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Report to Congress on the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration

Final Report

United States Department of Health and Human Services

Centers for Medicare & Medicaid Services

REPORT TO CONGRESS ON THE TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS DEMONSTRATION

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The Evaluation of the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration

Overview

Demonstration Authority

The *Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration* was mandated by Section 3113 of the Affordable Care Act (Pub. L. 111-148) (ACA), under which direct separate payments were made to laboratories performing certain complex laboratory tests billed with a date of service that would, under standard Medicare rules (at 42 C.F.R. section 414.510), be bundled into the payment to the hospital, or critical access hospital (CAH). Payment under the demonstration began January 1, 2012, and was conducted for two years.[1]

Section 3113(a)(2) of ACA defines the term ''complex diagnostic laboratory test'' to mean a diagnostic laboratory test— (A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; (B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; (C) which is billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code under such Coding System; (D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act (the Act); and (E) is described in section 1861(s)(3) of the Act (42 U.S.C.1395x(s)(3)).

Section 3113(a)(3) of ACA defines separate payment as "direct payment to a laboratory (including a hospital-based or independent laboratory) that performs a complex diagnostic laboratory test with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital if the test is performed after such period of hospitalization and if separate payment would not otherwise be made under title XVIII of the [(Act)] by reason of sections 1862(a)(14) and 1866(a)(1)(H)(i)" of the Act. In general terms, these provisions state that no Medicare payment will be made for non-physician services, such as diagnostic laboratory tests, furnished to a hospital or CAH patient unless the tests are furnished by the hospital or CAH, either directly or under arrangement. The date of service (DOS) rule at 42 C.F.R. section 414.510 is used to determine whether a hospital or CAH bills Medicare directly for a clinical diagnostic laboratory test provided by a laboratory (the hospital or CAH then would pay the laboratory if the laboratory provided the test under arrangement) or whether a laboratory bills Medicare directly for a clinical diagnostic laboratory test. Relevantly, Medicare pays the hospital or CAH, and the hospital or CAH, in turn, pays the laboratory (under arrangement) for laboratory tests when a test is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital or CAH.[2] However, under the Demonstration, a laboratory could bill Medicare directly for a certain

[1] Section 3113 mandated a 2-year Demonstration subject to a $100 million limit. This Demonstration was conducted for two years because the $100 million limit was not reached.

[2] CAHs are paid for most inpatient and outpatient services to Medicare patients at 101 percent of reasonable costs. CAHs are not subject to the Inpatient Prospective Payment System (IPPS) or the Hospital Outpatient Prospective Payment System (OPPS). https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CritAccessHospfctsht.pdf

complex clinical laboratory test which was ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital or CAH.

Section 3113(d) of ACA required the Secretary to submit a Report to Congress that includes an assessment of the impact of the Demonstration on access to care, quality of care, health outcomes, and expenditures under title XVIII of the Act (including any savings under such title), and such recommendations as the Secretary determines appropriate. This report fulfills that requirement. The following topics are included in this report.

Summary of the Demonstration

Laboratories could participate in the Demonstration on a claim by claim basis. For tests billed using HCPCS codes other than an NOC code, the Centers for Medicare & Medicaid Services (CMS) developed a Demonstration Test Code List of 36 HCPCS codes that met the Section 3113(a)(2) criteria. These codes and their full descriptions are shown in ***Table 1***. Laboratories could apply for a Demonstration Temporary G-code for tests billed using NOC codes that would otherwise meet the criteria set forth in section 3113(a)(2) by providing supporting information to CMS. CMS published a *Federal Register* notice (CMS-5058-N; 76 FR 39910, July 5, 2011) on July 5, 2011, informing laboratories of the opportunity to participate in the Demonstration. CMS did not receive any applications for Demonstration Temporary G-codes and hence did not issue any G-codes under the Demonstration.

