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Reimbursement Knowledge Guide for Diagnostics

NIH SEED Innovator Support Team

Introduction

The U.S. *in vitro* diagnostics (IVD) market size was valued at $55.29 billion in 2021. Growth in the sector has been steady in recent years, at about four to five percent per year. This growth has been fueled by an increase in the geriatric population, as well as a rise in chronic diseases requiring increased and regular IVD testing. In addition, awareness about diagnostic tests for viral disease detection (e.g., SARS CoV-2) and supportive government regulations have fueled growth in this market. Compared with other biomedical technologies—such as small molecule drugs and biologics as discussed in the Regulatory Knowledge Guides for Small Molecule Drugs and Biologics—the regulatory requirements for bringing a diagnostic to the market are simpler. But obtaining reimbursement for new, innovative diagnostics and imaging tests may be more challenging than for other technologies.

This guide provides an overview of how health insurers pay for new diagnostic tests, including those typically covered by insurance (such as routine tests for diabetes or cardiovascular monitoring) and those that typically are not (such as tests that are marketed for general wellness.) The guide also explains patients' potential exposure to out-of-pocket costs and the evidence innovators need to influence payers' decisions. Because it is crucial to clearly articulate to payers the value proposition for a new technology, this guide includes information on how innovators should use their research data to help identify the diagnostic's value. While coverage, coding, and payment decisions are not necessarily made in any order, developing a strategy for obtaining them should begin early, and well in advance of Food and Drug Administration (FDA) clearance or approval.

The guide starts with an overview of the reimbursement landscape, then describes the development of a reimbursement strategy, and concludes with information on implementing a reimbursement strategy

such as applying for new codes and engaging stakeholders. Although the authors have done their best to explain topics in plain language, implementation of knowledge can be challenging. Therefore, a series of reimbursement case studies have also been created to help innovators understand the many components of a reimbursement plan. Sections 3 and 4 correlate to stages outlined in the reimbursement case studies.

Link to Diagnostics Case Study #1 VitalScreen
Link to Diagnostics Case Study #2 CardioTropT
Link to Diagnostics Case Study #3 (CDx test)

If you have additional questions or want to connect with someone to discuss your specific situation, the National Institutes of Health Office of Extramural Research, Small Business Education and Entrepreneurial Development (SEED) office recommends you contact the SEED Innovator Support Team.

Please use the Word navigation panel to jump to relevant sections for your specific needs. Bolded terms within the text are defined in the Glossary.

After reading this Reimbursement Knowledge Guide, you will have a better understanding of the reimbursement landscape for medical diagnostics and how it can impact the development of new diagnostics. Topics that will be described are listed below:

- An overview of the diagnostics reimbursement landscape and how public and private stakeholders are involved in the reimbursement of diagnostics.
- The importance when developing a new diagnostic of working concurrently on both a regulatory strategy (comprising FDA-required data on safety and efficacy, as well as additional clinical evidence) and a reimbursement strategy (comprising billing codes and payment).
- Specific considerations about how Medicare, Medicaid, and commercial payers evaluate coverage of new diagnostics.
- How insurers assess new diagnostics for both accuracy and reliability as well as whether the test informs decisions about what treatments to pursue.
- What data should be collected during diagnostic development and testing to support the questions that regulators and payers will likely ask.

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1 Understand the Landscape

The U.S. healthcare system includes both public and private health insurance coverage for diagnostics. Coverage of a diagnostic and its reimbursement are determined by each payer's coverage policies. The two largest government insurance programs are Medicare and Medicaid, which are subject to federal and state requirements. Private plans and commercial payers have more flexibility to set coverage, and reimbursement determinations and the **out-of-pocket** costs to patients can vary significantly.

Medicare, national program policies for Medicaid and the Children's Health Insurance Program (CHIP), and implementation of major provisions of the **Affordable Care Act** (ACA) are all administered by a single federal agency, the **Centers for Medicare & Medicaid Services** (CMS). As a critical stakeholder in payer decisions for all three programs, CMS influences private sector coverage and reimbursement decisions, as commercial payers often follow Medicare's lead.

The U.S. *in vitro* diagnostics (IVD) market size was valued at $55.29 billion in 2021. Growth in the sector has been fueled by an increasing geriatric population and a rise in chronic diseases that require more frequent IVD testing. In addition, awareness about diagnostic tests for viral disease detection (such as for SARS CoV-2) and supportive government regulations have fueled growth in this market. Compared with other biomedical technologies, such as small molecule drugs and biologics, the regulatory requirements for bringing a diagnostic to the market are simpler. But obtaining reimbursement for new, innovative diagnostics may be more challenging than for other technologies, as it may require applying for a new reimbursement code. This guide will help innovators avoid costly mistakes that could impede their access to this large and growing market.

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1.1 Basic Tenets of Reimbursement Policies

Coverage, coding, and payment are the building blocks of healthcare reimbursement. Every payer aims to pay only for that which positively affects the health of the insured. Payers meet this aim by requiring detailed information about the item or service rendered to be described using a standard, specific identifier for the item or service, also known as a code.

Coverage, coding, and payment are the building blocks of healthcare reimbursement policies.

Payment is calculated based on the treatment inputs as communicated by the codes. These include a range of services and products time and materials related to the service, including physician, nurse, staff, and other healthcare provider compensation, capital equipment, medical supplies, utilities, and administrative overhead) combined with some outputs (such as improving quality of care, patient

safety, accelerated hospital discharge, or the cost avoidance of treating a worsening condition).

2 Medicare, Medicaid, and Commercial Payers

The largest and most influential categories of health insurers in the U.S. are Medicare (federal program for individuals over age 65 and those with a long-term disability), Medicaid and CHIP (joint federal and state medical assistance program for low-income individuals and children), and private commercial health insurance.

Both the federal and state governments play significant roles in providing health insurance coverage to Americans. The eligibility rules, benefits, and costs of the Medicare and Medicaid programs are broadly defined in federal law. But the federal government does not administer these programs alone. About one-third of Medicare enrollees obtain Medicare benefits that are administered by a health plan under contract to CMS, called Medicare Advantage.

Medicaid plans can vary significantly from one state to another. Medicaid is not a single program, as each state can define some aspects of its program within the state's budget constraints. For state Medicaid programs, CMS sets some national regulations and guidelines, but most coverage decisions are left to each of the states. CHIP—which provides health insurance to low-income children who fall outside the Medicaid eligibility window—also allows states to define some aspects of its program.

Companies that offer insurance to their employees often contract with private commercial payers. Individuals can also purchase insurance through the Health Insurance Marketplace.

2.1 Medicare Coverage

Medicare is an insurance program that has four parts, each of which confer benefits for certain types of healthcare expenditures.

- **Medicare Part A** covers inpatient care in hospitals, skilled nursing facility care, hospice care, and home health care. Diagnostic tests provided during a Medicare-paid inpatient hospital stay are typically paid under Part A.
- **Medicare Part B** covers services and supplies that are medically necessary to treat a health condition, such as doctor and other health care providers' services and outpatient care, durable medical equipment, home health care, and some preventive services. Diagnostic tests provided through outpatient imaging centers, clinical laboratories, and physician practices (e.g., radiology, pathology) are paid under Part B.
- **Medicare Part C**, also referred to as Medicare Advantage, is a voluntary alternative to traditional Part A and Part B coverage. Under Medicare Part C, the federal government pays commercial plans to administer CMS-approved Medicare benefits to enrolled beneficiaries. These plans must offer equivalent benefits to traditional Medicare.
- **Medicare Part D** is a voluntary prescription drug benefit.

Medicare covers diagnostics approved by the Food and Drug Administration (FDA) through the **Premarket Approval** (PMA) process and cleared by FDA through the **510(k)** process, as well as **laboratory developed tests** (LDTs) that undergo a review of their evidence. Of note, FDA can exercise regulatory discretion for LDTs, thus allowing these products onto the market without an FDA review.

