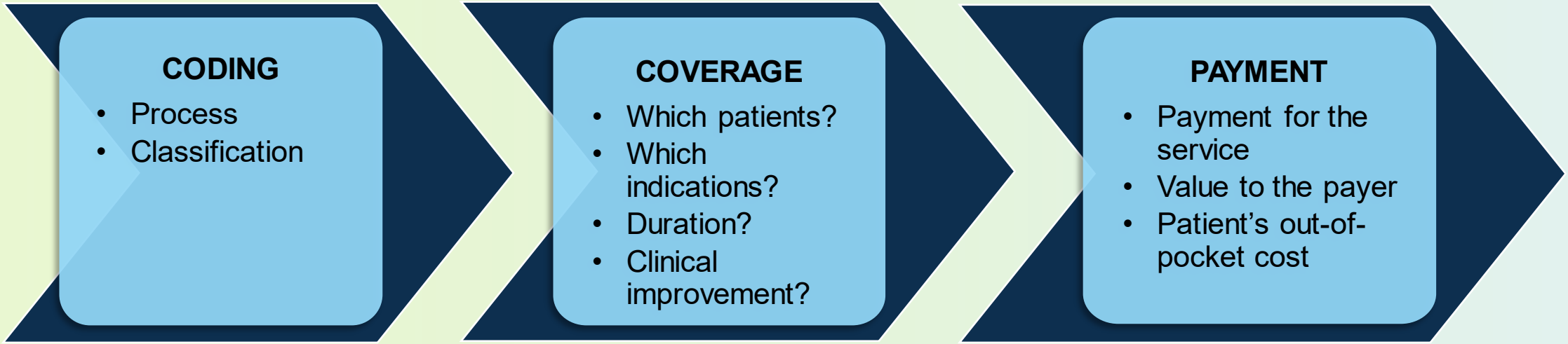
Diagnostic Test Case Study
Vitality Diagnostics (IVD)

Reimbursement Overview

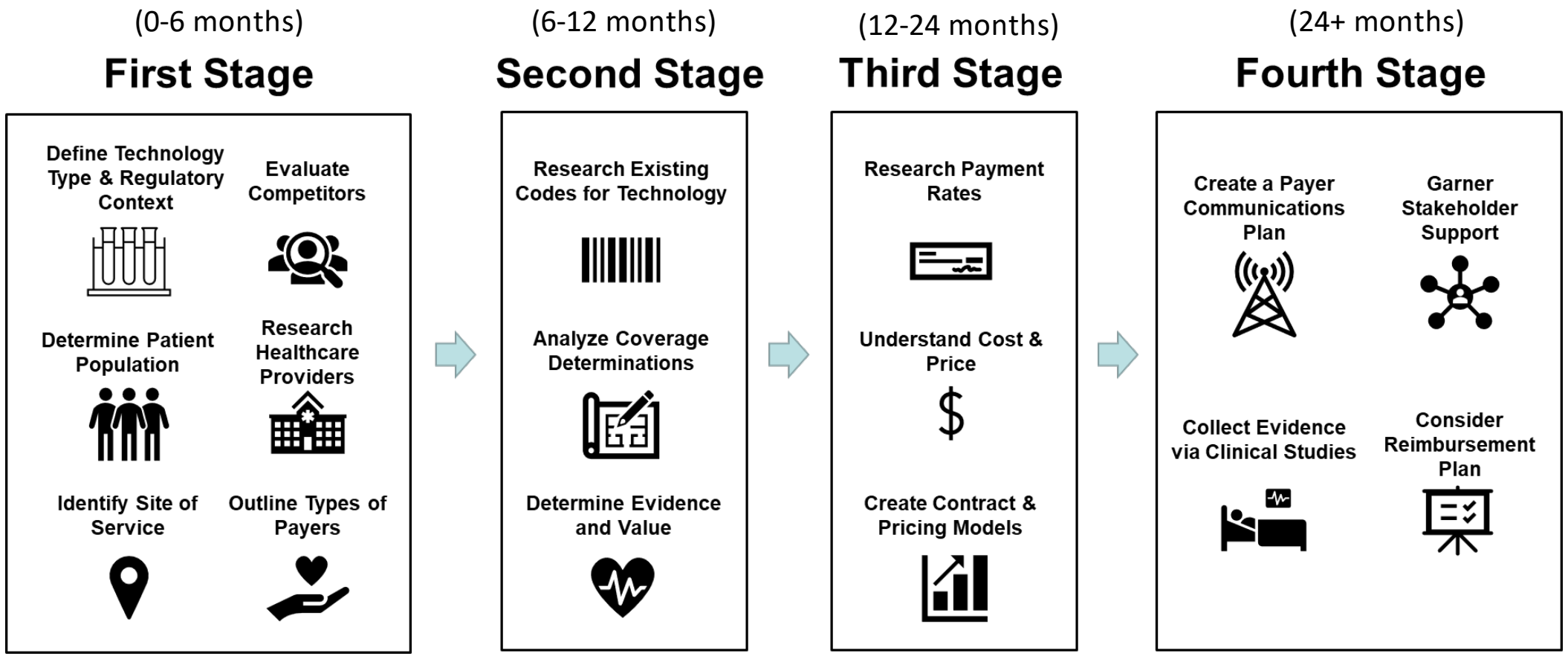
Bringing a diagnostic to market is a complex process. An innovator needs to understand the entire commercialization process and manage multiple tasks related to early-stage research and development, clinical studies, regulations, reimbursement and post-market surveillance. The goal of receiving Food and Drug Administration (FDA) approval is often considered the primary endpoint that leads a new diagnostic to commercial success and is often a pre-requisite for payer coverage. However, if a new diagnostic does not obtain the desired amount of reimbursement or is not even covered by payers, then physicians are highly unlikely to recommend and use the new diagnostic. Therefore, ensuring reimbursement for the new diagnostic is as important as obtaining 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 Diagnostic Test Reimbursement*. It will take you step-by-step through a process innovators may follow to develop a strategy for diagnostic test 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.



Introduction to Vitality Diagnostics' CEO and the CardioTropT test

Beth is the CEO of Vitality Diagnostics – a spin-out company of Magnolia Health System. In addition to a novel prenatal Laboratory Developed Tests (LDTs), she has developed a high-sensitivity troponin T test for the detection of heart attacks. Magnolia Health System's lab director is interested in expanding his test menu to include this test for its cardiology patients. The test is called CardioTropT test and is currently under FDA review. Once cleared by FDA, this will be an off-the-shelf IVD that can be utilized by labs around the nation.

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

Here's some background from Vitality Diagnostics's initial pitch to Magnolia Health System's lab director:

Product Description:

- Vitality Diagnostics is developing a high-sensitivity troponin T test called **CardioTropT.** They are often referenced as "high-sensitivity cardiac troponin (hs-cTn)" tests in the field.
- CardioTropT is used for the detection of myocardial infarction (MI; "heart attacks") based on measuring troponin T protein levels in the blood.
- It can be offered as a STAT test with a turnaround time of eight minutes.

Why CardioTropT?

- Every year, about 805,000 people in the United States have a heart attack and about 697,000 people died from heart disease in 2020 (per CDC data); the high-sensitivity Troponin US market size was valued at ~ USD 557 Million in 2020.
- Physicians can utilize this high sensitivity, blood-based test in the emergency room (ER) for more rapid detection of cardiomyocyte necrosis when other, traditional tests, often show false negatives on first draw.
- Currently, there is only one other **FDA-approved product on the market.**
- The CardioTropT test also mitigates the biotin interference with the assays that other test developers have not yet addressed (see FDA Safety Communication).

First Stage

First Stage

- Define Technology Type & Regulatory Context
- Evaluate Competitors
- Determine Patient Population
- Research Healthcare Providers
- Identify Site of Service
- Outline Types of Payers

Second Stage

- Research Existing Codes for Technology
- Analyze Coverage Determinations
- Determine Evidence and Value

Third Stage

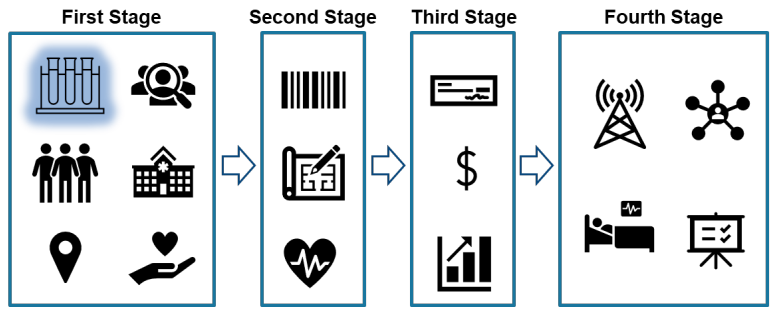
- Research Payment Rates
- Understand Cost & Price
- Create Contract & Pricing Models

Fourth Stage

- Create a Payer Communications Plan
- Garner Stakeholder Support
- Collect Evidence via Clinical Studies
- Consider Reimbursement Plan

First Stage: Define the Technology Type & Regulatory Context

Beth is excited for the potential of CardioTropT to improve outcomes for cardiology patients. Beth drafted a product description based on the intended use for the FDA submission of CardioTropT. She and her team determined that the 510(k) submission is a suitable pathway as they identified a predicate device that is already on the market. The 510(k) application for CardioTropT is currently under FDA review. Beth also hopes that any comparable diagnostic tests on the market will help her understand how her product can be reimbursed.



Beth drafts an intended use statement for CardioTropT based on what she envisions would go on the product label. She looked for examples on the web by searching for "high-sensitivity troponin T test" + "Intended Use." Here is what she drafted:

- "*CardioTropT is an immunoassay for the in vitro quantitative determination of cardiac troponin T (cTnT) in lithium heparin plasma. The diagnostic test is intended to aid in the diagnosis of myocardial infarction.*"

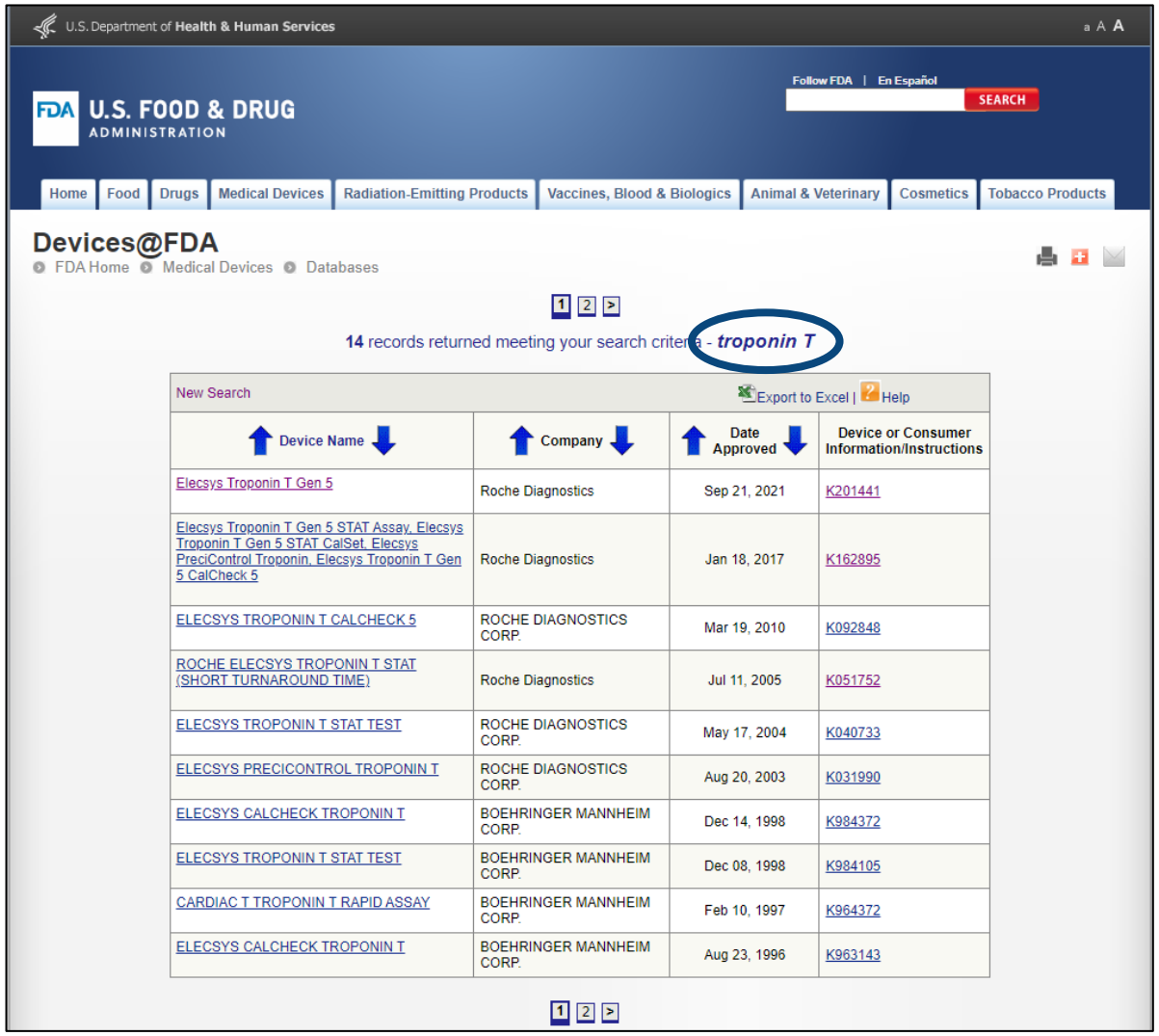
To prepare for the FDA premarket notification, Beth also searched the FDA in vitro diagnostic database for the terms "troponin T" and found the predicate device "Elecsys Troponin T Gen 5" with a similar intended use. She determines that there is one equivalent *high-sensitivity* FDA-approved IVDs on the market. Beth knows that FDA-cleared/approved devices are always preferred by payers. Fortunately, high-sensitivity troponin T tests are reimbursable, and the test should be repeated whenever there is an indication of potential myocardial infarction. In general, a Troponin test is repeated two more times (over 6 to 24 hours following the initial test).