Table 1
Demonstration test code list

HCPCS	Test code description
83890	Molecular isolation or extraction, each nucleic acid type
83891	Isolation or extraction of highly purified nucleic acid, each nucleic acid type
83892	Enzymatic digestion, each enzyme treatment
83893	Dot/slot blot production, each nucleic acid preparation
83894	Separation by gel electrophoresis, each nucleic acid preparation
83896	Nucleic acid probe, each
83897	Nucleic acid transfer, each nucleic acid preparation
83898	Amplification, target, each nucleic acid sequence
83900	Amplification, target, multiplex, first 2 nucleic acid sequences
83901	Amplification, target, multiplex, each additional nucleic acid sequence beyond 2
83902	Reverse transcription
83903	Mutation scanning, by physical properties
83904	Mutation identification by sequencing, single segment
83905	Mutation identification by allele specific transcription, single segment
83906	Mutation identification by allele specific translation, single segment
83907	Lysis of cells prior to nucleic acid extraction

HCPCS	Test code description
83908	Amplification, signal, each nucleic acid sequence
83909	Separation and identification by high resolution technique
83912	Interpretation and report
83913	RNA stabilization
83914	Mutation identification by enzymatic ligation or primer extension, single segment (e.g., oligonucleotide ligation assay, single base chain extension, or allele-specific primer extension)
83950	Oncoprotein; *HER-2/neu*
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP)
86215	Deoxyribonuclease, antibody
86225	Deoxyribonuclease acid (DNA) antibody; native or double stranded
86226	Deoxyribonuclease acid (DNA) antibody; single stranded
86235	Extractable nuclear antigen, antibody to, any method
86294	Immunoassay for tumor antigen, qualitative or semi quantitative
86300	Immunoassay for tumor antigen, quantitative; CA 15-3
86301	Immunoassay for tumor antigen, quantitative; CA 19-9
86304	Immunoassay for tumor antigen, quantitative; CA 125
86305	Human epididymis protein 4 (HE4)
86316	Immunoassay for tumor antigen, other antigen, quantitative; CA 50, 72-4, 549
87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
88371	Protein analysis of tissue by Western Blot, with interpretation and report
88372	Protein analysis of tissue by Western Blot, with interpretation and report; immunological probe for band identification, each

SOURCE: Centers for Medicare & Medicaid Services.

Although some of the HCPCS codes eligible for the Demonstration apply to only one laboratory test[3], many complex laboratory tests are billed using several HCPCS codes that represent different steps or test procedures (known as code stacking)[4]. Some HCPCS codes may be used multiple times to bill for a single test. The 2012 test directory for one large commercial laboratory identified as many as 320 laboratory tests associated with the Demonstration-eligible HCPCS codes.

[3] Example: HCPCS 83950 for oncoprotein; HER-2/neu

[4] Example: cytochrome P450 2C9 genotyping was billed by one laboratory with four HCPCS codes: 83891, 83894, 83898, and 83912.

In total, Demonstration line claims were submitted for 2,686 individual HCPCS codes, 0.02 percent of all claims for the 36 eligible HCPCS codes (Table 1).

Evaluation

Evaluation Design

A quasi-experimental design was developed to address the impact of the payment Demonstration on four research areas: (1) access to care, (2) quality of care, (3) health outcomes, and (4) costs and expenditures. Our original evaluation design could not be implemented, however, given the negligible uptake of the Demonstration. The final design included qualitative analysis to evaluate the reasons behind the lack of participation in the Demonstration and descriptive analysis of claims billed and reimbursed under the Demonstration.

Lack of Participation

On July 5, 2011, CMS published a notice in the **Federal Register**[5] to inform interested parties of an opportunity to participate in the Demonstration. The notice also served to notify interested parties that they must obtain a temporary code from CMS for tests currently billed using a ‘‘not otherwise classified (NOC)’’ code but that would otherwise meet the criteria set forth in section 3113 of ACA for being a complex diagnostic laboratory test under the Demonstration. The deadline for submitting supporting information to request a temporary code under the Demonstration was extended to encourage applications;[6] however, no applications for temporary codes were submitted.

The primary reason test developers/manufacturers reported for not applying for the Demonstration Temporary G-code process was the uncertainty in pricing of tests. Secondary reasons included the uniqueness of certain laboratory tests, the perceived eligibility of products, and issues related to the application process. The evaluation contractor interviewed Medicare Administrative Contractor (MAC) managers who believed that few, if any, laboratories in their regions were participating in the Demonstration project. Only one MAC had received any feedback from a laboratory. The American Medical Association (AMA) eliminated 21 Current Procedural Terminology (CPT) codes and developed new molecular diagnostic codes effective January 1, 2013. The 21 codes had been Demonstration-eligible HCPCS codes, and the new codes were not added to the Demonstration Test List. Therefore, one laboratory that had submitted claims in 2012 complained that it could no longer submit claims using these 21 codes.[7]

[5] 76 FR 39110 through 39111 (July 5, 2011).

[6] 76 FR 49491 (August 10, 2011).

[7] The HCPCS is comprised of Current Procedural Terminology (CPT-4) a numeric coding system maintained by the American Medical Association (AMA). The CPT-4 is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals.

