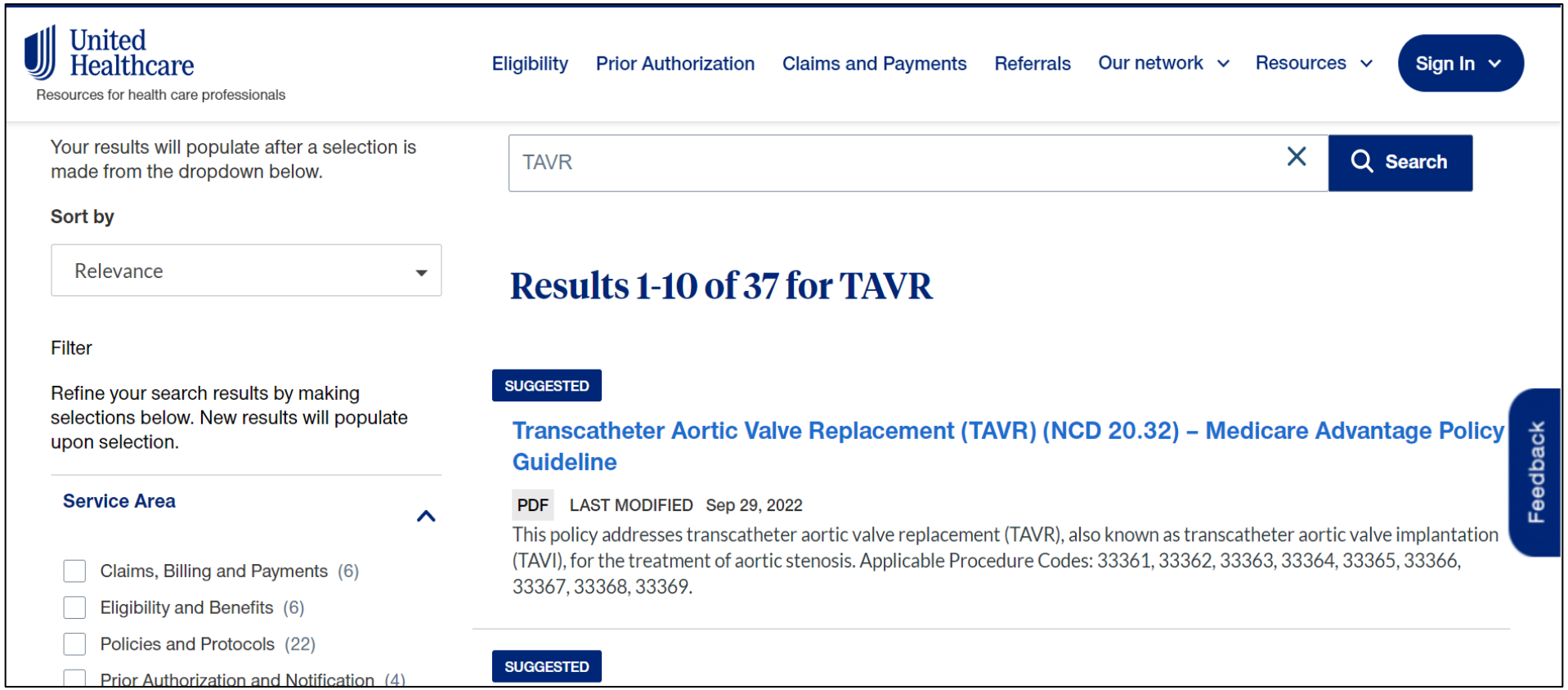
In this case, Ted wants to look up UnitedHealthcare (UHC) Medicare Advantage medical policies. His search returns Medicare Advantage policies as an option. He selects this option.



At the top right of the entry page, Ted enters "TAVR" into the search box.

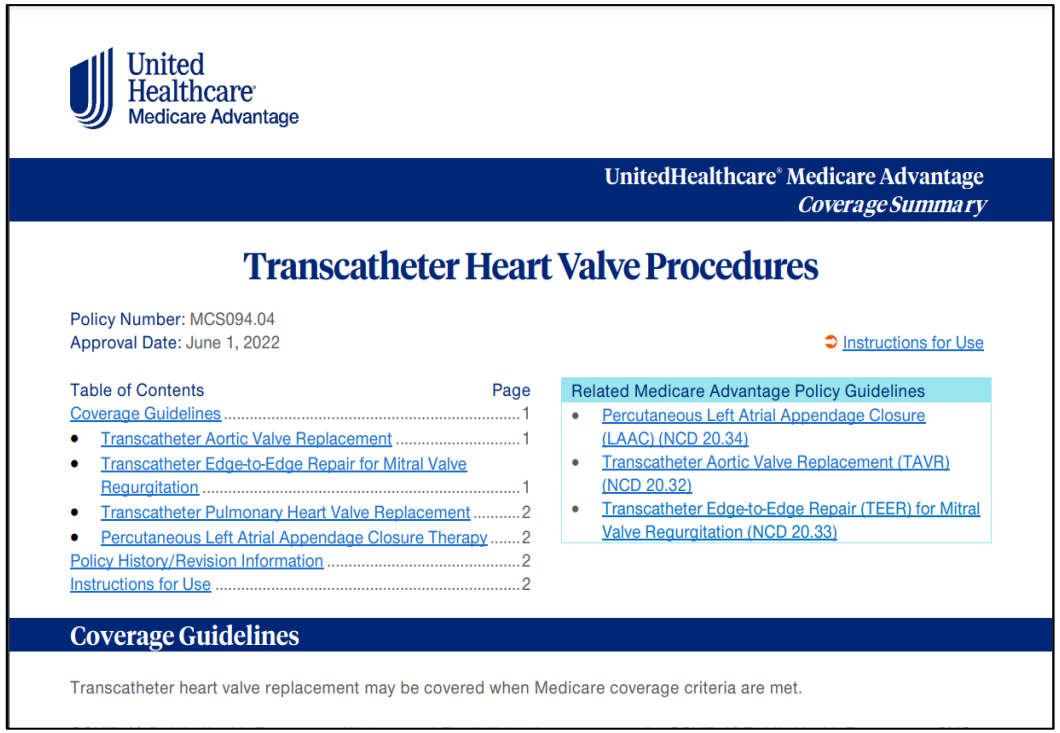
Second Stage: Analyze Specific Medical Policies