Key questions:

- What is the intended use?
- Is the product an FDA-regulated in-vitro diagnostic (IVD) or a CMS-regulated laboratory developed test (LDT)? Are there equivalent diagnostics on the market?
- Is this a repeat (one that can be done more than once in a lifetime) or a once-and-done test?

First Stage: Define the Technology Type & Regulatory Context

FDA Database Search



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1 2 >

14 records returned meeting your search criteria - ***troponin T***

New Search — Export to Excel | Help

Device Name	Company	Date Approved	Device or Consumer Information/Instructions
Elecsys Troponin T Gen 5	Roche Diagnostics	Sep 21, 2021	K201441
Elecsys Troponin T Gen 5 STAT Assay, Elecsys Troponin T Gen 5 STAT CalSet, Elecsys PreciControl Troponin, Elecsys Troponin T Gen 5 CalCheck 5	Roche Diagnostics	Jan 18, 2017	K162895
ELECSYS TROPONIN T CALCHECK 5	ROCHE DIAGNOSTICS CORP.	Mar 19, 2010	K092848
ROCHE ELECSYS TROPONIN T STAT (SHORT TURNAROUND TIME)	Roche Diagnostics	Jul 11, 2005	K051752
ELECSYS TROPONIN T STAT TEST	ROCHE DIAGNOSTICS CORP.	May 17, 2004	K040733
ELECSYS PRECICONTROL TROPONIN T	ROCHE DIAGNOSTICS CORP.	Aug 20, 2003	K031990
ELECSYS CALCHECK TROPONIN T	BOEHRINGER MANNHEIM CORP.	Dec 14, 1998	K984372
ELECSYS TROPONIN T STAT TEST	BOEHRINGER MANNHEIM CORP.	Dec 08, 1998	K984105
CARDIAC T TROPONIN T RAPID ASSAY	BOEHRINGER MANNHEIM CORP.	Feb 10, 1997	K964372
ELECSYS CALCHECK TROPONIN T	BOEHRINGER MANNHEIM CORP.	Aug 23, 1996	K963143

1 2 >

- Search for “Troponin T”
- Review list of devices
- Determine potential for Predicate Device

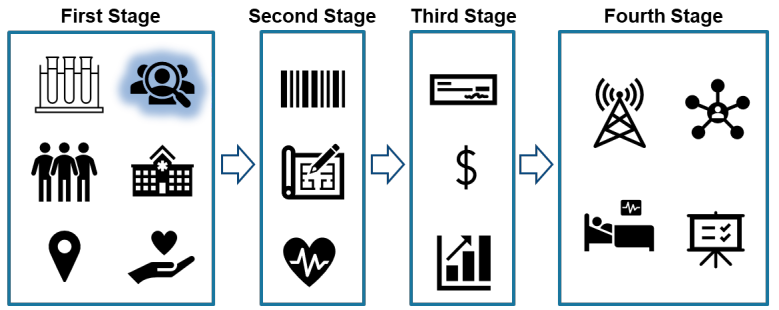
Source: FDA

First Stage: Evaluate Competitors

Beth is eager to assess the company's potential competitors – their market share, and product positioning.

Based on her research, Beth notes there are two predominant players/market competitors – Roche Diagnostics and Boehringer Mannheim Corp. but only one company appears to have a high-sensitivity test that can be offered at a below 10-minute turnaround time. This test is called Elecsys Troponin T Gen 5. If approved by FDA, CardioTropT would enter the market as an alternative to Roche's diagnostic.

Beth's online research indicates that the U.S. "High-Sensitivity Troponin Market size was valued at USD 557.05 Million in 2020 and is projected to reach USD 1190 Million by 2028", per this 2021 Verified Market Research article. Beth plans to conduct additional research on the market share of Roche's high-sensitivity assay to estimate CardioTropT's potential to saturate the market. Beth's research also shows that Roche's turnaround time is 9 minutes; CardioTropT showed reliable results within 8 minutes. Similar to Roche's test, the CardioTropT test is an electrochemluminescence immunoassay "ECLIA" intended for use on the cobas e 801 and 601 immunoassay analyzers. Beth's product will enter the market as an alternative to Elecsys Troponin T Gen 5 at a lower price point. Per CDC, every year, about 805,000 people in the U.S. have a heart attack. The CardioTropT test is blood-based; the diagnostic will be used primarily in Emergency Rooms. She refines her competitive advantage statement based on her research findings as this may impact stakeholder uptake and coverage decisions. In the future, Beth intends to create a point-of-care (CLIA waived) solution to be implemented directly at the bedside.

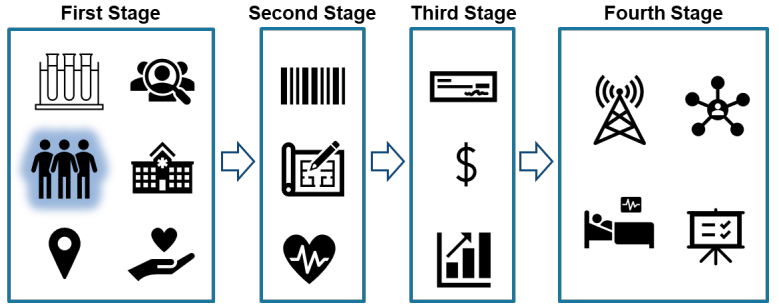


Key Questions:

- What competitor devices are on the market?
- What will differentiate Beth's product from competitors?

First Stage: Determine Patient Population

Beth knows she also needs to specify the patient population for her diagnostic. She consults with her clinical team to think through *who* will use CardioTropT and *where* they will use it. This is important as this information will not only inform the clinical study design and data collected but also reimbursement potential.



Beth is able to easily define the patient population for CardioTropT as:

- any patient with an indication of potential myocardial infarction
- anyone at age 20 and older
- any gender and ethnicity – although some ethnic groups have a higher risk of having heart disease per CDC

Per CDC, in 2019 individuals ages 55 and up (55 – 74; 75+) have the second highest admission rate after children under the age of 1. Additionally, Medicare was the second highest "primary expected source of payment" with 53% in 2019. This shows the importance of Medicare reimbursement for this patient group.

Her research also showed that myocardial infarction (i.e., a heart attack) is most often diagnosed in an emergency setting.

Key Questions:

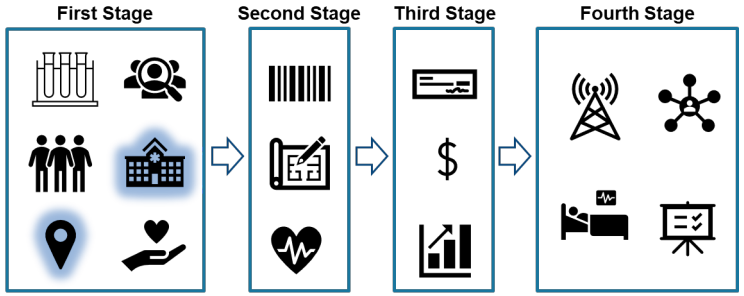
- Which patients would benefit most from the diagnostic test?
- Is there a certain age range these patients fall into?
- Is the test gender specific or agnostic?
- Which patient population offers the largest target market size, and has potentially the highest coverage rates?
- Are there certain socio-economic factors, such as high-risk populations, income, etc. that should be considered for this patient population?

First Stage: Research Healthcare Providers & Identify the Site of Service

Beth intends to determine which specific healthcare provider group would use CardioTropT. She also wants to identify the site of service based on the intended use for the identified patient population. This will inform whether the setting is considered inpatient or outpatient.

Beth talks to the healthcare providers on her board of advisors and verifies that the CardioTropT test (requiring a blood sample) – would predominantly be conducted in acute outpatient settings (emergency department services), mostly by Emergency Room physicians. This includes observation services, assuming that the physician has not written an order for inpatient admission. Measuring levels of Troponin T is part of the standard of care for patients with suspected MI. In general, a Troponin test is repeated two more times (over 6 to 24 hours following the initial test).

Beth is aware that some ER visits will result in an inpatient admission. Per this article, Beth uses the assumption that 13% of cardiac related ED visits would result in a hospital admission (inpatient setting). This means that the test would be rolled into the total cost of care (under one MS-DRG.) In such settings, payers would reimburse the hospital in one lump-sum payment and the test would not be itemized or paid separately by insurance – not an ideal scenario. Although the majority of tests would be administered in an outpatient setting, Beth plans to collect cost savings information on repeat testing in an inpatient setting specifically for high-sensitivity tests. In an outpatient setting, the focus is on having a margin (pending reimbursement rate research); in an inpatient setting, it is primarily on cost savings.



Key Questions:

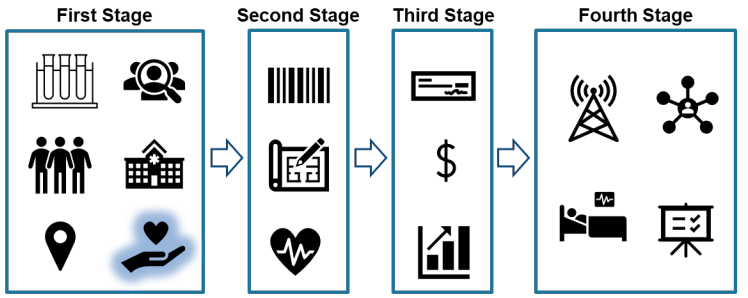
- Based on the intended use and target patient population, which particular group of healthcare providers would use the diagnostic (i.e., cardiologist, pediatrician, primary healthcare provider, etc.)?
- Where will the diagnostic be used – in an outpatient (doctor's office) or inpatient (hospital) setting?
- Is the diagnostic considered a standard of care (vs. an optional, add-on service)?

First Stage: Outline the Types of Payers for the Patient Population

Beth knows different types of payers – including Medicaid, Medicare, and commercial payers – should be evaluated. Not all payers may be appropriate for the target patient population of CardioTropT.

Based on her research of the patient population (all genders and ages 20 and above), Beth knows that all payers – except for Medicaid CHIP, would need to be considered in her coverage evaluation for the CardioTropT test. However, she also learned from the American College of Cardiology (ACC) that "[t]he average age of first myocardial infarction is 65.6 years old for men and 72.0 years old for women." This indicates that Medicare will play an integral role for reimbursement.

From her advisory council, Beth also understands that commercial payers often make coverage decisions based on Medicare/Medicaid coverage determinations. From prior experience, she creates a list of major commercial payers that include Aetna (including Innovation Health), Cigna, Anthem BlueCross BlueShield, CareFirst BlueCross BlueShield, and United Healthcare.



Key Questions:

- Based on the age of your target patient population, should any payers be excluded from the analysis?
- Would the test be predominantly used by a patient population with a specific payer, i.e., commercial payers only?
- Would these patients be willing to pay "out-of-pocket" or a cash price for the test?
- What motivators/incentives would stimulate patients to pay out of pocket?

Second Stage

First Stage

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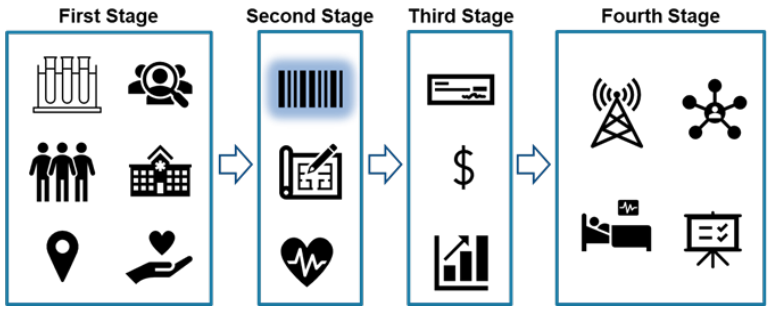
Second Stage: Research Existing Payment Codes for the Technology

Now Beth is ready to research existing Current Procedural Terminology (CPT®) codes for her technology. She wants to find references of the code(s) and diagnostic test (Troponin T) in various coverage determinations and also to search the CMS lab fee schedule for payment rates.