Access to Care

Six research questions were identified to evaluate the effect of the Demonstration on beneficiary and physician access to Demonstration tests (***Figure 1***). A primary goal of the Demonstration was to increase access to tests within 14 days of discharge from a hospital by allowing the independent laboratory to bill for the test rather than bundling payment into the hospital payment. Questions 1 and 5 were critical for assessing whether this occurred. If direct payment to the laboratory performing the test did not increase utilization, there would be little reason to change current payment policies.

Figure 1
Access to care research questions

1. Did utilization for Demonstration-eligible tests rise, fall, or remain the same during the Demonstration?
   a. Did changes in utilization differ by test, practice characteristics, beneficiary characteristics, treatment setting, or MAC?
   b. Were changes in utilization attributable to the Demonstration?
2. Did hospitals change the reference laboratories they use, and if so, why?
   a. Did hospital laboratories conduct more tests in-house?
3. Did laboratories change their marketing to hospitals or physicians as a result of the Demonstration, and if so, how?
4. Did the Demonstration improve independent laboratories' access to specimens collected during a beneficiary's hospitalization?
5. Has the Demonstration improved patients' access to eligible complex tests?
6. What barriers or problems accessing specimens or tests exist?

What was the impact of the Demonstration on beneficiary access to care?

Among the 405 beneficiaries whose complex test claims could be linked to a claim for an inpatient stay with a related diagnosis, 64 percent tests billed by independent laboratories and 52 percent of tests billed by hospital outpatient laboratories were conducted within 14 days of discharge, the period to which the DOS rule normally applies.[8] These findings suggest that the Demonstration provided access, or earlier access, to at least one complex test for 256 beneficiaries.

Quality of Care

The Demonstration had the potential to increase the quality of care for patients through earlier access to tests, which could result in more informed treatment, or by improvements in laboratory performance. Three questions were developed to evaluate the impact of the Demonstration on quality of care (***Figure 2***).

[8] We examined and compared final action, fee-for-service outpatient claims from institutional providers, such as hospital outpatient departments, (referred to hereafter as outpatient claims) and non-institutional providers, such as independent clinical laboratories (referred to hereafter as independent laboratory claims).

Figure 2
Quality of care research questions

1. Did the Demonstration affect turnaround times, error rates, or the need for additional specimens for eligible complex tests?
2. Did the Demonstration affect the number of procedures or surgeries performed as the result of the availability of certain tests?
   a. Were any changes in procedures or surgeries attributable to the Demonstration?
   b. Were there disparities by beneficiary characteristics?
3. Did physicians change the treatment plan for a given disease because of the Demonstration test results?

Question 1 evaluated the impact of the Demonstration on the quality of laboratory services. If the Demonstration increased laboratory payment over that provided under their arrangement with hospitals, laboratories may have been able to improve their services by increasing staff or quality control procedures. The Demonstration could also have affected error rates if test volume increased and laboratories gained experience with the tests.

Questions 2 and 3 focused on the effect of the Demonstration and the presumed increased availability of complex tests on the quality of treatment received by beneficiaries. Demonstration-eligible tests may guide physicians to more effective treatment decisions. For example, a patient who receives a positive HER 2/neu (HCPCS 83950) result will normally receive chemotherapy, since HER 2/neu-positive tumors respond to current chemotherapy agents. If the HER 2/neu test were available within 14 days of discharge, the medical plan could be decided and treatment begun sooner. Earlier diagnosis or treatment of aggressive cancers, such as stomach cancer, could improve quality of care and mortality.

What was the impact of the Demonstration on the quality of care received by beneficiaries?

The most common diagnoses associated with a test billed under the Demonstration were lung cancer (66 beneficiaries), colon cancer (24 beneficiaries), congenital factor VIII disorder (22), and myeloid leukemia (18). Multiple complex tests are recommended for use in the diagnosis or treatment of these disorders. The tests were billed using generic molecular assay codes, so it is not possible to determine whether appropriate tests were conducted for each patient.

Health Outcomes

Improvement in health outcomes was arguably the most important topic for the evaluation. Our research questions for the evaluation of the Demonstration's impact on beneficiary health outcomes are presented in ***Figure 3***.

Figure 3
Health outcomes research questions

1. Overall or by disease subgroup, how was the health status of beneficiaries changed by the Demonstration?
   a. Were the changes attributable to the Demonstration?
   b. Were there disparities by beneficiary characteristics?

