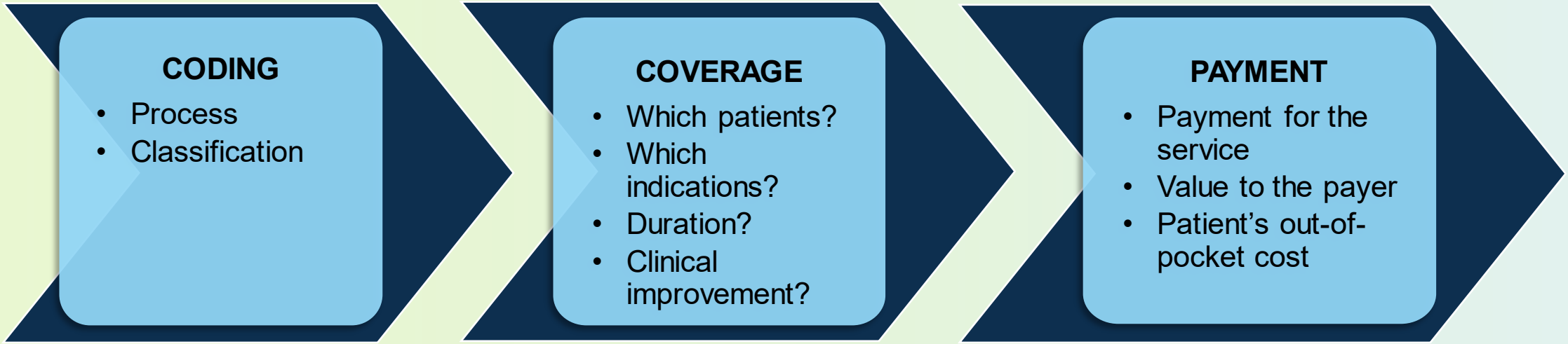
Diagnostic Test Case Study #3

Vitality Diagnostics & Companion Diagnostics

Reimbursement Overview

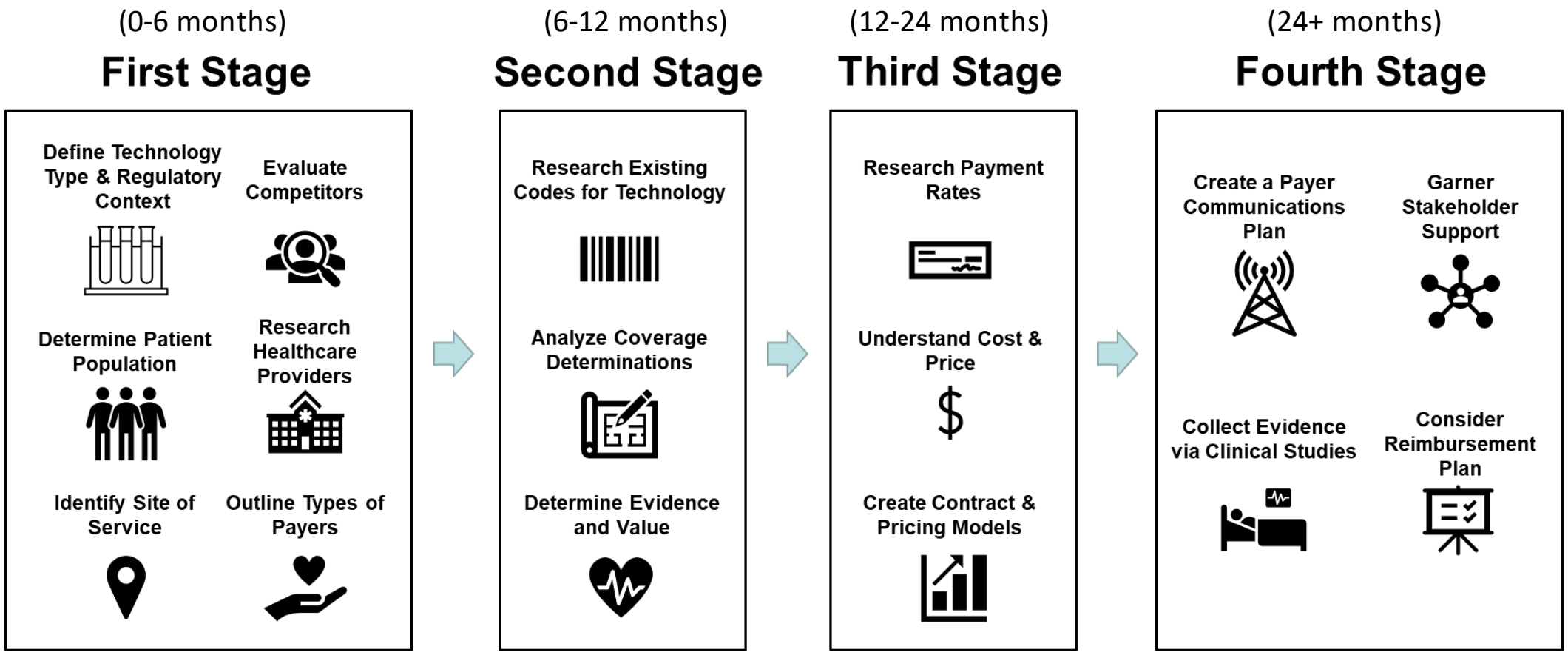
Bringing a diagnostic to market is a complex process. An innovator needs to understand the entire commercialization process and manage multiple tasks related to early-stage research and development, clinical studies, regulations, reimbursement and post-market surveillance. The goal of receiving Food 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 *Reimbursement Knowledge Guide for Diagnostics*. 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 OncMap Test

Beth is the CEO of Vitality Diagnostics – a spin-out company of Magnolia Health System. In addition to a novel prenatal Laboratory Developed Test (LDT), a high-sensitivity troponin T test, she is developing a Companion Diagnostic (CDx) test for Non-Small Cell Lung Cancer (NSCLC). The test is called OncMap and will first be utilized by Vitality Diagnostics as an LDT in their free-standing reference lab. Beth's goal is to gain FDA clearance so that the test can enter the market as an "official" CDx.

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

Here's some background from Vitality Diagnostics initial pitch to a large diagnostic manufacturer

Product Description:

- Vitality Diagnostics is developing a next-generation-sequencing (NGS), tissue- or plasma-based test for Non-Small Cell Lung Cancer (NSCLC) called **OncMap.**
- As a CDx, OncMap will be used to identify patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor (TKI) approved by FDA for that indication.
- OncMap will first be offered as a LDT to identify these NSCLC patients (without making treatment recommendations).

Why OncMap?

- Worldwide, lung cancer is the second most commonly diagnosed cancer (per the American Society of Clinical Oncology). NSCLC is the most common type of lung cancer in the U.S., accounting for 82% of all lung cancer diagnoses.
- Approximately 236,740 adults (117,910 men and 118,830 women) in the U.S. will be diagnosed with lung cancer (both small and non-small cell) in 2022.
- The five-year survival rate for NSCLC is 26%, compared to 7% for small cell lung cancer.
- Currently, there are four CDx on the market (three tissue-based, one plasma-based test) for this indication and for the five specific TKI's OncMap is targeting (Tarceva (erlotinib), Tagrisso (osimertinib), Iressa (gefitinib), Gilotrif (afatinib), Vizimpro (dacomitinib)).

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

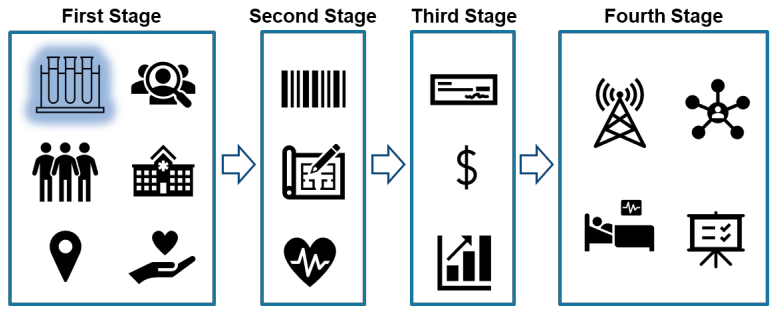
First Stage: Define the Technology Type & Regulatory Context

Beth is excited for the potential of OncMap to improve outcomes for oncology patients. Beth drafts two product descriptions – one for the near-term LDT application and one for the future CDx – based on the intended use of comparable devices. For the CDx path, she and her team determined that the Premarket Approval (PMA) application is a suitable pathway as she intends to enter the market as a follow-on plasma- or tissue-based CDx to the existing market leader FoundationOne CDx.™ Beth hopes that comparable CDx tests on the market will help her understand how her product can be reimbursed.

Beth drafts an intended use statement for OncMap CDx based on what she envisions would go on the test description. She reviewed the comparable device description – that she found via the FDA website listing cleared and approved CDx searching for "NSCLC" – and label information here. Here is what she drafted for the PMA application:

- *"OncMap is an NGS-based test intended as a companion diagnostic to identify patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor (TKI) approved by FDA for that indication"* (underlined portion not applicable to LDT).

Beth knows that FDA-cleared/approved devices are always preferred by payers. However, she is hopeful that coverage will also be favorable for an LDT – even though she will not be able to refer to treatment recommendations with TKIs for that indication in the test description (as this requires FDA-clearance/approval).



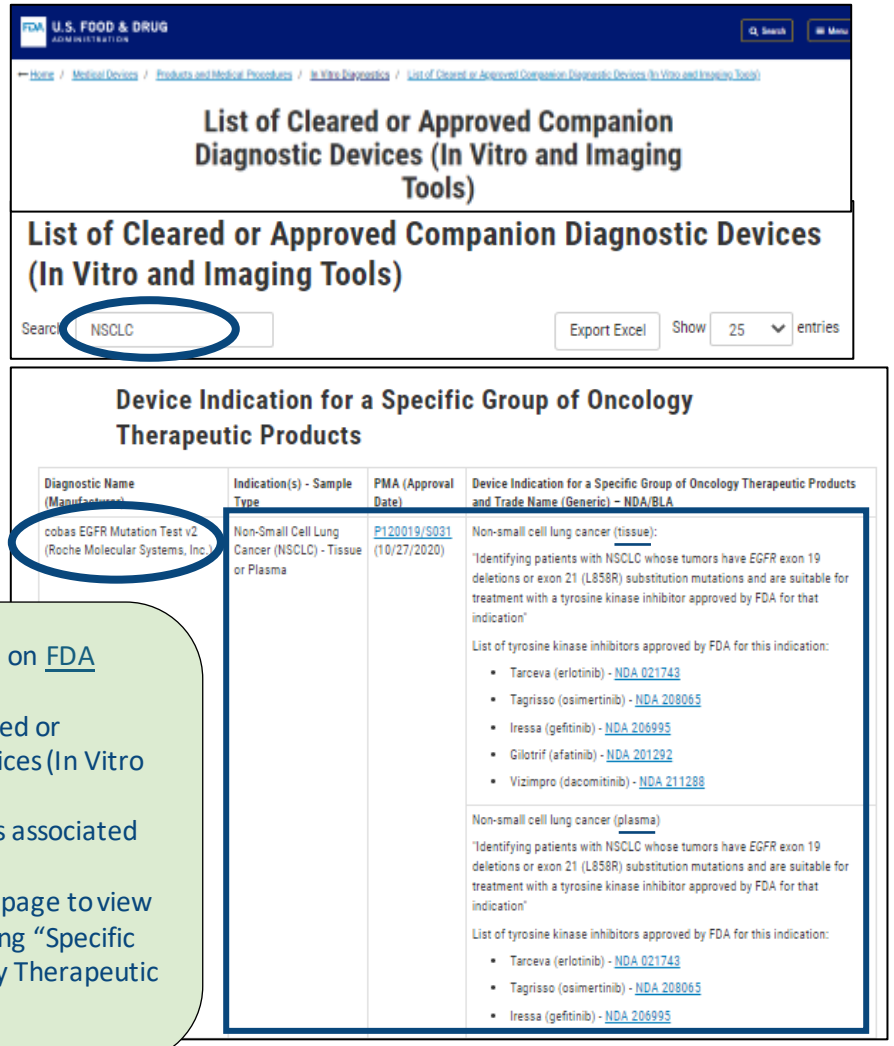
Key questions:

- 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 one-and-done test?

First Stage: Define the Technology Type & Regulatory Context

FDA Database Search

- Search for "NSCLC" on FDA page.
- Review list of Cleared or Approved CDx Devices (In Vitro and Imaging Tools)
- Identify biomarkers associated with indication.
- Scroll to bottom of page to view separate list covering "Specific Groups of Oncology Therapeutic Products."



U.S. FOOD & DRUG ADMINISTRATION

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)

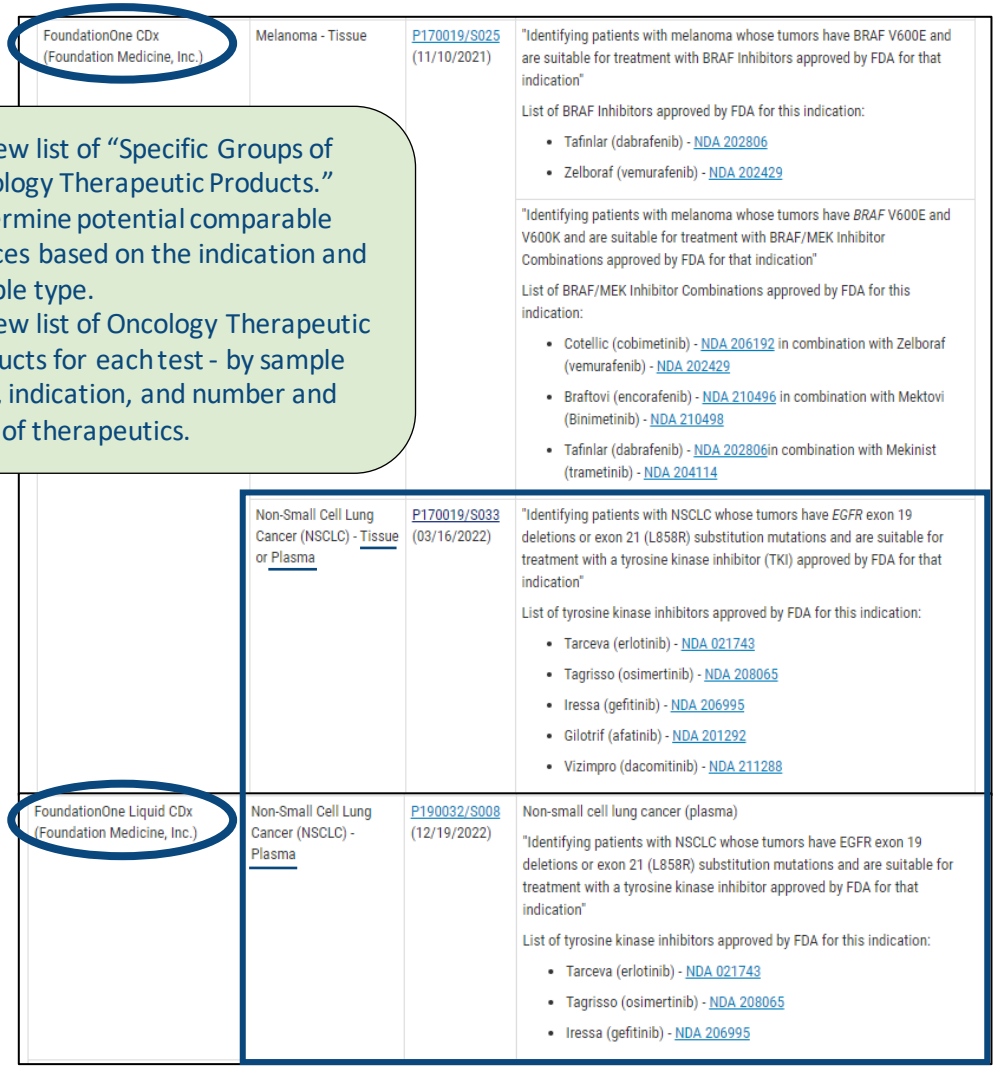
Search: NSCLC | Export Excel | Show 25 entries