Beth searches for existing CPT codes online using search terms such as "CPT + Troponin T " or "CPT + Troponin T + Highly Sensitive" or "CPT + Troponin test". Beth knows that CPT codes can be listed in commercial payers' coverage determinations, CMS lab fee schedules, or other lab test menus and that there may be one or multiple CPT codes for her test type, so she widens her search accordingly to ensure all codes have been considered. Her search returns the following CPT codes in CMS's billing and coding article on Troponin:

- 84484: TROPONIN, QUANTITATIVE
- 84512: TROPONIN, QUALITATIVE

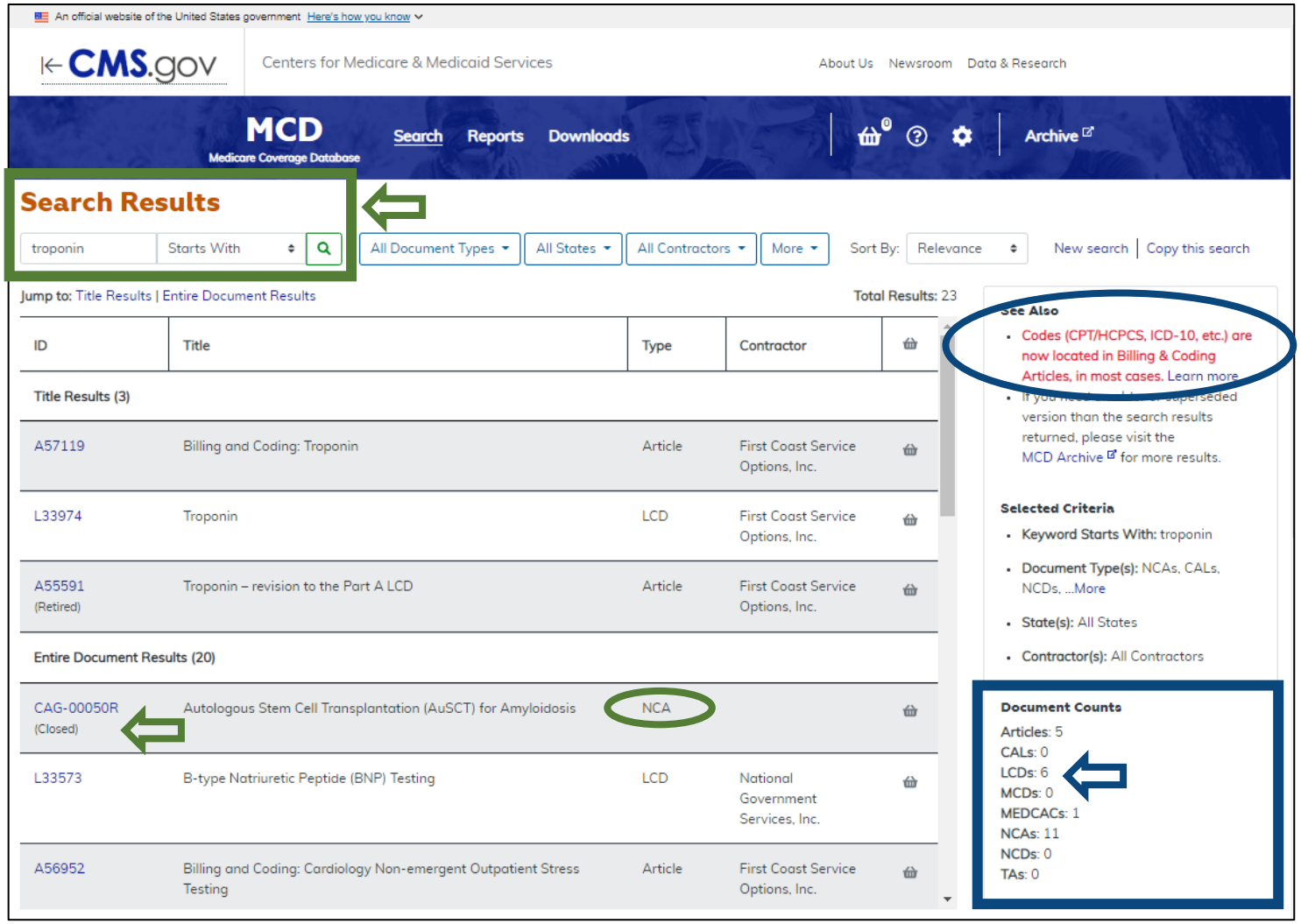
Beth narrows the code down to 84484 as the CardioTropT test is a quantitative test. Additionally, she verifies that, for instance, LabCorp uses the same CPT code for the Troponin T (Highly Sensitive) tests. Furthermore, as CardioTropT can be offered as a STAT test, she learns that the HCPCS code S3600 (STAT laboratory request) may also be billable by the provider. This information will serve tremendously helpful when talking to Magnolia Hospital's lab director who is interested in adding CardioTropT to his testing menu if covered by payers.

Key Questions:

- Are there existing CPT codes for the diagnostic?
- Which CPT code best fits my test (sometimes multiple)?
- Have only "unlisted" codes been used to date?
- If so, do you want to apply for a new CPT code?

Second Stage: Research Existing Payment Codes for the Technology

Navigating CMS's Medicare Coverage Database

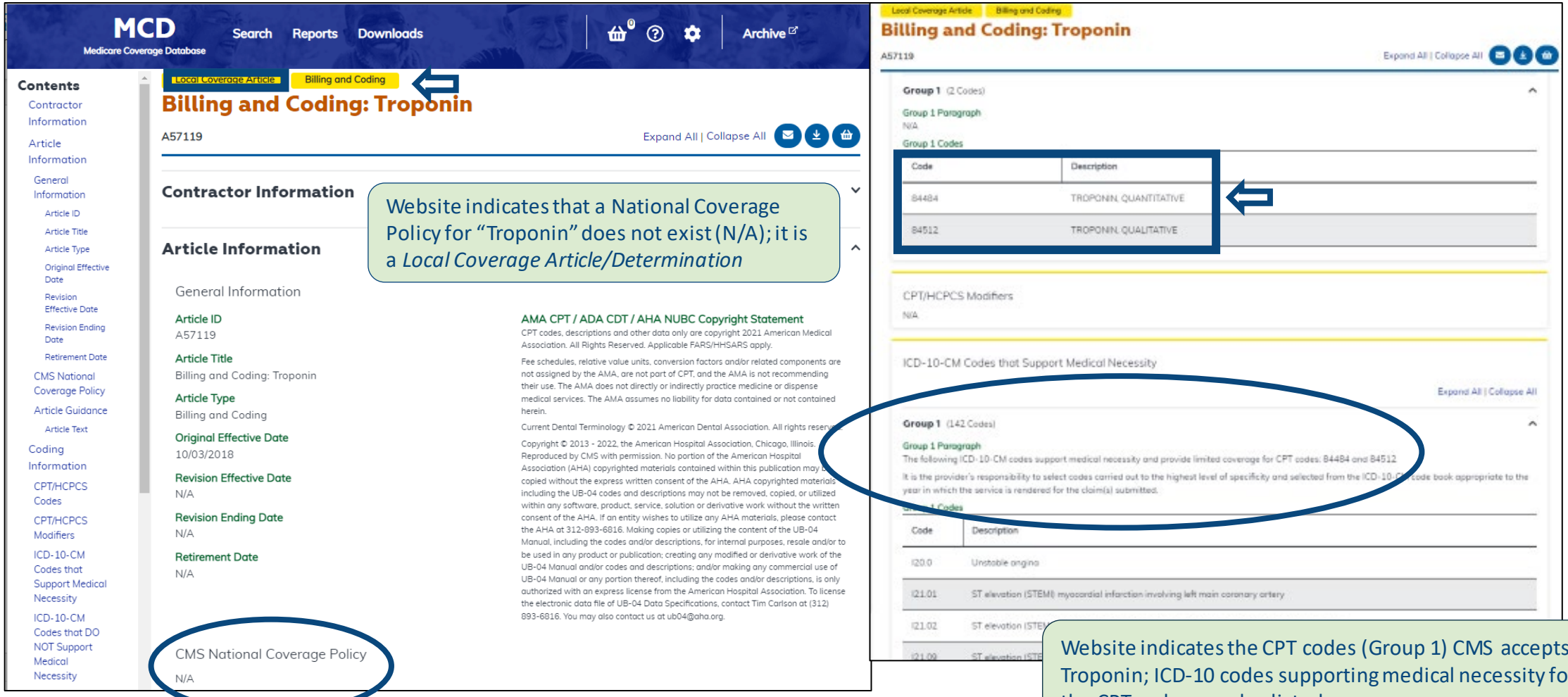


- Search for "Troponin"
- Website also indicates that "Codes (CPT…) are now located in Billing & Coding Articles"; look for "Billing and Coding" under "Title" column of search results
- Document Counts indicates 6 Local Coverage Determinations (LCDs); although there are also 11 National Coverage Analyses (NCAs) listed, further investigation shows that they are all "(Closed)" under the ID column; and no National Coverage Determinations (NCDs) currently exists

Source: CMS

Second Stage: Research Existing payment Codes for the Technology

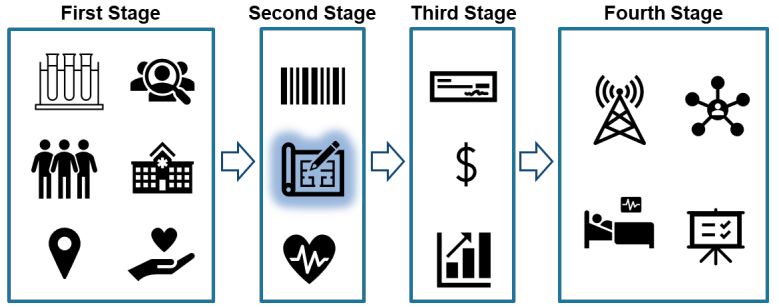
Navigating CMS Billing and Coding Article(s) for "Troponin"



Source: CMS

Second Stage: Analyze Coverage Determinations

With a potential CPT code in hand, Beth now wants to review coverage determinations to understand differences in coverage. She starts her assessment with CMS coverage determinations and then assesses commercial payer coverage policies.



Based on her research of CMS Billing and Coding articles for Troponin, Beth learns that there are specific ICD-10 diagnosis codes supporting medical necessity for the test given the intended use (MI diagnosis). A National Coverage Determination (NCD) does not currently exist – only Local Coverage Determinations (LCDs.) This indicates that there may be state specific coverage variances.

- For Medicare, existing LCDs for Troponin are administered by CMS contractors such as First Coast Service Options, and related ones under Novitas Solutions and others.
- For Medicaid, Beth learns that Washington State covers the test (CPT 84484) along with a STAT modifier (HCPCS S3600) for the fast turn-around-time of the test.
- However, when Beth searches commercial payer coverage policies by using an online query using "[commercial payer name] + Troponin + myocardial infarction" as search term, she learns that while BlueCross BlueShield of North Carolina covered Troponin T biomarker testing for MI diagnosis, payers like Aetna only reference CPT code 84484 in connection with Cardiovascular Disease Risk Tests (not diagnosis of MI) and consider it experimental; payers like United Healthcare do not cover the test when submitted with a screening diagnosis; Cigna determined that Troponin testing is experimental for uses other than acute myocardial injury diagnosis (including for screening, diagnosing or management of coronary heart disease).

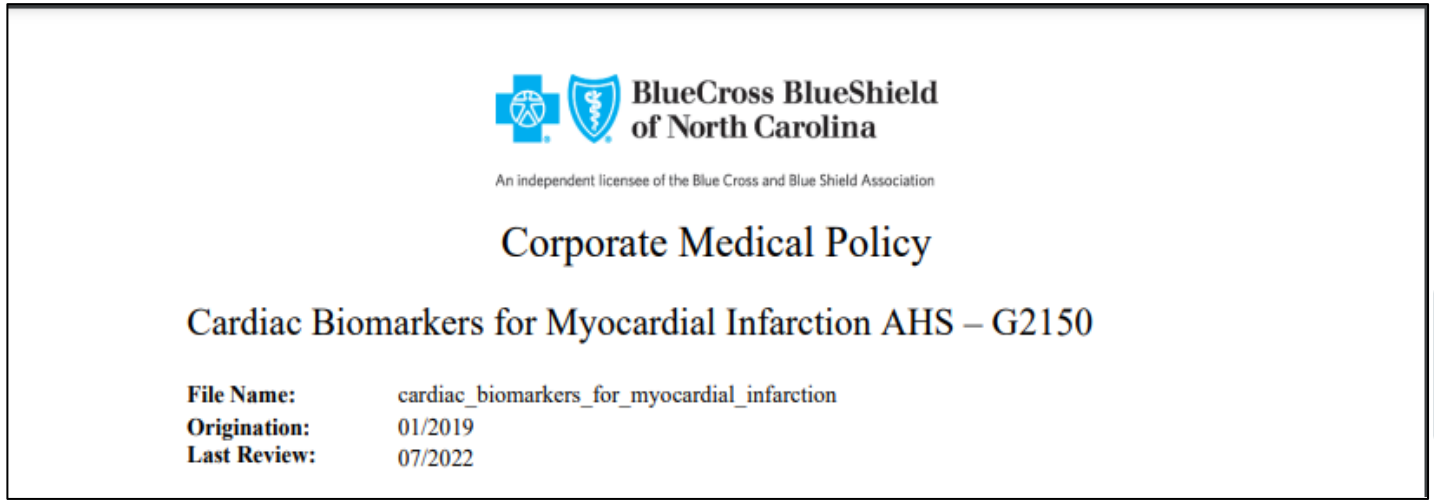
While discouraging, this is important information as Beth can look at the intended uses when the test is deemed experimental and work on potential counter arguments (data collection) or alternative intended uses of the test. Beth considers bringing in a Reimbursement Consultant to discuss her options including applying for a new CPT code.

Key Questions:

- Which coverage determinations exist for both commercial payers and Medicaid the technology given the identified CPT codes? Note: Commercial payers often make coverage decisions based on Medicare/Medicaid coverage determinations.
- Is the test deemed medically necessary or experimental (or both) by the payers? Note: Only tests that are "medically necessary" are covered.
- Are there payer-specific requisitions that need be met for coverage, e.g., specific diagnosis (ICD-10 code)?
- Are there special coverage requirements for diagnostics, e.g., for tests without FDA approval (such as for LDTs) must the lab be CAP accredited and or must the lab be an in-network lab?