Medicare will also cover certain items and services that are in the process of FDA review including FDA-approved **Investigational Device Exemption** (IDE) Category B devices, and hospital **Institutional Review Board** (IRB)-approved non-significant risk diagnostics. CMS established regulations that permit Medicare coverage and payment for items that have received an IDE by the FDA. Medicare has special provisions for coverage of investigational diagnostics under certain rules, described below. For a diagnostic to be considered for Medicare coverage, it must meet three criteria:

- Fall within at least one benefit category established in the Medicare laws (see Section 2.1.1)
- Not be specifically excluded by law
- Be "reasonable and necessary"

The paths for Medicare coverage for diagnostics include **National Coverage Determinations** (NCDs), Local Coverage Determinations (LCDs)—when an NCD does not exist—and coverage under special authorities such as the IDE program. In the absence of issued policies, **Medicare Administrative Contractors** (MACs) make individual determinations of coverage during claim adjudication. Medicare coverage determinations often inform coverage decisions of private/commercial payers.

2.1.1 Covered Diagnostic Product and Service Categories

Benefit Categories

Medicare benefits are defined by law. As such, Medicare will pay only for items or services that fall within the statutorily defined benefit categories. Determine which of the following defined benefit categories apply to your product:

- Diagnostic testing performed during a Medicare-paid inpatient or outpatient hospital service (note that laboratory tests are included in both the **Inpatient Prospective Payment System** (IPPS) and **Outpatient Prospective Payment System** (OPPS) and are not paid separately outside those payment systems)
- Diagnostic professional services billed by a pathologist or radiologist (e.g., professional component payment for a biopsy report)
- **Clinical Laboratory Improvement Amendments** (CLIA)-waived tests performed "incident to" a physician's service (also not separately payable)
- Outpatient diagnostic services provided by a clinical laboratory, when ordered by a physician or non-physician provider licensed to order such tests
- Diagnostic X-ray tests (note that while FDA regulates X-rays and other imaging equipment as medical devices, the reimbursement for these products is determined based on their clinical utility in providing diagnostic information)
- Initial preventive physical examination (i.e., "Welcome to Medicare" physical)

- Certain screening tests specifically defined in law:
    - Prostate cancer screening tests
    - Colorectal cancer screening tests
    - Screening for glaucoma
    - Cardiovascular screening blood tests
    - Diabetes screening tests
    - Ultrasound screening for abdominal aortic aneurysm
    - Screening mammography
    - Screening pap smear and screening pelvic exam
    - Bone mass measurement
    - X-ray, radium, and radioactive isotope therapy and technician services
    - "Additional preventive services" (explained further below)

Laboratory Tests

Generally, laboratory tests fall under a defined benefit category within Medicare if they are performed in a hospital (inpatient or outpatient) or other facility (such as a physician's office, dialysis center, or skilled nursing facility) as part of a service for which Medicare is paying. Laboratory tests that are not used to diagnose a condition or to inform a treatment decision may fall outside the established benefit category and are therefore noncovered.

Non-Defined Benefit Categories

Occasionally, an item or service has no defined benefit category but is integral to the provision of care by a healthcare provider. These items and services are sometimes covered as "incident to" the provider's care. The application of "incident to" is complex and may require consulting with the local MAC in your jurisdiction. Laboratory tests that are not used to diagnose a condition or to inform a treatment decision may fall outside the established benefit category and are therefore noncovered.

Preventive Services

Preventive services that are not specifically enumerated in law are eligible to receive Medicare coverage if they meet certain conditions. The ACA gives CMS the ability to extend coverage for additional preventive services (such as new vaccines or screening tests) using the NCD process. To obtain coverage as an "additional preventive service," new technologies must meet the following criteria:

- Reasonable and necessary for the prevention or early detection of illness or disability
- Recommended with an evidence grade of A or B by the U.S. Preventive Services Task Force
- Appropriate for individuals entitled to benefits under Medicare Part A (inpatient care) or enrolled under Medicare Part B (service and supplies); refer to the previous section for more detail.

2.1.2 Molecular Diagnostic Tests

If you are developing new molecular diagnostics, be aware that coverage and reimbursement is different from other diagnostics. CMS recognized that this rapidly expanding technology requires a specialized program to evaluate and cover tests with clinical utility. Due in part to differences in the regulatory framework for **clinical diagnostic laboratory tests** (CDLTs), in 2011 Medicare chose the Palmetto MAC to lead the development of Local Coverage Determinations (**LCDs**) for all molecular diagnostic tests. These LCDs were then adopted by most (about three-quarters) of the MACs, covering 27 U.S. states and three territories.

Palmetto continues to manage this program—called MolDX—and applies specific coverage criteria to new laboratory developed or FDA- cleared molecular diagnostic tests, ensuring that appropriate code descriptors are available to identify the tests for payment purposes. The **MolDX Manual** includes information on coverage, coding, and payment for molecular diagnostic tests.

Molecular diagnostics are increasingly evaluated using the ACCE framework, which takes its name from the main criteria for evaluating a genetic test—analytic validity; clinical validity; clinical utility; and associated ethical, legal, and social implications.

2.2 Medicaid and CHIP Coverage

Unlike Medicare, each state's Medicaid program is unique. While Medicare, Medicaid, and CHIP are federal health insurance programs, their financing is very different, and that impacts what services and diagnostics are covered under each program. Medicare benefits are funded through federal payroll taxes. In Medicaid and CHIP, however, program payment is allocated jointly between the federal and state governments. While covered benefits fall into mandatory and optional categories per federal law, states have flexibility in which optional benefits they elect to cover. This results in great variability from state to state with respect to what is covered in a state Medicaid program. Due to these differences, it is essential to research each state program's coverage of diagnostics like yours.

2.2.1 State-by-State Coverage

CMS-provided state overviews outline the unique features of each state's Medicaid program, including the populations that receive assistance in that state, which optional benefits are covered, what innovative demonstrations may be planned or underway, the portion of the population covered in Medicaid managed care plans, and programs operating under various waiver authorities.

2.2.2 Mandatory Benefit Categories

Under Medicaid, if a technology falls under a mandatory benefit category, the diagnostic is covered; if it does not fit, it is not covered. The following are mandatory benefit categories in the Medicaid program that may include diagnostic services:

- Inpatient hospital services
- Outpatient hospital services
- Early and periodic screening, diagnostic, and treatment services (EPSDT)
- Nursing facility services

- Physician services
- Rural health clinic services
- Federally qualified health center services
- Laboratory and X-ray services
- Nurse midwife services
- Certified pediatric and family nurse practitioner services

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Federal law requires that state plans must specify the amount, duration, and scope of each service it provides for the categorically needy (meeting defined financial or disability requirements) and each covered group of medically needy. States cannot arbitrarily deny or reduce the amount, duration, or scope of a required service to otherwise eligible beneficiaries because of diagnosis, type of illness, or condition. However, a **state Medicaid agency** (SMA) may place appropriate limits on a service based on such criteria as medical necessity (a term used to describe the coverage, including specific services, that is offered under a benefit plan) or on utilization management (techniques for evaluating the necessity of medical treatments and services on a case-by-case basis).

2.2.3 Early and Periodic Screening, Diagnostic, and Treatment Services

All children and youth under age 21 enrolled in Medicaid through the categorically needy pathway are entitled to the EPSDT benefit. EPSDT requires states to provide access to any Medicaid-coverable service in any amount that is medically necessary, regardless of whether the service is covered in the state plan. Services that maintain or improve a health condition or relieve pain are covered under EPSDT even if they do not cure the health condition.

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2.2.4 Other Coverage Considerations

Diagnostics with demonstrated effectiveness in improving care, and quality, and reducing downstream costs can entice states with CMS waivers (agreements between the federal government and the SMA permitting the state to experiment with benefits) to strongly consider coverage. Given the wide variety of payment mechanisms and places of service being adopted by SMAs (e.g., home and community), it is important to look carefully at the defined covered and non-covered services that appear in regulations and guidelines for each applicable program. A reimbursement consultant can be very helpful as innovators approach this analysis.

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2.3 Commercial Payer Coverage

Commercial health insurance is the most prevalent form of healthcare coverage in the U.S., covering approximately two-thirds of the population. As such, ensuring your new diagnostic is covered by commercial payers is a priority for obtaining reimbursement. Historically, commercial payers 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. This is especially true for devices that do not easily fit in a Medicare benefit category. For example, many private payers covered therapeutic continuous glucose monitors years before Medicare included them in a benefit category.

In recent years, many commercial payers have expanded their evidence review capabilities and may cover new services before Medicare does.