Ted searches for “TAVR” and it returns 37 documents. Ted has some reading to do!



Second Stage: Medical Policies Coverage Determinations

Ted finds that UHC Medicare Advantage Plans cover transcatheter aortic valve replacement and follow the CMS NCD.



United Healthcare Medicare Advantage

UnitedHealthcare® Medicare Advantage
Coverage Summary

Transcatheter Heart Valve Procedures

Policy Number: MCS094.04
Approval Date: June 1, 2022

Instructions for Use

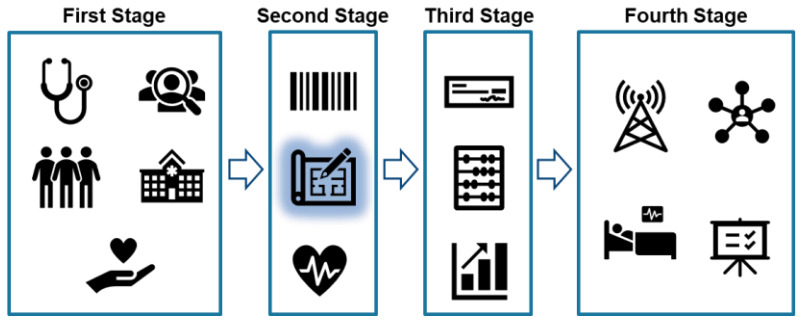
Table of Contents — Page

Related Medicare Advantage Policy Guidelines
- Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)
- Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32)
- Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33)

Coverage Guidelines

Transcatheter heart valve replacement may be covered when Medicare coverage criteria are met.

CMS considers TAVR as Category B devices and the UHC Medicare Advantage plan is responsible for coverage of these devices when criteria are met.
More information on reimbursement for clinical trials is provided in addition to a list of current clinical trials.



Key questions:

- What are the coverage indications for this type of procedure?
- What are the limitations of coverage for this type of procedure?

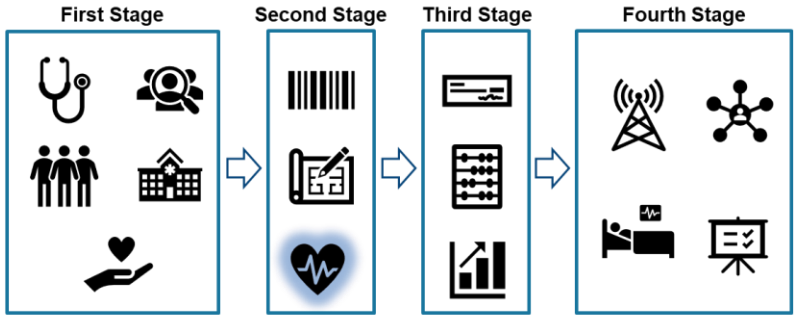
Second Stage: Identify Evidence

Ted recognizes that he needs to identify what evidence is required to show value and support a favorable coverage determinations for TAVR related products and procedures.

Ted has found through his searches in Journal of American College of Cardiology studies to support TAVR over surgical aortic valve replacement (SAVR).

- TAVR with a self-expanding prosthesis provided meaningful clinical benefits compared with SAVR.
- On average, patients put greater value on attributes that favored TAVR than SAVR, particularly in elderly populations.

Ted plans to work with his reimbursement consultant to appropriately provide evidence to support and possibly broaden the claims and benefits of his product



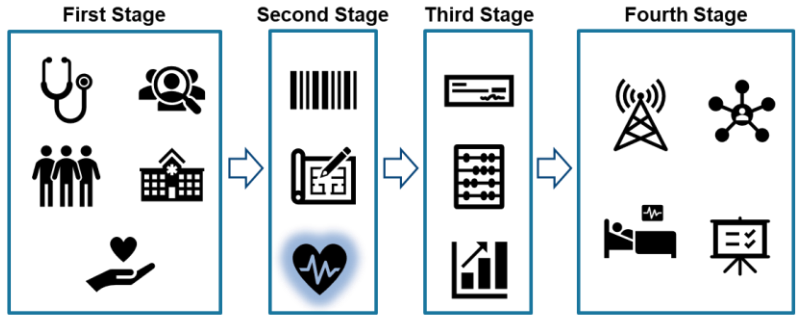
Key questions:

- What specific burden of illness values exist for this category of products and procedures?
- What are mortality value determinants presented for success?
- Are there medical societies that can advocate?