Device Indication for a Specific Group of Oncology Therapeutic Products

Diagnostic Name (Manufacturer)	Indication(s) - Sample Type	PMA (Approval Date)	Device Indication for a Specific Group of Oncology Therapeutic Products and Trade Name (Generic) – NDA/BLA
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	P120019/S031 (10/27/2020)	Non-small cell lung cancer (tissue): "Identifying patients with NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication" List of tyrosine kinase inhibitors approved by FDA for this indication: • Tarceva (erlotinib) - NDA 021743 • Tagrisso (osimertinib) - NDA 208065 • Iressa (gefitinib) - NDA 206995 • Gilotrif (afatinib) - NDA 201292 • Vizimpro (dacomitinib) - NDA 211288 Non-small cell lung cancer (plasma) "Identifying patients with NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication" List of tyrosine kinase inhibitors approved by FDA for this indication: • Tarceva (erlotinib) - NDA 021743 • Tagrisso (osimertinib) - NDA 208065 • Iressa (gefitinib) - NDA 206995

Source: FDA

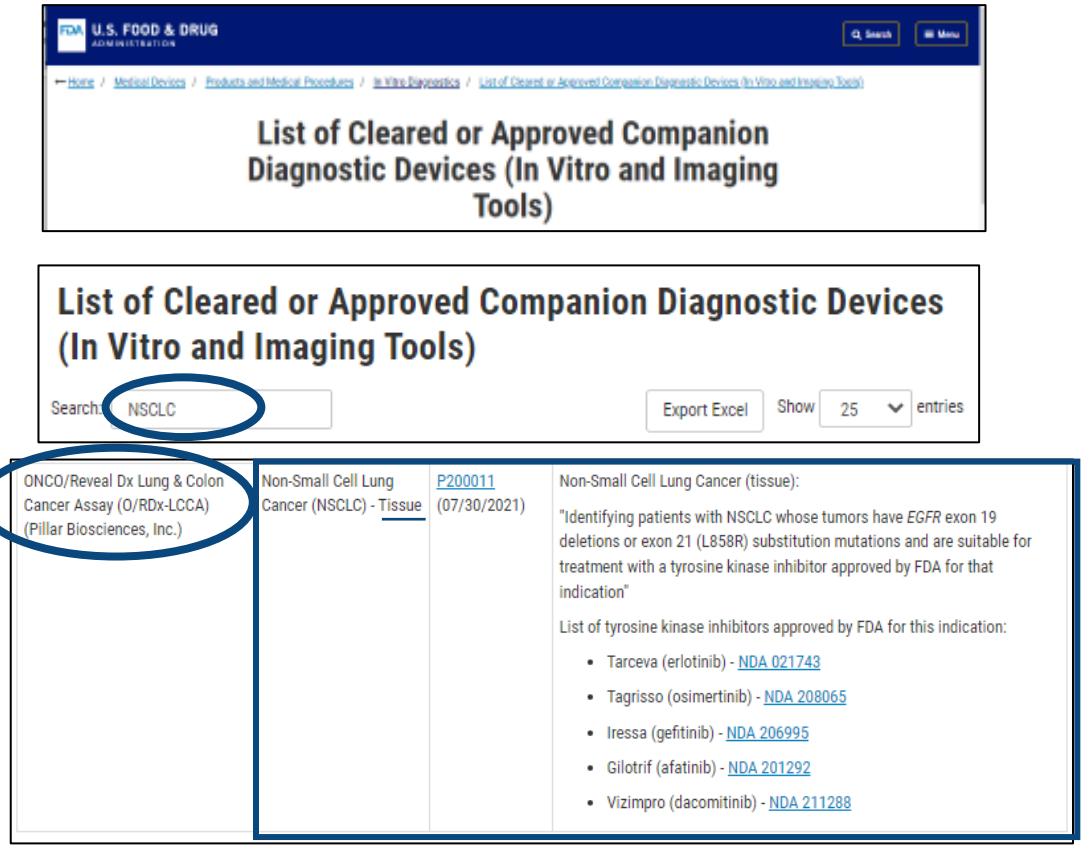
- Review list of "Specific Groups of Oncology Therapeutic Products."
- Determine potential comparable devices based on the indication and sample type.
- Review list of Oncology Therapeutic Products for each test - by sample type, indication, and number and type of therapeutics.



FoundationOne CDx (Foundation Medicine, Inc.)	Melanoma - Tissue	P170019/S025 (11/10/2021)	"Identifying patients with melanoma whose tumors have BRAF V600E and are suitable for treatment with BRAF Inhibitors approved by FDA for that indication" List of BRAF Inhibitors approved by FDA for this indication: • Tafinlar (dabrafenib) - NDA 202806 • Zelboraf (vemurafenib) - NDA 202429 "Identifying patients with melanoma whose tumors have *BRAF* V600E and V600K and are suitable for treatment with BRAF/MEK Inhibitor Combinations approved by FDA for that indication" List of BRAF/MEK Inhibitor Combinations approved by FDA for this indication: • Cotellic (cobimetinib) - NDA 206192 in combination with Zelboraf (vemurafenib) - NDA 202429 • Braftovi (encorafenib) - NDA 210496 in combination with Mektovi (Binimetinib) - NDA 210498 • Tafinlar (dabrafenib) - NDA 202806in combination with Mekinist (trametinib) - NDA 204114
	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	P170019/S033 (03/16/2022)	"Identifying patients with NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor (TKI) approved by FDA for that indication" List of tyrosine kinase inhibitors approved by FDA for this indication: • Tarceva (erlotinib) - NDA 021743 • Tagrisso (osimertinib) - NDA 208065 • Iressa (gefitinib) - NDA 206995 • Gilotrif (afatinib) - NDA 201292 • Vizimpro (dacomitinib) - NDA 211288
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	P190032/S008 (12/19/2022)	Non-small cell lung cancer (plasma) "Identifying patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication" List of tyrosine kinase inhibitors approved by FDA for this indication: • Tarceva (erlotinib) - NDA 021743 • Tagrisso (osimertinib) - NDA 208065 • Iressa (gefitinib) - NDA 206995

First Stage: Define the Technology Type & Regulatory Context

FDA Database Search (continued)



Source: FDA

First Stage: Evaluate Competitors

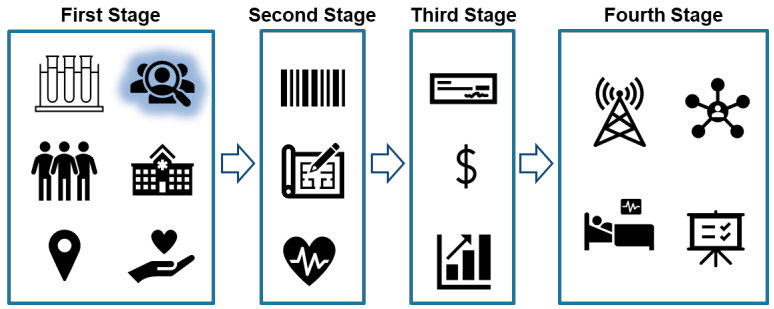
Beth is eager to assess the company's potential competitors – both their market share and product positioning.

Based on her research, Beth notes there are three predominant market competitors.

- There are currently, three offerings for this indication using *tissue* covering 5 TKIs (Foundation Medicine, Inc (FoundationOne CDx™), Roche Molecular Systems, Inc. (cobas EGFR Mutation Test v2), and Pillar Biosciences, Inc. (ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA));
- Foundation Medicine, Inc is also the only company offering a *plasma*-based test; covering all 5 TKIs that are also covered by the tissue-based offerings.

Beth's online research indicates that the "global oncology companion diagnostic market […] is expected to grow at a compound annual growth rate (CAGR) of 12.7% from 2020 to 2027," per this Grand View Research report. NSCLC "dominated the disease type segment with a revenue share of 25.3% in 2019 in the market for oncology companion diagnostics." Beth plans to conduct additional research on the market share of plasma- versus tissue-based CDx tests in the field of oncology.

If cleared/approved by FDA, OncMap would enter the market as a follow-on, single-site CDx and alternative to the FoundationOne CDx (tissue- or plasma-based test) at a slightly lower price point. In the near-term, she intends to serve oncologists in her region by offering the test as an LDT. She knows that she will need to educate physicians on the test as she will not be able to list the specific TKIs that correspond with the biomarkers on her test description. She refines her competitive advantage statement based on her research findings as this may impact stakeholder uptake and coverage decisions.

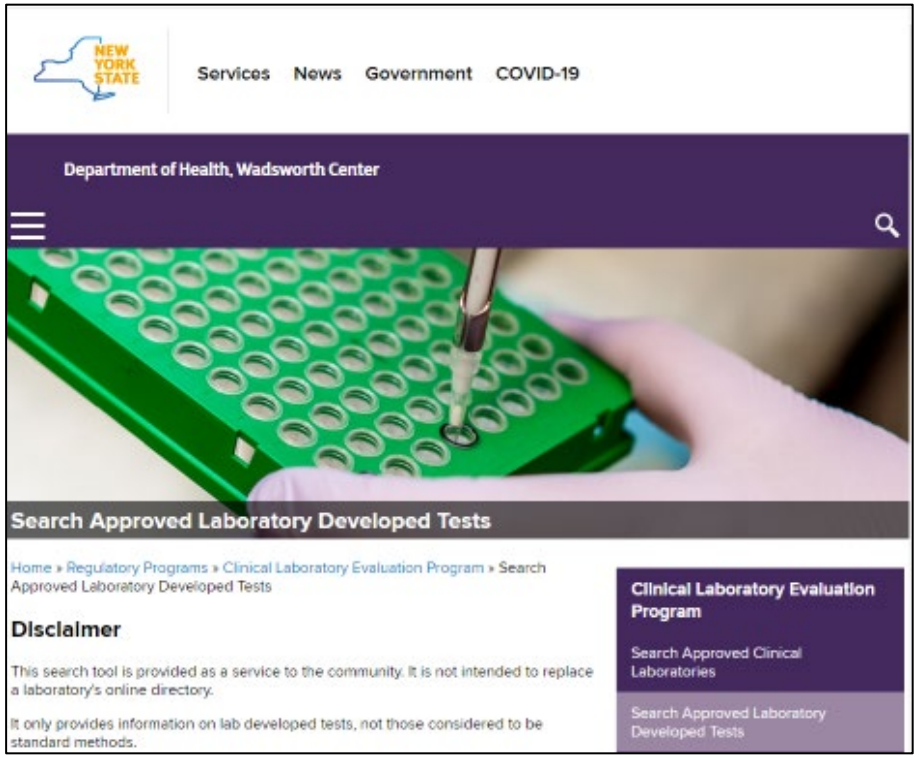


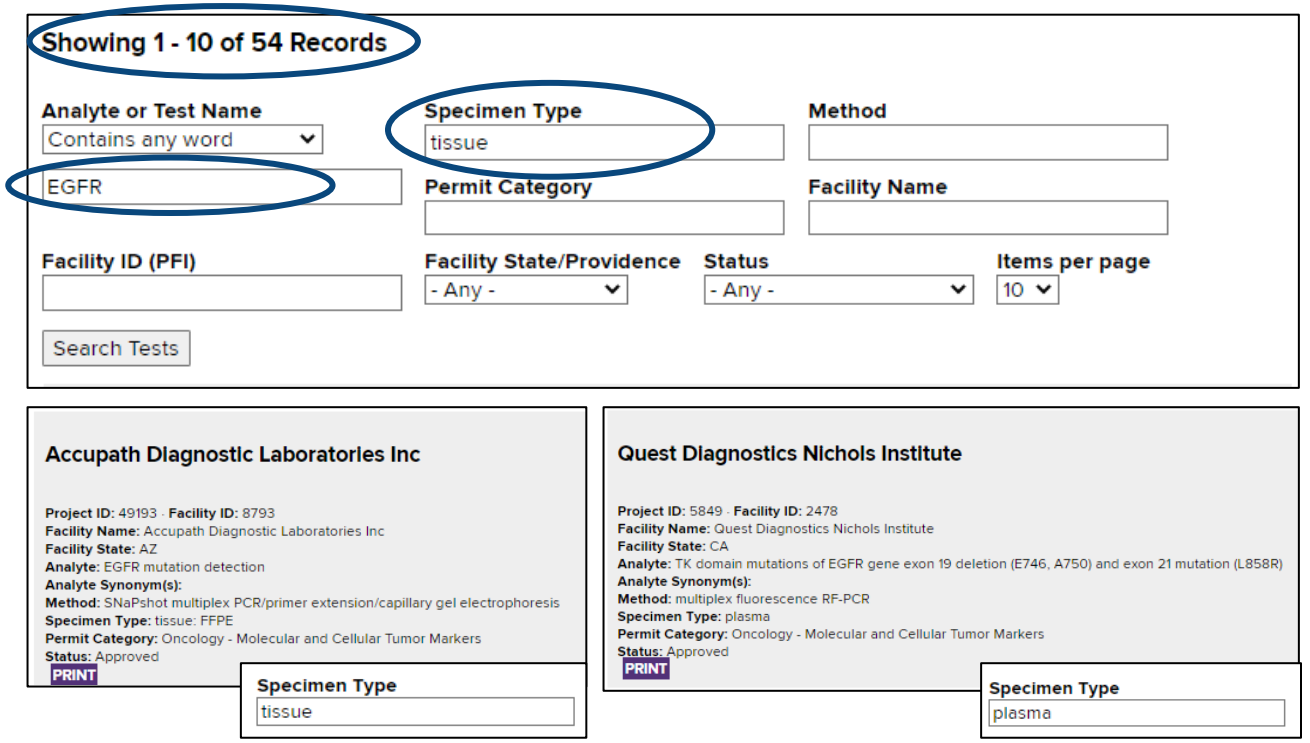
Key Questions:

- What competitor devices are on the market?
- What will differentiate this product from competitors?

First Stage: Evaluate Competitors

Example: New York State Department of Health, Wadsworth Center





- Searching Health Department's approved test lists, offers insights into how many *similar* LDTs have been approved by this governing body.
- Note: Although this search only reflects results for one state (New York), the laboratories listed are located across the nation.

- Go to New York State Department of Health website titled "Search Approved Laboratory Developed Tests."
- Search for "EGFR" under "Analyte or Test Name" and first "tissue" and then "plasma" under "Specimen Type."
- The search returned 54 results for "tissue." and 7 results for "plasma."
- Evaluate the results based on "Method," "Analyte," and other indicators.

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 benefit from OncMap. This is important because it will inform the clinical study design and data collected as well as the reimbursement potential.