Commercial payers almost always require FDA approval for a diagnostic, whether through a 510(k) or PMA, prior to approving coverage for its therapeutic use. Use of a diagnostic prior to FDA approval is typically considered investigational or experimental, and therefore not covered by commercial payers. While the safety and efficacy evidence required for FDA approval is important in obtaining commercial coverage, commercial payers frequently require additional clinical validity and clinical utility evidence above what is required for FDA approval before supporting new diagnostics coverage.

2.4 Coding

Providers (e.g., clinicians, various clinical settings, pharmacies) bill for services and products using data elements identified by the National Uniform Billing Committee as necessary for claims processing. Among the required data elements are the codes that describe the services and products used in the care and treatment of the patient.

The codes are required by the Health Insurance Portability and Accountability Act (HIPAA), which standardized the electronic transmission of certain health information. Code sets outlined in HIPAA regulations include **Current Procedural Terminology** (CPT®) maintained by the American Medical Association (AMA; HCPCS Level I); **Healthcare Common Procedure Coding System** (HCPCS) maintained by the Department of Health and Human Services (HCPCS Level II); International Classification of Diseases, 10th edition (ICD-10); Code on Dental Procedures and Nomenclature, and others.

Understanding which code set and coding system may apply to your diagnostic is an important step toward coverage. For more information, see Section 3.2 (coding and coverage) and Section 4.2 (applying for new codes).

2.5 Payment

Healthcare differs from other industries in that the unit of payment is variable. There is not a single payment amount or method for any diagnostic, as payment methodologies and amounts can vary from one payer to another, from one provider to another, and from one patient to another (based on severity of illness). Payments may also depend on the site of service where the diagnostic is delivered to patients. Because of these factors, you should have a basic understanding of healthcare payment models as well as the types of payments and payment systems and how they may apply to your diagnostic. If needed, a reimbursement consultant can provide additional guidance on what needs to be done and when.

2.5.1 Payment Models

For over 50 years, U.S. healthcare providers have been reimbursed on a **fee-for-service** (FFS) basis where each medical service and procedure is paid for separately. FFS creates incentives for providers to deliver more, and more expensive care. Payments are unbundled, so services are billed and paid for separately. Quality of care and patient overall health are not factored into FFS payments. As healthcare costs continue to rise, the once-prevalent FFS model is being supplanted by other payment systems that de-emphasize line-item reimbursement in favor of a more holistic approach on "bundles" of care and episodes of treatment.

In 2010, the ACA accelerated and provided a regulatory framework for a new vision for healthcare delivery and reimbursement—known as **value-based care**—aimed at replacing the traditional FFS model. The concept of value-based care relies on the implementation of **alternative payment models** (APMs) that reimburse healthcare providers based on cost-efficiency, coordination, value, and quality, rather than the number of services provided.

While the industry is moving towards APMs, FFS remains the most common methodology for reimbursing providers and outpatient services. CMS's Medicare fee schedule is the de facto industry standard for determining the methods of reimbursement. Whereas Medicare reimburses providers their fee schedule rate, commercial payers often reimburse providers a negotiated percentage of what Medicare pays for the same service (e.g., 120 percent of Medicare). For this reason, understanding Medicare's methods for determining payment amounts is vital.

2.5.2 Medicare

Inpatient Payments

Medicare uses the IPPS to pay for inpatient hospital services. Payments for acute care hospital inpatient stays are based on set rates under Medicare Part A and are updated annually. CMS's Division of Acute Care defines the scope of Medicare benefits for services provided by hospitals to inpatients, and develops, updates, and evaluates the IPPS for payments to hospitals for inpatient services and

associated capital costs. This division considers applications for temporary supplemental payments for new technologies under the IPPS (see Section 3.4). It also develops and maintains new and revised procedure codes for the ICD-10-Clinical Modification (ICD-10-CM) and ICD-10-Procedure Coding System (ICD-10-PCS) used for inpatient hospital services (see Section 4.2 for information on applying for new ICD-10-PCS codes).

Medicare severity diagnoses-related groups (MS-DRGs) are used to categorize different types of hospital stays based on the services the patient receives (e.g., normal newborn stay vs. neonate intensive care unit; those assignments then affect payment rates for the "typical" hospital visit**.** By paying a fixed amount based on a "typical" stay (e.g., three days for a "normal newborn"), the hospital has an incentive to manage costs. A new technology that helps the hospital do this (e.g., by reducing the risk of an infection or complication) may have a compelling value proposition, particularly if the innovator can show that the new product offsets other costs. It is important to have a new diagnostic added to the MS-DRG so that it can be accounted for in the IPPS.

Resource:
Evaluation of Severity-Adjusted DRG Systems

Outpatient Payments

Medicare uses a separate system to pay for outpatient hospital procedures (e.g., outpatient surgery where the patient is admitted and discharged the same day) called the OPPS. The OPPS payment bundle includes most implantable devices and low-cost drugs, as well as supplies and equipment integral to performing a service. Medicare pays some services separately, including, but not limited to:

- Many surgical, diagnostic, and non-surgical therapeutic procedures
- Blood and blood products
- Most clinic and emergency visits
- Some drugs, biologicals, and radiopharmaceuticals
- Brachytherapy sources
- Corneal tissue acquisition costs
- Certain preventive services

A hospital may receive multiple OPPS payments for a single outpatient encounter if multiple services are provided, unlike the IPPS, which pays a single bundled payment. Laboratory tests are packaged in both the **IPPS** and **OPPS**—they are not separately payable. Hospitals and laboratories may be fined by the Justice Department for colluding to circumvent Medicare's 14-day rule prohibiting separate charges for laboratory test samples taken during outpatient services if they attempt to bill these tests separately.

It is important to understand that laboratory tests are packaged in both the IPPS and OPPS—they are not separately payable.

Ambulatory Payment Classifications

CMS classifies outpatient services into ambulatory payment classifications (APCs) based on clinical and cost similarity. All services within an APC have the same payment rate as determined by CMS's OPPS. A critical OPPS feature is "packaging," or grouping integral, ancillary, supportive, dependent, and adjunctive services into the payment for the associated primary procedure or service. CMS sets payment rates for the combination of services likely to be required during the procedure. For example, an APC may consist of ancillary services, like intravenous fluids, some clinical laboratory tests, and care provided by hospital staff. Medicare does not permit services paid under the APC system to be "unbundled" and paid separately. This type of bundled payment functions similarly to how payment for items and services in the inpatient setting are paid according to DRG. Types of packaged items and services include:

- All supplies
- Ancillary services
- Anesthesia
- Operating and recovery room use
- Clinical diagnostic laboratory tests
- Capital-related costs
- Procedures described by add-on codes

2.5.3 Medicaid

Certain types of diagnostics may already be covered explicitly in various state Medicaid or CHIP programs. Other diagnostics might be covered under per diem rates (a fixed payment per day regardless of the charges or costs incurred for caring for a particular inpatient) or MS-DRGs (also a predetermined payment amount for services provided by hospitals to inpatients).

Providers and payers operating under fixed payment at-risk models may also be open to use of approved diagnostics that are new to the market and hold promise of benefit for the member and cost containment.

2.5.4 Commercial Payers

In addition to the FDA approval and additional clinical evidence (if warranted), commercial payers focus on the cost of the diagnostic, as captured in its coding. Commercial payers want to ensure the billing codes for the procedure, service, and product are sufficient to cover the cost associated with the diagnostic's use.

Commercial health plans' business model involves spreading the risks of high medical costs across a large population. Commercial payers compete for enrollees and negotiate with providers (e.g., hospitals, networks of physician practices) for preferred payment rates. In the employer-sponsored insurance environment, the employer selects the insurer and determines the benefit options for employees. Premium costs are typically shared between the employer and employee. To curb overuse of healthcare services patients may also incur co-insurance, co-payments, and deductibles, commonly

referred to as out-of-pocket expenses. Patients who receive a diagnostic may pay a fixed amount, or a percentage of what the provider has agreed to accept from the insurer.

Many commercial payers prefer per diems over DRG-based case rates because of their ability to deny days at the end of a hospital stay. **Per diem** payments provide a fixed amount for a patient day regardless of the charges or costs incurred for caring for a particular patient. In the most common arrangements, payers negotiate per diem rates then pay that rate without adjustment. If the payer and provider can accurately predict the number and mix of cases, they can accurately calculate a per diem rate.

