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Evaluation of the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration

Final Report

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FINAL REPORT

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EXECUTIVE SUMMARY

ES.1 Overview

ES.1.1 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

[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

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could bill Medicare directly for a certain 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.

ES.1.2 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 ES-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 ES-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

(continued)

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Table ES-1 (continued)
Demonstration test code list

HCPCS	Test code description
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
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.

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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.

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).

ES.2 Evaluation

ES.2.1 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.

ES.2.2 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

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[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.

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

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

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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]

ES.2.3 Access to Care

Six research questions were identified to evaluate the effect of the Demonstration on beneficiary and physician access to Demonstration tests (***Figure ES.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 ES.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

[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.

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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.

ES.2.4 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 ES.2***).

Figure ES.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

[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).

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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.

ES2.5 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 ES.3***.

Figure ES.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.

ES2.6 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

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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 ES.4***.

Figure ES.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

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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.

ES.3 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.

[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.

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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 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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CHAPTER 1
OVERVIEW OF THE TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS DEMONSTRATION

Clinical laboratory tests are a key component of modern health care. They play a complementary and integral role in quality medical care by helping physicians make diagnosis, prognosis, and treatment decisions. Technological advances have resulted in the development of complex tests that provide new information for decision making in patient care.[11] These tests often require specialized specimen processing or testing procedures and are often only available through external, specialized laboratories.

1.1 Background

The *Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration* was mandated by Section 3113 of the Affordable Care Act (Pub. L. 111-148). This demonstration allowed a separate Medicare FFS payment 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(b)(2)(i)(A)), 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 subject to a $100 million payment limit. The statute requires 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, which was delivered June 2015. This final report goes beyond the Report to Congress to evaluate more broadly the impact of the date-of-service rule on access to complex tests and the impact of complex laboratory testing on the outcomes of interest.

Section 3113(a)(2) 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; and (E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).

Section 3113(a)(3) 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 Social Security Act [(the Act)] by reason of sections 1862(a)(14) and 1866(a)(1)(H)(i)” of the Act. In general terms, the law states 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

[11] *Medicare Laboratory Payment Policy: Now and in the Future*. Institute of Medicine. National Academy Press. 2000. Available at http://www.nap.edu/catalog.php?record_id=9997

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by the hospital or CAH, either directly or under arrangement. Under the date of service (DOS) rule at 42 C.F.R. section 414.510(b)(2)(i)(A), 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.

Under the demonstration project, a laboratory that performs a complex diagnostic laboratory test could bill Medicare directly for a complex clinical laboratory test ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital or CAH. Laboratories choosing to directly bill Medicare under this demonstration could submit a claim with a Project Identifier 56. By submitting a claim with the Section 3113 Demonstration Project Identifier "56," the laboratory could participate in the demonstration on a claim-by-claim basis. Claims billed for this demonstration cannot include non-demonstration services on the same claim/bill. On July 5, 2011, CMS published a notice in the **Federal Register** (76 FR 39110 through 39111) to inform interested parties of an opportunity to participate in the *Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration*.

1.1.1 Demonstration Temporary G-Codes

In designing the demonstration, CMS created a Demonstration Test Code List that is derived from those tests/services that are an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; and that was then currently billed using a HCPCS code other than a NOC code (see Section 1.3). However, as a result of discussions with the laboratory community and analysis of Medicare Part B laboratory claims that were then currently using NOC codes and paid under a local coverage determination, CMS proposed evaluating the potential impact (policy and operational) of assigning temporary G-codes for the diagnostic laboratory tests defined in the law, but currently billed using NOC codes and meeting the other legislative requirements set forth in Section 3113.

For purposes of the demonstration, tests that would meet the criteria for being complex diagnostic laboratory tests, except that they were billed under Medicare using NOC codes and where the current payment rate setting method of gap-filling and cross-walking was not applicable, test manufacturers/developers may have requested a temporary G-code. CMS developed an approach that incorporated the scientific method and clinical utility to assign Demonstration Temporary G-codes for these tests based on the supporting information provided to CMS by the test manufacturer/ developer (**Table 1**).

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Table 1
Matrix: demonstration temporary G-codes assignment

Laboratory test	Diagnosis	Diagnosis: Primary vs. secondary cancer	Prognosis: Risk assessment	Treatment: Response to agent
Analysis of gene protein expression	G-11111	G-21111	G-31111	G-41111
Topographic genotyping	G-11112	G-21112	G-31112	G-41112
A cancer chemotherapy sensitivity assay	G-11113	G-21113	G-31113	G-41113

On July 5, 2011, CMS published a notice in the Federal Register (76 FR 39110 through 39111) to inform interested parties of an opportunity to participate in the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration (Appendix 1-1). The notice also served to notify interested parties that they must obtain a temporary G-code from CMS for tests currently billed using a NOC code but that would otherwise meet the criteria set forth in Section 3113 for being a complex diagnostic laboratory test under the demonstration. To obtain a temporary G-code under the demonstration, the test manufacturer/developer was required to provide supporting information about its test methodology, clinical utility, utilization; the Clinical Laboratory Improvement Amendment (CLIA) certificate number of the laboratories performing the test; current billing practices; and cost and other information (Appendix 1-2). The implementation contractor interviewed several MAC directors to learn about how they price laboratory tests, and what data they thought was useful for pricing tests. Information from these interviews was used to help develop the supporting information form. An open door forum was held to present the Demonstration to the public. Information about the Demonstration was also disseminated through industry publications.[12]

Following the publication of the July 5, 2011 notice, CMS received requests from the public to extend the deadline beyond August 1, 2011. CMS believed they could accommodate the public's request to extend the deadline for submitting the supporting information needed to request a Demonstration Temporary G-code and still begin payment under the demonstration beginning January 1, 2012 as planned. The decision was made to extend the deadline for submitting supporting information required for a temporary G-code under the demonstration. CMS published a second *Federal Register* notice (CMS-5058-N2) on August 10, 2011 extending

[12] CMS Launches ACA's Complex Diagnostic Laboratory Tests Demonstration Program, Announces July 21 Educational Call. ReedSmith, Health Industry Washington Watch. Posted on July 15, 2011, by Debra A. McCurdy.

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the deadline to September 6, 2011. *Note that no applications were received by the extended deadline, and hence CMS never assigned any temporary G-codes under the demonstration.*

1.2 Legislative Mandate

The Medicare Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration is specified in Section 3113 of the ACA as follows:

SEC. 3113. TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS.

1. Demonstration Project

    1. IN GENERAL – The Secretary of Health and Human Services (in this section referred to as the `Secretary') shall conduct a demonstration project under Part B title XVIII of the Social Security Act under which separate payments are made under such Part for complex diagnostic laboratory tests provided to individuals under such Part. Under the demonstration project, the Secretary shall establish appropriate payment rates for such tests.

    2. COVERED COMPLEX DIAGNOSTIC LABORATORY TEST DEFINED – In this section, the term "complex diagnostic laboratory test" means 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 Health Care Procedure Coding System (HCPCS) code other than a not otherwise classified 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; and
        e. is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).

    3. SEPARATE PAYMENT DEFINED – In this section, the term "separate payment" means 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 Social Security Act by reason of sections 1862(a)(14) and 1866(a)(1)(H)(i) of the such Act (42 U.S.C. 1395y(a)(14); 42 U.S.C. 1395cc(a)(1)(H)(i)).

2. Duration – Subject to subsection (c)(2), the Secretary shall conduct the demonstration project under this section for the 2-year period beginning on July 1, 2011.

3. Payments and Limitation – Payments under the demonstration project under this section shall—

    1. be made from the Federal Supplemental Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t); and

    2. may not exceed $100,000,000.

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4. Report – Not later than 2 years after the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project. Such report shall include—

    1. an assessment of the impact of the demonstration project on access to care, quality of care, health outcomes, and expenditures under title XVIII of the Social Security Act (including any savings under such title); and

    2. such recommendations as the Secretary determines appropriate.

5. Implementation Funding – For purposes of administering this section (including preparing and submitting the report under subsection (d)), the Secretary shall provide for the transfer, from the Federal Supplemental Medical Insurance Trust Fund undersection 1841 of the Social Security Act (42 U.S.C. 1395t), to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000.Amounts transferred under the preceding sentence shall remain available until expended.