Beth defines the patient population for OncMap as:

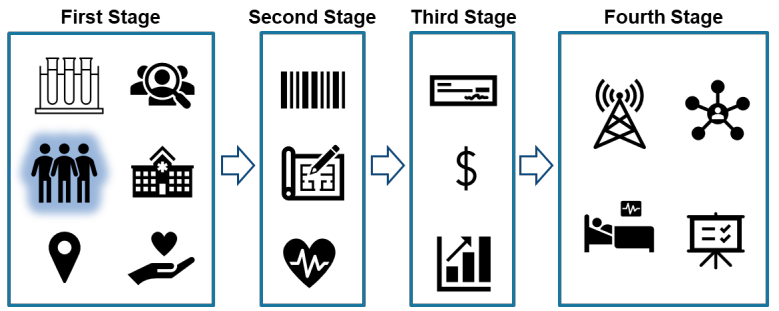
- Any patient with Non-Small Cell Lung Cancer (NSCLC)
- Majority of patients are 65 or older (minority younger than 45)
- Any gender and ethnicity – although some ethnic groups have a higher risk of developing lung cancer per the American Cancer Society (ACS)

Per ACS, about 84% of all lung cancers are NSCLC. ACS also states:

- Lung cancer mainly occurs in older people
- Most people diagnosed with lung cancer are 65 or older; a very small number of people diagnosed are younger than 45
- The average age of people when diagnosed is about 70

This shows the importance of Medicare reimbursement for this patient group.

Her research also showed that lung cancer is most often diagnosed by an oncologist in an outpatient 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?

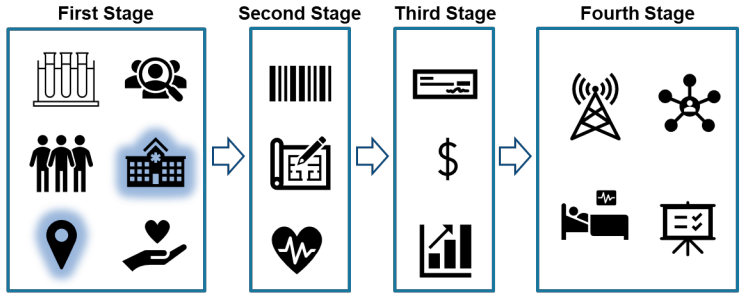
First Stage: Research Healthcare Providers & Identify the Site of Service

Beth intends to determine which specific healthcare provider group would use OncMap. 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 results from the OncMap test would predominantly be used in an outpatient settings by oncologists after either a tumor-tissue or a plasma-sample has been obtained. After a sample has been obtained, prepared, and shipped to the testing site, it will take approximately 12 days (from receipt of specimen and complete order) until results are available. Given the complexities of tumor sample collection, Beth is encouraged that a plasma-sample test will be viewed as highly competitive (faster, less-invasive) by providers she intends to target.

In general, a CDx, would have to be repeated for each tumor as the genetic makeup of each tumor is different (and not based on the location of the tumor).

This is good news as Beth wanted to rule out that the test would be utilized in an inpatient setting. This would have meant 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.



Key Questions:

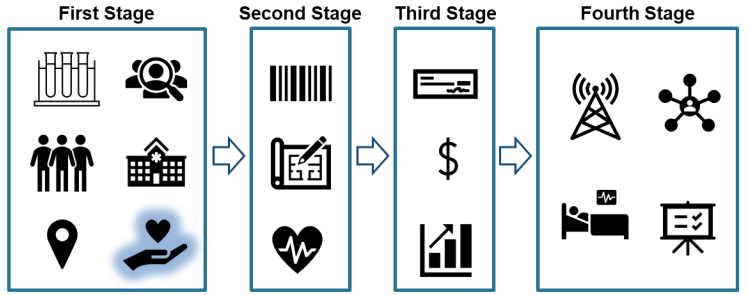
- Based on the intended use and target patient population, which particular group of healthcare providers would use the diagnostic (i.e., cardiologist, pediatrician, primary healthcare provider, etc.)?
- Where will the diagnostic be used – in an outpatient (doctor's office) or inpatient (hospital) setting?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

Based on her research of the patient population (all genders, majority 65 or older; minority younger than 45), Beth knows that all payers – except for (Medicaid) CHIP as children are not part of the target patient population – would need to be considered in her coverage evaluation for the OncMap test. Medicare will play an integral role for reimbursement. The ability to pay out-of-pocket for the test will depend on each patient's circumstance and should not be assumed.

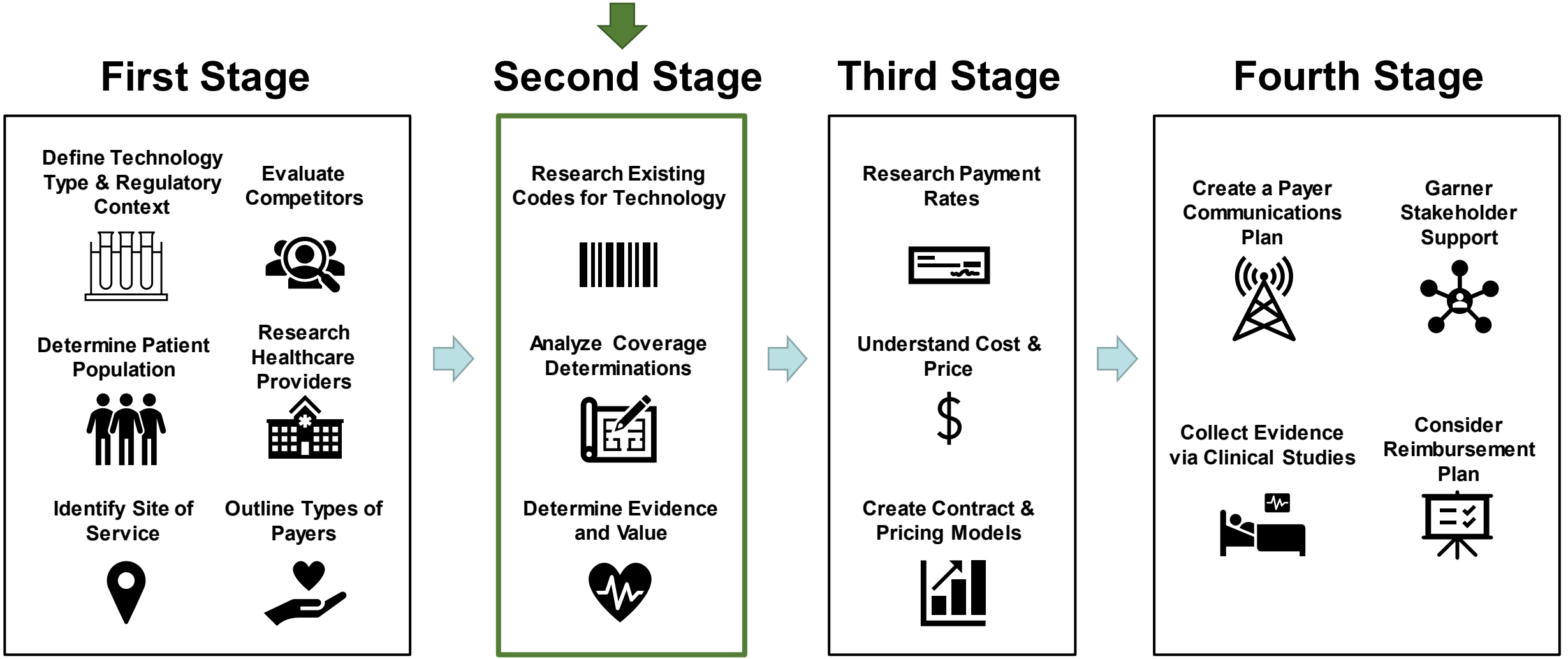
From her advisory council, Beth also understands that, historically, commercial insurers make coverage determinations by reviewing Medicare coverage requirements. In the recent past though, private payers have deepened their bench for evidence review and more often today are covering new items and services in advance of a Medicare coverage determination. 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



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 codes and diagnostic tests in coverage determinations, so she can search the CMS lab fee schedule for payment rates.

Beth uses FoundationOne's CDx to search for existing CPT codes using the search term "CPT + FoundationOne CDx." Beth knows that CPT codes can be listed in commercial payers' coverage determinations, CMS articles and lab fee schedules, or lab test menus. From her search, she learns that FoundationOne received a new Advanced Diagnostic Laboratory Test (ADLT) status from CMS in 2018; the reimbursement rate is $3,500. However, she also knows that ADLTs can only be used by the single lab that created the test. One of the requirements for ADLT status is FDA approval.

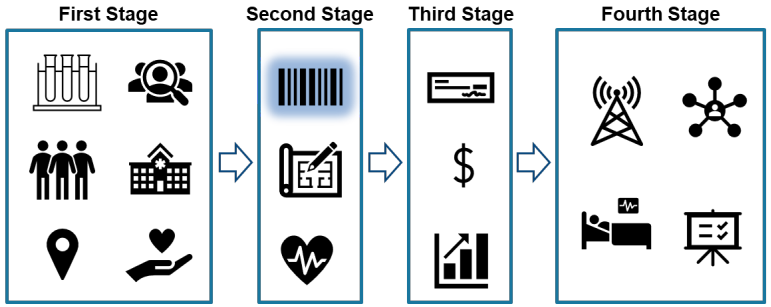
The code for the FoundationOne CDx™ is:

- HCPCS billing code 0037U: Trgt gen seq dna 324 genes (solid organ tumor tissue)

Due to the uniqueness of the test, this means FoundationOne applied for a code for its recently FDA-approved plasma sample-based test. It also means that Beth would need to apply for an ADLT (and specific sample type) after receiving FDA approval (if no other CPT code is available by then).

For the LDT, she looks up which Proprietary Lab Analysis (PLA) codes have been requested from the American Medical Association (AMA); these codes can also only be used by the lab that requested it for their LDT. While PLA codes are payable by Medicare (important for the diagnostic's patient population), they may not be paid by other payers such as commercial plans and or Medicaid. She finds the following PLA example:

- 0022U Oncomine™ Dx Target Test, Thermo Fisher Scientific, "Targeted genomic sequence analysis panel, cholangiocarcinoma and non-small cell lung neoplasia, DNA and RNA analysis, 1-23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapies to consider."

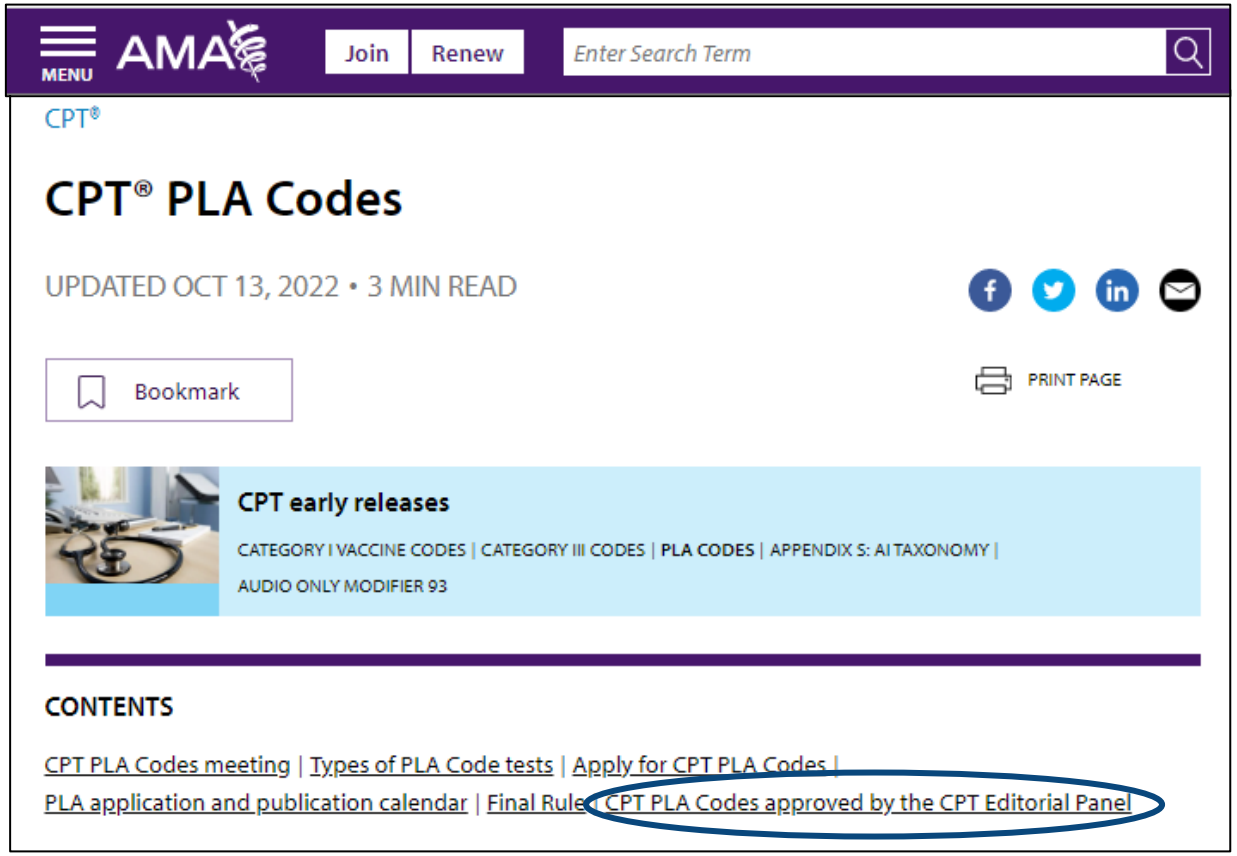


Key Questions:

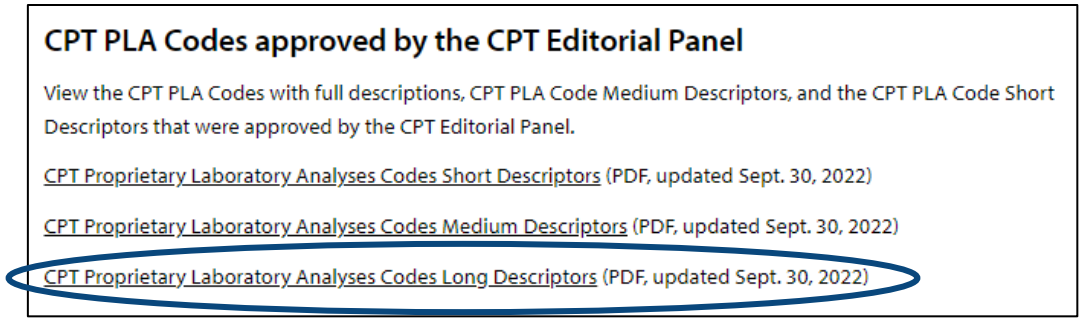
- Are there existing CPT codes for the diagnostic?
- Which CPT code best fits my test (sometimes multiple)?
- Have only "unlisted" codes been used to date?
- If so, do you want to apply for a new CPT code?

Second Stage: Research Existing Payment Codes for the Technology

How to find a list of updated CPT PLA Codes



- Go to AMA website titled "CPT PLA Codes."
- Click on "CPT PLA Codes approved by the CPT Editorial Panel" link to get directed to a list of CPT PLA Code links.



- Select the "…Long Description" PDF to view CPT PLA Codes with full descriptions approved by the CPT Editorial Panel.