3 Define a Diagnostics Reimbursement Strategy

Bringing a new diagnostic product to market requires many skill sets. You need to have a basic understanding of the entire commercialization process and manage multiple tasks related to early-stage research and development, clinical trials, regulations, reimbursement, and post-market surveillance. The goal of receiving FDA Market Authorization is often considered the primary endpoint that leads a new diagnostic to commercial success. However, if a new diagnostic does not obtain the desired amount of reimbursement or, even worse, is not covered by payers, clinicians are unlikely to use the new diagnostic. Therefore, from an innovator's perspective, ensuring reimbursement for a new diagnostic can be as important as obtaining regulatory approval.

The foundation of a strong diagnostics reimbursement strategy is research. Initially, you need to define your diagnostic device type and establish a plan for gaining regulatory approval (see the Regulatory Knowledge Guide for IVDs for a regulatory process overview). You will then need to formulate a **target product profile** (TPP), evaluate competitors, collect evidence, identify potential providers and payers, and determine the target patient population. In addition, developing a reimbursement strategy early in development may give you a better-informed understanding of the impact certain product design decisions could have on payment for the diagnostic.

Figure 1. Key Elements of a Reimbursement Strategy

Figure 1 outlines the key elements of a diagnostic reimbursement strategy. Note that developing a reimbursement strategy can be a substantial undertaking. If needed, you can engage a reimbursement expert to help guide the overall reimbursement strategy for your diagnostic or for specific aspects of it

(e.g., pricing, coding guidance). In addition, there are several NIH SEED Diagnostics Reimbursement case studies (listed below) that provide more in-depth discussion and examples on managing the multiple tasks related to early-stage research and development, clinical trials, regulations, reimbursement, and post-market surveillance. The stages in the case studies are covered in Sections 3 and 4 of this guide.

Link to Diagnostics Case Study #1 VitalScreen
Link to Diagnostics Case Study #2 CardioTropT
Link to Diagnostics Case Study #3 CDx test

3.1 Research (Stage 1 in the case studies)

3.1.1 Define the Technology Type

Because reimbursement for most routine diagnostics is typically part of the overall payment for a medical service, understanding the proposed context for use of a new product is critical. Key aspects of the TPP for reimbursement strategy include:

- Intended Use – What are the indications for the diagnostic, target patient populations, and site of care where the diagnostic will be used, as well as a comparison of the technology to the standard of care?
- Diagnostic Description – How similar is it to a predicate device or new technology? What design features does it have? How is the diagnostic unique when compared with alternatives?
- Contraindications – Does the diagnostic have decreased risk compared with alternatives?
- Non-Clinical Testing – What non-clinical studies will be needed to demonstrate the diagnostic is safe, and what are the consequences of a failure of the diagnostic?
- Clinical Studies – What clinical studies will be performed to support the indications for use of the diagnostic? What endpoints will be measured, and how will they help differentiate the technology from competitors? Will the studies address the clinical utility of the diagnostic (i.e., does it demonstrate an impact on treatment choices and patient outcomes)?

Creating a reimbursement strategy requires researching and defining the product's value proposition and positioning vis-a-vis competition. Understanding how competition is reimbursed can be highly informative for developing your own strategy.

Parallel Review Program

The FDA-CMS Parallel Review program is a collaborative effort intended to reduce the time between FDA marketing approval or clearance and a CMS NCD. A formal request for parallel review can be made only in the context of an NCD request. Parallel review is a voluntary process that the innovator seeking FDA and CMS approval elects to enter which commits them to working with both agencies during the process.

The parallel review pathway is distinct because CMS meets with innovators and manufacturers before FDA approval. By engaging FDA and CMS together—using the Early Payor Feedback program or some other mechanism—while the proposed diagnostic is under FDA review, you can develop a stronger evidentiary base in a more efficient manner. The FDA created the Early Payor Feedback program so innovators can discuss evidence requirements and other aspects of coverage with a panel of public and private payers. The FDA recommends engaging this panel as a first step for those interested in parallel review. Once both FDA and CMS agree to parallel review for a new diagnostic, the timing primarily follows the FDA process. This can accelerate patient access to innovative diagnostics and potentially shorten the time between FDA market approval and Medicare coverage and payment.

Note that only a handful of products have been covered through parallel review since the program began in 2011. Many devices eligible for parallel review by FDA requirements lack a benefit category for CMS, and as a result CMS has been unable to accept the requests for parallel review.

Diagnostics for Rare Diseases and Conditions

If your diagnostic will be used to diagnose or treat a rare disease—a condition that affects 8,000 or fewer patients per year nationwide—you can apply for **humanitarian use device** (HUD) status from FDA. The marketing application for these diagnostics is called **humanitarian device exemption** (HDE).

For such diagnostics, CMS allows the local MAC to determine coverage. This permits access to diagnostics involving small patient populations for which there are typically no other alternative treatments, but results in regional variation in coverage. Most MACs do not require the development of an LCD to cover a HUD, but some interaction with the MAC to supply necessary information should be expected. There are a very small number of diagnostics that are eligible for HDE designation, and most are companion diagnostics to a treatment for a rare condition or disease. This evaluation process by the MAC can be as short as 30 days or take 90 days or more.

3.1.2 Determine the Patient Population and Potential Payers

Is your new diagnostic applicable to specific target populations? For example, if your diagnostic targets a geriatric condition, you need to understand how new diagnostics are added to Medicare coverage. However, items and services that are not used by the aged (e.g., fetal heart monitoring) are not necessarily precluded from coverage. Rather, these items and services are generally approached on a case-by-case basis for coverage by MACs which evaluate claims for medical necessity on an individual versus a population-based determination.

Medicare covers approximately 20 percent of the nation—more than 60 million people. The vast majority (96 percent) of people over age 65 years old have Medicare. Medicare eligibility rules allow anyone who is receiving payments through Social Security disability insurance or are on hemodialysis with end-stage renal disease to qualify for Medicare.

If your target population is likely to include Medicaid or CHIP recipients, investigate (or potentially consult with a reimbursement expert) the coverage policies of state Medicaid plans – because coverage can vary widely outside of the federally mandated benefits. Medicaid reimbursement for

diagnostics may be different because states have broad discretion in determining coverage. Many states' Medicaid plans do not cover experimental or investigational services and items. Some states have waivers from CMS that give them the flexibility to not comply with certain requirements of Medicaid law. Often these waivers give states the ability to undertake experimental, pilot, or demonstration projects with additional flexibility to expand eligibility to additional populations, provide services not typically covered by Medicaid, or implement innovative delivery systems.

3.1.3 Identify Potential Sites of Service

When developing a reimbursement strategy, innovators developing new diagnostics should thoroughly research potential sites of service. A diagnostic can be used by healthcare providers in various healthcare settings, and coverage and reimbursement often depend on the type of setting where the technology is delivered.

Where a diagnostic is used (place of service) determines the patient's out-of-pocket expense.

Drugs, devices, and diagnostics can be used in multiple settings, e.g., inpatient, outpatient, home health, skilled nursing, etc., each of which are considered a different place of service (POS). For patients, this means that the same technology can have a different financial burden depending on where the service is delivered. For example, as described in Section 2.5.2, Medicare pays hospitals one rate per patient episode for care delivered in the inpatient hospital setting. However, if the patient received the same services in an outpatient department, the patient would have a different co-insurance responsibility. Be aware of how the POS affects patients' out-of-pocket expenses, and work to ensure the pricing does not have an unintended consequence of creating financial burden for patients who need these technologies.

3.2 Coding and Coverage (Stage 2 in the case studies)

A reimbursement assessment examines existing coding, coverage, and payment for the diagnostic within its context of use.

3.2.1 Research Existing Payment Codes

Of all healthcare claims, 96% are submitted electronically, so innovators should have a clear understanding of the payment code system used in the U.S. It is important to stay informed of the latest code set to understand potential coding changes that may impact your diagnostic. If you need to obtain a new code unique to your technology – research the process, identify the criteria required, and apply for a new code (or consult with a reimbursement expert for assistance). Information on applying for new codes is presented in Section 4.2. (Note: Molecular diagnostic tests use a different set of codes and have a different process for obtaining new codes.)