The Demonstration included classes of tests, such as genetic tests and gene or protein expression profiles, used for many types of disease, and specific tests that are applicable to a single disease. We planned to examine health outcome measures overall and for commonly ordered tests or common conditions. The design included the following measures when appropriate to the disease or condition: the stage of illness at diagnosis, morbidity, response to treatment, side effects of treatment, mortality, length of survival, and where appropriate, recurrence rates. We also planned to examine morbidity from treatment side effects if data were available.

What was the impact of the Demonstration on the health outcomes of beneficiaries?

Of the 458 beneficiaries who had a test billed under the Demonstration, 152 (33.2%) have since died. This proportion is much higher than that among the 1,476,590 beneficiaries who had a Demonstration-eligible test (tests that met the requirements for being complex diagnostic laboratory tests under the Demonstration but were not billed under the Demonstration) (6.9%). The time between the test and death was on average 24 days shorter for beneficiaries with a test billed under the Demonstration than those with a Demonstration-eligible test. Compared to beneficiaries with a Demonstration-eligible test, beneficiaries with a Demonstration-billed test were older, more likely to be male, and more likely to have a cancer diagnosis. The most common diagnosis among patients with a claim billed under the Demonstration was lung cancer. Mortality between patients with a lab test billed under the Demonstration and those with a Demonstration-eligible test were much closer for these lung cancer patients, 41 and 36 percent, respectively.

Utilization and Expenditures

Medicare paid laboratories directly for tests billed under the Demonstration. These tests were previously paid under arrangement with hospitals, and the laboratory payments under the Demonstration were not offset by a decrease in the payment to the hospital. Thus, CMS expenditures were expected to increase by at least the amount of the Demonstration payments. Medicare expenditures could also have increased if more tests were ordered by physicians. However, a shift in ordering from outside to inside the 14-day window would have affected expenditures only insofar as the payment rate under the CLFS differed from the Demonstration fee schedule. Medicare expenditures could have increased for some tests but decreased for others, depending on changes in utilization patterns across tests. We could have examined only the short-term impact of the Demonstration on Medicare expenditures.

Our research questions for the evaluation of the impact of the Demonstration on health care utilization and expenditures are shown in ***Figure 4***.

Figure 4
Utilization and expenditure research questions

1. Do Medicare expenditures rise, fall, or remain the same under the Demonstration nationally or by type of test, physician practice, or care setting?
   a. By beneficiary characteristics?
   b. Were changes in total Medicare expenditures attributable to the Demonstration?
2. Has the Demonstration influenced what codes were used, how they were stacked, or both when they were submitted to the MACs?
   a. If any, how did this change affect the revenue generation for the laboratories?
   b. Has the number of laboratories that submit these types of tests for payment changed as a result of the Demonstration?
3. Overall, or by disease subgroup, how did the Demonstration affect beneficiaries' health care utilization?
4. Overall, or by disease subgroup, how did the Demonstration affect beneficiaries' out-of-pocket costs?
5. Were there disparities by beneficiary characteristics?

The first question relates to whether Medicare expenditures changed as a result of the Demonstration. The second question relates to Medicare expenditures, but also to laboratory revenues. During the Demonstration, many complex tests (e.g., KRAS test) were billed as a set of HCPCS or test codes for payment by the MAC. With code stacking, one individual test may have more than one test code, and furthermore, any given test code could be billed in multiple units. In addition, different laboratories may stack codes differently for the same tests. Laboratories may shift the codes they use to bill for a test based on which codes were included in the Demonstration. Different laboratories may have conducted and billed for complex tests under the Demonstration than before the Demonstration, which could also affect the billed codes. Any shift in the set or number of codes billed for a test, and the number of tests billed, could affect laboratory revenues.

The third question examined changes in beneficiary utilization as a result of the Demonstration. Although generally beneficiaries have no copayments or deductibles on laboratory tests, the results of the tests may have affected other health care utilization (e.g., more procedures, less need for a physician office visit to extract an additional specimen, change in chemotherapy plan), and total beneficiary out-of-pocket costs.

What was the impact of the Demonstration on the health care utilization of beneficiaries?

A total of 173 Medicare Fee-for-Service (FFS) beneficiaries had a test paid under the Demonstration; many of the claims submitted under the Demonstration had $0 payments. These 173 patients had more than 31,000 subsequent health care claims. Laboratory testing and subsequent hospital visits account for nearly 30 percent of the total HCPCS codes paid by Medicare.