Second Stage: Determine Evidence and Value

Ted knows he needs to identify clinical evidence requirements necessary to support device reimbursement. He researches clinical trials conducted by his competitors to gain understanding of the study parameters that will need to be in place when he designs and conducts clinical trials.

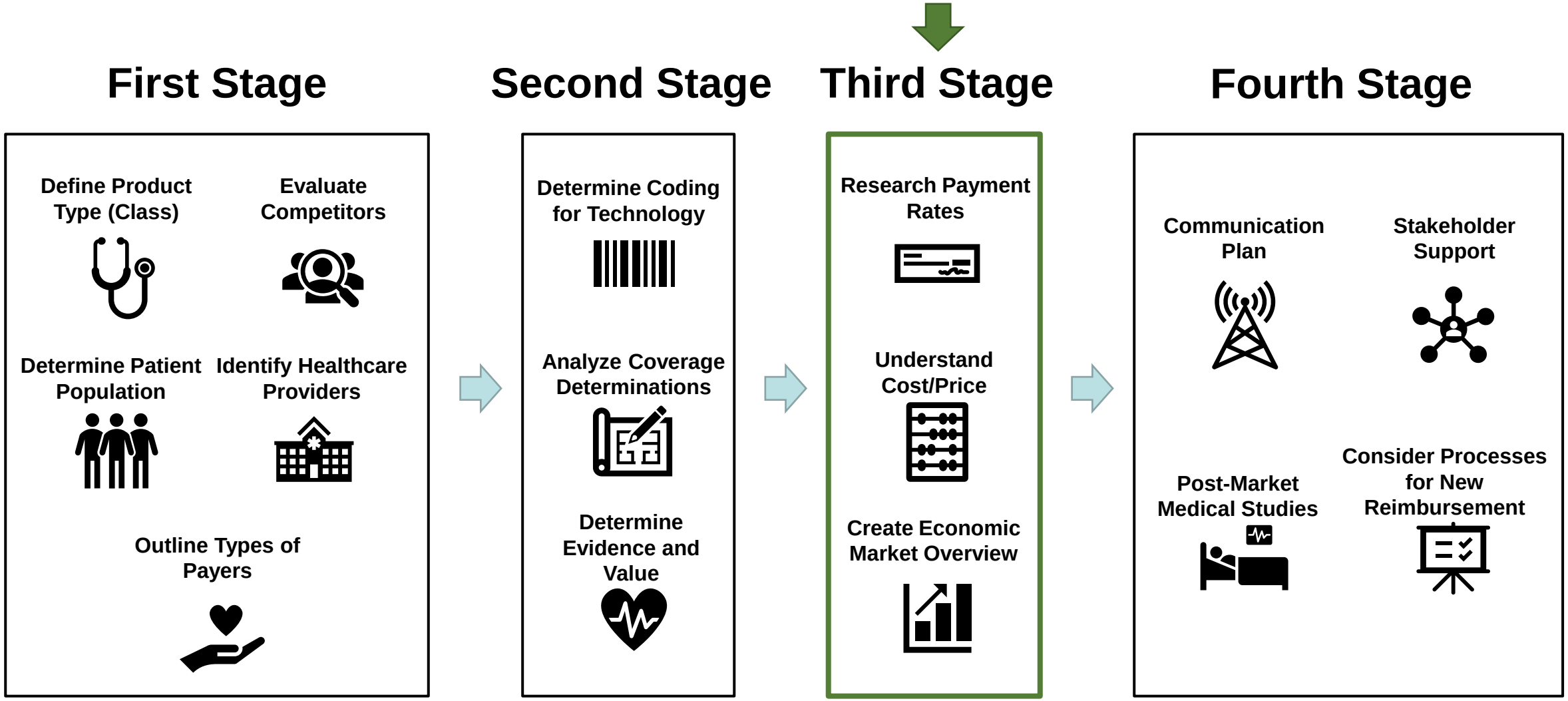
- Ted discovers through conversations with different **healthcare facilities** that they may have different clinical evidence requirements, which may be limitations of their willingness to pay for his product.
- Ted will need to identify facilities and surgeons willing to participate in clinical trials of his device. Once identified he will need to work with them to architect and finalize a study design that will ensure that the data collected will demonstrate impact that satisfies evidentiary requirements and medical necessity for adoption and utilization.
- He has also learned that recent information from American Heart Association/American College of Cardiology (AHA/ACC) has indicated that research may be conducted to determine efficacy on the use of TAVR in younger populations than previously studied. He may consider engaging AHA/ACC to learn more about clinical trials in younger patients to potentially increase his target market.