Current Procedural Terminology (CPT) Codes

HCPCS Level I is comprised of CPT, a numeric coding system maintained by the AMA (see Section 2.4). There are three categories of CPT codes:

- *Category I CPT* codes describe distinct medical procedures or services. These include radiology codes, pathology specialty and clinical laboratory services.
- *Category II CPT* codes are supplemental tracking or performance measurement codes. These are used to measure the quality of care provided by radiologists and pathologists, which is a factor in adjusting physicians' payment under the Medicare fee schedule.
- *Category III CPT* codes are temporary tracking codes for new and emerging technologies (including new diagnostic tests) to allow data collection and assessment of new services and procedures. Payers may deny claims involving Category III codes as "experimental" precisely because these codes are for "new and emerging technologies."

For molecular diagnostic tests, there are two types of Category III CPT codes: **Administrative Multi-Analyte Assays with Algorithms (MAAA)** and Genomic Sequencing Procedure (GSP) codes. MAAA codes describe tests that involve multiple genes or proteins. GSP codes describe next-generation sequencing tests. The MAAA procedure code describes all parts of the analysis leading to the score as a single service.

In response to the **Protecting Access to Medicare Act of 2014** (PAMA), which focuses on payment and coding of clinical laboratory studies paid for under the Medicare Clinical Laboratory Fee Schedule, the AMA developed a new category of HCPCS Level I (CPT) codes, known as Proprietary Laboratory Analyses (PLA). PLA codes describe proprietary clinical laboratory analyses and can either be provided by a single ("sole-source") laboratory (e.g., laboratory developed test) or be licensed or marketed to multiple providing laboratories (e.g., FDA approved companion diagnostic test).

PLA codes are given for tests that are performed on humans. These codes describe a proprietary test and take precedence over any other coding that may describe the test. When a PLA code is available for a test, the medical coder (entering the test provided as part of a care episode as part of a patient's medical record) must use the PLA code (which supersedes a CPT code.) The PLA code cannot be substituted with a CPT or MAAA code. For an example of a new diagnostic that would require a PLA code, see the Reimbursement Diagnostic Test Case Study #3 companion diagnostic test for non-small cell lung cancer.

PLA codes are payable by Medicare but may not be paid by other payers such as commercial plans and Medicaid.

PLA codes are contained in a non-Category I subsection of the Pathology/Laboratory CPT codes. When a specific PLA code is not listed, the test must be reported using either a CPT Category I laboratory code or an Administrative MAAA code, the latter are separately listed in Appendix O of the CPT

Manual. When an MAAA code describes a proprietary test, the MAAA code is cross-referenced in the coding book to the appropriate PLA code. The PLA code is the code that then gets reported. Importantly, PLA codes are payable by Medicare but may not be paid by other payers such as commercial plans and Medicaid.

Resources:
NIH SEED: All About CPT Codes
NIH SEED: Proprietary Laboratory Analyses (PLA) Codes Overview
NIH SEED: Reimbursement Workshop

HCPCS Level II Codes

HCPCS Level II codes are used to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). CMS is responsible for developing and maintaining HCPCS Level II codes.

Most diagnostics are coded P or R but may also be granted C, G, and U codes if applicable. (Table 1) For example, C codes are utilized to report magnetic resonance angiography and advanced imaging claims may use G codes.

Table 1. Common HCPCS Level II Codes for Diagnostics

Codes	Description
C	Drug, biological, and device codes used for the hospital Outpatient Prospective Payment System
G	Temporary codes for procedure and professional services
P	Pathology and laboratory services
R	Diagnostic radiology services
U	Clinical laboratory tests used by laboratories to bill for certain COVID-19 diagnostic tests

ICD-10 Codes

The **ICD-10** is the global health information standard for mortality and morbidity statistics developed and maintained by the World Health Organization. The ICD is used in clinical care to define diseases, study disease patterns, manage health care, monitor outcomes, and allocate resources. ICD diagnosis codes provide a description of the disease or injury that led to the patient/physician encounter. For example, ICD-10-CM diagnosis codes O09.511-O0.519 indicate the supervision of elderly primigravida (a woman who is pregnant for the first time at the age of 35 years or older), which may be used to support medical necessity for coverage of a non-invasive prenatal test to screen for fetal aneuploidy. For more detail about this example, see the Reimbursement Diagnostic Test Case Study #1 for non-invasive prenatal test.

ICD-10 codes are divided into two categories:

- ICD-10-CM (clinical modification) – Clinical modifications are diagnosis codes that all healthcare providers use. ICD-10-CM diagnosis codes on claims are used to determine coverage, not the amount to be paid to the provider for the services.
- ICD-10-PCS (procedure coding system) – The procedure codes are used only for inpatient reporting (hospital billing and coding).

Responsibility for maintaining the ICD is divided between two agencies in HHS:

- National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention maintains the classification of diagnoses
- CMS maintains the classification of procedures

ICD-10-CM diagnosis and ICD-10-PCS procedure codes on claims are used to assign discharges to the appropriate MS-DRG, which are paid at the rates determined by the IPPS (discussed in Section 2.5.2) or otherwise agreed to with commercial payers.

Coding Considerations for Advanced Diagnostic Laboratory Tests

An **advanced diagnostic laboratory test** (ADLT) is described in PAMA as a clinical diagnostic test that is offered and furnished only by a single laboratory. ADLTs include multianalyte assays with algorithmic analyses and other molecular diagnostic tests. An ADLT cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Tests that receive ADLT status from CMS are eligible for more frequent changes in their Medicare payment rates. To receive ADLT status, tests must meet Criterion A or Criterion B.

Tests that qualify as ADLTs under Criterion A are LDTs—tests that are *completely* designed, manufactured, and used within a single laboratory with a single CLIA certificate. To qualify as an ADLT under Criterion B, a laboratory would need to seek FDA approval or clearance (as though it planned to sell the test in interstate commerce), but its capacity to expand its market would be limited to the footprint of the laboratory holding the CLIA certificate where the test was designed, manufactured, and used. Importantly, clinical laboratories must apply to CMS to obtain ADLT designation. CMS guidance on the process for obtaining ADLT status is here.

ADLTs are described using Category I HCPCS (if the laboratory applies for and receives a CPT code from the AMA) or Category II HCPCS codes (if the laboratory does not receive a CPT code from the AMA). PLA codes also identify new and existing ADLTs.

3.2.2 Analyze Coverage Determinations

Medicare

As a defined benefit program, items and services that fall outside of Medicare's statutory benefits are excluded from coverage. This is called statutory exclusion. Benefits that are excluded by law include investigational or experimental items and services (with certain exceptions, described further in

Section 2.1) and convenience items like eyeglasses and hearing aids, cosmetic surgery, and long-term care.

Only an act of Congress can add benefits to Medicare. Diagnostic laboratory tests generally fall within an established Medicare benefit category, and therefore are coverable by Medicare. The paths for Medicare coverage for diagnostics include NCD, LCD, and Negotiated Rulemaking (see Section 2.1 for more NCD information). Understanding the current state of coverage in NCD or LCD can help you build a coverage, coding, and payment strategy. You can research NCD and LCD for items and services that are alternatives to your product or that could potentially be replaced by your product.

CMS, through horizon scanning and relationships with sister agencies, attempts to proactively anticipate the need for new or revised NCDs. Still, the majority of NCDs are the result of formal requests for coverage by external stakeholders. Often, the volume of requests for coverage is greater than the CMS capacity to undertake the NCD process. In these cases, CMS employs a waitlist for new and reconsidered **National Coverage Analyses** (NCAs), which are used to determine if an item is *reasonable and necessary*. An NCA is an evidence-based review of peer reviewed literature, and clinical guidelines, public comment, and other expert opinion to evaluate if the item or service reviewed improves net health outcomes. For diagnostic services, CMS considers a test as having the potential to improve health outcomes if it informs and potentially changes the clinical decision making of the treating provider.

CMS applies the hierarchical framework of Fryback and Thornbury (1991) to determine reasonable and necessary determinations. The framework includes:

- Level 1 assesses technical efficacy
- Level 2 addresses diagnostic accuracy, sensitivity, and specificity of the test
- Level 3 focuses on whether the item changes the physician's diagnostic thinking
- Level 4 concerns the effect on the patient management plan
- Level 5 measures the effect of the diagnostic information on patient outcomes

Stakeholders can begin to engage CMS in informal, confidential discussions prior to a formal request for coverage at any time. Stakeholders often use informal discussions with CMS to better understand the evidentiary requirements for the item or service as they plan a request for national coverage under Medicare.