Second Stage: Analyze Coverage Determinations

Analyzing Medical Coverage Policies; Example: Cigna



BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Cardiac Biomarkers for Myocardial Infarction AHS – G2150

File Name: cardiac_biomarkers_for_myocardial_infarction
Origination: 01/2019
Last Review: 07/2022

- Check "Last Review at the top of the Medical Coverage Policy
- Search [CTRL + F] for "Troponin" or "Troponin T" or "84484" related term(s)

When Cardiac Biomarkers For Myocardial Infaction is covered

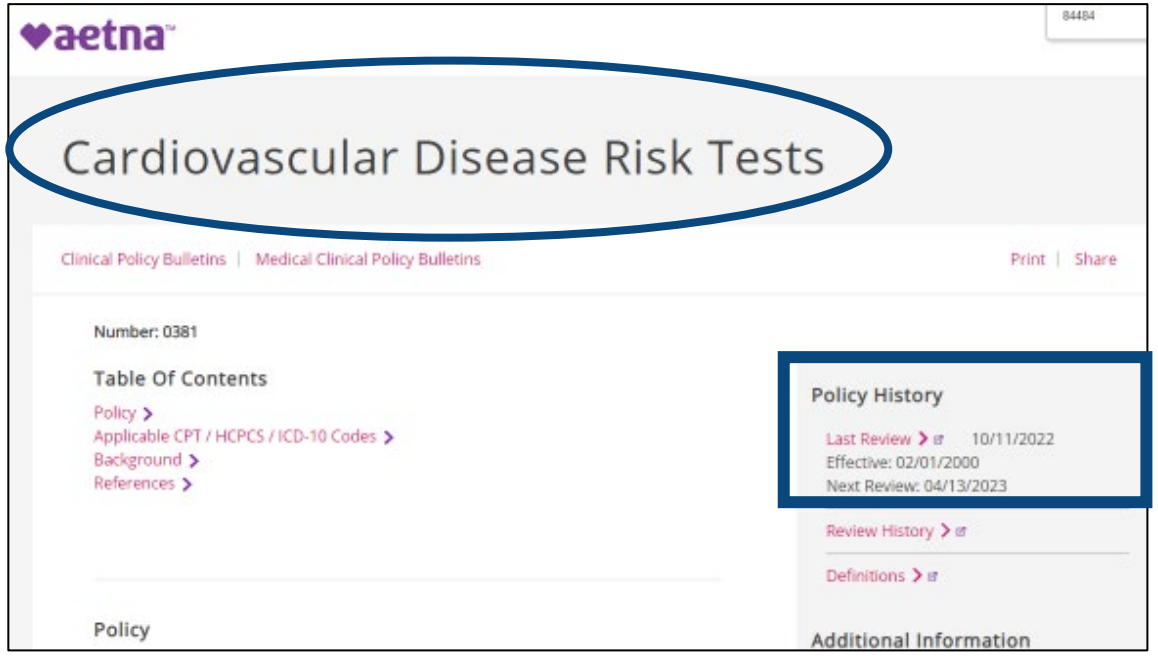
Reimbursement is allowed for measurement of cardiac troponin (troponin T or I) for the diagnosis of myocardial infarction (MI) in all patients presenting with signs and symptoms of acute coronary syndrome* (please see Note 1)

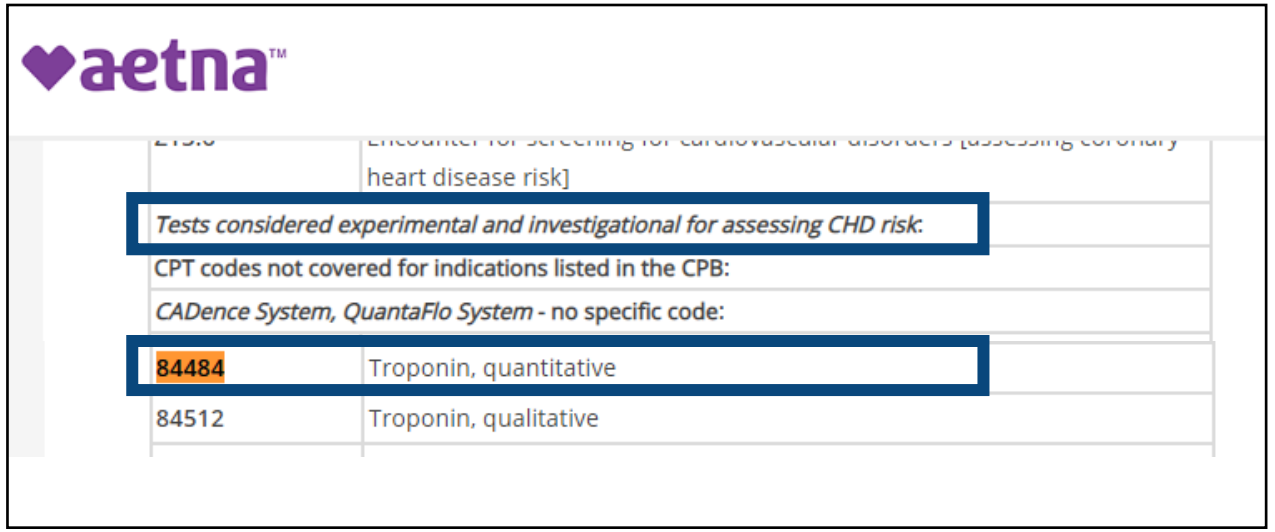
Source: Cigna

- Review sections in policy referencing Troponin; pay attention to which kind of troponin is referenced as some troponin biomarkers may be deemed experimental.
- Understand for which indications/diagnoses the test is covered

Second Stage: Analyze Coverage Determinations

Analyzing Medical Coverage Policies; Example: Aetna





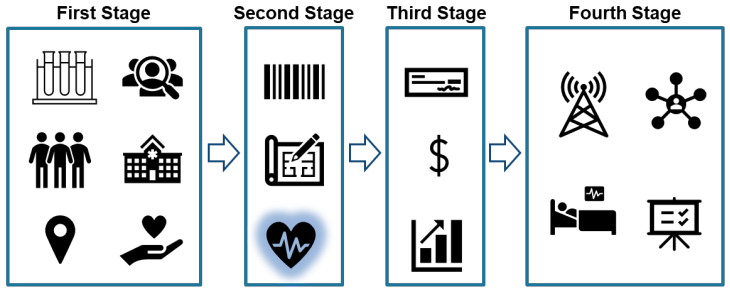
Source: Aetna

- Check "Last Review", "Effective Date" and "Next Review Date" at the top of the Medical Coverage Policy
- Search [CTRL + F] for "84484" or "Troponin" or related term(s)

- Review sections in policy referencing Troponin
- Understand why test is deemed "Experimental/Investigational"

Second Stage: Determine Evidence & Value

Beth knows that well-planned **evidence** collection can show **value** and support a favorable coverage determination. Coverage determinations are based on the type of payer and related to the technology. Favorable coverage determinations are also important to potential investors.



Beth knows that since the test is not yet considered standard of care, she needs to capture utilization data (based on CMS's outlined ICD-10 codes) to define evidence to support coverage and pricing for diagnostics like CardioTropT and does the following:

- Beth conducts an online search using "Troponin + evidence + utilization data" and finds several research articles, including this 2014 article.
- While high-sensitivity troponin T assays (supported by evidence-based medicine) are incorporated into the guidelines of the European Society of Cardiology, Beth could not find such guidelines in the U.S.
- She also discovered that societies such as the American Heart Association (AHA) and the American College of Cardiology (ACC) see "high-sensitivity cardiac troponin (hs-cTn) as the preferred biomarker, endorsement of 99th percentile upper reference limits to define myocardial injury," per this 2022 article.
- Beth knows providers and commercial payers alike will focus on the cost of the device, as captured in its coding (in addition to clinical evidence); they will look to ensure the billing codes for the procedure, service, and/or product are sufficient to cover the cost associated with the device's use in an outpatient (ER) setting and will save costs in an inpatient setting (after admission to a hospital bed from the ER).

  Beth plans to work with her Reimbursement Consultant to determine which evidence is needed for coverage under specific Medicare LCDs and for commercial payers.

Key Questions:

- Is the diagnostic considered standard of care or an optional, add-on service?
- Are there societies that advocate for this diagnostic?
- What evidence has been published on these types of diagnostic tests?
- Are there specific ICD-10 diagnosis codes that should be considered for evidence collection?

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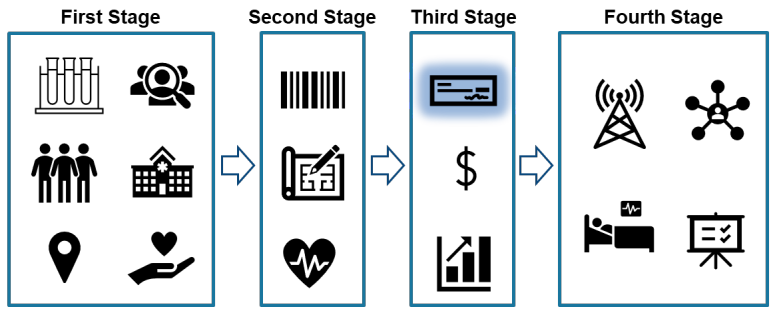
Third Stage: Research Payment Rates

With a potential CPT code in hand, Beth now wants to identify publicly available payment rates for CPT codes 84484.

Beth knows that most private payers base their reimbursement rates on the CMS rates; therefore, she investigates Medicare payment rates by following these steps:

- Look up the most current CMS "Clinical Laboratory Fee Schedule Files."
- Select File "22CLABQ4" as it has the most recent data (CY 2022 Q4 Release: Added for October 2022.)
- Click on and download the ZIP file and open the Excel spreadsheet.
- Search [CTRL+F] for preidentified CPT code(s) [84484] to see payment rates.

Based on these search criteria, she learns that the 2022 Clinical Diagnostics Laboratory Fee Schedule rate for CPT 84484 is $12.47. Beth notices the rates have not changed over the last three years. She also knows that even if a payment rate exists per the fee schedule, payment is based on the state specific local coverage determinations (see coverage section). This information is tremendously helpful, as she plans on entering the market as an alternative to Elecsys Troponin T Gen 5 at a lower price point.