1.3 Overview of Selected Details of Demonstration Relevant for Payment Options

In this section we provide an overview of selected details of the Medicare *Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration* that were relevant for the evaluation, including:

- Set of test codes whose payment rates were set under the demonstration
- Laboratories eligible for the demonstration
- Demonstration payment rates
- Demonstration time line

1.3.1 Set of Test Codes whose Payment Rates Were Set under the Demonstration

The demonstration established a separate payment amount for complex diagnostic laboratory tests as described in the legislation (see Section 1.2). For the demonstration, CMS created a "Demonstration Test Code List" of 36 test codes that are derived from those tests/services that are an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay and currently billed using a HCPCS code other than a NOC code. **Table 2** shows the final Demonstration Test Code List.

1.3.2 Laboratories Eligible for the Demonstration

The demonstration allowed for direct payments to laboratories that perform a qualified complex diagnostic laboratory test in which the specimen used for the test is collected from an individual while they are a hospital inpatient or outpatient and if the test/service is ordered by the patient's physician less than 14 days following the date of the patient's discharge from the hospital.

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Table 2
Demonstration test code list

HCPCS code	Short description	Test name or number of tests associated with code [1]	2010 Medicare test volume	2010 Medicare charges
83890	Molecule isolate	16	31,007	173,413
83891	Molecule isolate nucleic	308	328,777	1,847,270
83892	Molecular diagnostics	60	572,363	3,257,580
83893	Molecule dot/slot/blot	17	54,285	289,763
83894	Molecule gel electrophor	68	41,865	229,353
83896	Molecular diagnostics	41	1,306,338	7,309,322
83897	Molecule nucleic transfer	4	455	2,565
83898	Molecule nucleic ampli, each	269	1,492,544	23,202,802
83900	Molecule nucleic ampli 2 seq	56	73,597	2,935,683
83901	Molecule nucleic ampli addon	37	382,121	7,881,565
83902	Molecular diagnostics	6	62,691	967,961
83903	Molecule mutation scan	2	369,216	8,668,859
83904	Molecule mutation identify	K-ras Pyrosequencing	1,091,549	14,799,955
83905	Molecule mutation identify	0	638	15,261
83906	Molecule mutation identify	0	16	355
83907	Lyse cells for nucleic ext	13	32,592	620,112
83908	Nucleic acid, signal ampli	0	154,403	3,349,145
83909	Nucleic acid, high resolute	217	1,055,664	14,876,282
83912	Genetic examination	320	308,126	1,989,037
83913	Molecular, RNA stabilization	Prostate Cancer Gene 3 (PCA3)	11,317	200,654

(continued)

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Table 2 (continued)
Complex laboratory Demonstration test code list

HCPCS code	Short description	Test name or number of tests associated with code [1]	2010 Medicare test volume	2010 Medicare charges
83914	Mutation ident ola/sbce/aspe	26	222,759	4,300,744
83950	Oncoprotein, her-2/neu	HER-2/neu, Quantitative, ELISA	259	23,403
83951	Oncoprotein, dcp	2	204	18,296
86215	Deoxyribonuclease, antibody	Anti-DNase B (Streptococcal) Antibodies	1,006	18,819
86225	DNA antibody	7	178,384	3,480,853
86226	DNA antibody, single strand	Anti-DNA (Single-stranded) Antibodies, Quantitative, IgG	4,950	84,917
86235	Nuclear antigen antibody	13	788,816	19,755,495
86294	Immunoassay, tumor, qual	0	593	15,430
86300	Immunoassay, tumor, ca 15-3	5	266,757	7,601,387
86301	Immunoassay, tumor, ca 19-9	5	68,456	1,963,250
86304	Immunoassay, tumor, ca 125	6	131,980	3,781,782
86305	Human epididymis protein	3	2,138	63,070
86316	Immunoassay, tumor other	8	15,613	459,099
87149	DNA/RNA direct probe	4	4,672	128,968
88371	Protein, western blot tissue	0	2	57
88372	Protein analysis w/probe	0	59	1,803

[1] Column three refers to the number of tests or associated tests in the LabCorp Online test directory.

NOTE: Restricted to independent laboratories.

SOURCE: Centers for Medicare & Medicaid Services, LabCorp Online Test Directory; RTI Analysis of 2010 Medicare 100% Part B Physician/Supplier Claims.

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The demonstration allowed for separate payments in these cases for both hospital-based and independent laboratories. Laboratories must also have met all applicable Clinical Laboratory Improvement Amendments (CLIA) and other Medicare program requirements. There was no geographic restriction for participation and all Medicare Administrative Contractors (MACs) could process claims under the demonstration.

1.3.3 Demonstration Payment Rates

The demonstration began on January 1, 2012. The statute limited the demonstration period to no longer than two years or until $100,000,000 in payments had been made under the demonstration, whichever came first. Under the demonstration, there was a single national demonstration fee schedule used to pay for laboratory test codes included in the demonstration and billed using the Demonstration Project Identifier 56. There was no variation in payment rates for a given HCPCS code across localities.

The implementation contractor evaluated options for the Medicare payment for the laboratory services included in the demonstration. The contractor considered various sources to determine a potential payment amount for an individual test code, including but not limited to using the information from all of the sources to triangulate and create a payment rate that incorporates all of the payment information across data sources.

CMS chose the option of setting the allowed charges for each demonstration test code at an amount equal to the median allowed charges across localities (**Table 3**). CMS reasoning was as follows. First, the median rates are not that different from the current rates and adjusted for outliers. Second, the key policy issue under the demonstration is the unbundling of the payment—and since there is a lack of information on what the negotiated payment is between hospitals and laboratories performing tests under arrangement—it was not ideal to set precedent by using the maximum rate.

CMS allowed for temporary G-codes for complex tests billed using NOC codes in exchange for information on cost and other data from laboratories or test developers. For tests assigned a temporary G-code, potential sources of payment information were to include, but were not to be limited to, the current payment under Medicare Part B, payment data, if available, cost data and other information from manufacturers/laboratories submitted to CMS for purposes of this Demonstration. The implementation contractor was to recommend options for payment for these tests to include, but were not limited to, the calculation of mean weighted payment, the calculation of average of publically available list prices, and/or consultation with MAC Medical Directors.

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Table 3
Median allowed charges/payment

HCPCS	Median allowed charges	Median payments	HCPCS	Median allowed charges	Median payments
83890	$5.68	$5.67	83912	$5.71	$5.71
83891	$5.66	$5.65	83913	$19.13	$19.13
83892	$5.70	$5.69	83914	$21.52	$21.42
83893	$5.74	$5.74	83950	$92.26	$92.26
83894	$5.69	$5.67	83951	$92.26	$92.26
83896	$5.67	$5.66	86215	$18.98	$18.98
83897	$5.74	$5.74	86225	$19.61	$19.55
83898	$23.40	$23.30	86226	$17.35	$17.35
83900	$45.66	$45.10	86235	$25.44	$25.27
83901	$21.52	$21.44	86294	$28.10	$28.10
83902	$19.97	$19.84	86300	$29.73	$29.71
83903	$23.87	$23.78	86301	$29.78	$29.76
83904	$23.44	$23.44	86304	$29.74	$29.69
83905	$24.01	$24.01	86305	$29.81	$29.81
83906	$24.01	$24.01	86316	$29.81	$29.75
83907	$19.12	$19.09	87149	$28.72	$28.67
83908	$23.91	$23.91	88371	$28.42	$28.42
83909	$23.12	$23.08	88372	$27.89	$26.85

On November 12, 2010, CMS awarded RTI International a contract to design and implement the 3113 Demonstration[13]; on September 26, 2011, CMS contracted with RTI for the evaluation of the Demonstration, a final evaluation report, and a Report to Congress. The draft Report to Congress was delivered to CMS on May 29, 2015. This, the final evaluation report, includes not only the findings on the Section 3113 Demonstration included in the Report to Congress but broader analyses of the timing of complex tests after inpatient stays, and the impact of the use and timing of complex tests on health outcomes and healthcare quality, utilization, and expenditures.

[13] Kautter, J., Lynch, J., Coomer, N., Berse, B., & Leahy, S. (2015, April). *Design and implementation support for the treatment of certain complex diagnostic laboratory tests demonstration, final report*. Prepared for the Centers for Medicare & Medicaid Services under Contract # HHSM-500-2005-00029I.

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CHAPTER 2
EVALUATION DESIGN AND METHODS

As noted above, fewer than 1 percent of eligible tests were billed under the Demonstration in 2012, and almost no tests were billed under the Demonstration in 2013. Our original evaluation design[14] could not be implemented given the negligible uptake of the Demonstration. This section describes both the design and methods used to evaluate the impact of the Demonstration and those used to conduct a broader evaluation of the relationship between billing policies and the utilization, timing and impact of complex tests. The report includes findings reported in the final Report to Congress as well as findings from the broader evaluation.