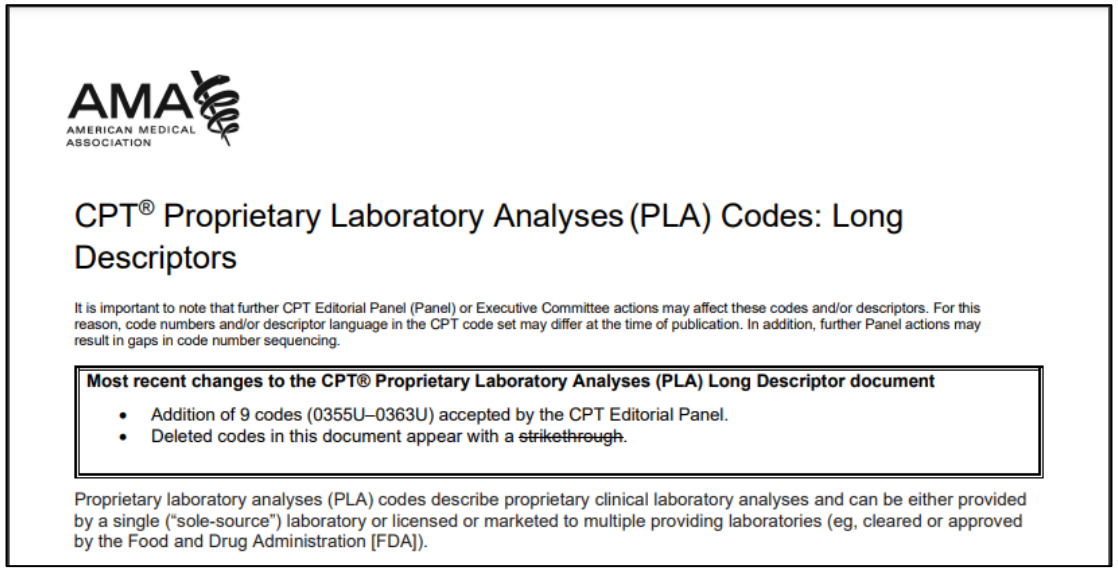
Note:

- PLA codes are update quarterly.
- A list of recently approved/changed codes is available online in the form of a PDF (see following slides).
- A comprehensive list of all PLA codes can only be accessed by purchasing the most recent CPT Code Book or an online CPT subscription.
- The content from both – the PDF listing recently approved PLA codes + CPT book, provides the most comprehensive picture.

Source: AMA

Second Stage: Research Existing Payment Codes for the Technology

How to search for specific test types



AMA AMERICAN MEDICAL ASSOCIATION

CPT® Proprietary Laboratory Analyses (PLA) Codes: Long Descriptors

It is important to note that further CPT Editorial Panel (Panel) or Executive Committee actions may affect these codes and/or descriptors. For this reason, code numbers and/or descriptor language in the CPT code set may differ at the time of publication. In addition, further Panel actions may result in gaps in code number sequencing.

Most recent changes to the CPT® Proprietary Laboratory Analyses (PLA) Long Descriptor document

- Addition of 9 codes (0355U–0363U) accepted by the CPT Editorial Panel.
- Deleted codes in this document appear with a ~~strikethrough~~.

Proprietary laboratory analyses (PLA) codes describe proprietary clinical laboratory analyses and can be either provided by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]).

Proprietary Name and Clinical Laboratory and/or Manufacturer	Code	Long Code Descriptor	Released to AMA Website	Effective Date	Publication
Oncomine™ Dx Target Test, Thermo Fisher Scientific, Thermo Fisher Scientific	▲0022 U	Targeted genomic sequence analysis panel, cholangiocarcinoma and non-small cell lung neoplasia, DNA and RNA analysis, 1-23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider	**Revision Released to AMA Website** December 30, 2021	**Revision Effective** April 1, 2022	**Revision Publication** CPT® 2023

Source: AMA

- Review the content of the PDF ("…Long Description").
- Search [CTRL + F] for specific references, such as "non-small."
- The results include:
  - Proprietary Name and Clinical Laboratory and/or Manufacturer
  - Code (CPT PLA)
  - Long Code Descriptor of the test
  - Date when the code was released on the AMA website
  - Effective date of the code
  - Publication (version)

Note: A PLA code does not identify whether the test is an FDA-approved/cleared IVD or a Laboratory Developed Test (LDT).

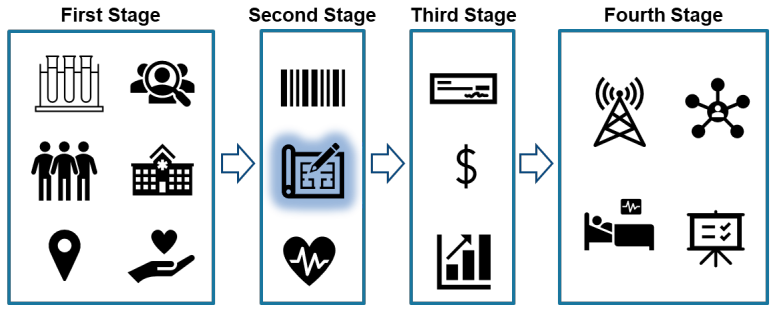
Second Stage: Analyze Coverage Determinations

Although Beth knows she will have to request either a new PLA and or ADLT code for her test, she knows codes have already been established for similar tests. She can use these codes to review coverage determinations. She starts her assessment with CMS and then commercial payer coverage.

From her search for CPT codes, she learns that this falls under "Molecular Pathology and Genetic Testing" and finds a CMS Local Coverage article. Beth also reads about molecular pathology procedures that are not covered services and determines OncMap should be covered. Beth discovers that there are no specific ICD-10 diagnosis codes that need to be used to support medical necessity. Group 1 Codes – both 0037U and 0022U – fall into this category. A National Coverage Determination (NCD) for diagnostic lab tests exists, and Beth reviews the NCD, as well.

When researching Medicaid Coverage Determinations, she discovers that Maryland covers the ADLT code (0037U) but does not cover the PLA code (0022U). Maryland does not require prior physician authorization for 0037U. This indicates that FDA approval/clearance is crucial for Medicaid coverage – ADLT versus PLA code coverage depends on the payer and if it is approved/cleared as a CDx.

When Beth searches commercial payer coverage policies by using an online query using "[commercial payer name] + 0037U/0022U," she learns that Aetna does not cover 0037U for tumor markers but does cover 0022U (LDT). Aetna also considers FoundationOne CDx not medically necessary for non-small cell lung cancer under the "Pharmacogenetic and Pharmacodynamic Testing" policy. However, when expanding her search to "Aetna + "0037U" + non-small cell" she finds this 2020 report titled "Payer Coverage Policies of Tumor Biomarker Testing." It lists which commercial payers cover either 0037U, 0022U, or both.

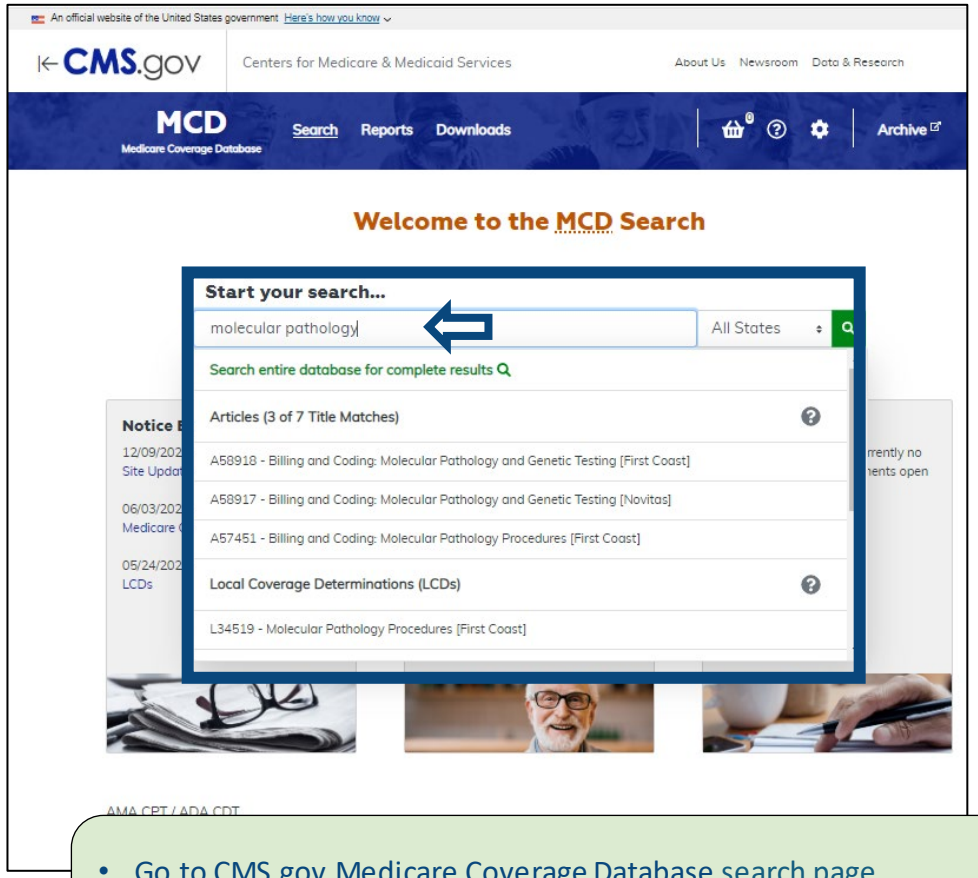


Key Questions:

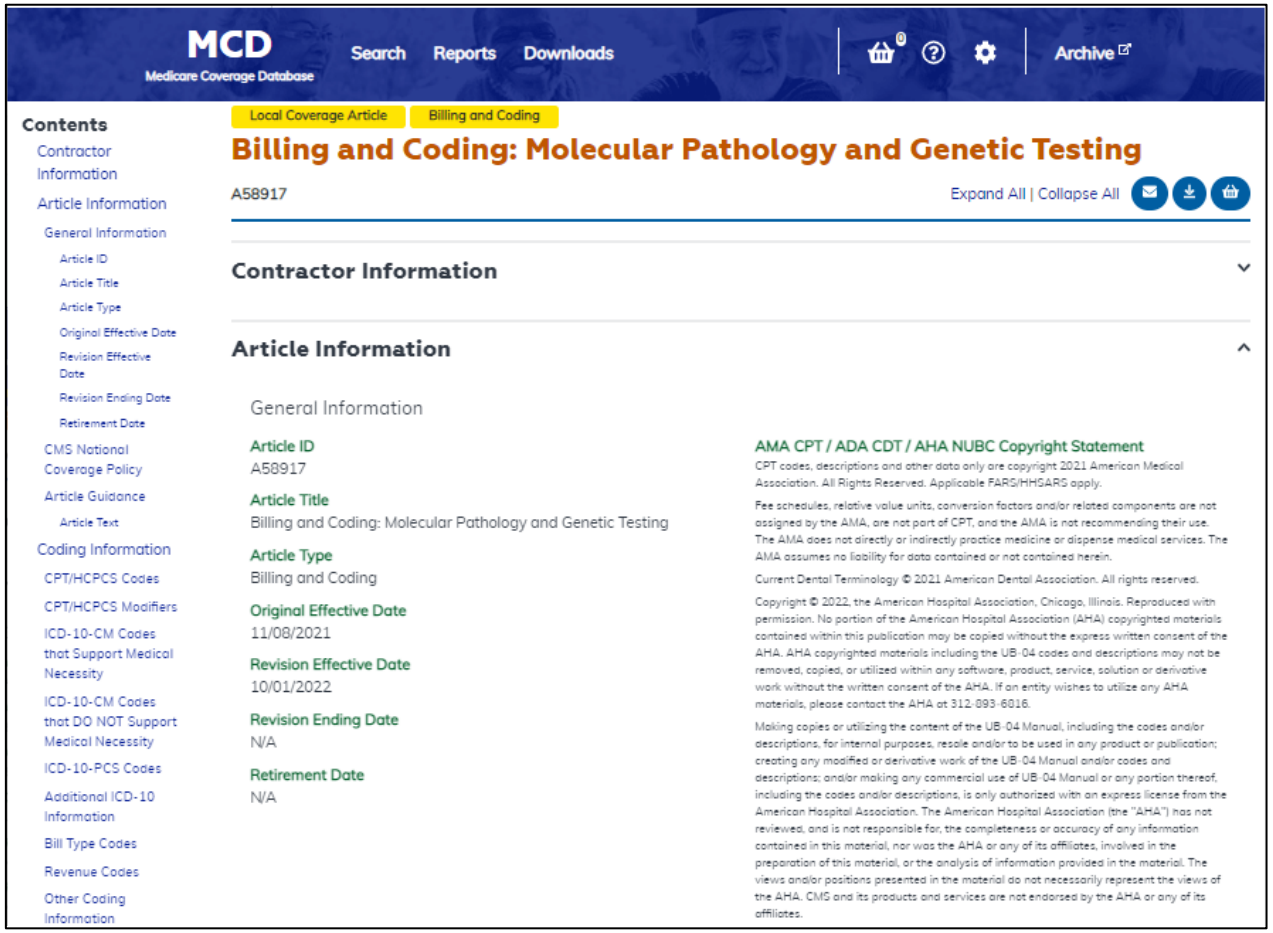
- Which coverage determinations exist for both commercial payers and Medicaid given the identified CPT codes? Note: Commercial payers often make coverage decisions based on Medicare/Medicaid coverage determinations.
- Is the test deemed medically necessary or experimental (or both) by the payers? Note: 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). Does the lab have to be CAP accredited or be an in-network lab?

