

# From Research to Revenue

Coverage and Reimbursement for Life Sciences Products

## Coverage and Reimbursement Considerations for In Vitro Diagnostics

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In vitro diagnostics (IVDs) present unique issues when it comes to coverage and reimbursement by government or private insurers. Unlike other medical devices, IVDs are often used for prevention or diagnosis, rather than treatment. Specifically, IVDs are used to test or investigate specimens originating from the human body. Some examples of IVDs are an oral swab used to test for the flu, a blood test used to test for HIV, or a pregnancy test. Although IVDs can prevent unnecessary treatment, they can also be used for unnecessary testing or can lead to unnecessary treatment if used inappropriately.

### *Payment for Innovative IVDs*

Historically, the standard for insurance coverage of healthcare items and services has been “reasonable and necessary,” and the standard for reimbursement has been “usual and customary” charges. Both of these standards have long been incorporated into the Medicare program, which is administered by the Centers for Medicare & Medicaid Services (CMS). CMS is the largest payer in the United

States and has become a benchmark for private insurers’ coverage and reimbursement decisions.<sup>1</sup>

“Coverage” refers to the issue of *whether* an insurer will, as a general matter, pay for a particular item or service. When a new item or service becomes available, Medicare does not usually make an explicit decision whether or not to cover it. Rather, Medicare or its contractors may decide whether to cover that item or service on a case-by-case basis, or not decide at all. Where Medicare pays for a bundle of services or items (for example, as part of an inpatient hospital visit), there may not be any need for Medicare to address whether a specific item or service within that bundle is covered—it is covered, as a practical matter, by virtue of being part of the bundle.

“Reimbursement” refers to the *amount* of money an insurer will pay for an item or service. Medicare generally determines the amount it will pay providers or suppliers on the basis of a coding system. A given item or service has a code, and that code is associated with a payment amount. To determine

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whether payers will cover and reimburse for a new technology, IVD manufacturers and suppliers and others seeking to understand the way IVDs are paid for should determine whether the product is generally covered, identify the payment system under which it will be reimbursed, discern the product's code within that system or apply for a new code, and determine the amount paid for that particular code.

### *Medicare Coverage*

In order to be covered by Medicare, a product or service must fall within one of Medicare's statutory benefit categories. The statute provides for coverage of products or services used in diagnosis, but limits such coverage to diagnosis of illness, injury, or malformation.<sup>2</sup> For this reason, Medicare is generally understood to exclude coverage for screening tests unless the law specifies that a particular screening test will be covered. Tests that are specifically covered include: diabetes screening tests, Pap smear tests, and cholesterol tests.<sup>3</sup>

The Affordable Care Act expanded Medicare's authority to cover "additional preventive services" that are (1) reasonable and necessary for the prevention or early detection of an illness or disability; (2) recommended with a grade of A or B by the United States Preventive Services Task Force; and (3) appropriate for Medicare Part A or B beneficiaries.<sup>4</sup> Medicare also began waiving or reducing the coinsurance or a deductible for certain preventive services recommended by the U.S. Preventive Services Task Force.<sup>5</sup> Such preventive services include screening tests that were previously excluded from Medicare coverage.

### *Use Must be Reasonable and Necessary*

Once an IVD has been found to fall into a covered Medicare benefit category, the next determination to be made is whether its use is reasonable and necessary. The first question in this determination is whether it has been the subject of a national cover-

age determination (NCD) or a local coverage determination (LCD). NCDs are issued by CMS and are binding on all Medicare contractors; as a result, they lead to consistent coverage throughout the country. LCDs are made by Medicare contractors and are binding only in the area covered by that contractor, so coverage can vary from region to region.<sup>6</sup> NCDs are publicly posted on the CMS website. All coverage determinations are appealable by the affected beneficiary.

Clinical laboratory tests have a unique history with regard to the NCD process. In 2001, 23 different tests were subject to NCDs, bringing uniformity to coverage of those tests.<sup>7</sup> However, the majority of coverage policy is still made at the local level by Medicare contractors.

Where there may not be sufficient evidence to provide coverage under a conventional NCD, CMS may issue a NCD that includes, "as a condition of payment, the development and capture of additional patient data to supplement standard claims data."<sup>8</sup> A request for supplemental data may mean that typical claims forms do not provide sufficient data to determine that use of the product is appropriate or that coverage is available only in a research setting. In such cases, CMS will set forth the criteria for data collection or clinical studies it will find sufficient to trigger coverage. Such criteria effectively prescribe new data collection or research initiatives.