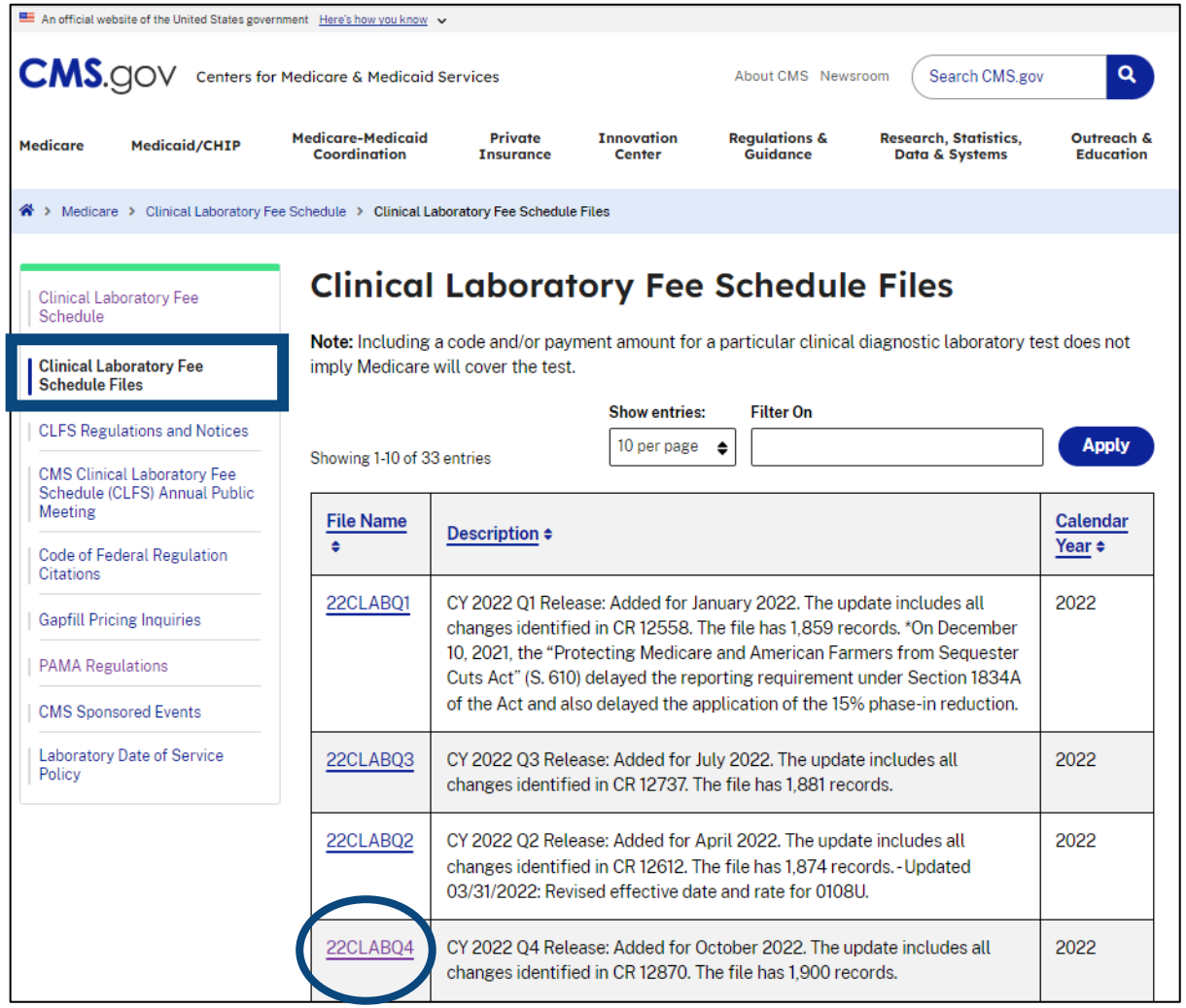


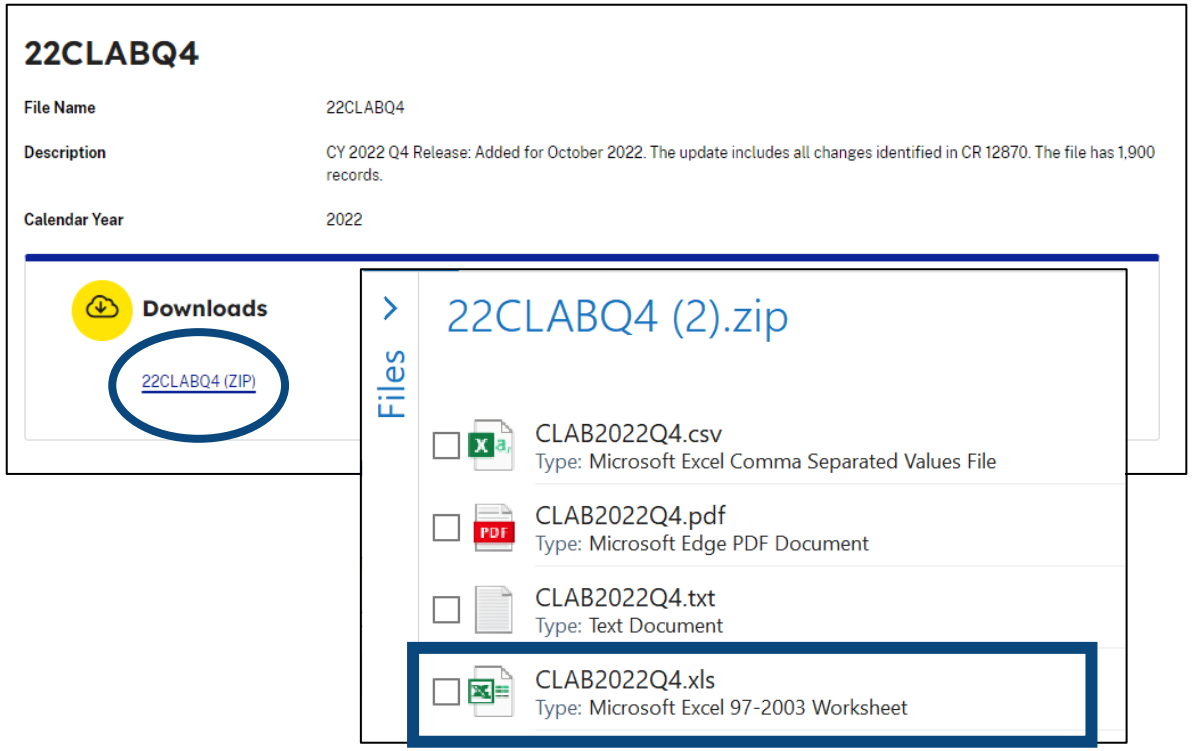
Key Question:

- Is there an existing CMS *lab* fee schedule? If so, what are the rates for the identified CPT code(s)?

Third Stage: Research Payment Rates

Navigating CMS Clinical Lab Fee Schedule Files



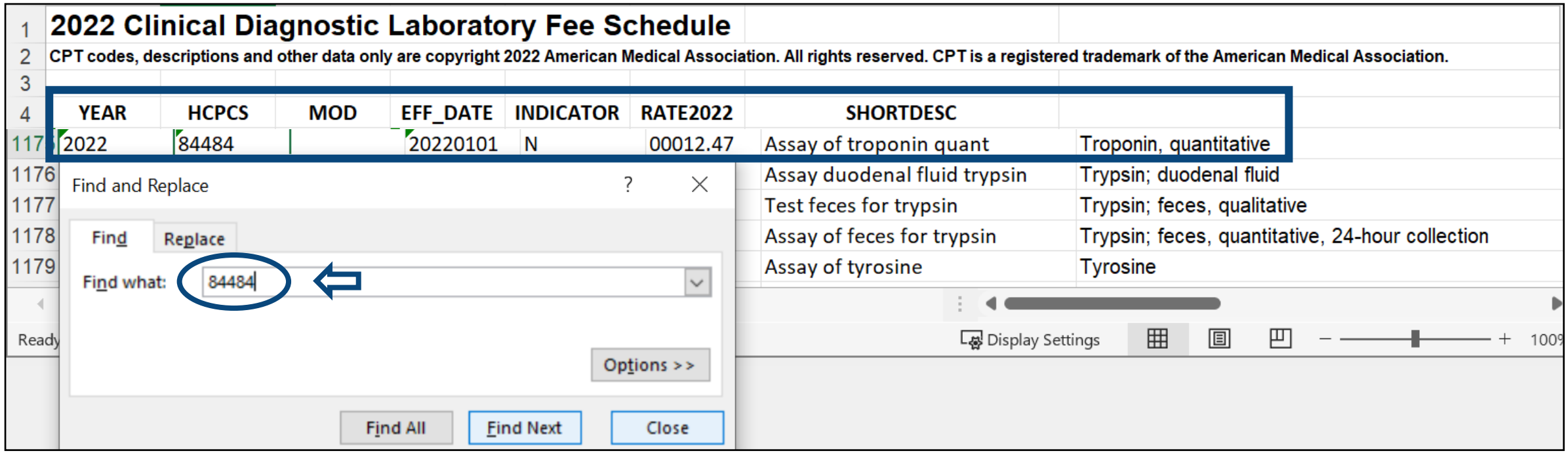


- Look up the most current CMS "Clinical Laboratory Fee Schedule Files."
- Select File "22CLABQ4" as it has the most recent data (CY 2022 Q4 Release: Added for October 2022.)
- Click on and download the ZIP file and open the Excel spreadsheet.
- Search [CTRL+F] for preidentified CPT code(s) [84484] to see payment rates.

Source: CMS

Third Stage: Research Payment Rates (cont.)

Navigating CMS Clinical Lab Fee Schedule Files



Source: CMS

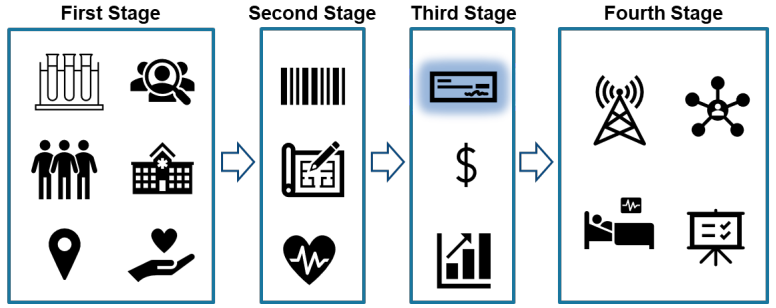
- Search [CTRL+F] for pre-identified CPT code(s) [84484].
- Check "SHORTDESC" to double-check applicability of test description to your diagnostic.
- Check "RATE2022" to understand what the current CMS Medicare payment rate is. I.e., for CPT 84484, the rate is $12.47.
- Check prior years' fee schedule to see if there were any changes in the rates.

Third Stage: Research Payment Rates (cont.)

As the CardioTrop T test can be ordered as a STAT test, Beth wants to check potential payment rates under the physician fee schedule. This would be important to communicate to a potential customer, such as the hospital lab director at Magnolia Health System.

Although Beth had learned that Washington State Medicaid covers the test (CPT 84484) along with the STAT modifier code HCPCS S3600 (a Level II code), through further research she discovers that CMS Medicare does not cover the stat lab modifier code as reflected on the HCPCS Codes summary page and in the query results on the CMS Physician Fee Schedule. A search for code S3600 returned the following: "No results S3600: The current Physician Fee Schedule does not price the requested HCPCS Code."

This is a discouraging finding, as a modifier code would have increased the reimbursement rate for hospital labs and the physicians they serve.

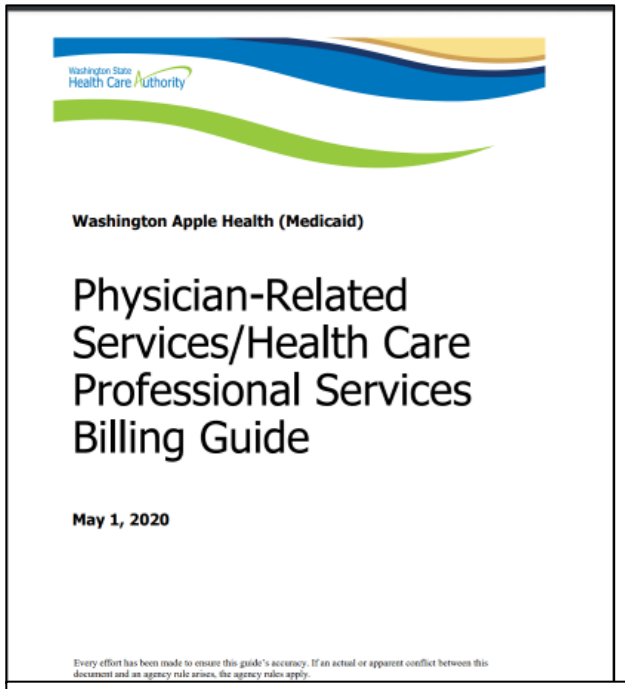


Key Question:

- Is there an existing CMS *physician* fee schedule? If so, what are the rates for the identified CPT code(s)?

Third Stage: Research Payment Rates (cont.)

Medicaid Agency Physician Billing Guides and Fee Schedules: Maryland

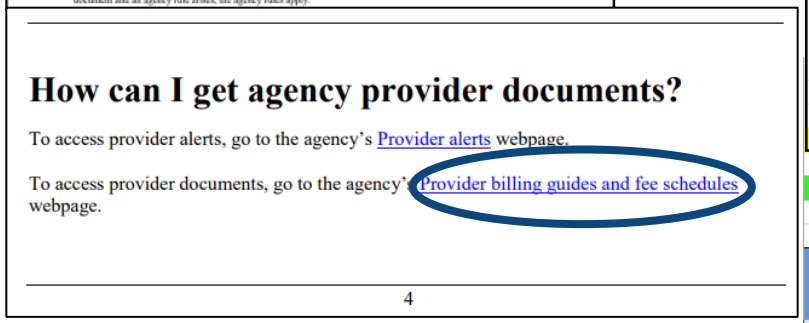


Washington Apple Health (Medicaid)

Physician-Related Services/Health Care Professional Services Billing Guide

May 1, 2020

Every effort has been made to ensure this guide's accuracy. If an actual or apparent conflict between this document and an agency rule arises, the agency rules apply.

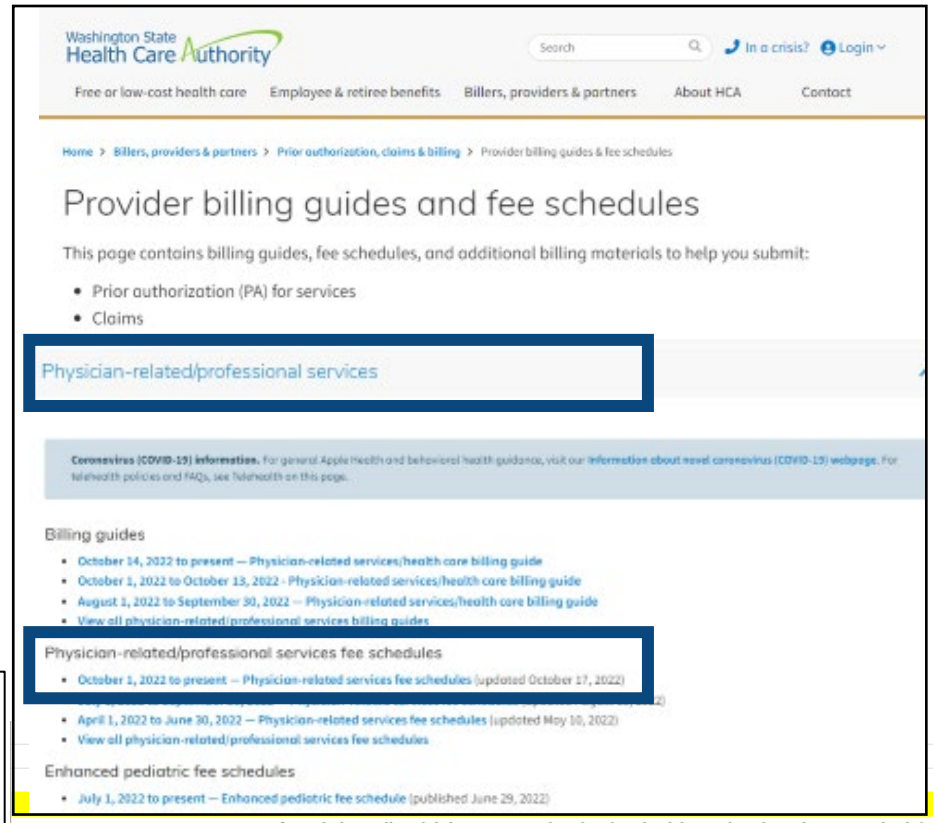


How can I get agency provider documents?