2.1 Research Areas and Questions

A quasi-experimental design was originally 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. The low participation in the Demonstration allowed descriptive analyses only of the impact of the Demonstration on the outcomes of interest. In this report, we used quasi-experimental analyses as well as descriptive analyses to examine questions on the impact of the use of complex tests on health outcomes, and healthcare quality, utilization, and expenditures. We focus on six conditions for which complex tests are recommended: breast cancer, lung cancer, ovarian cancer, leukemia, lupus, and heart transplants. We also investigated the reasons laboratories chose to bill or not to bill under the Demonstration.

2.1.1 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 by allowing the independent laboratory to bill for the test rather than bundling payment into the hospital DRG payment. Questions 1 and 5 were critical for assessing whether this occurred. If direct payment to the laboratory performing the test does not increase utilization, there would be little reason to change current payment policies.

Our broader evaluation of the impact of billing policies on access to care examined the factors associated with the receipt and timing of complex tests recommended for each of the six conditions of interest. We examined the characteristics of the beneficiaries, their healthcare providers, and the Medicare Administrative Contractors (MACs) responsible for the state in which the test was conducted and the one in which the beneficiary resided.

[14] Healy, D., Whitehead, N., Kautter, J., Coomer, N., McFarlane, E. G., & Siegel, S. (2012, February). *Evaluation of the Medicare payment demonstration for the treatment of certain complex diagnostic laboratory tests*. Draft Design Report.

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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?
   c. 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?

2.1.2 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***).

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 evaluates the impact of the Demonstration on the quality of laboratory services. If the Demonstration increased laboratory reimbursement 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.

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Questions 2 and 3 focus 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.

The broader evaluation of the impact of billing policies on quality of care examined the impact of receipt of a complex test on the treatment beneficiaries received by patients who did and who did not receive complex tests recommended for their condition of interest. Where the medical record sample size allowed, we also examined whether the characteristics of the beneficiaries affected the impact of complex testing.

2.1.3 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.

Because of low participation, we could only describe the association between receipt of a Demonstration-billed test and mortality. In the broader analysis, we examine and describe the association between the timing and receipt of a complex test with beneficiary mortality, survival, and morbidity overall and for each condition of interest.

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2.1.4 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 were not offset by a decrease in the DRG 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 change 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 are included in the Demonstration. Different laboratories may conduct and bill for complex tests under the Demonstration than before the Demonstration, which could also affect the billed codes. Any shift

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in the set or number of codes billed for a test, and the number of tests billed, could affect laboratory revenues.

The third question examines changes in beneficiary utilization as a result of the Demonstration. Although beneficiaries have no copay on laboratory tests, the results of the tests may change in 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.

The broader evaluation of the impact of the receipt and timing of complex tests examined test utilization and expenditures and total (excepting pharmaceuticals) healthcare utilization and expenditures overall and for each of the six conditions of interest.

2.2 Data Sources and Sample Selection

The evaluation used data from stakeholder interviews, medical record interviews, Medicare and commercial insurer claims, and the Section 3113 demonstration implementation. These analyses informed the stakeholder interview and medical records sample selection, the interpretation of implementation data, and the assessment of the research questions.

2.2.1 Stakeholder Interviews

We conducted stakeholder interviews with test developers, laboratories, and MACs regarding awareness of the Demonstration and the G-code applications process and their decisions regarding participation in the Demonstration. We also interviewed hospital and independent clinical laboratories regarding the impact of billing practices on the conduct and reporting of complex tests and their perception of the impact of such policies on beneficiaries' access to care. We interviewed physicians regarding their experience in ordering and using complex tests and how billing practices affect the timing of ordering the tests.

Test Developers—RTI conducted interviews with representatives from eight companies selected because they perform complex diagnostic tests including analysis of gene protein expression, topographic genotyping, or cancer chemotherapy sensitivity assays and because the company could have applied to receive a *"temporary Demonstration G-Code"* for a complex diagnostic laboratory test that is billed to Medicare using an NOC code. The main objective of the interviews was to understand their concerns about the Demonstration and why the company ultimately decided not to participate. The type and purpose of the tests conducted by the interviewed companies are listed in ***Table 4***.

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Table 4
Test developers interviewed

Laboratory	Tests reported by respondents	Test purpose
Laboratories A, B, D, F, G, H	Gene expression or gene mutation assays in solid tumor tissue collected during resection or biopsy	Diagnose malignancy, cancer type, or cancer subtype; or Predict response to treatment or prognosis for cancer patients
Laboratory C	Gene expression or proteomic assays in serum	Predict response to treatment or prognosis for cancer patients
Laboratory E	Gene expression assays in serum	Risk assessment for obstructive coronary artery disease

Medicare Administrative Contractors—RTI conducted an interview with the medical directors of eight MACs. The participants were selected because they were involved in policy development on local coverage decisions for complex laboratory tests or because they were administrators for regions with many laboratories that conduct complex tests. The focus of this interview was the awareness of the Demonstration by the MACs and the laboratories in their regions, and any feedback the MACs had received regarding the Demonstration.

Hospital and Independent Clinical Laboratories—RTI conducted interviews with hospitals and clinical laboratories to understand their experiences with the ordering of and reimbursement for complex laboratory tests. Interviews were requested from 10 hospitals and four independent clinical laboratories sites.

Hospitals were considered eligible if they met any of the following criteria:

- Patient of the hospital had a test billed under the demonstration as an outpatient or under Part b.
- The hospital laboratory billed tests under the demonstration.
- The hospital was a frequent ordering provider for demonstration-eligible tests that were not billed under the demonstration.

From the eligible hospitals, we selected 10 hospitals based on geographic location, with priority given to hospitals in the states in which we planned to conduct medical records abstraction. We made multiple contact attempts to each selected site. Recruiters attempted to identify contacts at each site through both e-mail and phone. Efforts focused on reaching the operations director of the hospital pathology lab (or the lab that conducts complex diagnostic laboratory tests), a staff person in charge of day to day operations for the hospital pathology lab (or the lab that conducts diagnostic laboratory tests), or a staff person in charge of Medicare billing. Recruiters made a minimum of three and a maximum of eight contacts per site. Three

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sites agreed to participate. These sites included a comprehensive cancer center (site 1), a large independent clinical laboratory (site 2), and two units of an academic medical center (site 3).

The main objectives of the interviews were to:

- Determine if sites were aware of the demonstration and if so, how they heard about it
- Determine reasons for participating or not participating
- Determine what impact the demonstration had or could have had on sites had they known about it

Key information sought from clinical laboratories and hospitals is outlined in ***Table 5*** below. Interviews were conducted by three-person teams, including (1) a health communication team member, (2) a note taker (could be from health communication or other project staff), and (3) a genetic testing expert.

Table 5
Key information sought by site

Group	Group description	Key information sought
Clinical laboratories	Independent CLIA-certified laboratories that conduct clinical tests billed using 1 or more of the 36 HCPC codes eligible to be billed under the demonstration. These are labs whose primary purpose is perform a broad range of clinical tests, including molecular tests.	▪ Awareness of demonstration ▪ Reason for not billing tests under the Demonstration ▪ Effect of date of service rule on laboratory cost and timing of test performance
Hospital pathology directors	Directors of hospital pathology departments responsible for determining hospital policies on ordering and paying for external testing and on performing and billing for tests conducted by the hospital laboratory	▪ Specimen storage polices ▪ Arrangements with external laboratories ▪ Perceived impact of date of service rule on patient access to care and quality of laboratory testing.

Physician Interviews—RTI conducted three in-depth interviews with physicians who ordered complex tests using a structured interview guide (Appendix A) developed to answer the research questions.

The sampling frame was drawn from the abstracted medical records. Once the universe of respondents was identified, we partnered with a recruitment firm specializing in health care provider recruitment to contact and schedule the physicians. Based on market values for 60-

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minute interviews, physicians were offered an incentive of $300. We attempted to contact all of the physicians who ordered a complex tests and for whom we could find contact information. We used both phone calls and emails to recruit physicians. If a physician agreed to participate, a trained RTI staff member conducted the interview via telephone. The interviews were audio-recorded with an RTI staff member simultaneously taking notes as a backup. Each interview lasted approximately 30–45 minutes. Once interviews were completed, we entered the interview notes into an ordered matrix in Microsoft Excel. A trained analyst reviewed the matrix to identify key themes and summarize the findings.