### *FDA Approval*

Generally, Food and Drug Administration (FDA) approval is required for national Medicare coverage of products. One notable exception relates to IVDs that are considered laboratory developed tests (LDTs). These are tests that are administered at specialized facilities, as opposed to tests that are manufactured and sold to health practitioners or used by patients at home. Medicare coverage of LDTs generally does not depend on FDA approval, as the FDA exercises "enforcement discretion" with regard to these tests.<sup>9</sup> Regardless of whether FDA

approval of a device is required for Medicare coverage, such approval is persuasive evidence of the medical effectiveness and safety of a device, both of which make Medicare coverage more likely.

Another category of devices that do not require FDA approval for Medicare coverage are those subject to an Investigational Device Exemption (IDE) application and determined by FDA to be “Category B” devices, which represents a conclusion by FDA that the device is “non-experimental/investigational.”<sup>10</sup> This exception is particularly relevant to circumstances where Medicare might reimburse for a device, rather than the service resulting from the use of a device. An example is a glucose meter, which Medicare covers in most circumstances.

#### *Medicare Reimbursement*

Once a determination has been made that an IVD is covered, Medicare reimbursement for the device depends on the provider setting, for example, hospital laboratory, physician office laboratory, independent laboratory, dialysis facility laboratory or nursing facility laboratory. Each setting relies on a coding system to identify items or services for which payment is made. An IVD may have its own code, or it may be part of a bundle of items or services that all share a common code, depending on the system.

#### *Outpatient Payments: Clinical Laboratory Fee Schedule*

Laboratory tests performed in an outpatient setting are reimbursed under the Clinical Laboratory Fee Schedule. Laboratories are paid the lesser of the fee schedule amount or their charge. At its inception in 1984, this fee schedule contained 56 different fee schedules for different geographic regions and specified dollar reimbursement rates for various IVDs.<sup>11</sup> The reimbursement rates have been increased periodically to adjust for inflation and vary depending on the location in which the test is performed. The Schedule is updated annually via a process that pro-

vides opportunities for public input, and a developer of a new test should be involved throughout this process to maximize the likelihood that its test is reimbursed appropriately.<sup>12</sup> Around mid-year, CMS publishes on its website a list of codes for which payment amounts will be determined for the coming year. At the same time, it publishes a notice and request for public comment in the Federal Register. CMS then holds a public meeting and receives comments. Based on comments and data from the meeting, CMS publishes a Preliminary Clinical Laboratory Fee Schedule and invites written public comments. The Final Clinical Laboratory Fee Schedule is published with responses to comments near the end of the year. The new reimbursement rates go into effect on January 1 of the following year.

Medicare has two mechanisms by which it incorporates new tests into the fee schedule: “crosswalking” and “gap-filling.” Crosswalking refers to using the reimbursement rate for a test already on the schedule as the basis for reimbursement of a new test. The new test is crosswalked if it is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.<sup>13</sup> The new test is assigned the same reimbursement amount as the existing test and is reimbursed at the lower of the local fee schedule amount or the national limitation amount.<sup>14</sup> If a test is crosswalked to multiple tests, it is reimbursed at the combined rate for the two tests,<sup>15</sup> and if a test is crosswalked to a portion of a test, it receives a portion of that test’s reimbursement rate.

When a new diagnostic test is not “comparable” to any test already on the Clinical Laboratory Fee Schedule, the reimbursement rate for that test is determined by gap-filling. In the first year, each contractor sets the rate, based on charges for the test itself and comparable tests, resources required to perform it, and other payers’ payment rates. After the first year, the median of the contractor-specific rates is set as the national limitation amount and used as the test’s reimbursement rate or, in some circumstances, CMS may use a cross-

walk to reset the payment amount on a national basis.<sup>16</sup>

#### *Inpatient Payments: Prospective Payment System*

In the inpatient setting, CMS makes payments according to a prospective payment system (PPS). Under the PPS CMS estimates the cost of treating a patient with a particular diagnosis, based on previous years' costs of treating patients with that diagnosis. Because prospective payments are based on an estimate of the past average cost of treating a patient with a given diagnosis, the cost of a new test is not likely to be reflected in such payments until its use is widespread enough that it is reflected in that average. To account for this, the Medicare system allows manufacturers to apply for a new technology add-on payment or a new technology pass-through code.<sup>17</sup> Obtaining approval of such applications is difficult, though, because the applicant must show that the technology provides substantial clinical improvement over predecessor technology and meets certain cost thresholds.