To access provider alerts, go to the agency's Provider alerts webpage.

To access provider documents, go to the agency's Provider billing guides and fee schedules webpage.

4



Washington State Health Care Authority

Free or low-cost health care | Employee & retiree benefits | Billers, providers & partners | About HCA | Contact

Home > Billers, providers & partners > Prior authorization, claims & billing > Provider billing guides & fee schedules

Provider billing guides and fee schedules

This page contains billing guides, fee schedules, and additional billing materials to help you submit:

- Prior authorization (PA) for services
- Claims

Physician-related/professional services

Billing guides

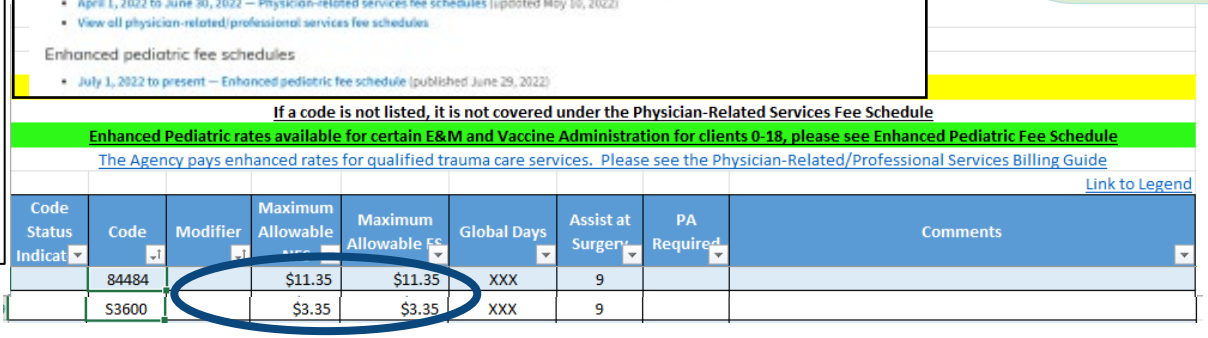
- October 14, 2022 to present — Physician-related services/health care billing guide
- October 1, 2022 to October 13, 2022 - Physician-related services/health care billing guide
- August 1, 2022 to September 30, 2022 — Physician-related services/health care billing guide
- View all physician-related/professional services billing guides

Physician-related/professional services fee schedules

- October 1, 2022 to present — Physician-related services fee schedules (updated October 17, 2022)
- April 1, 2022 to June 30, 2022 — Physician-related services fee schedules (updated May 10, 2022)
- View all physician-related/professional services fee schedules

Enhanced pediatric fee schedules

- July 1, 2022 to present — Enhanced pediatric fee schedule (published June 29, 2022)



If a code is not listed, it is not covered under the Physician-Related Services Fee Schedule

Enhanced Pediatric rates available for certain E&M and Vaccine Administration for clients 0-18, please see Enhanced Pediatric Fee Schedule

The Agency pays enhanced rates for qualified trauma care services. Please see the Physician-Related/Professional Services Billing Guide

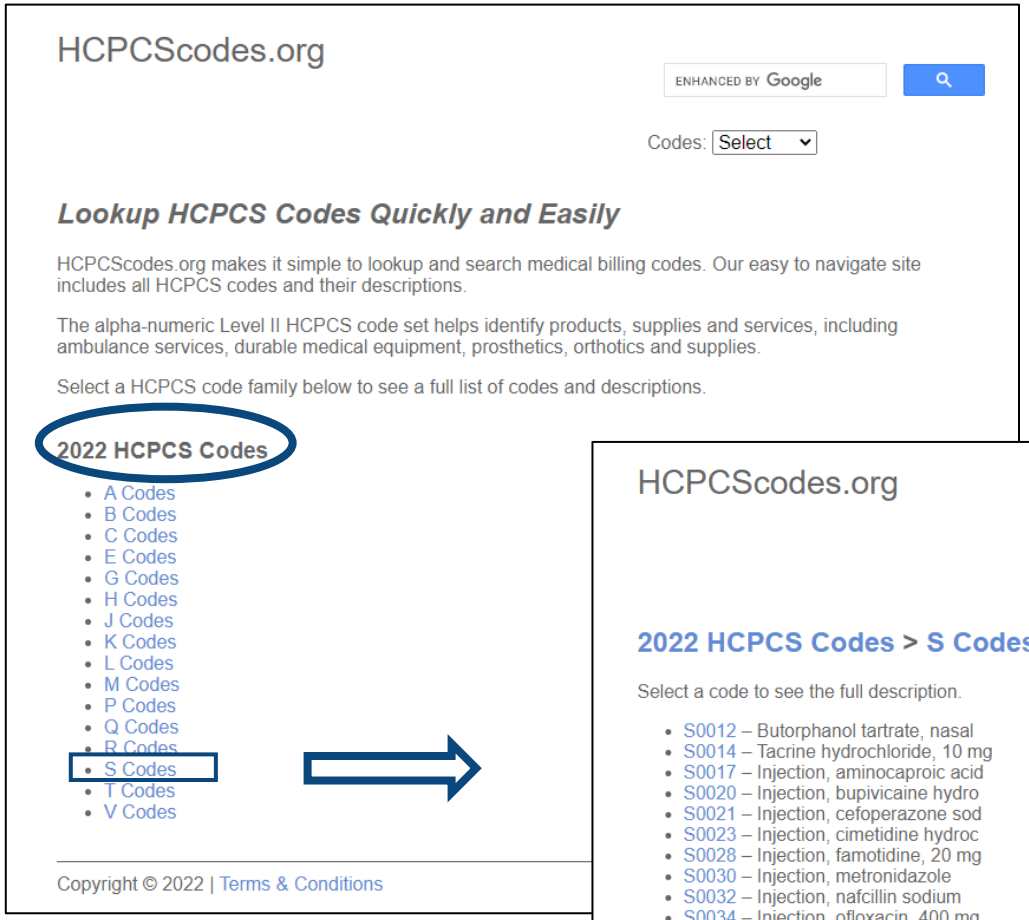
Link to Legend

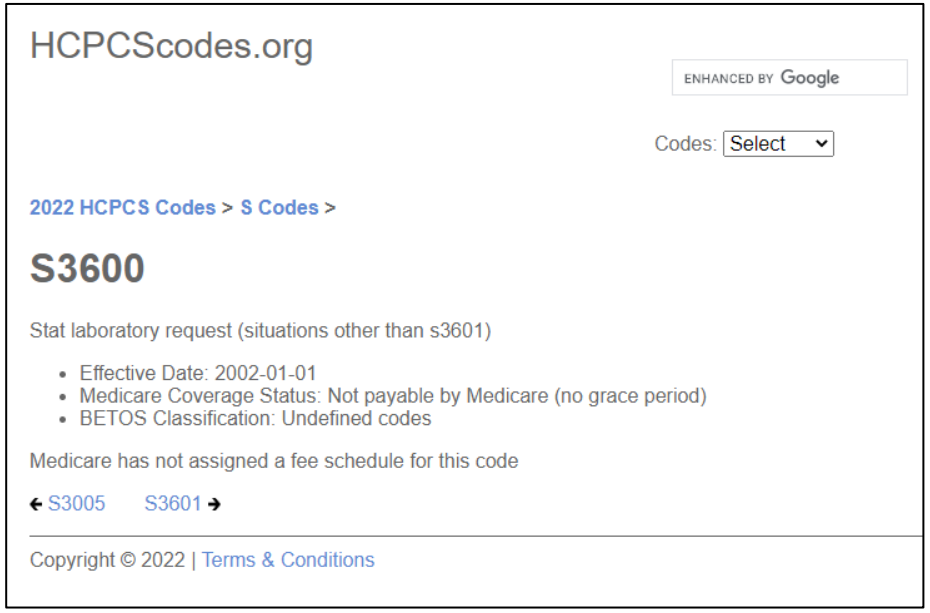
Code Status Indicat	Code	Modifier	Maximum Allowable	Maximum Allowable FS	Global Days	Assist at Surgery	PA Required	Comments
	84484		$11.35	$11.35	XXX	9		
	S3600		$3.35	$3.35	XXX	9		

- Open Medicaid Billing Guide; e.g., for Washington State OR navigate directly to Washington State Health Care Authority page
- Search document for references to "fee schedule" to find payment rate
- On Washington State Health Care Authority page, navigate to "Physician-related/professional services" section
- Click on most up to date "fee schedule"
- Download Excel spreadsheet, search for [CTRL + F] CPT code 84484 and S3600

Third Stage: Research Payment Rates (cont.)

HCPCS Codes Lookup Tool





- Go to https://hcpcscodes.org/
- Select which HCPCS code you are looking for: “S”
- Search [CTRL+F] for S Code code(s) [S3600]
- Click on hyperlink to view summary:
  - Effective Date
  - Medicare Coverage Status
  - Medicare Fee Schedule Status
  - Other

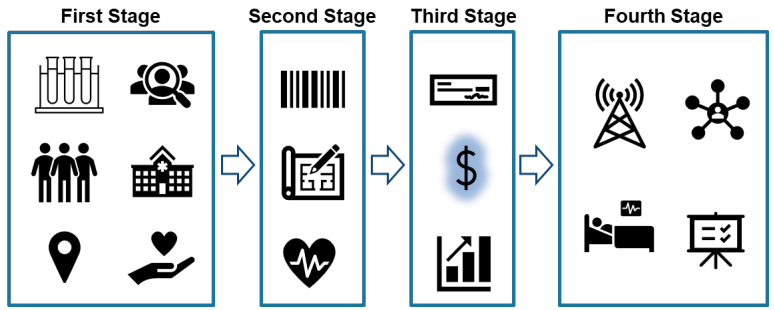
Third Stage: Research Payment Rates (cont.)

Coverage Summary Findings for Diagnosis of MI

Payer	CPT 84484	HCPCS S3600	References
CMS Medicare	✓ **$12.47**	✗ Current Physician Fee Schedule does not price the requested HCPCS Code	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files
CMS State Medicaid Agencies			
Washington	✓ **$11.35**	✓ **$3.35** Payment is limited to one STAT charge per episode (not once per test)	https://www.hca.wa.gov/assets/billers-and-providers/physician-related-servs-bg-20200501.pdf https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-and-billing/provider-billing-guides-and-fee-schedules
West Virginia	✓ **$11.22**	TBD; "C-Carrier priced"	https://dhhr.wv.gov/bms/FEES/Documents/Clinical%20Diagnostic%20Lab%20Fees/PDF/BMS-2022%20CLFS-Rev%203.8.22.pdf https://dhhr.wv.gov/bms/FEES/Pages/WV-Medicaid-Physician's-RBRVS-Fee-Schedules.aspx
…			
Aetna	✗ *Experimental*	✗	http://www.aetna.com/cpb/medical/data/300_399/0381.html
BlueCross BlueShield of North Carolina	✓	✗	https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/cardiac_biomarkers_for_myocardial_infarction.pdf

Third Stage: Understand the Cost and Price of the Test

Beth is now ready to investigate a Medicare price and private payer charge for CardioTrop T based on the total cost of the test and the market price tolerance. She knows coverage does not always equal cost coverage.



Beth first establishes the total cost of the test:

- Her team calculates the Cost of Goods Sold (COGS, direct costs including reagents, etc.) between $3.00 to $3.75 based on volume predictions of 10,000-15,000 units; this aligns with what she found other manufacturers estimated (per this article).
- Her business advisor estimates indirect costs (incl. sales force costs and other overhead) to range from $3.00 to $5.00 per unit; for a total cost of $6.00 to $8.75.
- Beth wants to break even or make a profit and compares her test cost to the lowest CMS payment rate of $12.47 for the pre-selected CPT code (84484).

Fortunately, the payment rate is higher than the total cost of the test – even if she invested more in marketing activities. She plans on discussing pricing options with her business advisors.

Her next step is to find out the average out-of-pocket costs incurred by patients for this test (in case their insurance does not cover the test in whole or part.) To determine the max out-of-pocket cost for the test, Beth utilizes Inova Health System's Patient Estimate tool; she searches for CPT 84484 and determines that the self-pay cost could be ~$96.00. She finds runs the same search using her own insurance information and finds that based on her high-deductible PPO plan, she would have to pay ~$66.00 out-of-pocket.