The objective of the physician interviews was to speak with physicians who ordered complex laboratory tests billable under the Demonstration. Specifically, we sought to understand:

- How physicians use complex laboratory test results in making treatment decisions;
- If physicians have had problems with access to complex tests or test quality related to the date of service rule; and
- Physician perceptions of the impact of complex tests on patient outcomes.

Participant characteristics. The three physicians we interviewed ranged in years of practice from 5 to 21. Two were direct employees of a health system, and one was employed by a university medical school. Two were specialists in hematology/oncology and one was a heart failure specialist. A summary of characteristics can be found in ***Table 6***.

Table 6
Physician characteristics

Type of provider, specialty	Years in practice	Employment	Tests commonly ordered
Heart failure specialist, palliative care	5	Health System	AlloMap
Hematology and Oncology	11	Health System	FISH Panel
Hematology and Oncology	21	University	Oncotype DX

2.2.2 Medicare and Commercial Claims

The evaluation team analyzed secondary data from Medicare claims for the years 2010 through 2013 and Truven Health MarketScan® Database for 2011 through 2013. Medicare data sources included the 100% inpatient MedPAR file, the Carrier/Part B Physician/Supplier file and Outpatient file, the Medicare enrollment denominator file, the Medicare hierarchical condition categories (HCC) risk score file, and the Medicare Provider of Service file. Truven Health MarketScan® Database includes voluntarily submitted claims from employer-sponsored health

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insurance plans. These analyses used annual enrollment, facility header, inpatient, outpatient, inpatient services, and enrollment detail files.

2.2.3 Medical Records Abstraction

RTI conducted medical chart abstraction to better understand what complex tests were used in the diagnosis, when the tests were used, and treatment of the six focus conditions. The target sample size was 500 beneficiaries; 250 known to have had received a demonstration-eligible test and 250 with a diagnosis in one of the six focus areas for which no claim for complex testing could be identified.

RTI subcontracted with Telligen, a CMS Quality Improvement Organization, to conduct the medical records abstraction. As a QIO, Telligen is authorized to collect and abstract charts in three states: Colorado, Illinois, and Iowa. A clustered sampling strategy was used: We first identified hospitals that met our eligibility criteria using a list purchased from the American Hospital Association. The hospital eligibility criteria and the reasons for the criteria were the following:

- The hospital had to be in one of the three states for which Telligen was authorized to request records.
- The hospital had to have affiliated oncology services, because four of the conditions were cancers and many of the complex tests of interest are used in cancer diagnosis or treatment.
- The hospital and affiliated oncology service had to have interoperable medical records so that we could obtain information on outpatient and inpatient tests and treatments.

We selected a list of 17 of the largest hospitals as the initial sample, with the goal of recruiting 9 hospitals. A lead letter was mailed to each hospital requesting participation and explaining the purpose of the study and the need for medical records. A telephone discussion was scheduled with each hospital to discuss the required data elements and the process and timeline for providing the medical records. The list of beneficiaries with the diagnoses of interest who were treated at each of the nine recruited hospitals in 2012 and 2013 was obtained from Medicare claims data and their medical charts were requested from the hospital. We requested charts on patient admissions for up to 1 year before or after the index admission. For beneficiaries for whom a demonstration test had been ordered, the index admission was the admission most proximal to the ordering of the demonstration test. For beneficiaries for whom no claim for a demonstration test had been found, the index admission was the first admission within 2012 and 2013 for which the diagnosis of interest was identified.

2.3 Comparison Groups, Analytic Methods, and Power Analysis

The small number of beneficiaries who received a complex test billed under the Demonstration did not allow for comparative statistical analysis. Therefore, the analyses regarding Demonstration-billed tests are descriptive or qualitative. When possible, we present

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similar descriptive analyses for the Medicare population or disease subgroup as a whole to provide context for the Demonstration analyses.

For the broader evaluation, we conducted modeling analyses to examine the relationship between receipt of complex tests, dates of service, and healthcare and beneficiary characteristics to identify factors that predicted the receipt of complex tests or the impact of complex tests on the outcomes of interest. The statistical methodology and power analyses, where relevant, are discussed with the results of the specific analyses. The specific codes used to identify the diagnoses, procedures, and complex tests of interest are presented in Appendix A. Estimating test utilization is challenging because complex tests provided to hospital inpatients or, outside of the Demonstration, within 14 days of discharge, are paid under the hospital DRG, and thus are not identifiable in the Medicare claims data.

Because the Demonstration was nationwide, no Medicare contemporaneous comparison group was available. To approximate the effect that removal of the date-of-service rule may have on the receipt and timing of complex tests, we examined test utilization and timing among individuals enrolled in employer-sponsored insurance plans whose healthcare claims were available through Truven Health MarketScan® Database for 2011 through 2013.

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CHAPTER 3
BARRIERS AND FACILITATORS TO PARTICIPATION

3.1 Awareness of the Demonstration

3.1.1 Test Developers

Overall awareness of the Demonstration varied among the test developer laboratories. Several companies were unaware of the Demonstration, but others were quite aware and involved in its development. Those companies not directly involved in the development of the Demonstration learned about it through trade associations, the *Federal Register*, and the CMS website. Only a few of the companies interviewed reported attending the Open Door Forum; the majority did not.

Only a few companies knew about the *Section 3113 Demonstration: Treatment of Certain Complex Diagnostic Laboratory Tests*. One company knew of the Demonstration as the *"14-day rule demonstration project."* Three companies were very knowledgeable about the project. Of these, one representative knew about it from experience at a previous job and one company reported being actively involved with lobbying to have the DOS rule addressed in the ACA legislation. One company said it did not *"know much"* about the project and another said it was not aware of the project either until the interview or just in the previous few months prior to the interview. Another company knew about the Demonstration, but at the time the Demonstration began, the company was only 2 years old, had few customers, and did not have sufficient number of tests that would have fallen under the 14-day rule because most of its samples came from outpatient clinics.

Representatives from the companies interviewed reported learning about the Demonstration project in a variety of ways. One company (B) was involved in the creation of the Demonstration project. Three others heard about it through a trade association, one (H) through the *Federal Register*, one (A) through phone calls, and one through phone calls, research, and an RTI team member (F).

Respondents were asked where they saw advertising or information about the Demonstration project. Two companies reported seeking information directly from CMS or saw ads on the CMS website. Two other companies found out about the Demonstration from a trade association directly. As one company stated: *"The [trade association] does a good job in sending out information that pertains to labs whenever [there is] a new transmittal or new meeting. Usually those groups are fantastic in making sure information gets to their members. Also the American Clinical Laboratory Association sends out information"* (C). Two companies had not seen any advertisements. One company (F) learned about it from a variety of sources, such as colleagues in the Department of Veterans Affairs and conversations with colleagues.

About half of the companies had sought information about the Demonstration. One company (C) had looked on distribution lists from industry news organizations, one (D) had asked its lawyers about the project, and one company (F) had used "self-guided" research or had talked with colleagues. Three companies said they had not sought out any more information (B, E, F).

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Five companies (A, C, E, F, H) did not attend the Open Door Forum in July 2011. One (B) attended, and one (D) was unsure. The company that attended indicated that the forum was not very helpful because of its timing. The company indicated that it was not expecting a demonstration, so the company's demonstration team was not able to attend.

3.1.2 Hospital, and Clinical Laboratories

We conducted interviews with two hospitals and one clinical laboratory. Because the number of interviews is insufficient for synthesis, we summarize the findings for each individual interview. Two of the sites were aware of the demonstration.

Site 1 is a large, designated comprehensive cancer center with multiple laboratories, including a molecular pathology laboratory. RTI conducted a single group interview with representatives from the Clinical Revenue and Reimbursement Department and the Pathology and Lab Medicine Department (n = 3). The respondents were aware of the Demonstration. They had learned of the demonstration through an electronic mailing.

Site 2 is a large, independent clinical laboratory that provides medical laboratory tests and services using a nationwide network of both specialty testing laboratories and primary clinical laboratories. RTI interviewed the laboratory's government program liaison (n = 1). This laboratory was aware of and participated in the Demonstration.

Site 3 is an academic health system with regional labs, all of which are independently licensed and managed. RTI staff visited two sites and conducted a group interview at each site. The first interview was with lab and billing personnel (n = 5), and the second interview was with billing, coding, and compliance personnel (n = 4).

The health system uses external independent laboratories for some types of tests and when the test volume is too large to handle internally. The hospital lab is the most comprehensive, and as an academically affiliated hospital, it is able to do more of the complex diagnostic tests. Much of the genotype testing is done at external labs. When the health system was consolidated, the decision was made to use an independent national laboratory as the primary reference lab.