Second Stage: Research Existing Payment Codes for the Technology

Searching CMS Medicare Coverage Database for "Molecular Pathology"



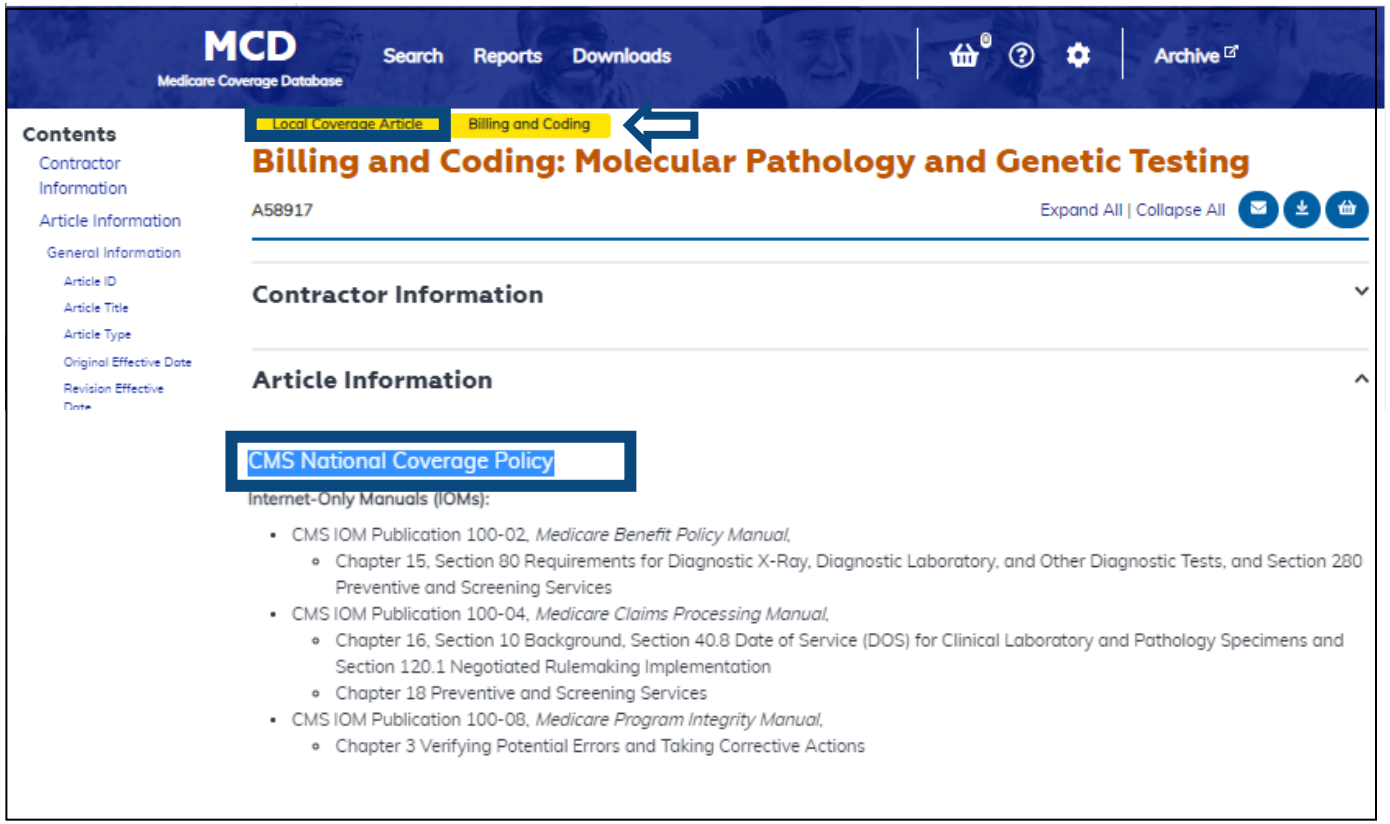
- Go to CMS.gov Medicare Coverage Database search page
- Search for "Molecular Pathology"
- Page returns applicable articles and local coverage determinations



Source: CMS

Second Stage: Research Existing Payment Codes for the Technology

Navigating Local Coverage Articles for "Molecular Pathology"



Source: CMS

- Website shows a CMS National Coverage Policy by publication number, chapter, and section.
- CMS IOM Publication 100-02 Chapter 15, Section 80 can be utilized for additional searches.

Website indicates which CPT codes (Group 1) CMS accepts for tests. There are no specific ICD-10 codes required to support medical necessity for the CPT codes listed.

Second Stage: Research Existing Payment Codes for the Technology

Understanding "Excluded Test" Criteria

Article Guidance

Article Text

Many applications of the molecular pathology procedures are not covered services given a lack of benefit category (e.g., preventive service or screening for a genetic abnormality in the absence of a suspicion of disease) and/or failure to meet the medically reasonable and necessary threshold for coverage (e.g., based on quality of clinical evidence and strength of recommendation or when the results would not reasonably be used in the management of a beneficiary). Furthermore, payment of claims in the past (based on "stacking" codes) or in the future (based on the new code series) is not a statement of coverage since the service may not have been audited for compliance with program requirements and documentation supporting the medically reasonable and necessary testing for the beneficiary. Certain molecular pathology procedures may be subject to medical review (medical records requested). The medical records must support the service billed.

Molecular pathology tests for diseases or conditions that manifest severe signs or symptoms in newborns and in early childhood or that result in early death (e.g., Canavan disease) are subject to automatic denials since these tests are generally not relevant to a Medicare beneficiary.

The following types of tests are examples of services that are not relevant to a Medicare beneficiary, are not considered a Medicare benefit (statutorily excluded), and therefore will be denied as Medicare Excluded Tests:

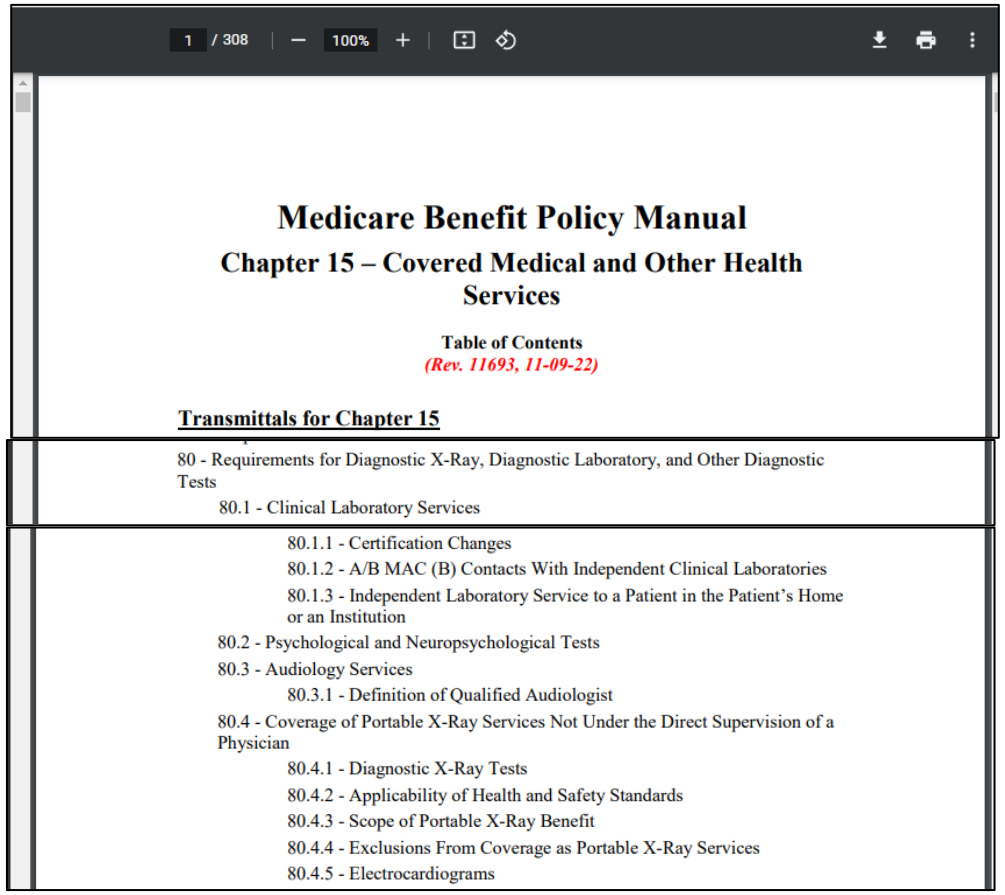
- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law
- Tests performed to determine carrier screening
- Tests performed for screening hereditary cancer syndromes
- Prenatal diagnostic testing
- Tests performed on patients without signs or symptoms to determine risk for developing a disease or condition
- Tests performed to measure the quality of a process
- Tests without diagnosis specific indications
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial

Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered.

- Article indicates which applications of molecular pathology procedures are not covered – mainly preventative and screening services.

Second Stage: Research Existing Payment Codes for the Technology

Navigating National Coverage Articles for "Molecular Pathology"



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Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

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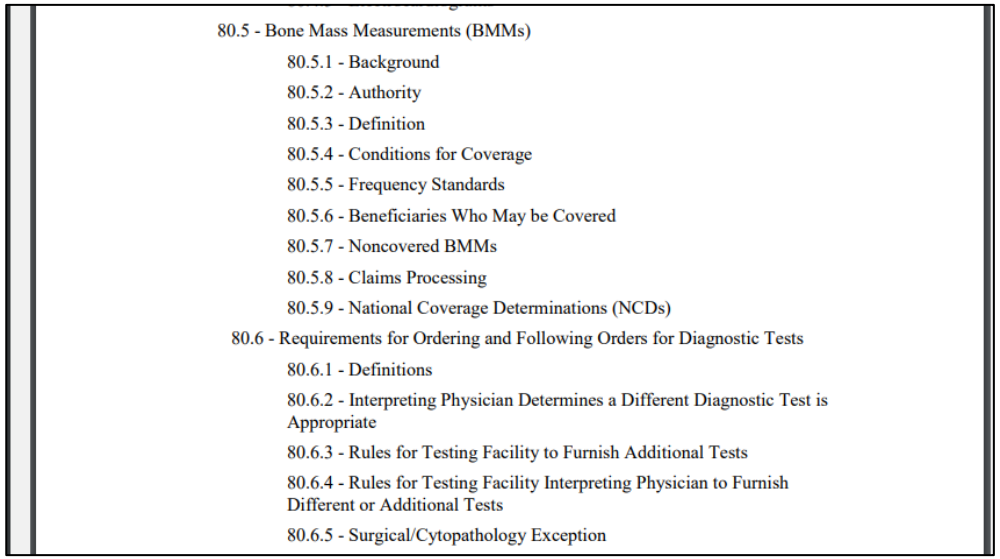
(Rev. 11693, 11-09-22)

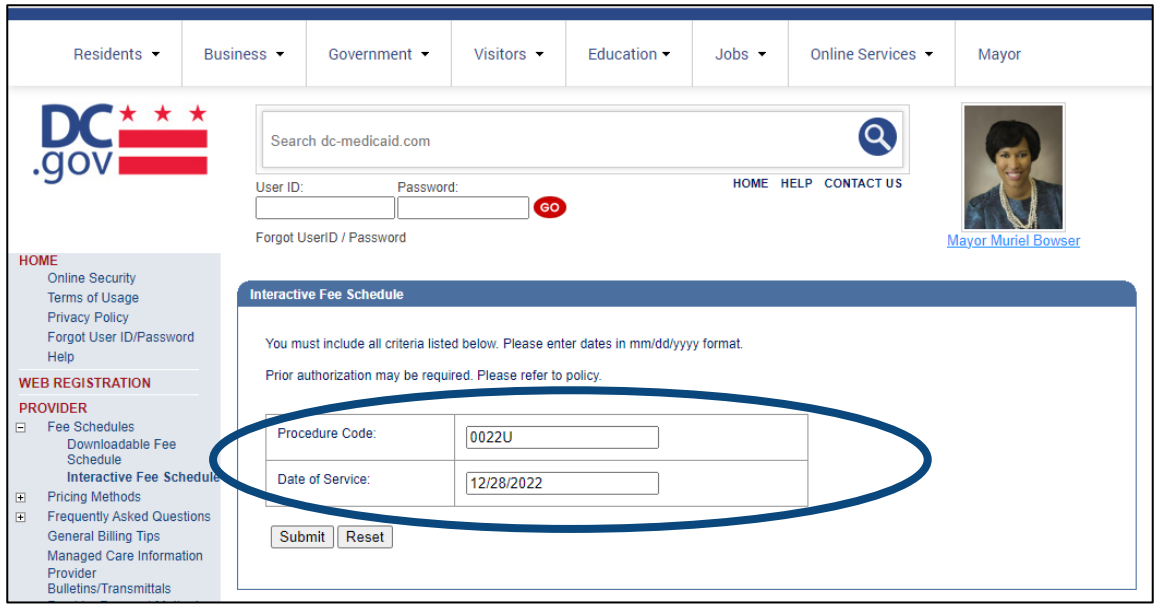
Transmittals for Chapter 15



- Web search for "CMS IOM publication 100-02" was conducted based on Local Coverage Article reference to National Coverage Determinations.
- Search returned CMS.gov page for 100-02.
- Based on Local Coverage Article reference, Chapter 15 was selected (a PDF document); Section 80 lists all NCD references and requirements for Diagnostic x-rays, laboratory, and other tests.

Second Stage: Research Existing Payment Codes for the Technology

Navigating Medicaid Coverage Example – District of Columbia



- Visit dc-Medicaid.com
- Search interactive fee schedule tool for, e.g., "0022U;" enter a date of service
- Hit submit to review coverage details

Interactive Fee Schedule Response

Information requested time: Wed Dec 28 2022 15:43:23 GMT-0500 (Eastern Standard Time)

Price does not include cutbacks, assessment fees, etc. Payment is not guaranteed.

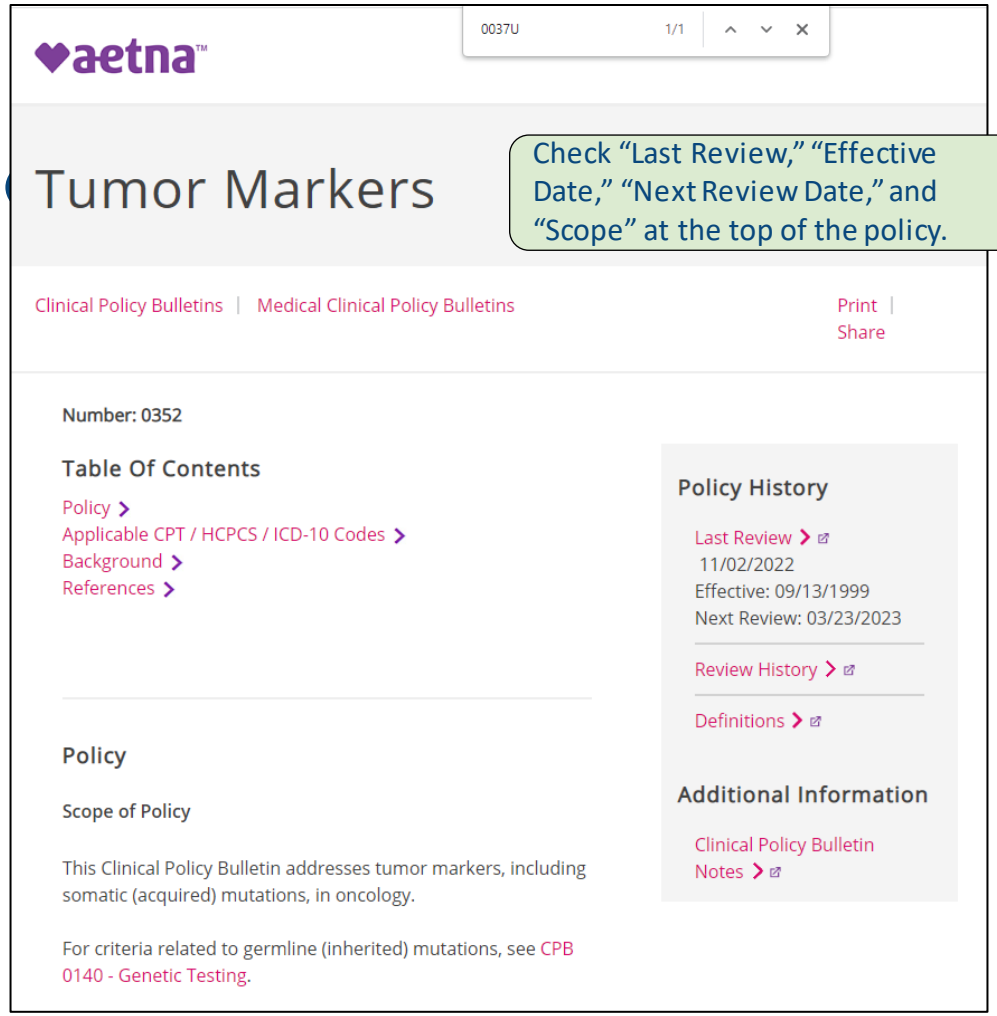
Procedure Code: 0022U - Price by Modifier for Date of Service 12/28/2022