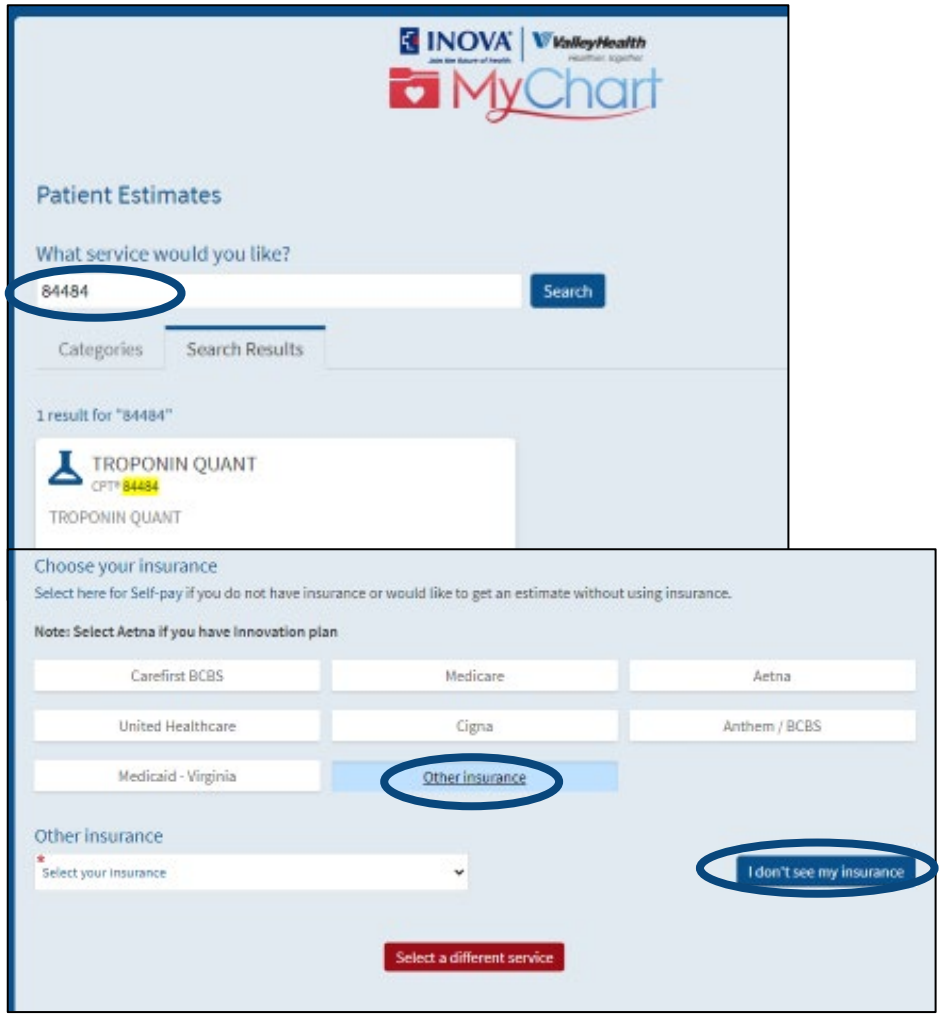
Beth determines that the viable price range for CardioTrop T is between $10.00 – $12.47 for hospital labs purchasing the test from Vital Diagnostics.

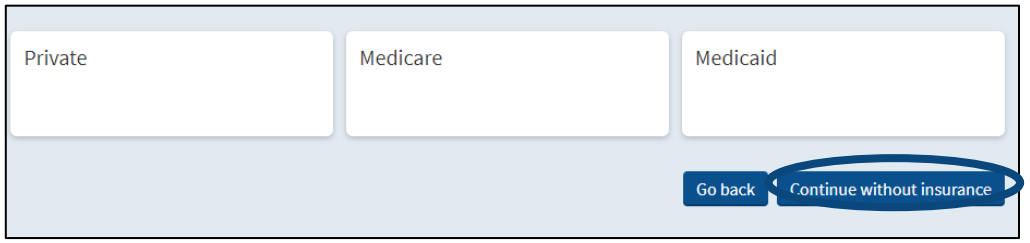
Key Questions:

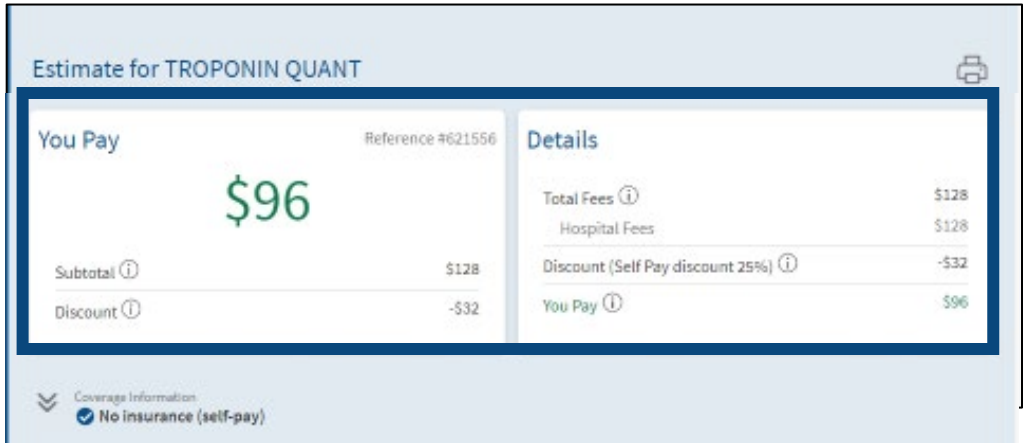
- What direct costs (material and labor) are incurred producing the diagnostic? What are indirect (fixed or variable) costs – such as administrative and personnel costs – associated with the product?
- What is the existing payment rate for the test (if any)? What is the break-even point? Note: The price of a product and the payment rate are usually different.
- What are average out-of-pocket costs for the test?

Third Stage: Understand the Cost and Price of the Test

Out-of-Pocket/Self-Pay Price Estimating







Source: Inova

- Search for self-pay estimating tool on hospital page; Note: this is a requirement per the CMS Price Transparency Rule
- Go to, e.g., https://www.inova.org/patient-and-visitor-information/hospital-charges
- Search for [CTRL + F] CPT code 84484
- Click on "Troponin Quant", "Other Insurance", "I don't see my insurance", "Continue without insurance"

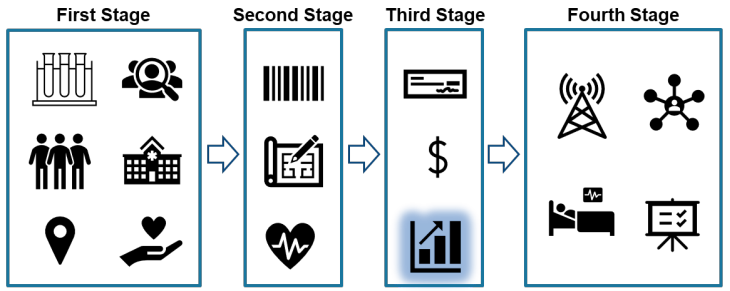
Third Stage: Create Contract and Pricing Models

Beth knows that many factors impact price, including the Cost of Goods Sold (COGS), existing (or potentially new) payment rates, the product's value proposition and differentiation, market size, the anticipated place of service (setting), and the purchasing power of distributors.

Beth understands that even if a test has an established coverage determination and average reimbursement rate, special rates may be negotiated with each payer by the lab/provider. Beth plans to work together with Magnolia Health System's lab director to meet with the Chief Medical Officers (CMOs) of each major commercial payer to negotiate a potential payment rate (although they currently deem the test experimental) for Magnolia Health System's lab. Beth believes that there is a strong value proposition (lower cost/cost savings per this article) and that supporting CMS coverage may have a favorable impact. Since Beth is deeply vested in the partnership with Magnolia's lab director, Beth also plans to review the lab's billing capabilities – including:

- Obtaining prior or pre-authorizations from insurance before conducting the test
- Billing commercial payers (charge without contract; pre-negotiated rate with contract)
- Billing Medicare/Medicaid (based on CMS Clinical Laboratory Fee Schedule rate)
- Processing patients' out-of-pocket costs/payments

Beth creates a charge/pricing matrix for hospital labs and encourages Magnolia Health's lab director to conduct a similar exercise for the identified payers based on annual volume estimates (as the lab not Vital Diagnostics would conduct the test and bill the various payer or collect out-of-pocket payments). This is important, as the CMS Hospital Price Transparency rule went into effect on January 1, 2021 – requiring hospitals to provide clear, accessible pricing information online about provided products/services.



Key Questions:

- Is the diagnostic filling an unmet need? What is the product's value proposition and differentiation in comparison to other products on the market?
- What is the prevailing market price of similar products on the market (if any)?
- How big is the target market?
- What is the anticipated place of service (e.g., out-patient or in-patient)?
- Who are the purchasers of the diagnostic?

Third Stage: Understand the Cost and Price of the Test

Summary Findings

Cost Assumptions	Value/Rate
Volume Assumption	10,000-15,000 units
Cost of Goods Sold (COGS direct costs (incl. reagents, etc.)	$3.00 - $3.75 per unit
indirect costs (incl. sales force costs and other overhead)	$3.00 - $5.00 per unit
TOTAL COST	**$6.00 to $8.75**
CMS Reimbursement Rate by Code	**Rate**
Medicare	
CPT 84484	$12.47
HCPCS S3600 (Level II code; STAT modifier code)	N/A
Medicaid (Washington State example)	
CPT 84484	$11.35
HCPCS S3600 (Level II code; STAT modifier code)	$ 3.35

Viable Price Range (allows for cost coverage/small margin for both – Vital Diagnostics and labs)	**$10.00 – $12.47 per unit** (based on vol. agreement / negotiated per unit rate)

Fourth Stage

First Stage

- Define Technology Type & Regulatory Context
- Evaluate Competitors
- Determine Patient Population
- Research Healthcare Providers
- Identify Site of Service
- Outline Types of Payers

Second Stage

- Research Existing Codes for Technology
- Analyze Coverage Determinations
- Determine Evidence and Value

Third Stage

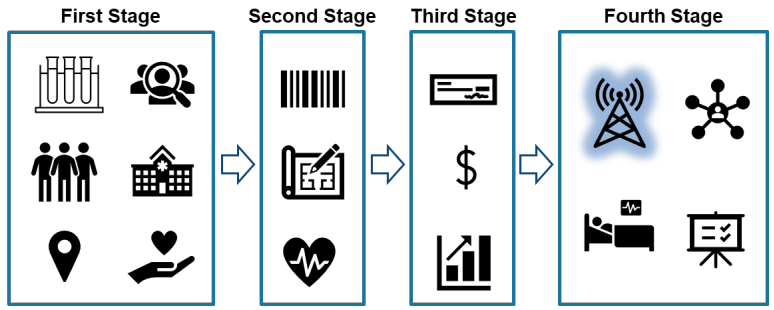
- Research Payment Rates
- Understand Cost & Price
- Create Contract & Pricing Models

Fourth Stage

- Create a Payer Communications Plan
- Garner Stakeholder Support
- Collect Evidence via Clinical Studies
- Consider Reimbursement Plan

Fourth Stage: Create a Communications Plan

Beth's final goals for her reimbursement strategy include developing a communications plan to inform stakeholders of CardioTrop T's attributes to garner support, drive market adoption, and receive optimal coverage.



Beth understands that she will need a **communications plan** to differentiate CardioTrop T and incentivize stakeholders to switch from conventional to high-sensitivity troponin assays (which requires favorable reimbursement). She personalizes messaging for the following stakeholder groups:

- **ER Physicians:** Sharing cost-benefits information on implementing CardioTrop T (over conventional tests) will be crucial. Talking points (incl. CardioTrop T's value proposition) will be essential in identify and working with physician champions. Beth plans to utilize Magnolia's lab director's existing relationships for warm introductions. Her goal is for the lab director to attend their rounds to talk peer-to-peer about high-sensitivity troponin testing.
- **Professional Medical Societies:** Working with the AHA and ACC – that have already endorsed "high-sensitivity cardiac troponin (hs-cTn) as the preferred biomarker," per this 2022 article – to engage the American College of Emergency Physicians (ACEP) and other emergency medicine societies and their stakeholders in conversations about CardioTrop T's attributes and market differentiation. She is considering partnering with them on a Continuing-Medical-Education (CME) level course on this topic.
- **Laboratories (hospital/reference/etc.):** Adding a high-sensitivity assay (in addition or lieu of conventional troponin tests) needs to be a value-add for the lab (cost-savings/reimbursement)
- **(Commercial) Payers:** Discussing favorable CMS Medicare LCDs in connection to evidence gaps (as described in commercial payers' policies) to understand specific coverage requirements. CardioTrop T's pending FDA-clearance is another differentiator.
- **Patient Advocacy Groups:** Integrating the voice of the patient will also be crucial in conversations with physicians and advocacy groups.

Key Questions:

- Who are the key decisions makers for the determinants of providers, commercial payers, and Medicaid that set reimbursement rates, collect payments, process claims, and pay provider claims?
- Can we claim that the new device provides payers with both, clinical and economic benefits over currently available alternatives?

Fourth Stage: Garner Stakeholder Support

Example tactics by stakeholder

Stakeholder	Goal/Tactic	Medium
ER Physicians	• Refine value proposition based on research • Develop talking points • Publish research findings, press release(s) on test developments • Get invited to grand rounds	• Presentations (grand rounds, etc.) • Publications (research findings) • Test summary/1-pager; including research study findings (peer-reviewed articles)
Professional medical societies	• Create CME-qualifying course on high-sensitivity troponin tests	• Meetings • Conferences • Working Groups
Laboratories (hospital/reference/ etc.)	• Establish value proposition / market differentiation • Communicate reimbursement potential • Equip lab directors with talking points for conversations with physicians (lab's customers)	• Test summary/1-pager; including average reimbursement rate
(Commercial) Payers	• Create presentation on research findings and value proposition; focus on new developments/research findings since payment policy was last reviewed	• Meetings • Conferences
Patient Advocacy Groups	• Collect testimonials from patients • Learn about impact of high-sensitivity / STAT testing on quality of care	• Focus groups • Member meetings

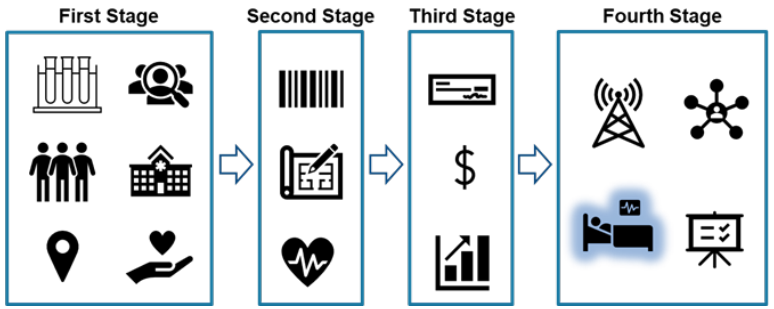
Fourth Stage: Collect Clinical Evidence by Conducting Clinical Studies

Beth assesses whether an additional study is needed – apart form what has already been collected for the FDA 510(k) application, to collect evidence impacting commercial payers' coverage decisions.