None of the individuals interviewed were aware of the Demonstration prior to being contacted about the site visit. They were surprised they had not heard about it because the health system generally tracks these kinds of opportunities by monitoring communications from CMS (e.g., CMS Alert) or they hear about them from the MAC. However, this site undertook a major expansion about 3 years ago. At the time the Demonstration was announced, it was busy rolling out new clinical sites, integrating the EHR, and other tasks. The respondents suggested that they may not have attended to the Demonstration announcement because the organization was focused on major organizational changes. In addition, the respondents felt there may be issues with internal communication in terms of who sees and reviews potential demonstration projects. The individuals who reviews potential opportunities may not have known enough about complex diagnostic testing to understand the advantages of the Demonstration.

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3.2 Participation in Demonstration

3.2.1 Claims

The overall volume of Demonstration line claims submitted for individual HCPCS codes was 2,686, which is 0.02 percent of all submitted claims for the 36 eligible HCPCS codes (***Table 7***). The volume of claims billed under Demonstration modifier 56 for each individual HCPCS codes was less than 1 percent of the total volume of claims for the code; the highest proportion of claims was 0.2 percent for HCPCS code 83907 (lyse cells for nucleic extraction).

Table 7
Total and Demonstration claims by HCPCS code

HCPCS code	2012–2013 total	Demonstration	%	HCPCS code	2012–2013 total	Demonstration	%
Total	10,529,281	2686	0.03				
83890	98,618	40	0.04	83912	890,261	161	0.02
83891	768,840	349	0.05	83913	19,938	6	0.03
83892	256,516	107	0.04	83914	423,701	311	0.07
83893	25,752	0	0.00	83950	1,214	0	0.00
83894	88,125	35	0.04	83951	2,661	0	0.00
83896	634,842	350	0.06	86215	7,534	0	0.00
83897	3,266	0	0.00	86225	723,770	0	0.00
83898	535,485	439	0.08	86226	52,651	0	0.00
83900	339,764	142	0.04	86235	1,236,784	0	0.00
83901	400,283	187	0.05	86294	39,894	0	0.00
83902	82,107	43	0.05	86300	1,409,707	1	<0.01
83903	240,151	0	0.00	86301	491,824	1	<0.01
83904	183,478	65	0.04	86304	883,784	2	<0.01
83905	1,344	0	0.00	86305	14,512	0	0.00
83906	225	0	0.00	86316	149,422	0	0.00
83907	103,884	253	0.24	87149	27,499	0	0.00
83908	220,336	0	0.00	88371	11	0	0.00
83909	170,911	141	0.08	88372	187	0	0

In total, there were 458 beneficiaries for which Demonstration test codes were billed under the Demonstration. This corresponded to a volume of Demonstration test codes billed under the Demonstration of 521, including 53 from hospital outpatient laboratories (outpatient)

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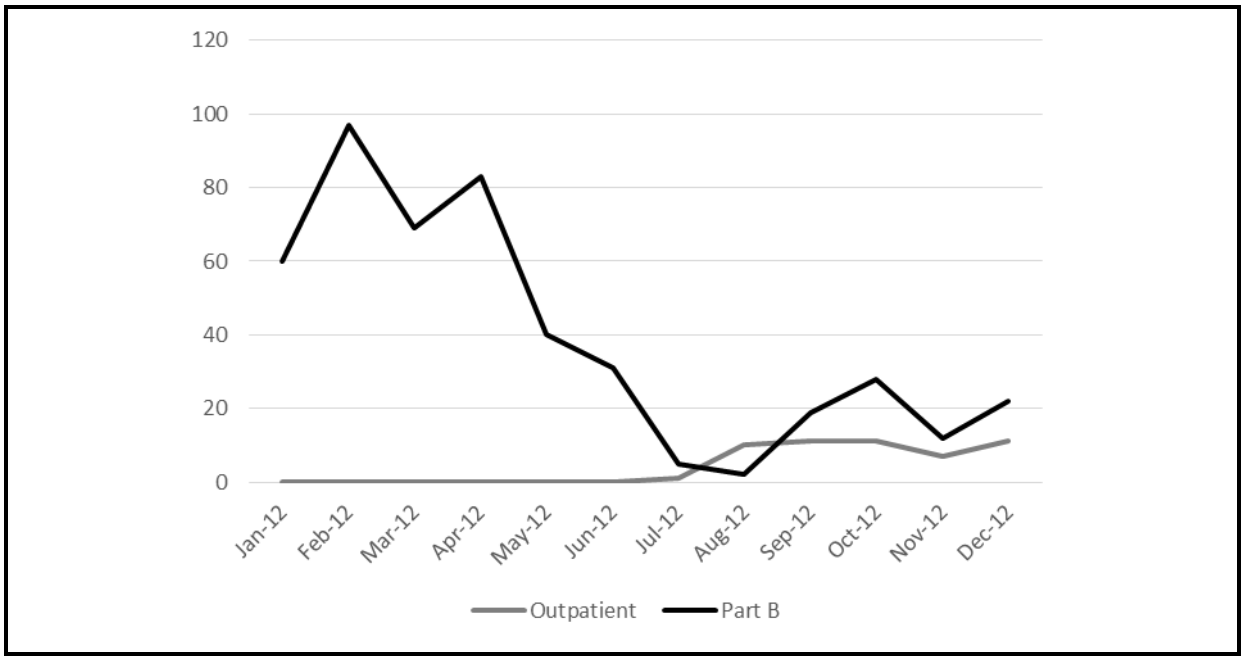
and 468 from independent laboratories (Part B). (Table 7). A single beneficiary had two claims filed in 2013; the remainder of Demonstration claims were filed in 2012. The timing of outpatient and Part B claims filed differed (***Figure 5***). Part B claims filed peaked early in 2012 and declined beginning in May 2012, while no outpatient claims were filed until July 2012. The diagnosis for which the claim was filed also differed by type of claim. Over 80 percent of Part B claims were related to malignant neoplasms (64.7%) or hematologic or lymphatic malignancies (17.1%) while fewer than 1 percent of outpatient claims were related to malignancies (***Table 8***).

Figure 5
2012 Demonstration claims by month



SOURCE: Design and Implementation Support for the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration. Kautter et al. April 2015

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Table 8
Volume of claims by diagnosis and type

Description	Outpatient		Part B		Total	
	N	%	N	%	N	%
Total	53	10.2	468	89.8	521	100.0
Malignant neoplasms	2	0.3	303	58.1	305	58.5
of trachea, bronchus, and lung	0	0.0	124	23.8	124	23.8
of colon	1	0.1	48	9.2	49	9.4
of rectum, rectosigmoid junction, and anus	0	0.0	14	2.7	14	2.7
other primary	1	0.1	59	11.3	60	11.5
Secondary	0	0.0	55	10.6	55	10.6
Screening or history	0	0.0	3	0.6	3	0.6
Hematologic and lymphatic malignancies	0	0.0	80	15.4	80	15.4
Other neoplasms and tumors	1	0.1	32	6.1	33	6.3
Other hematologic disorders	1	0.1	49	9.4	50	9.6
Other disorders or conditions	49	9.4	25	4.8	74	14.2

3.2.2 Lack of G-code Applications

As noted above, CMS did not receive any G-code applications that met the eligibility criteria. The primary reason test developers reported for not applying for the G-code process was the uncertainty in pricing. Secondary reasons included the uniqueness of certain lab tests, the perceived eligibility of products, and issues related to the application process.

Pricing Uncertainty—Seven of the eight companies interviewed indicated that the uncertainty related to pricing was a major factor in deciding not to apply for the G-code. Laboratory B, which conducted a test highly used in clinical practice, was concerned that it may lose the payment rate for the test that had been established with the MAC if the G-code rate was different. Laboratory B felt that the G-code pricing process was not transparent, and it was not sure how the Demonstration would have affected reimbursement. Had it been assured that pricing would not differ to local coverage decisions, it may have considered applying. Other laboratories were concerned about how the Demonstration would ultimately affect the price of their tests, the inability to know the Demonstration payment rate when applying, and the lack of opportunity for negotiating the Demonstration price.

Laboratory C was concerned about the confidentiality of information related to pricing. Further, it was concerned that the application did not require complete information about the true cost of developing the test, which may have skewed the pricing. It perceived that not knowing what the payment rate or even range would be a major hurdle.

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However, two laboratories thought it was possible that their reimbursement rate might have increased by participating in the Demonstration. Laboratory G mentioned that it would have been incentivized to participate if there was a way it could know the positive implications of the Demonstration, such as an increase in patients per year using its test.