Key questions:

- What clinical evidence requirements are needed to support different healthcare providers?
- Are there payer-specific requisitions that need be met for coverage?
- Can a product for a specific procedure be covered for use in a clinical study?

Third Stage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Third Stage: Research Payment Rates

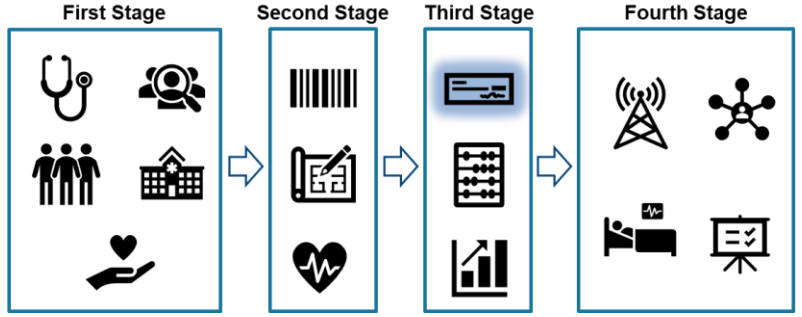
Now that Ted has a better understanding of:

a) how to describe his technology – including the intended use
b) what competitors are in the marketplace
c) which patient population would benefit the most from his technology
d) which healthcare provider would most likely use the device
e) at what type of site of service
f) which payers to focus on
g) what CPT codes exist for the procedure

Ted discovers that he will need to search the CMS schedule for payment rates.

Medicare sets its rates based on providers' historical costs, through a transparent public process. Medicare pricing for specific CPT codes can be found using the Medicare Physician Fee Schedule Look-Up Tool. Medicare rates can be used as a guide.

Ted understands that non-Medicare payers have their own methodology for paying providers. Payers can set their own rates and may or may not publish them.

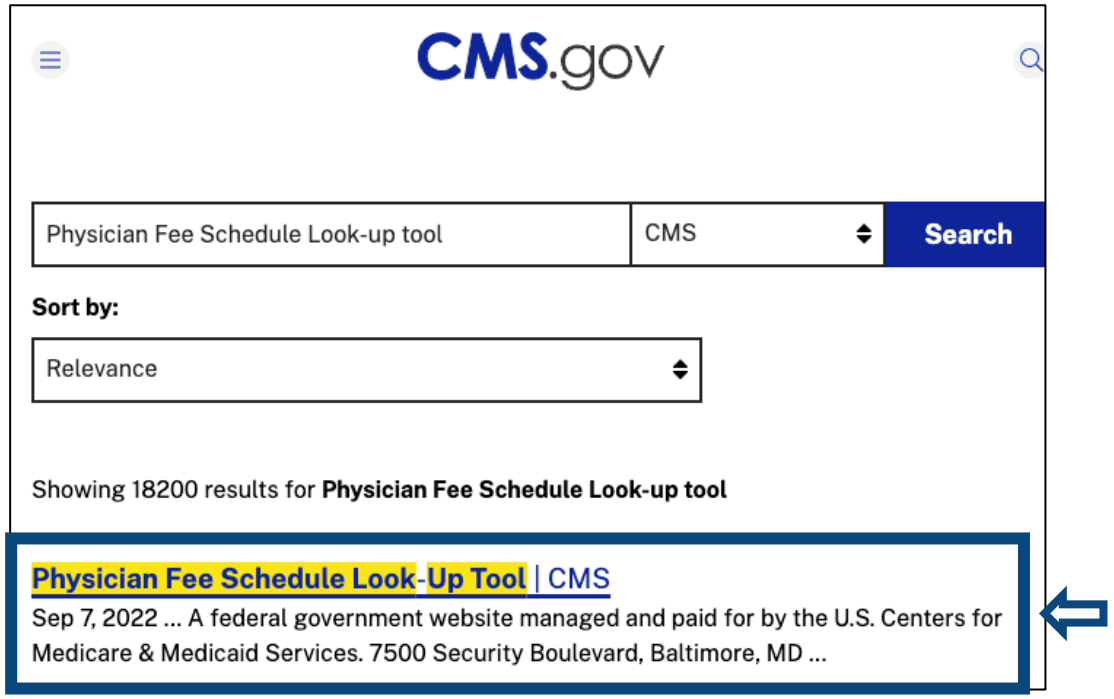


Key questions:

- What are the current fee schedules and the effective dates they apply?
- Where can you find examples of coding and coverage pricing specific to your product?