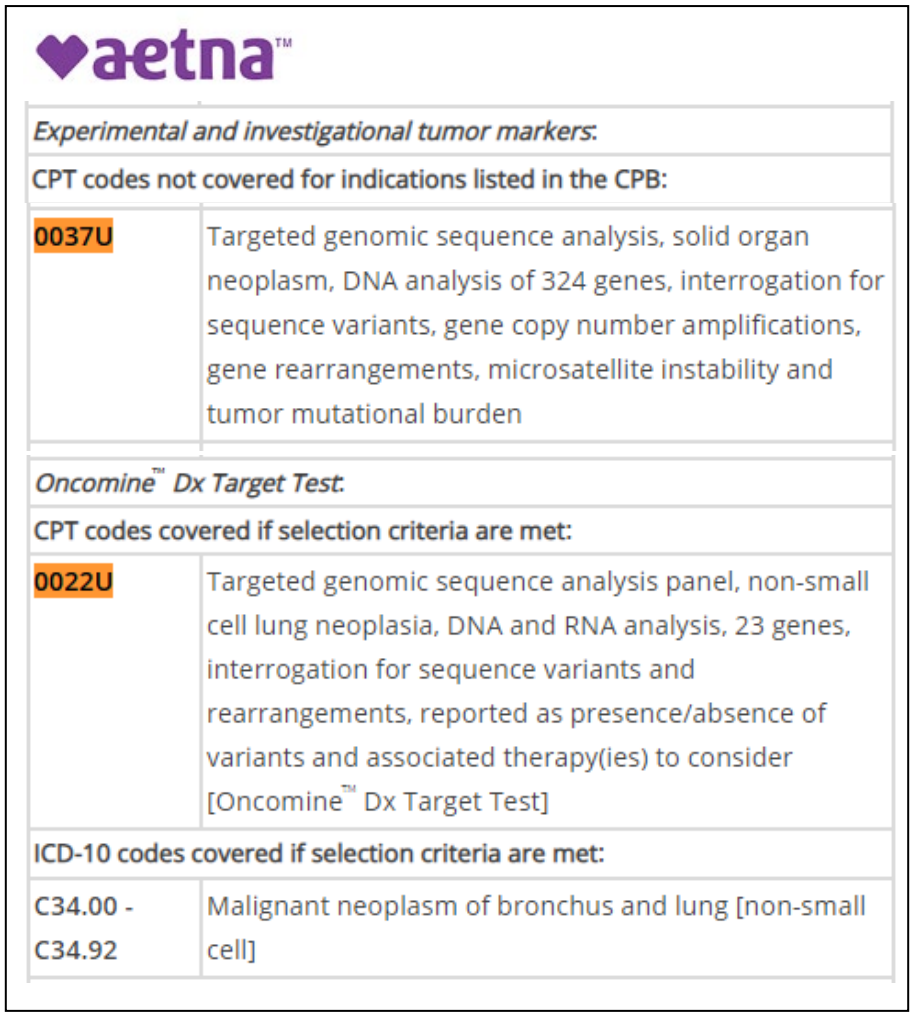
Procedure Description											
Begin Date	End Date	Mod1	Mod2	Mod3	Mod4	PA Required	Fee	Max Units	Facility Pricing	Manual Pricing	Covered Benefit
TRGT GEN SEQ DNA&RNA 1-23 GN											
TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, NON-SMALL CELL LUNG NEOPLASIA, DNA AND RNA ANALYSIS, 23 GENES, INTERROGATION FOR SEQUENCE VARIANTS AND REARRANGEMENTS, REPORTED AS PRESENCE/ABSENCE OF VARIANTS AND ASSOCIATED THERAPY(IES) TO CONSIDER											
10/01/2017	12/31/9999					NO	$0.00	1			NO

New Inquiry Print

Second Stage: Analyze Coverage Determinations

Analyzing Medical Coverage Policies Example – Aetna

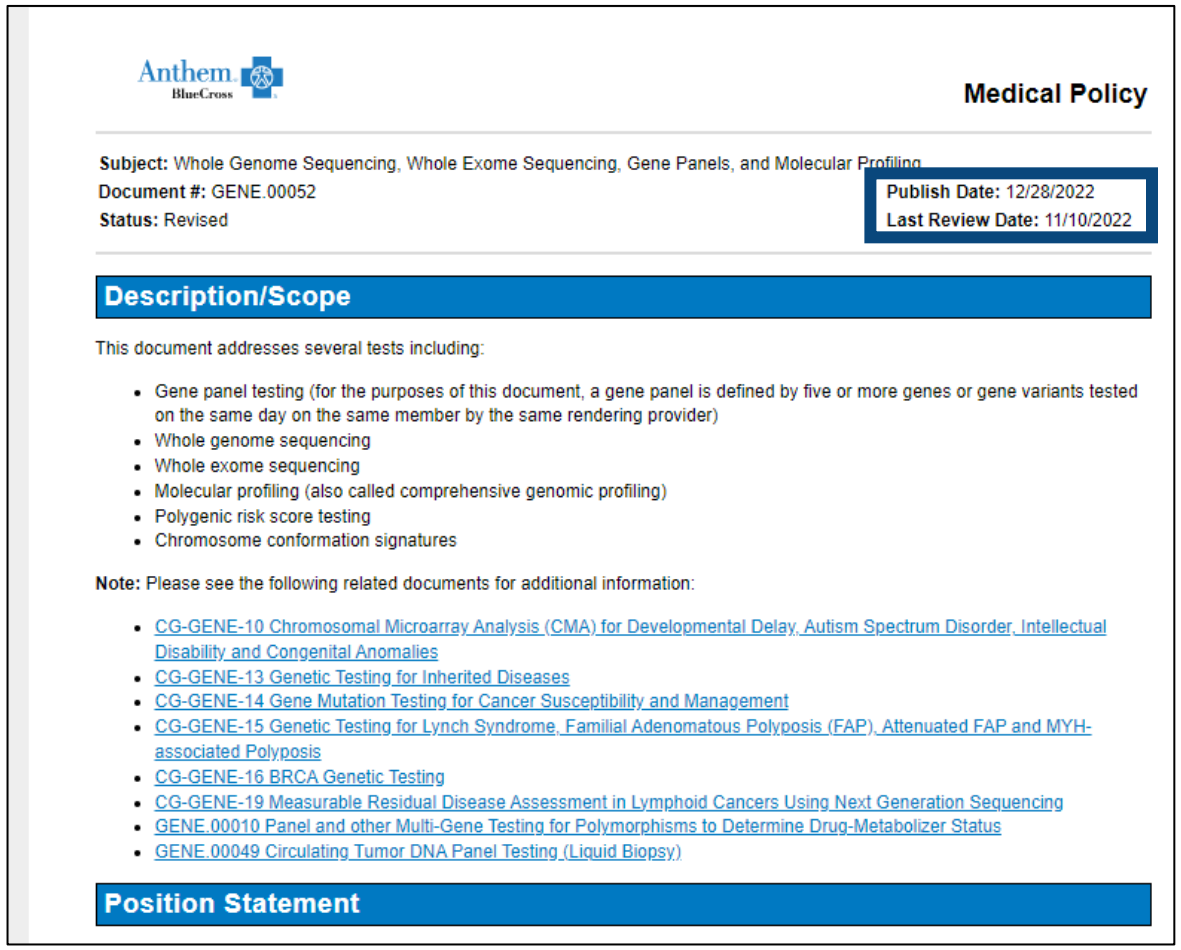




Source: Aetna

Second Stage: Analyze Coverage Determinations

Analyzing Medical Coverage Policies Example – Anthem



Anthem BlueCross

Medical Policy

Subject: Whole Genome Sequencing, Whole Exome Sequencing, Gene Panels, and Molecular Profiling
Document #: GENE.00052
Status: Revised

Publish Date: 12/28/2022
Last Review Date: 11/10/2022

Description/Scope

This document addresses several tests including:

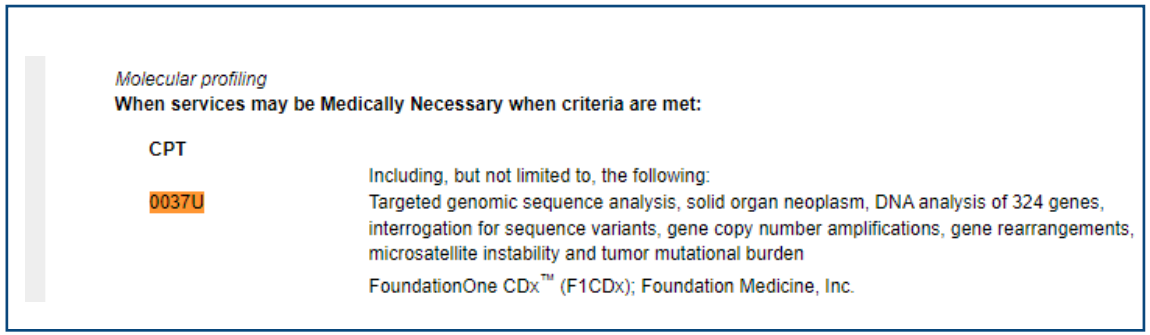
- Gene panel testing (for the purposes of this document, a gene panel is defined by five or more genes or gene variants tested on the same day on the same member by the same rendering provider)
- Whole genome sequencing
- Whole exome sequencing
- Molecular profiling (also called comprehensive genomic profiling)
- Polygenic risk score testing
- Chromosome conformation signatures

Note: Please see the following related documents for additional information:

- CG-GENE-10 Chromosomal Microarray Analysis (CMA) for Developmental Delay, Autism Spectrum Disorder, Intellectual Disability and Congenital Anomalies
- CG-GENE-13 Genetic Testing for Inherited Diseases
- CG-GENE-14 Gene Mutation Testing for Cancer Susceptibility and Management
- CG-GENE-15 Genetic Testing for Lynch Syndrome, Familial Adenomatous Polyposis (FAP), Attenuated FAP and MYH-associated Polyposis
- CG-GENE-16 BRCA Genetic Testing
- CG-GENE-19 Measurable Residual Disease Assessment in Lymphoid Cancers Using Next Generation Sequencing
- GENE.00010 Panel and other Multi-Gene Testing for Polymorphisms to Determine Drug-Metabolizer Status
- GENE.00049 Circulating Tumor DNA Panel Testing (Liquid Biopsy)

Position Statement

Source: Anthem



Molecular profiling
When services may be Medically Necessary when criteria are met:

CPT	
0037U	Including, but not limited to, the following: Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden FoundationOne CDx™ (F1CDx); Foundation Medicine, Inc.

- Check "Publish" and "Last Review Date" at the top of the Medical Policy
- Search [CTRL + F] for "0037U" or "0037U"
- Review sections in policy referencing CPT codes; pay attention to potential coverage limitations and references to specific tests
- Understand which indications/diagnoses the test is covered for

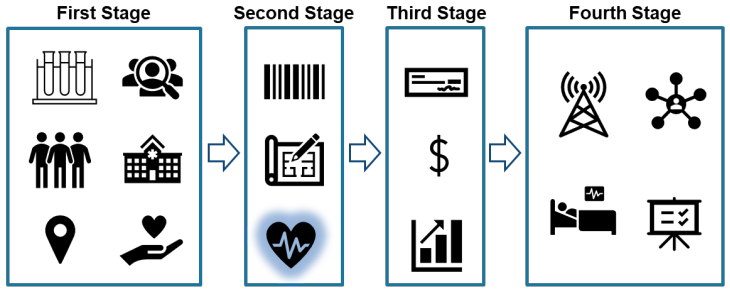
Second Stage: Determine Evidence & Value

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 are 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 ICD-10 codes outlined in coverage policies) to define evidence to support coverage and pricing for diagnostics similar to OncMap.

- Beth conducts an online search using "EGFR +NSCLC + evidence + utilization data."
- She finds several research articles, including a 2022 article on real-world evidence, a 2022 article including a review of available evidence, and a 2017 article with utilization data, as well as a 2020 article on health and budget impact.
- She also reviews ClinicalTrial.gov for research on CDx specific to treatments, such as Osimertinib.
- Beth discovers several articles in ASCO Journal of Clinical Oncology that are worth reviewing.
- Beth knows providers and commercial payers 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, or product are sufficient to cover the cost of using the device in an outpatient setting.

Beth plans to work with her Reimbursement Consultant to determine what evidence is needed for coverage under Medicare/Medicaid and for commercial payers.



Key Questions:

- Is the diagnostic considered standard of care or an optional, add-on service?
- Are there medical 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?

Third 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

Third Stage: Research Payment Rates

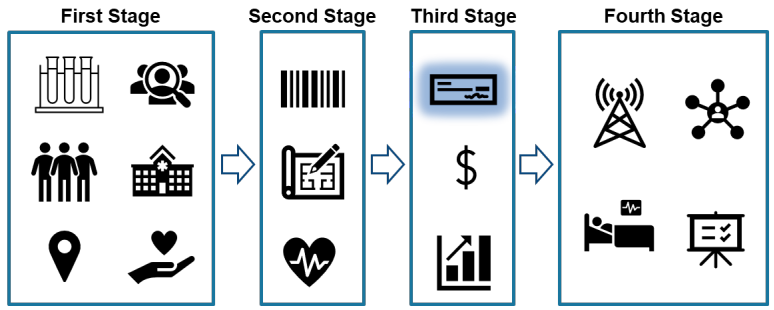
With the payment codes of similar tests in hand, Beth is ready to identify publicly-available payment rates for codes 0037U and 0022U.

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

- Looking up the most current CMS "Clinical Laboratory Fee Schedule Files."
- Selecting File "22CLABQ4" as it has the most recent data (CY 2022 Q4 Release: Added for October 2022).
- Downloading the ZIP file and opening the Excel spreadsheet.
- Searching [CTRL+F] for preidentified CPT code(s) [0022U or 0037U] to see payment rates.

Based on these search criteria, she learns that the 2022 Clinical Diagnostics Laboratory Fee Schedule rate for 0037U is $3,500.00 (325 genes) and for 0022U is $1,950.00 (1-23 genes). It is noteworthy that these payment rates are based on solid tumor-tissue based tests (and its respective code). **Beth knows she will have to check on plasma-based codes and payment rates by repeating this exercise**.