NCDs follow a specific approval timeline (nine months for most NCDs, and 12 months for certain NCDs requiring more information). NCDs are uniformly applicable across Medicare Part A and Part B programs. Medicare Part C must provide equivalent coverage as the NCD, but the Medicare Advantage plan may add rules (such as a prior authorization) for providing coverage.

In the absence of a NCD, MACs may develop LCDs that are applicable within their jurisdiction. LCDs may be developed in the absence of an NCD or as a supplement to an NCD if the LCD policy does not

conflict with national policy. Local Coverage Articles supplement the LCD by adding coding and billing instructions important for claims processing.

Stakeholders may also request a reconsideration of the benefit category determination or any provision of an existing NCD or LCD by submitting a formal request in writing to CMS or the local MAC. Both NCDs and LCDs may be reconsidered if new evidence is available. In addition, MACs must consider all LCD reconsideration requests from beneficiaries residing or receiving care in the MAC and providers doing business in the MAC.

Other Payers

Most commercial payers base their coverage on Medicare policies which are developed in a transparent public process required by law. This transparency means that all commercial payers can see how Medicare covers a new technology and can determine whether they should follow Medicare's policy or take a different approach. Commercial payers document coverage determinations in their coverage policies; however, not all insurers make these policies publicly available. It may be useful to either align your reimbursement strategy or identify a clear difference from currently covered technologies. You may benefit from reviewing available coverage policies to identify where they may benefit from either aligning their reimbursement strategy to, or identifying a clear difference from, currently covered technologies.

Commercial payers pioneered the adoption of clinical decision support to implement prior authorization requirements for certain diagnostic imaging tests. Radiology benefits management (RBM) and laboratory benefits management (LBM) programs apply logic, including information from medical specialties' clinical guidelines and the Choosing Wisely initiative of the American Board of Internal Medicine, to curb overuse of higher-cost tests that do not provide additional information that is essential for clinical decision-making. RBM and LBM programs are provided to health plans to help implement prior authorization programs for advanced imaging and some laboratory tests, particularly molecular diagnostic tests.

Considerations for Molecular Pathology Tests

Some payers provide payment coverage for molecular pathology tests only when used in conjunction with a specific ICD-10-CM code (see Section 3.2.1). For example, an ICD-10-CM code I20.0 for unstable angina is required for coverage of a quantitative troponin test like the one discussed in Reimbursement Diagnostic Test Case Study #2. If a particular test is provided in conjunction with an ICD-10 diagnosis code that is not specified by the payer, payment coverage may be denied. The innovator should review each payer's coverage determinations to understand coverage requirements for their diagnostic.

3.2.3 Determine Evidence and Value

Medicare Required Evidence

Medicare coverage policy can happen at either the national or local level. CMS and its contractors use evidence to determine coverage. Historically, most coverage determinations have been made by MACs as approximately 80 percent of Medicare coverage determinations are LCDs. CMS and its MACs both

use the same evidentiary standards and the same general evidence-based process to evaluate the available evidence for a device requesting coverage.

CMS divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies, 2) the relevance of findings from individual studies to the Medicare population, and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

Typically, the hierarchy of evidence is as follows:

1. Randomized controlled trials
2. Non-randomized controlled trials
3. Prospective cohort studies
4. Retrospective case control studies
5. Cross-sectional studies
6. Surveillance studies (e.g., using registries or surveys)
7. Consecutive case series
8. Single case reports

CMS also considers the generalizability of the evidence to the Medicare population, which is overwhelmingly over age 65 and typically has at least one chronic condition. It is important to understand that even well-designed and well-conducted trials may not supply the evidence needed for an NCD (which includes applicability of setting (community practice) and biologic plausibility in the aged) if the results cannot be generalized to the Medicare population. CMS will perform meta-analyses to ascertain the strength and quality of evidence in the body of literature, which is especially helpful when there is a dearth of large-scale studies to evaluate.

Coverage with Evidence Development (CED) is a paradigm whereby Medicare develops a NCD to cover items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data (e.g., in a registry). CED is a paradigm reserved for only a select subset of NCDs. Since 2006, CMS has finalized 22 NCDs with CED requirements. Of these, four CED decisions were related to coverage of diagnostic tests. An example of a CED (laboratory test) can be found here.

Advanced imaging evidence is defined by a new program called the Appropriate Use Criteria (AUC) program that was established under PAMA. It is focused on increasing the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries. The AUC program requires clinicians to use a Clinical Decision Support Mechanism (CDSM) when they furnish advanced diagnostic imaging services, including computerized tomography, positron emission tomography, nuclear medicine, and magnetic resonance imaging. Clinicians who order these services will need to consult with CDS software and obtain feedback. Exceptions to consulting CDSMs include imaging services that are ordered for an inpatient and paid under Part A, and medical emergency situations.

In 2017, CMS established a list of Priority Clinical Areas for the application of AUC. Those include:

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and nontraumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Cervical or neck pain

The codes used for AUC include **CPT** codes and HCPCS C codes for advanced diagnostic imaging along with an HCPCS modifier describing adherence to AUC or an exception, and a HCPCS G code identifying the specific CDSM used. As of January 1, 2022, AUC information must be included on the furnishing professional's claim to receive payment. In the future, CMS is required to apply prior authorization for ordering professionals that have "outlier" ordering patterns.

Medicaid Required Evidence

Because each state's Medicaid program is different, innovators will want to consult directly with the SMA, **Managed Care Organization** (MCO) or similar entity about evidence needed to get a diagnostic covered under a particular Medicaid program. (For more detailed information about Medicaid program requirements, see Section 2.2) The more closely the evidence aligns to the specific program population, the more applicable and persuasive the evidence will be.

Examples of medical evidence are:

- Randomized controlled clinical trials (best)
- Observational studies
- Retrospective analysis of patient samples

Commercial Payers Evidence Requirements

Commercial payers almost always require FDA approval, whether through a 510(k) or PMA, prior to approving coverage for a test marketed as an *in vitro* diagnostic (although they may cover **LDTs** with proven clinical utility even in the absence of FDA Premarket Approval or clearance.) In most other cases, though, diagnostic use prior to FDA approval is typically considered "investigational" or "experimental," and therefore not covered by the insurer. While the safety and efficacy evidence required for FDA approval is important in obtaining commercial coverage, commercial payers frequently require greater clinical evidence to support new diagnostics coverage. In addition to clinical evidence, commercial payers will focus on the cost of the diagnostic, as captured in its coding. Commercial payers will look to ensure the billing codes for the procedure, service, and product are sufficient to cover the cost associated with the diagnostic's use.

3.3 Payment (Stage 3 in the case studies)

3.3.1 Research Payment Rates

When researching payment rates, it is important to know that Medicare sets its rates based on providers' historical costs, and that Medicare pricing for specific CPT codes can be found using the Medicare Physician Fee Schedule Look-Up Tool. While Medicare rates can be used as a guide, note that non-Medicare payers can have their own methodology for paying providers and the authority to set their own rates. There are several specific payment systems (described below) innovators should be familiar with since they can impact reimbursement of diagnostics.

Clinical Laboratory Fee Schedule (CLFS)

The CLFS is Medicare's payment system for clinical laboratory tests performed by independent clinical laboratories, hospitals, outpatient clinics, and other providers when they are paid under Medicare Part B and not packaged. For most CDLTs, payment rates are set using the volume-weighted median of private payer rates reported by certain laboratories every three years. The CLFS rates are available on the CMS website. The method used to set a rate for a new test depends on several factors, including whether the test has received FDA clearance or approval.

Medicare Physician Fee Schedule

Medicare pays for services furnished by physicians (surgery, office visits, and other professional services) and services furnished by many other non-physician practitioners under a payment system known as the **Medicare Physician Fee Schedule** (PFS). The PFS uses a system called "relative value units (RVUs)" to set payment amounts. Each year, the AMA leads a panel called the RVU Update Committee (RUC), which considers how to assign RVUs for various technologies. The RUC meets three times each year, in the month following the CPT Editorial Panel meeting. The RUC's member specialty societies are responsible for recommending changes to the RVUs assigned to procedures in their specialty, including whether and how to account for new technologies. The RUC's recommendations are forwarded to CMS. CMS determines what the final RVU assignments will be, following notice-and-comment rulemaking. The PFS is budget neutral in the aggregate. In other words, there is a pre-defined total budget for Medicare physician services, considering all services provided across all specialties. Therefore, for every increase in payment there is a corresponding decrease elsewhere in the system.