In the inpatient hospital context, an inpatient is assigned a Diagnosis-Related Group (DRG) code based on the condition for which he or she is being treated. Medicare pays the hospital a predetermined, fixed amount for each patient, based on DRG code. The payment amount is set by CMS using the average cost of treating a given condition across all patients, based on hospitals' self-reported costs. The cost of any IVDs performed during that patient's course of treatment is considered covered by this payment.<sup>18</sup> Currently, DRG codes are categorized by a system for classifying diseases called ICD-9. However, by 2013, a new ICD-10 system will be implemented.<sup>19</sup> The new system subdivides many of the current DRGs. A single code under ICD-9 may become over a dozen separate, specific codes under ICD-10. Currently, if a patient is reimbursed based on a DRG, Medicare generally pays the same amount regardless of whether certain items or services used in the patient's treatment are individually covered. However, the new level of specificity

under ICD-10 may result in a DRG being defined so narrowly as to exclude the use of certain diagnostic tests that do not logically comport with the DRG.

#### *Coding*

The coding standards relevant to IVDs are mainly the Healthcare Common Procedure Coding System (HCPCS) and a subset of HCPCS called the Current Procedural Terminology (CPT). These are the code systems that can result in a specific payment for an IVD-related service.<sup>20</sup> Outside of these coding systems, it is possible to be paid for tests that are instead billed under a generic "miscellaneous" code, but such reimbursement must be negotiated on an ad hoc basis with individual Medicare contractors, sometimes on a patient-by-patient basis. It can be burdensome to obtain approval through this process and difficult to maintain consistent payment. Where an existing code does not correlate to the desired reimbursement and existing codes are arguably insufficient to describe an item or service, entities usually request a new CPT code or non-CPT HCPCS code.

#### *Applying for New CPT Codes*

Requests for new CPT codes are made to the American Medical Association (AMA). The AMA maintains the CPT, which is used by CMS and private insurers for reimbursement.<sup>21</sup> Requests for new codes or for changes to existing codes are submitted to the AMA's CPT Advisory Committee and Editorial panel, which holds three meetings per year to assign new codes. For clinical laboratory tests, a Pathology Coding Caucus meets before the Editorial Panel and advises the Panel on clinical laboratory coding petitions. The AMA considers the following: whether many health care professionals administer the test, whether the clinical efficacy of the test has been proven, whether it is FDA-approved, and whether it is performed in multiple locations.<sup>22</sup>

A new clinical laboratory test may require a new CPT code for reimbursement purposes, unless it

falls under an existing code. A new code is issued when it is determined that no existing CPT code adequately or accurately describes a new test. In some cases, it may be desirable to argue that a new test should be issued a new code in order to differentiate it from older but similar tests.

The period between approval of a new test and assignment of a new CPT code can create a dilemma for manufacturers. A manufacturer must make the case that a new test is sufficiently different from the tests covered by any existing code to warrant the creation of a new code. However, the manufacturer likely wants providers to be reimbursed for the test using existing codes during the time spent waiting for the AMA to create a new code. A conflict may arise because if a test is dissimilar enough from all existent tests to warrant a new code, then it is too dissimilar for providers to accurately use an existing code to request reimbursement. Manufacturers may have to choose between not requesting a new code for the new test or not suggesting a clear path to reimbursement during the introduction of a product, the very time period that may be critical to the test's acceptance in the marketplace.

#### *Applying for New HCPCS Codes*

Where an existing HCPCS code does not correlate to the desired reimbursement, entities usually request a new code from CMS. The CMS website contains information about the HCPCS coding process, as well as the forms that must be completed when requesting a coding change.<sup>23</sup> In between annual updates to HCPCS, temporary HCPCS codes are available; such temporary codes can be changed, added or deleted on a quarterly basis. In making HCPCS decisions regarding devices or services involving devices, CMS considers the following criteria: FDA approval; whether the code is applicable nationally rather than regionally; whether the item has a different function from any existing code; and whether at least 3 percent of the population uses the item in three months (to justify the administrative burden of a new code). The CMS HCPCS

Workgroup makes decisions regarding the HCPCS coding process. The workgroup issues its final decision in the form of a letter to the applicant. Any reconsideration is usually considered as part of the next year's cycle, although there is a pilot program allowing reconsideration within the year.