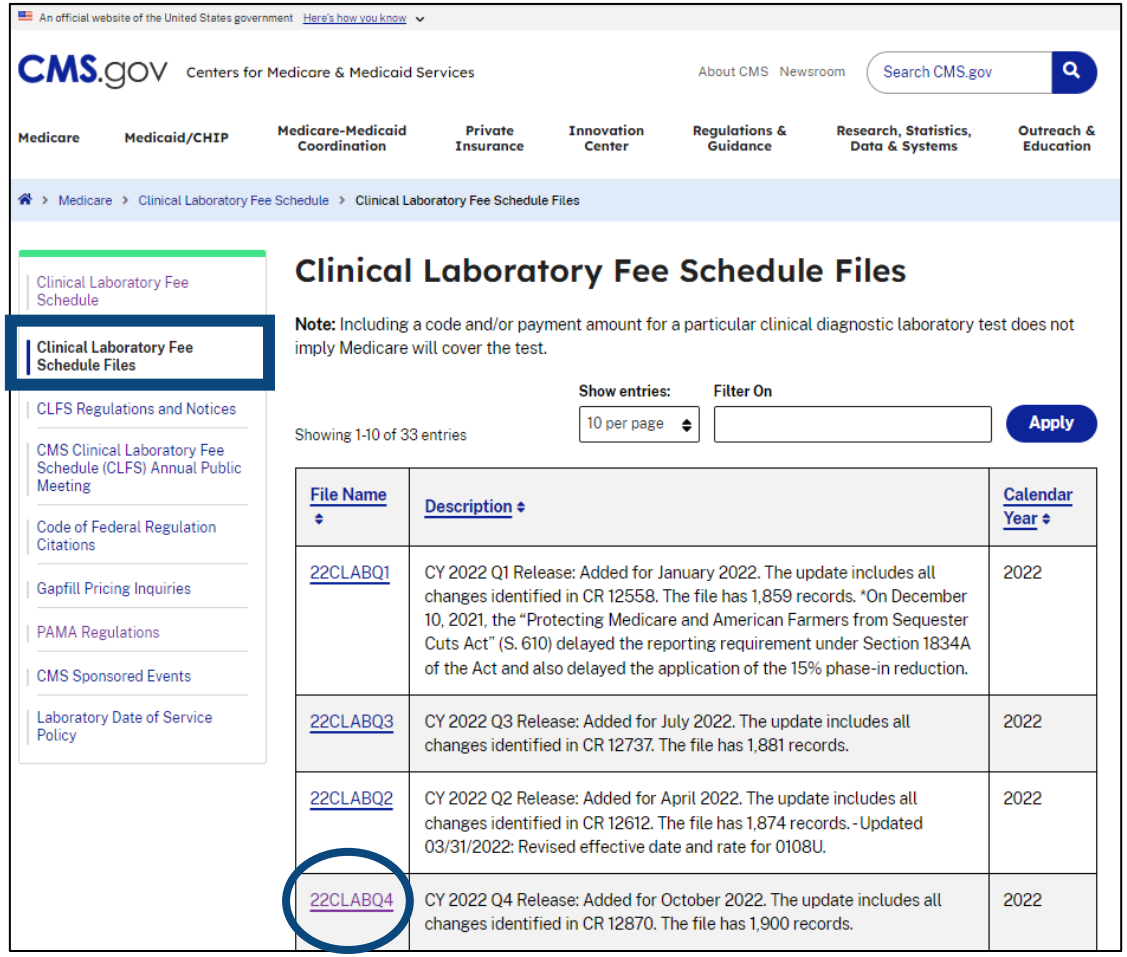
Beth also notices the rates have not changed over the last three years. She knows that even if the fee schedule includes a payment rate, the payment is based on the state specific local coverage determinations (see coverage section). This information is tremendously helpful, because it establishes that the FDA-cleared FoundationOne CDx (CPT 0037U) has a much higher reimbursement potential. In addition, searching for the term "lung" or "gene" in the fee schedule returned generic CPT codes with much less reimbursement potential. This confirms that acquiring an ADLT status (if no other equivalent CPT code is established by then) and or a PLA code (for Medicare) is the best path forward.



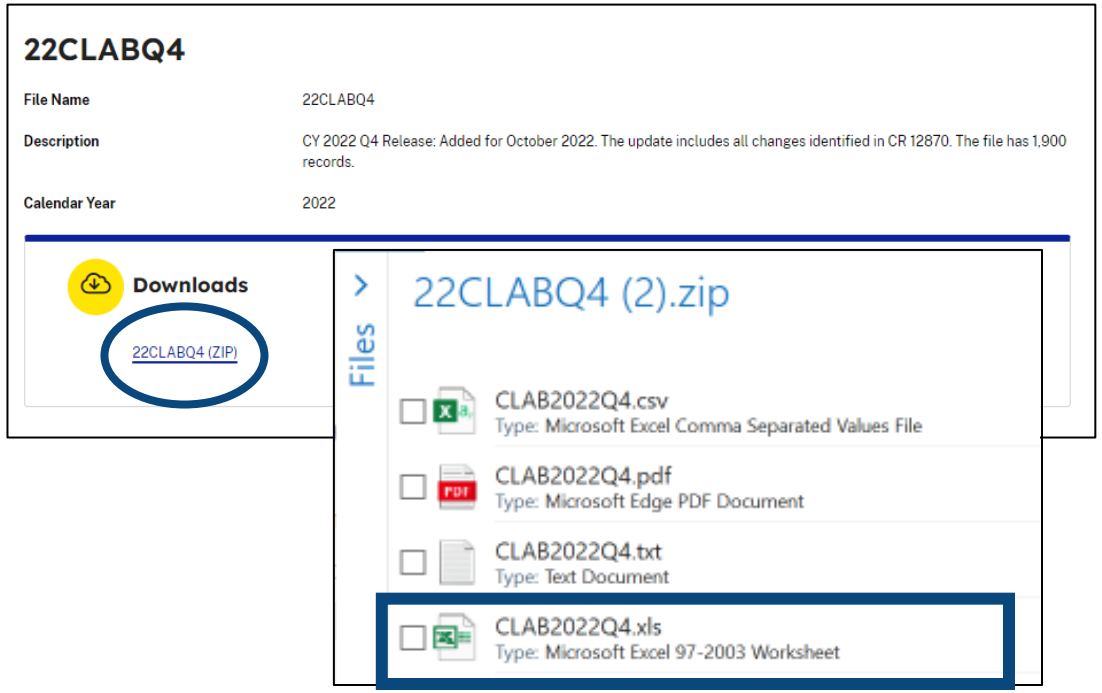
Key Question:

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

Third Stage: Research Payment Rates
Navigating CMS Clinical Lab Fee Schedule Files



Source: CMS



- 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) [0022U or 0037U] to see payment rates.

Third Stage: Research Payment Rates (continued)

Navigating CMS Clinical Lab Fee Schedule Files

1	**2022 Clinical Diagnostic Laboratory Fee Schedule**							
2	**CPT codes, descriptions and other data only are copyright 2022 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.**							
3								
4	**YEAR**	**HCPCS**	**MOD**	**EFF_DATE**	**INDICATOR**	**RATE2022**	**SHORTDESC**	**LONGDESC**
46	2022	0037U		20220101	N	03500.00	Trgt gen seq dna 324 genes	Targeted genomic sequence analysis, solid organ neoplasm, dna analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
32	2022	0022U		20220101	N	01950.00	Trgt gen seq dna&rna 1-23 gn	Targeted genomic sequence analysis panel, cholangiocarcinoma and non-small cell lung neoplasia, dna and rna analysis, 1-23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider

Source: CMS

- Search [CTRL+F] for preidentified CPT codes [0022U or 0037U].
- Check "SHORTDESC" to double-check applicability of test description to your diagnostic – including the number of genes sequenced.
- Check "RATE2022" to understand what the current CMS Medicare payment rate is (the CPT 0037U the rate is $3,500).
- Check prior years' fee schedule to see if there were any changes in the rates.

Third Stage: Research Payment Rates (continued)

Coverage Summary Findings for NSCLC CDx – Tissue-Based

Payer		CPT 0037U (325 genes)		CPT 0022U (1-23 genes)	References
CMS Medicare	✓	$ 3,500.00	✓	$ 1,950.00	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files
CMS State Medicaid Agencies					
Washington DC	✗	N/A	✗	N/A	https://www.dc-medicaid.com/dcwebportal/nonsecure/feeScheduleInquiry
Kentucky	✓	$ 3,500.00	✓	$ 1,950.00	https://www.chfs.ky.gov/agencies/dms/DMSFeeRateSchedules/2022ClinicalLabRates.pdf
Ohio	✓	$ 2,625.00	✗	N/A	https://medicaid.ohio.gov/static/Providers/FeeScheduleRates/Laboratory/LabServicesPayment.pdf
…					
Commercial Payers (Per contractual/negotiated rates)					
Aetna	✗	N/A	✓		https://www.aetna.com/cpb/medical/data/300_399/0352.html
Anthem	✓		✗	N/A	https://www.anthem.com/dam/medpolicies/abc/active/policies/mp_pw_e000224.html
Cigna	✓		✓		https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0520_coveragepositioncriteria_tumor_profiling.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 OncMap based on the total cost of the test and the market price tolerance. She knows coverage does not always equal cost coverage.

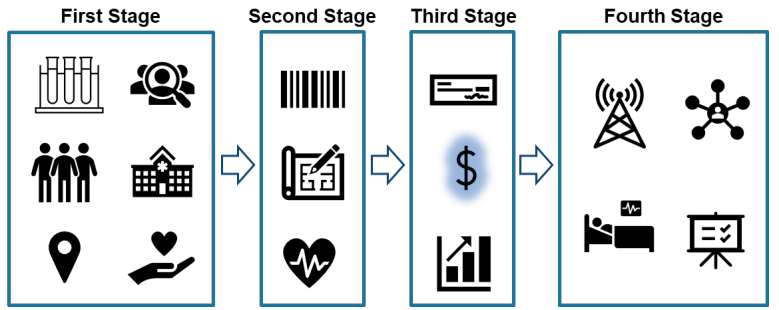
Beth first establishes the total cost of the test:

- Her team calculates the Cost of Goods Sold (COGS) – direct costs including reagents, etc. - for a panel with 300+ genes between $2,550 to $4,050, based on volume predictions of 1,000 – 2,500 units as the max run rate is 25 samples per run.
- Her business advisor estimates indirect costs (including sales force costs and overhead) to range from $500 to $800 per unit; for a total cost of $3,050 to $4,850.
- Beth wants to break even or make a profit and compares her test cost to the CMS payment rate for 0037U of $3,500.

The higher the volume, the more likely it will be that all costs can be recovered and make a profit. She plans on discussing pricing options with her business advisors. Per this article, FoundationOne charges for their CDx $6,193.90 in Canada which equates to approximately $4,583 in the U.S.

Given that the OncMap panel is a 300+ gene panel, Beth determines that the viable price range for OncMap – as a *tissue*-based test, is between $3,500 – $4,850. Once she has acquired more information on plasma-based reimbursement rates, she will review and adjust pricing based on sample type.

The max out-of-pocket cost for patients would be $4,850 (without insurance coverage). However, Beth realizes that this may not be affordable for many and that other testing companies (like FoundationOne) offer financial assistance programs for patients for that very reason.

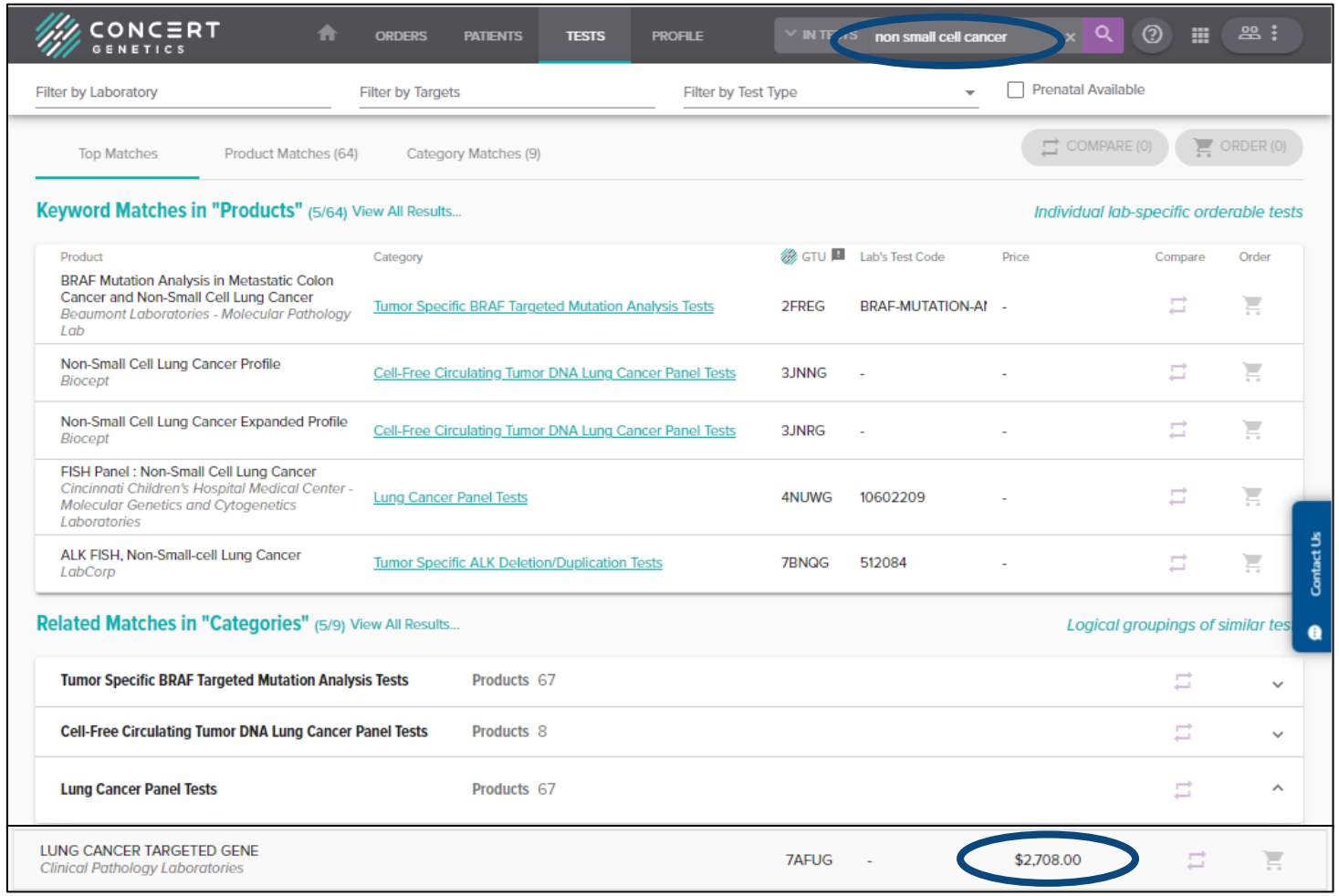


Key Questions:

- What direct costs (material and labor) are incurred producing the diagnostic? What are indirect (fixed or variable) costs (e.g., 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 (if applicable)?

Third Stage: Understand the Cost and Price of the Test

Price Comparison



Source: Concert Genetics

- Search page for test using terms, such as “non-small cell lung cancer” under “IN TESTS” section at top.
- Review “Product” description and “Category” at top of page for similar tests.
- Expand search and identify other similar tests under “Related Matches” at bottom of page.
- Evaluate any “Price” figures – if listed.

Note:
- For illustrative purposes only.
- NIH does not endorse any company or webtool used in this case study.
- A free profile must be set up before you can search the test list.

Third Stage: Create Contract and Pricing Models

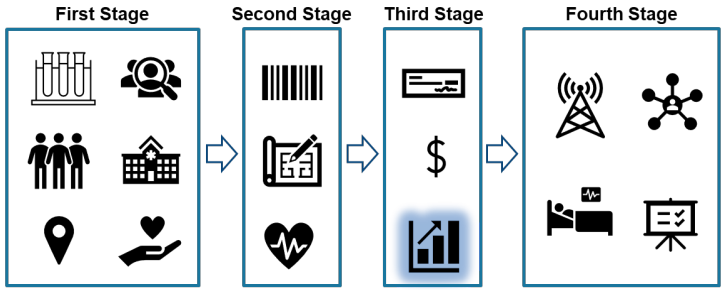
Beth knows that many factors impact price, including the COGS, existing (or potentially new) payment rates, the product's value proposition and differentiation, market size, the anticipated place of service (setting), and the purchasing power of distributors.