Third Stage: Research Payment Rates on CMS.gov

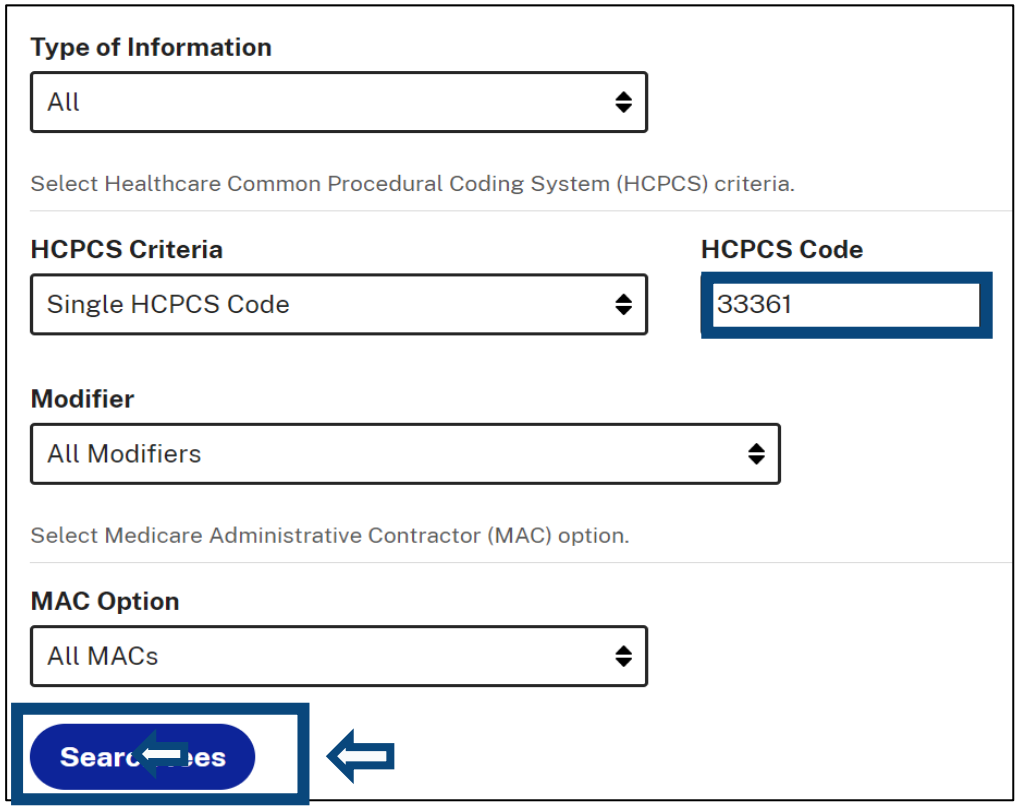
Ted performs a search for “Physician Fee Schedule Look-Up Tool” on the CMS website and selects “Physician Fee Schedule Look-Up Tool.”



Third Stage: Searching for Payment Rates

Ted scrolls down and selects “Begin Search”

Ted enters the code 33361. This is one of the procedure codes for TAVR. He selects “Search fees” at the bottom of the page.



Note: For this site, HCPCS and CPT codes are used interchangeably. Any HCPCS code or CPT code can be entered. However, not all codes have pricing assigned.

Third Stage: Payment Rates Results

Ted's results are displayed at the bottom of the same page. There may be more than one page of results, as pricing is by MAC locality. From the 10 lines displayed, the average reimbursement for the Facility Price for the professional services associated with TAVR is **$1,231.23**.

HCPCS Code	Modifier	Short Description	Mac Locality	Non-Facility Price	Facility Price
33361		Replace aortic valve perq	0000000	$1,196.56	$1,196.56
33361		Replace aortic valve perq	0111205	$1,262.38	$1,262.38
33361		Replace aortic valve perq	0111206	$1,262.38	$1,262.38
33361		Replace aortic valve perq	0111207	$1,262.38	$1,262.38
33361		Replace aortic valve perq	0111209	$1,277.70	$1,277.70
33361		Replace aortic valve perq	0111251	$1,220.73	$1,220.73
33361		Replace aortic valve perq	0111252	$1,268.43	$1,268.43
33361		Replace aortic valve perq	0111253	$1,216.24	$1,216.24
33361		Replace aortic valve perq	0111254	$1,184.95	$1,184.95
33361		Replace aortic valve perq	0111255	$1,160.51	$1,160.51

Third Stage: Research Payment Rates By MS-DRG

Ted remembers that two bills will be submitted in association with the TAVR procedure, the bill for the services by the healthcare professional and the facility bill. Average payment for the two DRG codes associated with TAVR is below.

The reimbursement of the DRG is important information for Ted to have when pricing his device. Ted recalls that the cost of the device is “bundled” into the DRG reimbursement. He does not want the pricing of his device to exceed the DRG reimbursement.

MS-DRG	Description of Procedure	FY 2022 Average Medicare Base Payment
266	Endovascular cardiac valve replacement and supplement procedures with MCC	$46,476
267	Endovascular cardiac valve replacement and supplement procedures without MCC	$36,915

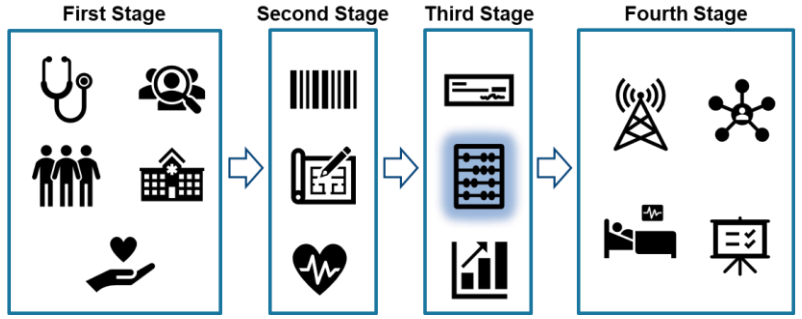
Third Stage: Understand Cost and Price

Ted recognizes that cost and pricing can be very tricky and are an essential piece of his reimbursement strategy.