Medicare Rates' Impact on Commercial Payers Rates

Medicare creates individualized payment rates—based on codes—for reimbursement in multiple settings: inpatient hospital, outpatient hospital, physician offices and clinics, etc. These payment systems are based on FFS reimbursement; in other words, entities (either the provider or the institution) submit a claim using a code, and they are reimbursed by the insurer per claim. However, the payments are prospectively set each year via a regulatory rulemaking process that takes into account historical payments, costs, and other factors. Every year CMS proposes payment rates via rulemaking and then publishes finalized rate tables for each provider setting that set the rates for the upcoming year.

Commercial payers tie their rates to Medicare rates. Based on publicly available information, commercial payers generally reimburse at 120 percent of the Medicare payment rate and Medicaid generally reimburses at 70 percent (assuming Medicare is 100 percent of the rate).

Medicare Payment Rules and Prospective Payment Systems

Medicare payment rules are usually updated annually. CMS proposes payment rates and policy changes for the following year and those rates and changes are open for public comment. In some instances, CMS also holds public meetings to gather additional input. The payment rules for inpatients, outpatients, and physicians are most likely to see the introduction of new technology. These are described briefly below.

Historical Costs' Impact on New Technologies

When incorporating new technology into the IPPS and OPPS payment rates, Medicare looks at several years of costs, or the historical costs. CMS collects claims data and cost reports from providers, then analyzes those reports to propose rates for both the MS-DRG classification (for inpatient services) or the APC for outpatient and ambulatory care services. Typically, two years of historical data are needed to determine these rates; given the time lapse in receiving and analyzing data, this means that a technology that is first introduced into the care delivery system in 2022 may not be reflected in a payment rule until 2025 and may not go into effect as part of a CMS payment system until January 1, 2026. CMS publicizes the proposed rates via a Notice of Proposed Rulemaking. Stakeholders have an opportunity to comment on the proposed rates before they are finalized. The rulemaking process may take place based on a Calendar Year sequence or a Fiscal Year sequence.

The most up-to-date information on the federal payment rules described below is available in the Federal Register. In addition, CMS maintains websites for each payment program, where more specific information is available.

Resources:

CMS: Inpatient Prospective Payment System
CMS: Outpatient Prospective Payment System
CMS: Prospective Payment Systems
CMS: Medicare Physician Fee Schedule
CMS: Durable Medical Equipment, Prosthetics/Orthotics & Supplies Fee Schedule

3.3.2 Understand the Cost and Price of Test

In healthcare, cost sharing refers to the patient's portion of costs for healthcare services covered by their health insurance plan. Patients typically pay their portion in the form of deductibles, coinsurance, or copayments (out-of-pocket expenses). These out-of-pocket expenses differ for Medicare, Medicaid, commercial health plans, and benefit plans within a health plan.

- Deductibles are the amount of spending a beneficiary incurs before coverage begins

- Coinsurance is a specified percentage paid by the beneficiary (e.g., Medicare enrollees often pay 20 percent of the Medicare fee schedule for outpatient services, but they do not pay coinsurance for clinical laboratory services)
- Copayments are a specified amount paid by the beneficiary

3.3.3 Pricing Models

As discussed in Section 2, the three largest categories of insurers are Medicare, Medicaid and CHIP, and private commercial payers. The purchasers and payers of a diagnostic can be different. Moreover, different payers have different eligibility rules, patient populations, and benefits.

Purchasers are the entities that buy diagnostics for use to deliver care (e.g., hospitals, physician offices, retail pharmacies). Purchasers buy diagnostics through the developer, manufacturer, or distributor. But, as explained further below, patients rarely pay the full cost of their treatment; most patients have third-party payers involved in reimbursing the purchasers.

Payers include end consumers (i.e., patients) and third-party payers. Third party payers include commercial health plans, which offer products to employers and to individuals, and government programs (e.g., Medicare and Medicaid, each of which may have specific eligible populations). Third-party payers are *paying* the provider for a diagnostic on behalf of the patient, typically based on a set or negotiated rate. The price the provider actually paid for the device may be different from the estimated cost upon which the third-party payer negotiated a reimbursement amount.

Each payer has its own methods for setting payment amounts for diagnostics. Payers consider several factors, including demographics and patient mix, in developing payment policies. For example, care for end-stage renal disease is almost entirely paid for by public payers. In contrast, while all payers have maternal and child health policies, some payers like Medicare have such a small patient mix needing these services that a diagnostic for those patient populations will hold less interest to them.

Importantly, third-party payers typically purchase services from the healthcare system; relatively few medical devices are directly reimbursed by payers.

Setting a realistic price for a diagnostic is a crucial part of a reimbursement plan and can be a complex and difficult undertaking. Many factors impact the price, including the Cost of Goods Sold, 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 just to name a few. If needed, a reimbursement consultant can provide additional guidance.

3.4 New Technologies

Prior to setting payment rates for new technologies, CMS analyzes historical data and cost reports from providers. The OPPS has a provision for New Technology APCs for technologies that are truly new and significant enough to warrant having a unique HCPCS code. The purpose of the New Technology APC is to provide payment under the OPPS for technology that 1) is not appropriately reported by an existing HCPCS code assigned to a clinical APC, or 2) is appropriate to report by a new HCPCS code.

For an inpatient hospital stay, the IPPS pays one bundled payment which covers the costs for all acute care services, including the operating room, nursing care, supplies, lab services, radiology, and room and board. Technology is also generally covered within this bundled payment. In some cases, **New Technology Add-On Payment** (NTAP) can provide an additional payment to hospitals above the standard MS-DRG if CMS determines that certain criteria are met. If it is determined that a new technology merits an add-on payment under the IPPS, it may be applied for no more than three years. CMS uses this window to gather cost information that is then used to recalibrate the MS-DRG, incorporating any changes brought about by the new technology.

In general, for a technology to receive add-on payments, an innovator must provide evidence of the following:

Newness – A technology is considered new until claims data reflecting the use of that technology becomes available. The technology must also *not* be "substantially similar" to existing technologies. The three criteria for substantial similarity are: (1) uses the same or similar mechanism of action compared with existing technology to achieve a therapeutic outcome, (2) is assigned to the same MS-DRG compared with existing technology, and (3) involves the treatment of the same or similar type of disease and patient population compared with existing technology. If the technology meets all three criteria, it is not considered new.

To be considered new, a technology must have one of the following attributes: 1) uses a different mechanism of action compared with existing technology to achieve a therapeutic outcome, (2) is assigned to a different MS-DRG compared with existing technology, or (3) involves a different treatment of disease and patient population compared with existing technology.

Cost – The technology is inadequately paid under the existing MS-DRG system as shown by the average standardized charge for inpatient cases receiving the technology exceeding the cost threshold.

Substantial Clinical Improvement – Use of the technology must significantly improve clinical outcomes for a patient population as compared with currently available treatments. Clinical data must be specific or generalizable to the Medicare patient population.

Sometimes new technologies (particularly those that are low cost and have well-understood clinical evidence) can obtain payment without a formal coverage determination, such as when diagnostics are part of a covered service or when a MAC opts to determine coverage claim by claim. To explore this, consult the local MAC Medical Director for advice on how to move forward. You can find the local MAC Medical Director's contact information by selecting the "Local Coverage MAC Contacts Report" from the dropdown menu of the Medicare Coverage Database.

Resource:

CMS: Medicare NCD and LCD Coverage

Adding New Technologies to Medicare Plans

As discussed in Section 3.2.1, PLA codes are another option for Medicare to pay for novel technologies offered by clinical laboratories. PLA codes can be requested only by the clinical laboratory or manufacturer that offers the test. It is important to understand PLA codes (in case you need to apply for one) and the benefits of requesting such a code. Furthermore, researching existing PLA codes via the AMA CPT PLA Codes can give you important insights about your competitors. The "CPT PLA Codes approved by the CPT Editorial Panel" section allows you to download recently approved codes that show the following information:

- Proprietary name and clinical laboratory and 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 of the CPT code book)

A comprehensive list of all PLA codes can only be accessed either via the purchase of the most recent CPT Code Book or an online subscription. The content from both—the PDF listing of recently approved PLA codes plus the CPT book—provides the most comprehensive picture.