By entering the market as an additional player for tissue-based testing and targeting a competitive price point between $3,500 – $4,850 along with the high rates of NSCLC cases, Beth believes that the market is ready for an alternative to FoundationOne. Beth understands that even if a test has an established coverage determination and average reimbursement rate, special rates may be negotiated with each payer. Beth plans to utilize code 0037U for her test; while it is a proprietary code, she learned that it can be used as a cross-walk "so that the resources used in this code can be better estimated by a Medicare Administrative Contractor (MAC)" (see Maryland MAC example). Beth believes that there is a strong value proposition per this article: "cost efficiencies in testing and improved outcomes could be expected from the decrease in the use of inappropriate therapies."

Beth also plans to review the lab's billing capabilities including:

- Obtaining prior or pre-authorizations from insurance before conducting the test (if applicable)
- 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 Medicare/Medicaid, commercial payers, and consumers based on potential annual volume estimates.



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., outpatient or inpatient)?
- Who are the purchasers of the diagnostic?

Third Stage: Understand the Cost and Price of the Test

Summary Findings for a Tissue-Based Sample

Cost Assumptions	Value/Rate
Volume Assumption	1,000-2,500 units
Cost of Goods Sold (COGS direct costs (incl. reagents, etc.)	$2,550 – $4,050 per unit
indirect costs (incl. sales force costs and other overhead)	$500 – $800 per unit
TOTAL COST	**$3,050 – $4,850**

CMS Reimbursement Rate by Code	Rate
Medicare	
CPT 0037U (325 genes)	$ 3,500
CPT 0022U (1-23 genes)	$ 1,950
Medicaid (Kentucky State example)	
CPT 0037U (325 genes)	$ 3,500
CPT 0022U (1-23 genes)	$ 1,950
Medicaid (Ohio State example)	
CPT 0037U (325 genes)	$ 2,625
CPT 0022U (1-23 genes)	N/A

Viable Price Range (allows for cost coverage/small margin for Vital Diagnostics)	**$3,500 – $4,850 per unit** (based on volume negotiated per unit rate)
Patient: Self-pay/Out-of-pocket Price	**$3,500**

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

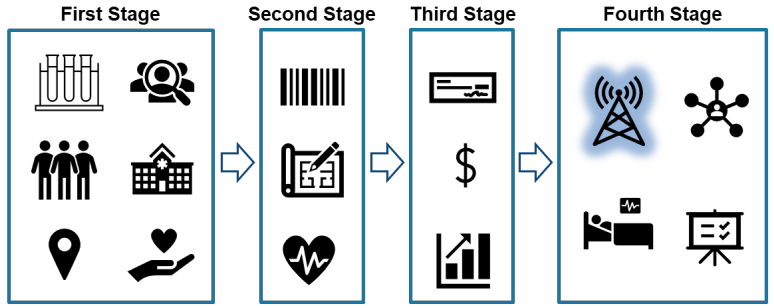
- Create a Payer Communications Plan
- Garner Stakeholder Support
- Collect Evidence via Clinical Studies
- Consider Reimbursement Plan

Fourth Stage: Create a Communications Plan

Beth's final goals for her reimbursement strategy include developing a communications plan to inform stakeholders of OncMap's attributes to garner support, drive market adoption, and receive optimal coverage.

Beth knows she needs a **communications plan** to differentiate OncMap and incentivize stakeholders to switch. She personalizes messaging for the following stakeholders:

- **Oncologists:** Share cost-benefits information on implementing OncMap (over current market leaders). Show OncMap's value proposition as the second company to offer a plasma-based test to find physician champions. Use her board members existing relationships with oncologists for warm introductions.
- **Professional Medical Societies:** Work with medical associations (e.g., the American Society of Clinical Oncology and the American Association for Cancer Research) and precision medicine industry groups (e.g., Personalized Medicine Coalition) on provider educational materials. Convene with payers to drive adoption.
- **Commercial Payers:** Discuss favorable CMS Medicare coverage determinations in connection to evidence gaps (as described in commercial payers' policies) to understand specific coverage requirements. Use OncMap's pending FDA-clearance as another differentiator.
- **Patient Advocacy Groups:** Integrate the voice of the patient in conversations with physicians, advocacy groups, and payers.



Key Questions:

- Who are the key decisionmakers that set reimbursement rates, collect payments, process claims, and pay provider claims?
- Will the new device provide payers with both clinical and economic benefits over currently available alternatives?

Fourth Stage: Garner Stakeholder Support

Example Tactics by Stakeholder

Stakeholder	Goal/Tactic	Medium
Oncologists	• Refine value proposition based on research • Develop talking points • Publish research findings, press releases on test developments • Attend a tumor board	• Presentations (grand rounds, etc.) • Publications (research findings) • Test summary/one-pager that includes research study findings (peer-reviewed articles)
Professional Medical Societies	• Create a CME-qualifying course on benefits of plasma-based testing • Collaborate on research studies	• Meetings • Conferences • Working Groups
Commercial Payers	• Create a 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 plasma-based (over tissue-based) testing on quality of care	• Focus groups • Member meetings

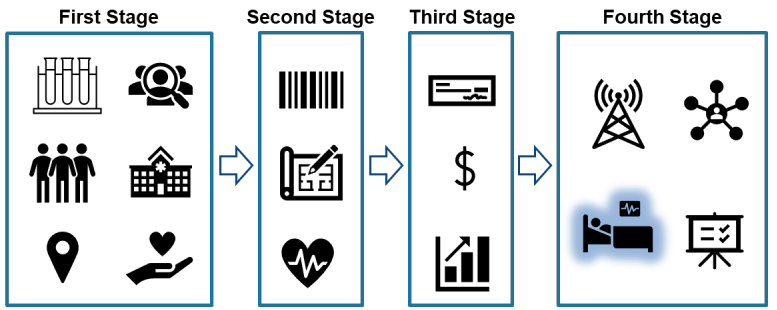
Fourth Stage: Collect Clinical Evidence by Conducting Clinical Studies

Beth assesses whether an additional study is needed – apart from what has already been collected for the FDA PMA submission – to collect evidence impacting commercial payers' coverage decisions.

Although Beth's team has already collected validation information for OncMap as part of the PMA submission, the data does not necessarily address all evidence gaps evaluated by payers.

She creates a list of all research studies referenced 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. Beth wants to integrate this information into study designs as soon as possible.

Additionally, Beth plans on researching any available cost-benefit studies that show differences between test types (including sample types, i.e., tissue-versus plasma-based 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

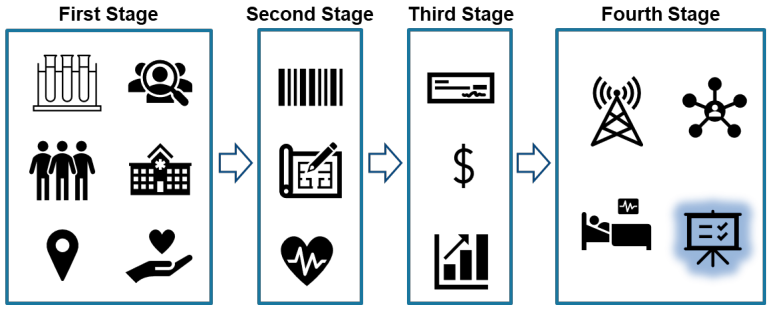
Summary of Payer Coverage Policies Research References by Intended Use

Commercial Payer	Reference	Publication Year	Summary Finding(s)
CPT	**0037U**		
Aetna	Wild C, Grössmann N. FoundationOne CDx: Genetic profiling of solid tumours. Rapid Assessment 014. Vienna, Austria: Ludwig Boltzmann Institute for Health Technology Assessment; 2019.	2019	"Currently, there is no scientific evidence that diagnostics with multi-gene panels for the development of therapy recommendations that lead to better clinical outcomes. Few biomarkers are validated and recommended by the EMA, as well as by the FDA. Many more are at a research stage, although many expectations and hopes are being raised for multi-gene panels. It can be predicted that multi-gene panels will have the potential to stimulate a broad off-label use of drugs without having to test them for clinical relevance in clinical trials. These consequences should be given attention, as many approved oncology medications only have a marginal benefit (0-2 according to ESMO Magnitude of Clinical Benefit Scale) and may represent a potential therapeutic option but have little actual clinical relevance."
Aetna			Aetna considers FoundationOne Liquid CDx not medically necessary for assessing candidacy of members with non-small cell lung cancer for treatment with osimertinib (Tagrisso), erlotinib (Tarceva), or gefitinib (Iressa) because there is no proven advantage of the FoundationOne Liquid CDx over targeted EGFR mutation testing or small targeted panels for this indication.
...	...	...	...

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 new PLA code for OncMap. She plans to integrate this into her reimbursement strategy – specifically her communications plan, to drive market adoption.

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



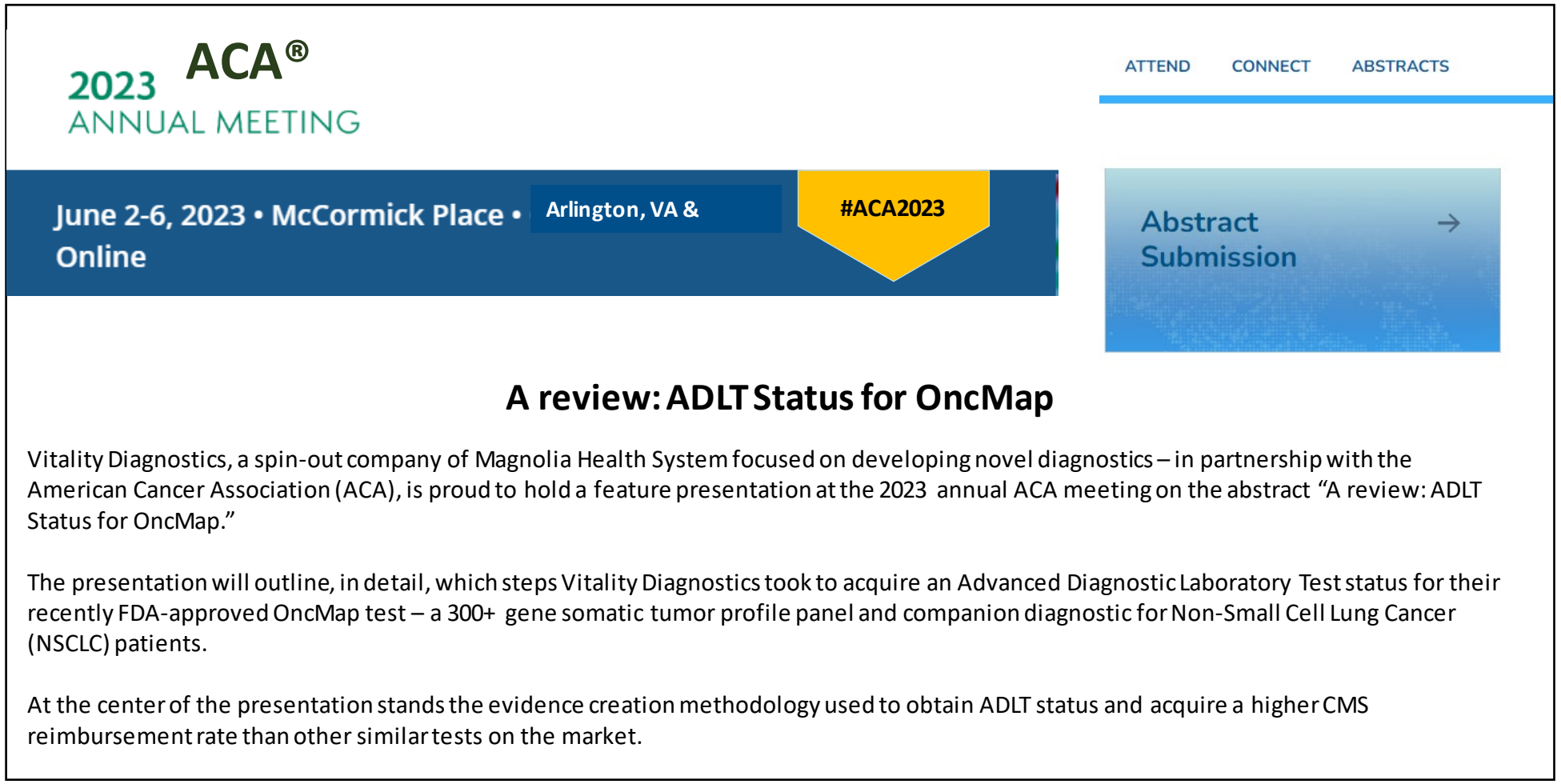
Key Questions:

- 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

OncMap Success

The following is a fictional portrayal of what success for OncMap may look like



A review: ADLT Status for OncMap

Vitality Diagnostics, a spin-out company of Magnolia Health System focused on developing novel diagnostics – in partnership with the American Cancer Association (ACA), is proud to hold a feature presentation at the 2023 annual ACA meeting on the abstract "A review: ADLT Status for OncMap."

The presentation will outline, in detail, which steps Vitality Diagnostics took to acquire an Advanced Diagnostic Laboratory Test status for their recently FDA-approved OncMap test – a 300+ gene somatic tumor profile panel and companion diagnostic for Non-Small Cell Lung Cancer (NSCLC) patients.

At the center of the presentation stands the evidence creation methodology used to obtain ADLT status and acquire a higher CMS reimbursement rate than other similar tests on the market.

Summary Findings: By Stage

First Stage

- Technology Type & Regulatory Context: Next-generation-sequencing (NGS), tissue- or plasma-based test for Non-Small Cell Lung Cancer (NSCLC). Test will first be offered as LDT, and then seek Premarket Approval from FDA to market CDx
- Competitors: FoundationOne CDx™ (FoundationOne); cobas EGFR Mutation Test v2 (Roche Diagnostics)
- Patient Population: Any patient with Non-Small Cell Lung Cancer (NSCLC)
- Healthcare Providers & Site of Service: Oncologists, conducted in outpatient settings
- Types of Payers: All payers – except for Medicaid CHIP; esp. Medicare

Second Stage

- Existing Payment Codes: ADLT HCPCS Code – 0037U for FoundationOne CDx™; PLA code - 0022U for Oncomine™ Dx Target Test (Thermo Fisher Scientific)
- Coverage Determinations: Medicare, existing LCAs; commercial payer coverage is either dependent on indication for use/diagnosis or is deemed experimental
- Evidence and Value: The test is not yet considered standard of care; capture utilization data (based on ICD-10 codes outlined in coverage policies) to define evidence to support coverage and pricing for diagnostics like OncMap

Third Stage

- Payment Rates: The CMS 2022 Clinical Diagnostics Laboratory Fee Schedule rate for CPT 0037U is $3,500 and for CPT 0022U is $1,950
- Cost and Price: Total cost of $3,050 – $4,850; viable price range of $ 3,500 – $4,850 for hospital labs purchasing the test from Vital Diagnostics
- Contract and Pricing Models: Create a charge/pricing matrix for Medicare/Medicaid, commercial payers, and consumers based on potential annual volume estimates

Fourth Stage

- Communications Plan: Personalize messaging for stakeholder groups: Oncologists, 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 referenced in each of the commercial payer's coverage policies to understand the rationale for denial; plan to researching any available cost-benefit studies that show differences between test types (including sample types, i.e., tissue- versus plasma-based testing)
- Reimbursement Plan for New Diagnostic: Consider applying for ADLT status and a new PLA code for the test

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