What was the impact of the Demonstration on Medicare FFS and beneficiary expenditures?

After adjudication, 173 beneficiaries had claims paid under the Demonstration, totaling $40,402—$34,997 claims billed by independent laboratories and $5,405 in claims billed as hospital outpatient claims. The claims were all incurred in 2012, which may be related to the

elimination of 21 CPT codes, which were Demonstration-eligible HCPCS codes and the establishment of new molecular diagnostic codes by the AMA effective January 2013. The new codes were not included in the Demonstration Test List, so many previously eligible tests could no longer be billed under the Demonstration. Average Medicare expenditures[9] in 2012 were substantially higher for beneficiaries who had a claim paid by the Demonstration, more than $34,000 for patients with an outpatient claim and more than $44,000 for patients with an independent laboratory claim, compared to less than $10,000 for an average beneficiary, likely reflecting the large proportion of cancer diagnoses among patients with a paid Demonstration claim. Of all expenditures for beneficiaries with a claim paid under the Demonstration, lung cancer represented 30 percent of the Medicare FFS expenditures, hematologic malignancies represented 28 percent, brain cancer represented 14 percent, colon cancer represented 12 percent, and several other cancers represented the remaining diagnoses.

Discussion and Recommendations

The Demonstration was implemented in the midst of multiple known and proposed billing and market changes for molecular diagnostic tests. Within the same time period as the Demonstration design and implementation, Palmetto GBA, a MAC, began the MolDX project under contract with CMS. The MolDX project registers sole-source molecular diagnostic tests and establishes clinical utility expectations and payment amount. The AMA also began reviewing molecular diagnostic Current Procedural Terminology (CPT) codes,[10] developed new codes, and effective January 1, 2013, deleted 21 codes eligible for the Demonstration. The new codes were not included in the Demonstration codes, so many previously eligible tests could no longer be billed under the Demonstration.

The technological and market environment for molecular diagnostic tests was also changing rapidly during the time period with the implementation of new technologies. New testing and sample preparation procedures require less tissue, resulting in more tests being done on specimens obtained during outpatient procedures. The combination of increased uncertainty about the pricing of Temporary Demonstration G-codes and ultimately, pricing of tests under the Clinical Laboratory Fee Schedule, and the increased use of specimens obtained from outpatient biopsies for complex testing may have contributed to the lack of Demonstration uptake for tests billed using HCPCS codes.

Impact of the Demonstration

Given the extremely low participation in the Demonstration, it did not have a significant impact on the care received, health outcomes, or expenditures among the Medicare beneficiary population as a whole. It is possible that the Demonstration allowed more timely access to complex laboratory testing for a few individual beneficiaries. There is no evidence that the Demonstration improved health outcomes or reduced Medicare or beneficiary expenditures for

[9] Overall Medicare expenditures include hospital inpatient, hospital outpatient, physician/supplier, skilled nursing facility, home health, durable medical equipment, and hospice expenditures.

[10] CPT codes are developed, copyrighted, and maintained by the American Medical Association, and are included in the Healthcare Common Procedure Coding System (HCPCS) as Level 1 HCPCS codes.

those beneficiaries who had a test billed under the Demonstration. The small number of beneficiaries, as well as the limited health status and outcome information that was available to us at the time of this report, however, do not allow us to make definitive conclusions.

Demonstration-eligible laboratory tests were associated with a wide variety of diagnoses. Of the 521 laboratory tests billed under the Demonstration, 305 laboratory tests were associated with a cancer diagnosis. Lung and colon cancer were the most common diagnoses, 24% and 9% of diagnoses, respectively. Other diagnoses commonly associated with Demonstration claims were non-malignancy hematologic disorders (10%) and coagulation defects (6%). Oncology is heavily reliant on molecular pathology and complex laboratory tests, so it is unsurprising that many of these tests were for beneficiaries with cancer diagnoses. The concentration of lung and colon cancer may reflect the greater need for inpatient admissions for resection of lung and colon tumors compared to breast cancer. Beneficiaries with Demonstration claims represent only a small fraction of Medicare FFS beneficiaries who had complex tests in 2012. The reasons for billing under the Demonstration for the tests for these few hundred beneficiaries are not clear.

Recommendations and Next Steps

The low participation rates preclude a thorough assessment of the effect of the DOS rule and the Demonstration on Medicare beneficiaries' access to care, the quality of the care received, their health outcomes, or the impact on beneficiary or Medicare expenditures. Therefore, we are unable to make recommendations for Medicare policy in this area.

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