It is good to understand that PLA codes are payable by Medicare but may not be paid by other payers such as commercial plans and Medicaid.

Adding New Technologies to Medicaid Plans

States have broad discretion in determining coverage, subject to federal law. Because diagnostics might be covered under a per diem, or DRG, or as a separate item, the SMA, MCO, provider, or other entity operating a Medicaid program in the state might be a decisionmaker when new technologies become available.

Notably, many states do not cover experimental or investigational services and items. Neither the federal Medicaid statute nor the regulations define what constitutes an experimental treatment. The state's determination of whether a service is experimental must be reasonable and should be based on the latest scientific information available.

Another way states may cover new technologies is through waivers. Waivers are agreements between the federal government and the SMA permitting the state to experiment with benefits, such as by covering in-home personal care or requiring beneficiaries to have a job to keep receiving benefits.

4 Develop Evidence, Apply for Codes, and Engage Stakeholders (Stage 4 in the case studies)

In the final stage of the reimbursement process, you will need to continue to differentiate your product, ensure classification codes are in place, communicate the product's value, and solicit

stakeholder support to aid in market adoption.

4.1 Assessment of Clinical Evidence

Refer to Section 3.2.2 for information related the clinical evidence required for coding and coverage.

Clinical safety and efficacy data give insights into the marketability and differentiation of the diagnostic. It is imperative that the data you collect support the questions that regulators and payers will ask, which means considering these questions when building the research protocol.

If your diagnostic will have significantly better clinical outcomes over the competition, these outcomes should be measured in your clinical studies, and you will want to show payers they are valuable from an economic perspective. If you collected validation information about test performance as part of your regulatory application, you may need to collect additional evidence on different clinical applications that may influence commercial payers' coverage decisions. In addition, demonstrating a positive impact on different patient populations (beyond those included in the regulatory review) can also improve the value proposition of a new diagnostic.

4.2 Applying for New Codes

4.2.1 Requesting a New CPT Code

If you will need to obtain a new CPT code that is unique to your technology, research the process, identify the criteria required, and apply for a new code prior to completing the regulatory review process. If needed, you can engage the services of a reimbursement consultant to assist you through the process. (Note that molecular diagnostic tests use a different set of codes and have a special process for obtaining new ones.)

The AMA recommends following these steps when applying for a new CPT code:

1. Review the current CPT code book's index to determine if an existing code can be used. Both general and specific criteria must be met, as described below.
2. If a new code is proposed, follow AMA conventions for denoting changes (e.g., strikethrough, underline) and punctuation (e.g., semicolons).
3. Develop a clinical vignette that describes the "typical patient" who would receive the procedure or service, including the diagnosis.
4. Consult with the medical specialty society that represents practitioners who perform the procedure or service for input on your code change proposal prior to submitting it.
5. Submit all required information with your application, meet all required deadlines, and make timely responses to any inquiries from specialty society or AMA staff.

The application for a code change includes general criteria that apply to all Category I and Category III (emerging technology) codes. Note that Category II CPT codes are used for quality and performance measures, rather than for medical procedures that may involve the use of established or emerging medical technology.

The general criteria for Category I and Category III include that the proposed:

- Descriptor is unique, well-defined, and describes a procedure that is clearly identified and distinguished from existing CPT codes
- Code does not fragment an existing code or combine two or more existing codes
- Code represents the procedure as it is typically performed, and not extraordinary circumstances

Additionally, Category I codes must meet the specific criteria of:

- All devices and drugs used in the procedure or service have received FDA clearance or approval, if required
- The procedure is performed by many healthcare professionals across the U.S.
- The procedure is consistent with current medical practice
- The procedure has supporting evidence of its clinical efficacy in literature that meets the AMA's requirements

Applications for Category III (emerging technology) codes are not required to have FDA approval or clearance, but must meet the following specific criteria:

- The procedure is performed in humans
- Either the application has the support of at least one medical specialty whose members would perform the service or the procedure has supporting peer-reviewed literature in English, or there is at least one IRB-approved protocol of a study, an ongoing U.S.-based clinical trial, or other evidence of evolving clinical use.

New Category III CPT codes are released biannually (January and July) with a six-month delay before activation for implementation.

Resource:
NIH SEED: CPT Codes Presentation
NIH SEED: Reimbursement Workshop

4.2.2 Requesting HCPCS Level II Codes

HCPCS Level II codes are used to identify products, supplies, and services not included in the CPT codes, such as ambulance services and DMEPOS. CMS is responsible for developing and maintaining HCPCS Level II codes.

In many cases, new items and services are adequately described in existing HCPCS Level II codes. However, some new technologies may warrant differentiation through the creation of new codes or revisions to the descriptor of an existing code. This is especially the case in molecular pathology.

Three types of coding revisions to the HCPCS may be requested. They are:

- Add a new code. This could include requests to split an existing code category into its components or into subcategories.
- Change the language used to describe an existing code. A request can be made to change an existing code when a stakeholder believes that the descriptor for the code needs to be revised to provide a better description of the category of products represented by the code.
- Discontinue existing code. When an existing code becomes obsolete or is duplicative of another code, a request can be made to discontinue the code. This could include requests to combine existing codes.

CMS applies the following criteria to determine when there is a demonstrated need for a new or modified code or the need to remove a code:

- When an existing code adequately describes the item in a coding request, no new or modified code is established. An existing code adequately describes an item in a coding request when the existing code describes products with the following:
- Functions similarly to the item in the coding request
- No significant therapeutic distinctions from the item in the coding request
- When an existing code describes products that provide almost the same functionality with only minor distinctions from the item in the coding request, the item in the coding request may be grouped with that code and the code descriptor modified to reflect the distinctions.
- A code is not established for an item that is used only in the inpatient setting or for an item that is not diagnostic or therapeutic in nature.
- A new or modified code is not established for an item that is regulated by FDA, unless FDA allows the item to be marketed. Documentation of FDA approval is required to be submitted with the coding request application.
- Applications for non-drug items that are not regulated by the FDA and not yet available in the U.S. market will be considered incomplete and will not be processed.
- The determination to remove a code is based on CMS' consideration of whether a code is obsolete (e.g., products no longer are used, other more specific codes have been added) or duplicative and no longer useful (e.g., new codes are established that better describe items identified by existing codes).

4.2.3 Requesting New ICD-10 Codes

Proposals for new codes should include a description of the requested code and the rationale for why the new code is needed. Supporting references and literature may also be submitted. Proposals should be consistent with the structure and conventions of the classification system. Requests for an ICD procedure code should include:

- Background information on the procedure
- Patients on whom the procedure is performed

- Outcomes and any complications
- Manner in which the procedure is currently coded
- Discussion of reasons the existing ICD-PCS codes do not adequately capture the procedure
- Recommended options for new or revised code titles

The process for requesting new/revised ICD-10 PCS codes is posted on the CMS website. The ICD Coordination and Maintenance (C&M) Committee considers requests to create new ICD-10-CM and ICD-10-PCS codes or to revise codes for greater utility. The C&M Committee is co-chaired by NCHS and CMS representatives. The Committee's role is advisory, with the Director of NCHS and the Administrator of CMS making all final diagnosis and procedure coding decisions, respectively.

Public meetings are held twice a year, generally in March and September, to discuss proposed revisions. Public comments are encouraged both at the meetings and in writing. Meeting participants are encouraged to ask questions concerning the clinical and coding issues and to offer recommendations. A summary report is posted on the CMS website within approximately one month of the meeting, at which time the public is offered an opportunity to make additional written comments before the end of the comment period imposed by the C&M Committee.

Resource:

CMS: HCPCS General Information

4.3 Stakeholder Engagement and Communications

The stakeholder community for your product will depend on the target patient population and **TPP**. If the product will fulfill an unmet need, patient advocacy groups could be powerful influencers. Other organizations that represent underserved communities or minorities may also have influence on payers.

Certain stakeholders are important because of the roles they play in influencing reimbursement decisions. Physician organizations, medical specialty societies, trade associations representing manufacturers of diagnostics, and trade associations whose members are part of the customer base and supply chain may all be helpful partners. Joining a professional organization, attending healthcare conferences, and practicing a pitch for the diagnostic in front of investors can all help as a reimbursement strategy is developed and implemented. Sometimes engaging federal, state, or local policymakers can help advance the case for the technology.

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