Ted understands that at market entry the price of the device cannot be based on manufacturing costs until supply can be quantified and manufacturing adjusted for volume. Furthermore, as the total cost for his TAVR device is "bundled" within DRG reimbursement, Ted understands that he should not price his device greater than the set reimbursement rates.

Ted has learned that the average cost of current TAVR valves on the market is $32,000. For his pricing strategy, Ted should consider Athena A-Valve's value over the competition. For example, new materials may play a role in improvement of quality of life. The pricing can reflect a device's benefits like ease-of-use, reduced rate of downstream inpatient admissions, or the decreased need for more intensive treatments.

In summary, the ultimate goal of a pricing strategy is to develop a product price that is defensible to all the stakeholders involved. Ted plans to continue to work with his reimbursement consultant to appropriately price his product based on the claims and benefits.



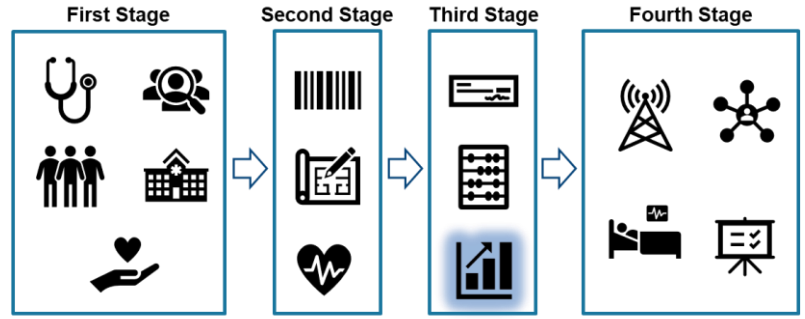
Key questions:

- Where can you find coverage criteria on national coverage determinations for your product?
- Can you determine product pricing based on manufacturing costs (material and labor)?
- Where can you find examples of coding and coverage pricing specific to your product?

Third Stage: Create Economic Market Overview

Ted knows that he needs to analyze the economic and market value of his product. Ted does research using journal articles to support the overview needed.

- Ted finds that according to the Journal of American College of Cardiology in 2018, approximately 209.3M patients suffered from valvular heart disease globally, which caused about 2.6M deaths that year.
- His research from the American Journal of Management Care presented a model that estimates between 2018 and 2028, approximately 465,000 inoperable Americans with Symptomatic Severe Aortic Stenosis (SSAS) will be treated with TAVR. These procedures will yield a cumulative social benefit of up to $48B, with roughly 80% of that benefit accruing to patients and 20% accruing to device manufacturers.
- A paper in the Journal of the American College of Cardiology reports that TAVR reduced initial length of stay an average of 4.4 days and decreased the need for rehabilitation services at discharge compared to SAVR.
- Ted also finds a paper from a Circulation: Cardiovascular Interventions that shows that TAVR patients are more likely than SAVR patients to be discharged to home as opposed to a skilled nursing facility.



Key questions:

- What specific economic values exist for this category of products and procedures?
- Where can you find the type of information needed?
- Are there societies that advocate?

Fourth Stage

First Stage

- Define Product Type (Class)
- Evaluate Competitors
- Determine Patient Population
- Identify Healthcare Providers
- Outline Types of Payers

Second Stage

- Determine Coding for Technology
- Analyze Coverage Determinations
- Determine Evidence and Value

Third Stage

- Research Payment Rates
- Understand Cost/Price
- Create Economic Market Overview

Fourth Stage

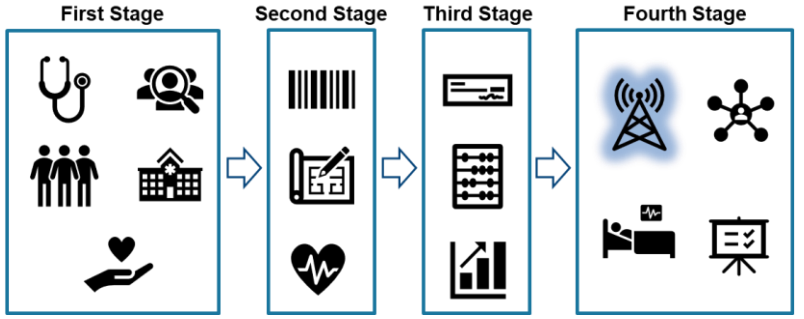
- Communication Plan
- Stakeholder Support
- Post-Market Medical Studies
- Consider Processes for New Reimbursement

Fourth Stage: Communication Plan

Ted looks to establish goals for his reimbursement strategy in the final stage of his reimbursement process. He will develop a communication plan to demonstrate that his product addresses unmet needs for TAVR and market adoption for his product.

Ted's outreach to the American College of Cardiology and AMA societies brings to light that he needs a **communication** plan to differentiate his product from the gold standard TAVR products.