Uniqueness of Tests—Two companies thought that the uniqueness of their tests would not be a good fit for the G-code option under the Demonstration. Laboratory C was concerned that the uniqueness of its test would be minimized in the Demonstration, saying, *"Routine hospital lab tests are very different than ours. The impact on the system would have been very different since our patient population is small."* Laboratory C commented that it wished it had the opportunity to have more in-depth discussions about how its test could fit. Laboratory B also felt there was not an appropriate *"bucket"* for its test in the proposed matrix of G-codes, and there was not a set of codes where its test could fit.

Perceived Eligibility—Three companies did not apply because they did not believe their tests were eligible for the Demonstration, either because of timing or the nature of their tests. Laboratory H did not believe that its test was eligible for the Demonstration. Laboratory E said its test is not affected by the DOS rule. Laboratory C's test was not commercially available during the Demonstration period.

Application Process—Respondents also reported issues in the application process that were a hurdle to participation. Two companies (Laboratories B and C) indicated that the application process period was too short to pull the required data. Laboratory A felt that a template that described the structure and process of the Demonstration, particularly related to Food and Drug Administration (FDA)-cleared tests versus FDA noncleared tests, would have been helpful.

Laboratory B also described what it viewed as substantial confusion surrounding the G-code process. It felt that it was not clear if the Demonstration applied to tests without an HCPCS code. In January 2010, it was told by CMS that it did not need to apply for an HCPCS code prior to the Demonstration; if a code was needed, CMS would assign one. Once the Demonstration procedures came out, this company said it was told it could not participate because it did not have an HCPCS code and that the Demonstration was only for the inpatient setting. Laboratory B later learned it would have to apply for the G-code to participate in the Demonstration project.

3.2.3 Demonstration Participation for Eligible HCPCS

The RTI Demonstration Implementation team investigated the low participation during the Demonstration through the MACs, and hospital and independent clinical laboratories.

Medicare Administration Contractors—RTI interviewed management at five MACs about the Demonstration: Novitas Solutions, Cahaba Government Benefit Administrators, Palmetto Government Benefit Administrators, CGS Administrators, and NHIC, Corp. These MACs covered seven contract regions made up of 28 states and Washington, DC. The majority of MAC managers were not very familiar with the Demonstration and believed that few, if any, laboratories in their regions were participating in the Demonstration project. RTI asked the MACs if any laboratories in their region had submitted claims or had problems submitting claims

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under the Demonstration. One MAC had received feedback from a laboratory that submitted claims in 2012 that complained that it could no longer submit claims using the 21 codes that were eliminated in 2013 as part of the American Medical Association (AMA) revision of molecular diagnostic HCPCS codes.

Hospital and Clinical Laboratories—Site 1. Comprehensive Cancer Center. The comprehensive cancer center (Site 1) did not participate in the Demonstration. The decision team read through the provided guidelines and consulted with other cancer centers to determine whether the Demonstration was relevant and of benefit to them. Based on internal and external consultation, they decided not participate. One factor in the decision was logistical considerations related to their Tax Equity and Fiscal Responsibility Act (TEFRA) exemption status.

Respondents noted that the Demonstration added a layer to existing complexities around molecular reimbursement, thus making participation unappealing. Further, they noted that a change in codes made during the timeframe of the Demonstration made participation seem "confusing and overwhelming." When asked if they would have been more likely to participate if the Demonstration had it occurred at another time, they indicated that it was possible but reiterated that the decision would have been based on perceived value to the patient.

They also noted that, although not as critical for a large institution like theirs, delays in reimbursement and low rates of reimbursement from CMS create barriers for participation. The team noted specifically that CMS reimbursement rates do not take into account time and effort contributed by pathologists to provide a fully informed interpretation and recommendation to the medical oncologist. Another concern expressed by the team was delay or denial of reimbursement for perceived duplicative testing. For example, another institution may conduct some initial testing then send the sample to the cancer center for more extensive testing but reimbursement for the latter is often denied (because it is considered duplicative testing). Finally, respondents noted that the administrative complexity of the Demonstration was a barrier to participation. Respondents emphasized the "need to try to make it as administratively simple as possible."

> *"[Our] pathology lab spends lots of time looking at results and correlating with patient history—that's a huge expense that CMS doesn't take into account."*

Site 2: Large Independent Clinical Laboratory. The independent clinical laboratory was aware of the Demonstration. The laboratory decided to participate based on a risk benefit calculation. The calculation revolved around the level of system changes that would be required to participate in the Demonstration versus the backlash from clients over not participating. When considering whether to participate in the Demonstration, the heads of the relevant divisions at the laboratory (Billing & Reimbursement, Legal, Technical Staff) met to discuss the system capabilities that would be required for participation, such as additional information that needs to be captured, off-line billing or workarounds that may be needed, and the financial and human resources that would be needed to implement those changes.

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The laboratory's representative noted the consideration that its competitors may participate in the Demonstration as facilitating the company's decision to take part in the Demonstration. It had clients who were excited about the Demonstration and if LabCorp had not participated in the Demonstration it may have lost those clients to a competitor that did participate. The barriers to participation included

> *"Anytime we participate in a demonstration it does cause inefficiencies. You're not going to make a major system change for a demonstration that is only going to last a short time. … In this competitive market,[the demonstration's impact on market share] is always a consideration."*

- the cumbersome nature of integrating the Demonstration into existing billing systems;
- the packaging of complex tests with other noncomplex tests outside of the Demonstration (i.e., the company had to figure out how to separate regular claims and Demonstration claims for billing purposes); and
- the lack of clarity on the exact changes needed for the Demonstration, which resulted in difficulty communicating billing changes to clients, especially in cases of a claim denial.

Site 3: Academic Health System. Several of the respondents at the academic health system said the Demonstration would have been of potential interest because it would have resulted in higher reimbursement for complex diagnostic tests. They noted that, with billing using the DRG, the laboratory always gets the "short end of the stick."

A key barrier to participation for this site was their experience with a prior CMS demonstration. The health system participated in a previous demonstration and had a negative experience overall. Specifically, the MAC was not familiar with the terms of the demonstration and was not able to provide the necessary support. The site was also not able to get the support it needed directly from CMS.

> "*There wasn't a lot of instruction or guidance provided by CMS. A lot of times we had to contact them [MAC] if we ran into issues, and they didn't really know how to answer our questions."*

A potential barrier to a demonstration like this is the need to make changes in the EHR (e.g., algorithms for billing). The EHR team has many priorities, and it can be difficult to get changes made for purposes of a demonstration.

The site also noted that it would also want to understand the net gain/loss from participation. Specifically, it questioned whether an increase in reimbursement for complex laboratory tests would be counterbalanced by a decrease in DRG reimbursement.

Finally, as a relatively new health system, the site does not feel well positioned to "jump in and take a lot of risks." It would be concerned about the increased workload with a demonstration. For the previous demonstration it had to hire an additional staff member. Changes in billing procedures are time intensive. As one respondent stated, *"If it takes somebody 2–3 hours to be able to bill for that test, it almost becomes not worth it. "*

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Based on their previous experience, the respondents said they would want more information before deciding whether to participate in a demonstration. Specifically, they would want to understand what CMS is trying to achieve and "*How would it truly affect us? How it would truly affect our patients? What's the bottom dollar?"* They would also want to be assured that their MAC is fully informed and able to support their participation. They recommended that CMS involve the MACs in designing interventions to be sure they are feasible.

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CHAPTER 4
IMPACT OF THE DEMONSTRATION ON THE OUTCOMES OF INTEREST

Fewer than 1 percent of eligible complex laboratory tests performed during 2012 and 2013 were billed to the Demonstration (See Table 10). Given the minimal uptake, the Demonstration can have had very little impact on access or quality of care, health outcomes, or health utilization among the Medicare population as a whole. In this chapter, we investigate the outcomes of interest among the beneficiaries who did have a test billed to the Demonstration.

4.1 Access to Care

4.1.1 Stakeholder Perceptions

The laboratories, hospitals, and physicians that we interviewed were almost unanimous in their initial response to our questions regarding the impact of the date-of-service rule on the quality or access of care: At their institution, reimbursement does not determine patients' access to services or the quality of their healthcare.

The comprehensive cancer center (Site 1) respondents indicated that the date-of-service rule would have no bearing on patient access to care and quality of laboratory testing. They noted that decisions about sending samples for testing are driven by clinical expertise (i.e., medical oncologist recommendation) versus other factors. As such, the Demonstration would not have changed patient care. Respondents stated explicitly that decisions about specimen testing are driven solely by clinical (i.e., "patient is first"), not reimbursement, factors. Further, they noted that because they primarily use their in-house laboratory, the current Medicare payment policy regarding the date-of-service rule does not impact internal laboratory cost.