Although Beth's team has already collected validation information for CardioTrop T as part of the 510(k) application, the evidence does address test performance but not necessarily all clinical applications evaluated by payers.

She creates a list of all research studies references in each of the commercial payer's coverage policies to understand the rationale for denial. This will help evaluate if a clinical study would be necessary to collect additional information supporting a change in coverage policies.

Additionally, Beth plans on researching existing risk scores methodologies that include references to Troponin T testing.



Key Questions:

- Is a clinical study needed to collect evidence; if yes, under which circumstances?
- Has the product produced better results toward existing population to include the real-world patient population?
- How can you expand the number of hospital sites performing the screening test and case volume to show clinical utility?

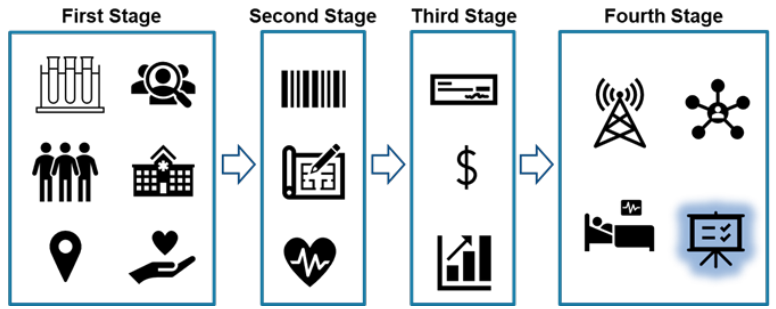
Fourth Stage: Collect Clinical Evidence by Conducting Clinical Studies

Summary of Payer Coverage Policies Research References by Intended Use

Commercial Payer	Reference	Publication Year	Summary Finding(s)
Intended Use	Diagnosis of (acute) myocardial infarction		
Aetna	Baig SZ, Coats WC, Aggarwal KB, Alpert MA. Assessing cardiovascular disease in the dialysis patient. Adv Perit Dial. 2009;25:147-154.	2009	Cardiac troponin I appears to be more specific than cardiac troponin T or creatine kinase MB subunits in the diagnosis of acute myocardial infarction.
…	…	…	…
Intended Use	Cardiovascular Disease Risk Assessment		
BlueCross BlueShield of North Carolina	Cosentino, F., et al. (2020). 2019 ESC Guidelines on diabetes, prediabetes, and cardiovascular diseases developed in collaboration with the EASD: The Task Force for diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD). European Heart Journal, 41(2), 255- 323. https://doi.org/10.1093/eurheartj/ehz486	2020	The guideline also noted high-sensitivity cardiac troponin T as not adding incremental "discriminative power" for patients with DM without known CVD (Cosentino et al., 2020), although elevated high-sensitivity cardiac troponin T was noted as an independent predictor of renal decline and CV events in patients with type 1 diabetes (Cosentino et al., 2020)
Cigna	Hoff J, Wehner W, Nambi V. Troponin in Cardiovascular Disease Prevention: Updates and Future Direction. Curr Atheroscler Rep. 2016 Mar;18(3):12.	2016	the use of [Cardiac troponin] as prognostic biomarker for the primary assessment of cardiovascular risk in asymptomatic patient has only recently been described. […] Evidence continues to show that high-sensitivity troponin is emerging as one of the most powerful prognostic biomarkers for the assessment of cardiovascular risk in the general population.
…	…	…	…

Fourth Stage: Consider Reimbursement Plan for a New Diagnostic

Beth also acknowledges that there may be a future need to consider additional evidence collection for new reimbursement vehicles and to request a novel CPT code for CardioTrop T. She plans to integrate this into her reimbursement strategy – specifically her communications plan, to drive market adoption.



Based on her conversations with her reimbursement consultant, Beth includes a plan to strengthen the medical necessity criteria by creating supporting evidence for **new reimbursement** mechanisms and improve the value proposition for CardioTrop T.

Since the there is only one other (predicate) diagnostic on the market (with FDA-approval/clearance), Beth believes that this type of test with – in contrast to other tests – high-sensitivity and turn-around-time differentiation should be reimbursed at a higher rate than what is currently set for CPT 84484.

Beth integrates her thinking into her reimbursement plan and will research detailed requirements on requesting a new CPT code in the coming months; her reimbursement plan includes an addendum with a timeline and resource requirements for obtaining a new CPT code. In the meantime, she plans on executing her communications plan while the new CPT code application process is set in motion.

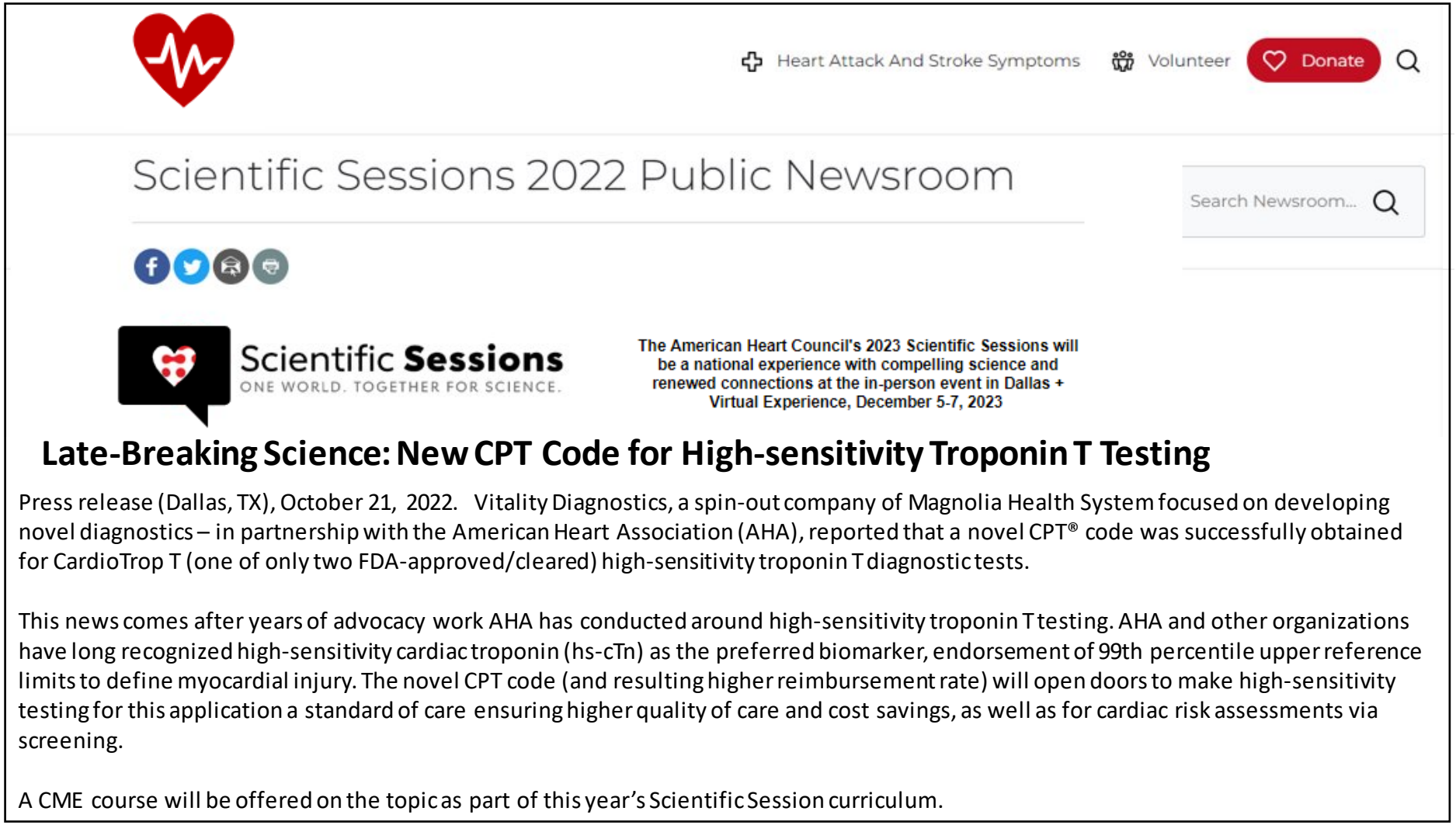
Key Questions:

- Will technological changes be made to my test in the future; will it be considered a new diagnostic?
- If so, what are the pros and cons of applying for a new CPT code?
- What steps do I need to take to obtain coverage for my new diagnostic?

SUMMARY

CardioTrop T Success

The following is a fictional portrayal of what success for CardioTrop T may look like*



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The American Heart Council's 2023 Scientific Sessions will be a national experience with compelling science and renewed connections at the in-person event in Dallas + Virtual Experience, December 5-7, 2023

Late-Breaking Science: New CPT Code for High-sensitivity Troponin T Testing

Press release (Dallas, TX), October 21, 2022. Vitality Diagnostics, a spin-out company of Magnolia Health System focused on developing novel diagnostics – in partnership with the American Heart Association (AHA), reported that a novel CPT® code was successfully obtained for CardioTrop T (one of only two FDA-approved/cleared) high-sensitivity troponin T diagnostic tests.

This news comes after years of advocacy work AHA has conducted around high-sensitivity troponin T testing. AHA and other organizations have long recognized high-sensitivity cardiac troponin (hs-cTn) as the preferred biomarker, endorsement of 99th percentile upper reference limits to define myocardial injury. The novel CPT code (and resulting higher reimbursement rate) will open doors to make high-sensitivity testing for this application a standard of care ensuring higher quality of care and cost savings, as well as for cardiac risk assessments via screening.

A CME course will be offered on the topic as part of this year's Scientific Session curriculum.

Summary Findings: By Stage

First Stage

- Technology Type & Regulatory Context: immunoassay for determination of cardiac troponin T in plasma; IVD under FDA regulation
- Competitors: Elecsys Troponin T Gen 5 (Roche Diagnostics) – high-sensitivity test; Boehringer Mannheim Corp other predominant market player
- Patient Population: any patient with an indication of potential myocardial infarction; anyone at age 20 and older – especially, ages 55 and up
- Healthcare Providers & Site of Service: Emergency Room physicians, predominantly be conducted in acute outpatient settings
- Types of Payers: all payers – except for Medicaid CHIP; esp. Medicare

Second Stage

- Existing Payment Codes: 84484: TROPONIN, QUANTITATIVE; 84512: TROPONIN, QUALITATIVE
- Coverage Determinations: Medicare, existing LCDs; commercial payer coverage is either dependent on indication for use/diagnosis or is deemed experimental
- Evidence and Value: capture utilization data to define evidence to support coverage and pricing – e.g., 2019 article "Use of troponins in clinical practice: Evidence in favour of use of troponins in clinical practice," along with theme "high-sensitivity cardiac troponin (hs-cTn) as the preferred biomarker, endorsement of 99th percentile upper reference limits to define myocardial injury," per this article

Third Stage

- Payment Rates: the CMS 2022 Clinical Diagnostics Laboratory Fee Schedule rate for CPT 84484 is $12.47
- Cost and Price: Total cost of $6.00 to $8.75; viable price range $10.00 – $12.47 for hospital labs purchasing the test from Vital Diagnostics
- Contract and Pricing Models: create charge/pricing matrix for hospital labs (as the lab not Vital Diagnostics would conduct the test and bill the various payer or collect out-of-pocket payments); consider CMS Hospital Price Transparency rule went into effect on January 1, 2021

Fourth Stage

- Communications Plan: Personalize messaging for stakeholder groups: ER Physicians, Professional medical societies, Laboratories (hospital/reference/etc.), (Commercial) Payers, and Patient Advocacy Groups
- Stakeholder Support: Establish long term relationships with key stakeholders (see above) and find product champions
- Clinical Evidence Curation/Clinical Studies: Create list of all research studies references in each of the commercial payer's coverage policies to understand the rationale for denial; research existing risk scores methodologies that include references to Troponin T testing
- Reimbursement Plan for New Diagnostic: consider additional evidence collection to request a novel CPT code

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GLOSSARY

Glossary

- **ACC**: American College of Cardiology
- **AHA**: American Heart Association
- **CDC**: Centers for Disease Control and Prevention
- **CMS**: Centers for Medicare and Medicaid
- **COGS**: Cost of Goods Sold
- **CPT®**: Current Procedural Terminology
- **HCPCS**: Healthcare Common Procedure Coding System
- **hs-cTn**: High-Sensitivity Cardiac Troponin
- **ICD-10**: International Classification of Diseases Diagnosis Codes
- **IVD**: In Vitro Diagnostic
- **LCD**: Local Coverage Determination
- **LDT**: Laboratory Developed Test
- **MCO**: Managed Care Organization
- **MI:** Myocardial Infarction
- **MS-DRG**: Medicare Severity Diagnosis Related Groups
- **NCD**: National Coverage Determination
- **SMA**: State Medicaid Agency