- The plan will need to highlight advantages of the Athena A valve over its competitors so will need to include comparisons to other similar products; positive clinical outcomes such as improved quality of life (QoL) data and favorable patient reported outcomes (PROs); and societal and health-economic benefits.
- Ted's plan will communicate the product value and evidence-based data on the safety and effectiveness of the Athena A-Valve system.



Key questions:

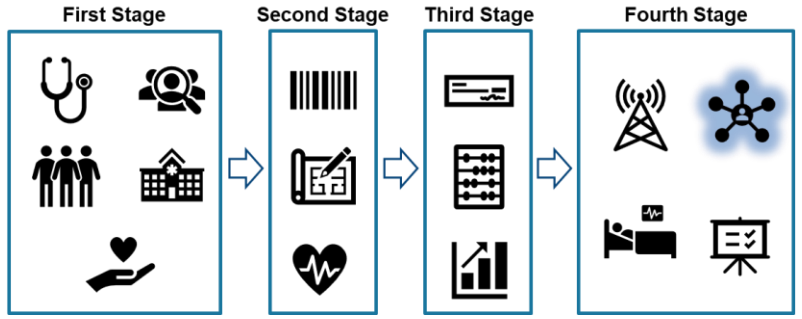
- Can you claim that the new device provides payors with both clinical and economic benefits over currently available alternatives?
- What elements need to be considered in a communications plan?

Fourth Stage: Stakeholder Support

Ted recognizes that for his reimbursement strategy he will need stakeholder support for his TAVR device to gain market adoption.

Ted will need to engage early with stakeholders and identify champions to establish long-term relationships. Each stakeholder plays an important role in successful commercialization. Potential stakeholders include the following:

- **Patients**, along with advocacy groups, patients can be important drivers for the adoption of advanced medical treatments.
- **Physicians** have to be willing to use the procedure or device both in real-world clinical practice and as part of clinical trials, as well as to advocate for its adoption with their employers and peers to support market demand.
- **Facilities**, such as hospitals and clinics, have to be willing to try new procedures and devices, despite potential burdens it may have on their clinical and administrative staff.
- **Professional medical societies** must be open to updating their guidelines to include new and innovative products once sufficient clinical evidence has been provided, as this is a huge driver in securing coverage from payers.



Key question:

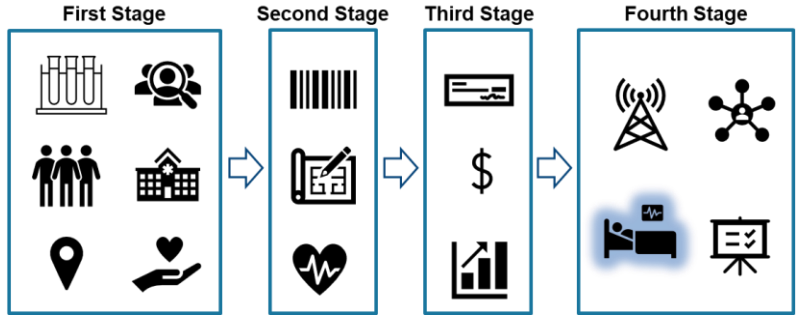
- Who are your stakeholders and payers and what are their needs and expectations?

Fourth Stage: Post-Market Medical Studies

Ted acknowledges that for his reimbursement strategy, he will need additional clinical support for Athena A-Valve to gain market adoption.

His strategy may include **post-market medical studies** providing comparative views applicable to gold-standard TAVR products.

- Ted realizes that these studies could also show that Athena A-Valve provides a better net health outcome than the similar products.
- Patients at extreme-risk (for open-heart surgery) may provide an opportunity for use expansion. Studies will be needed to evaluate the safety and effectiveness of the Athena A-Valve system in a subset of subjects with extreme risk. A comparative analysis of results to existing products will determine whether the Athena A-Valve proves to be a more effective device for this patient population.
- Ted may also consider engaging in studies of a younger population to determine if there are circumstances in which his device could be utilized to avoid surgical intervention with the same or better outcomes.



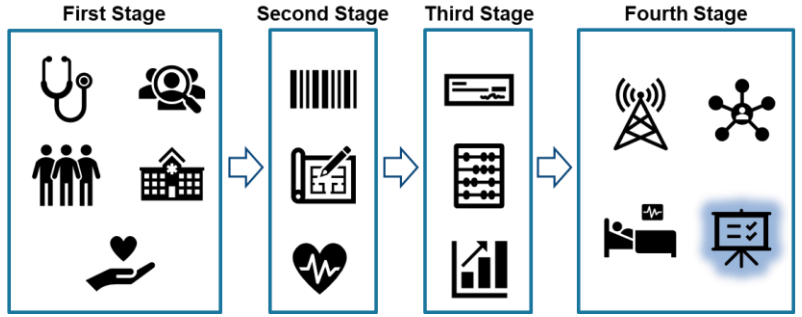
Key questions:

- What studies do you need to conduct to demonstrate device success when compared to existing devices within peer-reviewed journals?
- How can you expand the number of hospital sites utilizing your device as well as the patient population?

Fourth Stage: Consider Processes for New Reimbursement

Ted also acknowledges that for his reimbursement strategy, he may need to consider additional evidence for new reimbursement to demonstrate that his device meets expanded needs for TAVR and market adoption.