During the Demonstration, the independent clinical laboratory (Site 2) reported that billing was the only change they observed: there were no changes related to specimen integrity, type of tests ordered, or quality assurance performed on the tests. Medical indication remained the primary determinant in what tests are ordered, and all quality assurance monitoring on tests remained the same.

Respondents at the academic health system (Site 3) also did not believe the Demonstration would have impacted the quality of patient care. Physicians order the tests they believe are needed without regard to price or reimbursement rates. If questions are asked about whether a particular very expensive test was needed, this typically occurs *after* the fact. Ideally physicians consult with the pathologists about the value of different tests; however, the respondents were unsure whether this happens routinely. Physicians make decisions about when to order tests "based on the importance of timely results." Conducting some tests quickly is critical for determining the treatment plan and can shorten the hospital stay. For example, bacterial and viral testing can determine whether the patient gets antibiotics, and whether and for how long a hospital stay is required.

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The participants at the academic health system also noted that another factor in physicians' decisionmaking about which tests to order is patient demand. Patients sometimes ask for particular tests based on how doctors explain the tests, the influence of direct-to-consumer advertising, or to what extent patients and families do their own research.

> "A *patient may hear about a certain type of condition and read up about it on the computer and say, 'Yeah, I have that symptom…you need to run this test on me.'"*

Two of the interviewed physicians also initially noted no problems with access to complex tests or quality related to the date-of-service rule. One physician said he routinely takes into account the date-of-service rule and waits 14 days to order Oncotype Dx. This is not necessarily a hospital policy per se, but "*just how we do things*." Oncotype [Genomic Health] uses marketing, website, and ordering procedures to remind providers about the date-of-service rule. Two physicians noted that their health system/hospital waits 14 days after discharge to order tests for all patients regardless of payer type. Although physicians indicated that clinical need is always the primary factor in ordering complex tests, they noted that the cost to patients, particularly if the test was not covered by the insurance provider, was the biggest factor in deciding not to order the test. Two physicians indicated that their care manager always discusses insurance and cost implications with patients before ordering.

The only potential negative impact to patients of participation in the Demonstration, which was mentioned by Site 3, was that patients would receive two bills rather than one, which could cause confusion and frustration. Also, with new procedures implemented as part of a demonstration, billing can get delayed.

4.1.2 Timing of Demonstration Claims

We were able to link the complex tests billed under the Demonstration and an inpatient stay for a related diagnosis for 42 of 53 (79%) beneficiaries with an outpatient Demonstration claim and 363 of 468 beneficiaries (78%) with a Part B Demonstration claim (***Table 9***). Among the beneficiaries whose complex test claim could be linked to a claim for an inpatient stay with a related diagnosis, 64 percent of tests with Part B claims and 52 percent of tests with outpatient claims were conducted within 14 days of discharge, the period to which the DOS rule normally applies.

Table 9
Time between discharge and receipt of Demonstration test by claim type

		Linked to inpatient stay	
	Not linked to inpatient stay	Test performed ≤ 14 days after inpatient discharge	Test performed > 14 days after inpatient discharge
Part B	105	234	129
Outpatient	11	22	20

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4.2 Quality of Care

4.2.1 Stakeholder Perceptions

One of the Demonstration outcomes of interest was its impact on external laboratories' access to specimens collected during an inpatient admission and stored at the hospital where the specimen was collected. The comprehensive cancer center has a dedicated tumor biorepository. As a part of standard processing, a small section of each specimen is immediately frozen and bio banked. Slides are then reviewed by a pathologist in the tissue qualification laboratory to ensure that the correct tissue (i.e., tumor vs. normal) has been extracted. The center conducts the vast majority of tissue and blood specimen testing internally. All germ line testing is done externally, primarily under an umbrella contract with another medical facility. In some cases, other vendors are used at the specific request of a patient. Hereditary cancers testing is conducted externally because of the high level of expertise required; however, the center is building the capacity to handle this testing internally. In cases where a specimen is released to an external facility for testing, the center typically sends slides but keeps the tissue block in the repository for future testing or other patient needs.

The cancer center also provides testing services for external facilities. The respondents indicated that they experience delays in getting tissue blocks or slides from external facilities when they request them. Before performing surgery, they prefer to compare the original tissue collected to the current tissue to determine any changes in the tumor characteristics. They try to delay surgery until they have the original tissue, but may have to go ahead. The respondents did not feel the external hospital was reluctant to share the tissue, however. They felt the external facilities were overwhelmed with the number of requests for slides.

Specimen storage was less of an issue for the laboratory staff we interviewed at the academic medical center (Site 3). The laboratory at the smaller site unit does not have a biorepository. It does keep specimens for infection control purposes for 2 years. The pathology department holds specimens for much longer periods of time. The independent clinical laboratory observed no changes in specimen integrity or types of tests ordered during the Demonstration. Their quality assurance monitoring procedures remained the same.

The interviewed physicians indicated that complex tests are becoming more of the standard of care for treating their patients and less about experimental testing. In general, the complex tests allow physicians to better assess risk in their patients. For example, AlloMap is used to assess risk of rejection for heart transplant patients; the FISH panel for myelodysplastic syndromes (MDS) is used to assess whether a patient has gene mutations; and Oncotype tests are used to predict local recurrence of breast cancer and benefits of chemotherapy.

The physicians perceived the type of complex test to be a major factor in whether the date-of-service rule would impact patient outcomes. For example, AlloMap, which is used for monitoring heart transplant patients for signs of rejection, is not ordered until several months after the transplant procedure so is almost always on an outpatient basis. Consequently, the date of service rule does not have an impact. However, the oncologists felt the Oncotype Dx test needs to be performed close to the time of surgery.

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"Most of the other ones get done in house, they don't seem to care. There is not the same timing consideration. Oncotype/Breast is a good example because you want that done near their surgery. Other tests you can argue you need them later. For lung cancer, you can test that later. Some tests are supposed to be done 5 years after your surgery. Sometimes it can be a day or two delay because there are so many steps to the test. In most cases we say come back in two weeks because we will be pretty sure we will have the test back by then."

One of the oncologists noted that it would improve patient care to be able to order tests earlier as it slows down decision making about treatment and creates anxiety for patients. However, he noted the date of service rule is just one of many potential causes for delays in care.

4.2.2 Diagnoses Associated with Complex Tests

Eighteen of the 22 beneficiaries who had a Demonstration test billed as an outpatient claim within 14 days of discharge had a generic diagnosis of other abnormal clinical findings (ICD9 code 796). The other four cases included one beneficiary with each of the following diagnoses: polyarteritis nodosa, streptococcal septicemia, malignant neoplasm of the colon, and neutropenia. Polyarteritis nodosa is a disease of the blood vessels in which the small and medium arteries become swollen and damaged. Although testing for antinuclear antibodies (Demonstration-eligible HCPCS code 86235) is used in this condition to rule out systemic lupus erythematosus (http://www.nlm.nih.gov/medlineplus/ency/article/001438.htm), the test billed under the Demonstration was a quantitative assay for cancer antigen 19-9 (HCPCS code 86301). The tests associated with the other diagnoses were billed using code stacks, making it difficult to identify what test was ordered.

Among beneficiaries who had a Demonstration test billed as a Part B claim within 14 days of discharge, the most common diagnoses associated with the test were lung cancer (66 beneficiaries), colon cancer (24 beneficiaries), congenital factor VIII disorder (22), and myeloid leukemia (18). These tests were all billed using generic molecular assay codes, so it is not possible to determine what test was conducted.

4.3 Health Outcomes

Of the 458 beneficiaries who had a test billed under the Demonstration in 2012, 152 (33.2%) had died by the end of 2013. This proportion is much higher than the average among the 1,476,590 beneficiaries who had a Demonstration-eligible test (but not billed under the Demonstration) in 2012 (6.9%). In addition, the time between the test and death was on average 24 days shorter for beneficiaries with a test billed under the Demonstration. The most likely explanation for this difference is that it reflects differences in the diagnoses and characteristics of the beneficiaries who had a test billed under the Demonstration. 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 (***Table 10***). There were no racial differences between the groups. 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

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patients, 41 and 36 percent, respectively. Providers may also have ordered tests for very sick patients earlier than usual, and those tests were preferentially billed under the Demonstration.