Those wishing to understand the world of coverage and reimbursement of IVDs need master a few basic concepts: coverage standards, the Clinical Laboratory Fee Schedule, HCPCS and CPT codes. Though the systems governing IVDs can seem complex and confusing at first, a familiarity with these concepts immensely simplifies the coverage and reimbursement analysis.

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<sup>1</sup> “CMS Roadmaps Overview.” Centers for Medicare & Medicaid Services. Available at: [https://www.cms.gov/QualityInitiativesGenInfo/downloads/RoadmapOverview\\_OEA\\_1-16.pdf](https://www.cms.gov/QualityInitiativesGenInfo/downloads/RoadmapOverview_OEA_1-16.pdf).

<sup>2</sup> 42 U.S.C. § 1395y.

<sup>3</sup> *Id.*

<sup>4</sup> Affordable Care Act, Section 4104.

<sup>5</sup> *Id.*;

[http://www.medicareinteractive.org/page2.php?topic=counselor&page=script&slide\\_id=387](http://www.medicareinteractive.org/page2.php?topic=counselor&page=script&slide_id=387)

<sup>6</sup> “Medicare Coverage Determination Process: Local Coverage Determinations.” Centers for Medicare & Medicaid Services. Available at: [https://www.cms.gov/DeterminationProcess/04\\_LCDs.aspx#TopOfPage](https://www.cms.gov/DeterminationProcess/04_LCDs.aspx#TopOfPage).

<sup>7</sup> “Medicare Coverage – General Information: Lab NCDs.” Centers for Medicare & Medicaid Services. Available at: [https://www.cms.gov/CoverageGenInfo/04\\_LabNCDs.aspx](https://www.cms.gov/CoverageGenInfo/04_LabNCDs.aspx).

<sup>8</sup> “Medicare Coverage – General Information: Coverage with Evidence Development.” Centers for Medicare & Medicaid Services. Available at: [https://www.cms.gov/CoverageGenInfo/03\\_CED.aspx](https://www.cms.gov/CoverageGenInfo/03_CED.aspx)

<sup>9</sup> Recent statements by the FDA, however, have indicated that the exercise of discretion may soon cease and LDTs will be subject to the same approval standards as other medical devices. See FDA Announcement of Public Meeting on LDT Regulation, 75 Fed. Reg. 34463 (June 17, 2010).

<sup>10</sup> “FAQs about IDE.” U.S. Food and Drug Administration. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm>.

<sup>11</sup> “Medicare Laboratory Payment Policy and Patient Access to Technology.” Steinwald, Bruce. U.S. House of Representatives. March 1, 2001.

<sup>12</sup> 42 CFR § 414.506.

<sup>13</sup> 42 CFR § 414.508.

<sup>14</sup> 42 CFR § 414.509.

<sup>15</sup> Many laboratories with complex tests that are themselves comprised of many tests use “code stacking” (or billing multiple codes) to bill for the multiple individual component tests.

<sup>16</sup> 42 CFR § 414.508.

<sup>17</sup> “Acute Inpatient PPS: New Medical Services and New Technologies.” Centers for Medicare & Medicaid Services. Available at: [http://www.cms.gov/AcuteInpatientPPS/08\\_newtech.aspx#TopOfPage](http://www.cms.gov/AcuteInpatientPPS/08_newtech.aspx#TopOfPage).

<sup>18</sup> *See generally:*

<https://www.cms.gov/PropMedicareFeeSvcPmtGen/>.

<sup>19</sup> “ICD-10: Overview.” Centers for Medicare & Medicaid Services. Available at: <http://www.cms.gov/ICD10/>.

<sup>20</sup> Medicare Payment Advisory Commission, Clinical Laboratory Services Payment System (2009), available at

[http://www.medpac.gov/documents/MedPAC\\_briefs\\_Payment\\_Basics\\_09\\_clinical\\_lab.pdf](http://www.medpac.gov/documents/MedPAC_briefs_Payment_Basics_09_clinical_lab.pdf)

<sup>21</sup> *See generally:*

<http://www.cms.gov/MedHCPCSGenInfo/>.

<sup>22</sup> “Applying for CPT Codes.” American Medical Association. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page>.

<sup>23</sup> *See generally* “HCPCS Level II Coding Procedures” Centers for Medicare & Medicaid Services. Available at <http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LevelIICodingProcedures.pdf>.