- Ted's final efforts will need to include a plan to strengthen his market presence and improve the value proposition and quality of care from TAVR procedures.
- If Ted can successfully revise his product (better materials that will increase the durability and longevity of the valve making it a more attractive alternative to the younger population than the open surgical procedure) to significantly differentiate from competitors such a change will require a new regulatory application and potentially necessitate application for New Technology Add-on Payment (NTAP). To qualify for an NTAP, Ted's revised device must meet the following criteria:
  - Newness: A technology is only eligible to receive NTAP if it is within the 2-3 year newness period, usually beginning from the date of FDA marketing authorization. The technology must also not be "substantially similar" to existing technologies.
  - Cost: The technology is inadequately paid under the existing MS-DRG system
  - Substantial Clinical Improvement: Use of the technology must significantly improve clinical outcomes for a patient population as compared to currently available treatments. Clinical data must be specific or generalizable to Medicare patient population.



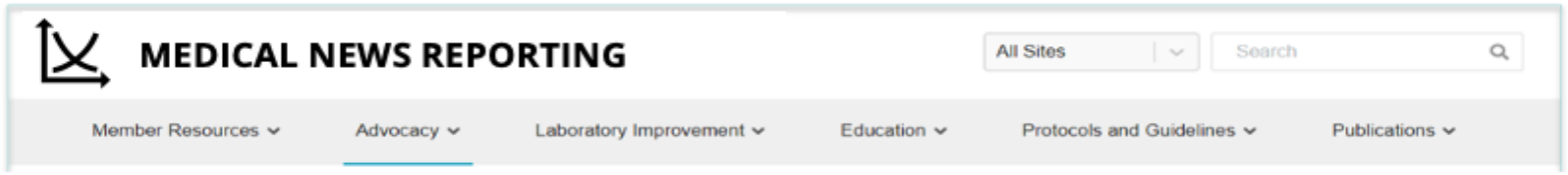
Key question:

- What further studies or product improvements could be considered to differentiate Ted's product from those already on the market?

SUMMARY

Athena A-Valve Success*

*The following is a fictional portrayal of what success for Athena A-Valve may look like



Athena Med Tech introduces the Athena A-Valve System

September 27, 2022, 2:00 AM EDT

Press release (Rockville, MD), September 27, 2022. Athena Med Tech is introducing Athena A-Valve®, an innovative transcatheter heart valve, to address the unmet medical needs of TAVR (Transcatheter Aortic Valve Replacement) procedures and expanding use of TAVR. “This represents a strong milestone for Athena Med Tech in the US market following the FDA approval for the Athena A-Valve system. As our first market entry product and a key building block of our US commercialization strategy, we are targeting both value-based care providers as well as fee-for-service providers. We will be able to use existing CPT codes, enabling us to initiate discussions with payors to support our US expansion”, says Ted Persson, CEO of Athena Med Tech. The Athena A-Valve® will be able to increase the number of hospitals and physicians performing the TAVR procedure, thereby expanding its availability to patients who are ineligible for surgical aortic valve replacement.

Summary Findings: By Stage

First Stage

- Product Type: Transcatheter heart valve; class III medical device that requires FDA approval
- Competitors: Sapien 3™ and Sapien 3 Ultra™ from Edwards Lifesciences; Evolut R™ and Evolut PRO™ from Medtronic; Lotus Edge™ by Boston Scientific
- Patient Population: Adult patients who are at high or extreme risk for open-heart surgery with symptomatic severe aortic stenosis
- Healthcare Providers & Site of Service: Team of interventional cardiologist, cardiac surgeon, imaging specialists, and an anesthesiologist in an in-patient setting
- Types of Payers: Medicaid, Medicare, and commercial payers who have Medicare Advantage plans

Second Stage

- Coding for Technology: 33361- 33366: Transcatheter aortic valve replacement
- Coverage Determinations: TAVR is nationally covered for the treatment of symptomatic aortic valve stenosis when furnished according to a FDA-approved indication and when all conditions are met
- Evidence and Value: Ted must identify clinical evidence requirements necessary to support device reimbursement and ensure that the data collected will demonstrate impact that satisfies evidentiary requirements and medical necessity for adoption and utilization.

Third Stage

- Payment Rates: The average reimbursement for the professional services associated with TAVR is $1,231.23. Average Medicare payment for the two DRG codes associated with TAVR is $36,915 and $46,476.
- Cost and Price: For his pricing strategy, Ted should consider Athena A-Valve's value over the competition to develop a product price that is defensible to all the stakeholders involved.
- Economic Market Overview: Research within JACC and AJMC reveal the value of TAVR affecting close to half million patients per year resulting in a social benefit of close to $48 billion dollars.

Fourth Stage

- Communications Plan: Develop communication plan to demonstrate that he can differentiate from the gold standard TAVR products.
- Stakeholder Support: Establish long term relationships with key stakeholders and find product champions
- Post-market Medical Studies: Studies could show that Athena A-Valve provides a better net health outcome than the similar products
- Reimbursement Plan for New Device: With revision to his device, Ted may consider applying for a New Technology Add-on Payment.

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