Table 10
Characteristics of all and deceased beneficiaries with Demonstration-eligible and Demonstration-billed tests

	All					Deceased				
	Demonstration eligible		Demonstration billed			Demonstration eligible		Demonstration billed		
	N	%	N	%	p-value	N	%	N	%	p-value
Total	1,476,133	100	457	100	—	101,504	7	152	33	< 0.01
Male	414,326	28	220	48	<0.01	38,019	37	85	56	<0.01
Mean Age	69.6	—	71.8	—	<0.01	74.0	—	73.8	—	0.81
Mean Days between Test and Death	—	—	—	—	—	138.3	—	114.7	—	0.01
Cancer Diagnosis	517,967	35	393	86		74,654	14	135	34	

4.4 Health Care Utilization

The vast majority of claims submitted under the Demonstration were associated with a cancer diagnosis. This diagnosis is reflected in subsequent health care use among the 173 beneficiaries who had a claim reimbursed under the Demonstration (***Table 11***).

Table 11
Health care use in 2012 among beneficiaries with a Demonstration-reimbursed laboratory test

Type of health care use	Number of claims	Percent of total claims
Laboratory Tests	9,379	29.6
Imaging	3,878	12.3
Hospital Stay	3,923	12.4
Oncology Treatment	2,168	6.8
Other	12,303	38.9
Total	31,651	100.0

Source: LabEval_jl02_prog1_Freq.xlsx

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4.5 Medicare and Beneficiary Expenditures

After adjudication, 173 beneficiaries had claims reimbursed under the Demonstration, totaling $40,403—$34,997 claims billed under Part B and $5,405 claims billed as outpatient claims. The claims were all incurred in 2012, not surprising given the elimination of 21 of the Demonstration-eligible HCPCS codes in January 2013. Of the $100,000,000 allocated for payments under the Demonstration, $99,959,597 was left untouched at the Demonstration's end.

Table 12
Total Demonstration reimbursements

		Cumulative demo (1/12–12/13)		
HCPCS	Label	Outpatient	Part B	Total
Total	—	$5,405	$34,997	$40,403
83890	Molecule isolate	—	68	68
83891	Molecule isolate nucleic	277	872	1,149
83892	Molecular diagnostics	11	656	667
83893	Molecule dot/slot/blot	—	—	—
83894	Molecule gel electrophor	85	38	123
83896	Molecular diagnostics	34	3,610	3,644
83897	Molecule nucleic transfer	—	—	—
83898	Molecule nucleic ampli, each	515	4,844	5,358
83900	Molecule nucleic ampli 2 seq	1,689	2,648	4,338
83901	Molecule nucleic ampli addon	689	7,338	8,027
83902	Molecular diagnostics	120	799	919
83903	Molecule mutation scan	—	—	—
83904	Molecule mutation identify	375	1,374	1,749
83905	Molecule mutation identify	—	—	—
83906	Molecule mutation identify	—	—	—
83907	Lyse cells for nucleic ext	707	1,504	2,212
83908	Nucleic acid, signal ampli	0	—	—
83909	Nucleic acid, high resolute	786	2,243	3,029
83912	Genetic examination	—	131	131
83913	Molecular, RNA stabilization	—	115	115
83914	Mutation ident ola/sbce/aspe	86	8,759	8,845

(continued)

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Table 12 (continued)
Total Demonstration reimbursements

HCPCS	Label	Cumulative demo (1/12–12/13) Outpatient	Part B	Total
83950	Oncoprotein, her-2/neu	—	—	—
83951	Oncoprotein, dcp	—	—	—
86215	Deoxyribonuclease, antibody	—	—	—
86225	DNA antibody	—	—	—
86226	DNA antibody, single strand	—	—	—
86235	Nuclear antigen antibody	—	—	—
86294	Immunoassay, tumor, qual	—	—	—
86300	Immunoassay, tumor, ca 15-3	29.73	—	30
86301	Immunoassay, tumor, ca 19-9	—	—	—
86304	Immunoassay, tumor, ca 125	—	—	—
86305	Human epididymis protein 4	—	—	—
86316	Immunoassay, tumor other	—	—	—
87149	DNA/RNA direct probe	—	—	—
88371	Protein, western blot tissue	—	—	—
88372	Protein analysis w/probe	—	—	—

Overall, average Medicare expenditures in 2012 were substantially higher for beneficiaries who had a claim reimbursed by the Demonstration, more than $34,000 for patients with an hospital outpatient laboratory demonstration-billed claim and more than $44,000 for patients with an independent laboratory demonstration-billed claim, compared to less than $10,000 for an average Medicare FFS beneficiary (***Table 13***). This most likely reflects the fact that the large majority of these patients had cancer. Of all expenditures for beneficiaries with a claim reimbursed by the Demonstration, lung cancer represented 30 percent of the expenditures, hematologic malignancies represented 28 percent, brain cancer represented 14 percent, colon cancer represented 12 percent, and several other cancers represented the remaining diagnoses.

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Table 13
Average expenditure per beneficiary

		Beneficiaries in Demonstration	
	All beneficiaries	Outpatient	Part B
Part B, Including Laboratory	$2,743	$15,521	$14,881
Hospital Outpatient	$1,369	$8,778	$8,165
Durable Medical Equipment	$284	$970	$885
Skilled Nursing Facility	$792	$1,023	$1,237
Home Health	$599	$922	$1,442
Hospice		$205	$298
Inpatient	$3,671	$4,962	$6,750
Total	$9,458	$34,302	$44,779

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CHAPTER 5
UTILIZATION OF COMPLEX TESTS AND THEIR IMPACT ON THE OUTCOMES OF INTEREST

5.1 Introduction

This chapter begins our broader examination of the utilization of complex tests among Medicare beneficiaries and the impact of such tests on beneficiaries' access to health, quality of care, health outcomes, and expenditures. In this chapter, we examine these issues among all Medicare beneficiaries, regardless of diagnosis.

5.2 Methods

5.2.1 Claims Data Analyses

In 2011, the American Medical Association issued new billing codes for molecular pathology tests. The codes were divided into two tiers. Tier 1 consisted of codes for tests of specific genes, meant to be the only code for the test and to be billed once per ordered test. The Tier 2 codes reflected specific molecular pathology methodologies and were meant to be used for new tests and tests not included in the Tier 1 codes. In the analysis of Medicare claims data, we defined complex tests as those billed using the 36 Demonstration test codes (see Chapter 2, Table 1), the Tier 1 gene-specific test codes and Tier 2 molecular pathology methodology codes adopted by Medicare in 2013 (see Appendix C, Table C.3), and 5 tests billed using NOC codes (see section 6.3.5.3). For MarketScan claims, we included these codes plus the S-codes used by private insurers for high volume, high-priced tests. The full list of codes is provided in Appendix B. In comparisons of Medicare and MarketScan claims, the MarketScan population was limited to beneficiaries aged 55 to 64 years to increase the comparability of the populations.

5.3 Access to Care

Between 1.3 and 1.5 million Medicare beneficiaries, 3% to 4% of the Medicare population, received one or more complex tests each year between 2010 and 2013 (***Table 14***). Medicare beneficiaries are approximately 40% more likely to receive a complex test than private-payer beneficiaries age 55 to 64.

Of the 258 Medicare beneficiaries for whom we abstracted medical records, 140 (54%) had received at least one complex test. The most common tests are shown in ***Table 15***. These tests are used in the diagnosis and monitoring of autoimmune disease or cancer, reflecting the conditions chosen for abstraction. Detailed findings from the medical records abstraction will be presented in the results for each condition of interest.

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Table 14
Medicare and MarketScan beneficiaries who received at least one complex test, 2010–2013

	Total Medicare beneficiaries	Medicare beneficiaries who received a complex test		Total private payer beneficiaries	Private payer beneficiaries who received a complex test[1]		
Year	Number	Number	Percent	Number	Number	Percent	p-value
2010	33,041,639	1,320,576	4.0		*		
2011	33,737,525	1,406,747	4.2	7,926,325	419,545	2.9	<0.001
2012	34,088,764	1,476,216	4.3	8,052,222	535,057	3.0	<0.001
2013	34,264,225	1,509,896	2.9	6,795,416	426,821	2.1	<0.001

[1] May not include all private payer claims; reporting is voluntary.

Table 15
Complex tests received by more than 5% of beneficiaries with abstracted medical records

	Beneficiaries	
Test	Number	Percent
Antibodies to double-stranded DNA. Used in the evaluation of autoimmune disease.	29	11.2
Fluorescent in situ hybridization. Method for identifying the number of copies of a specific sequence of DNA.	21	8.1
Antibodies to nucleus. Used in the evaluation of autoimmune disease.	19	7.4
Karyotyping. Visual assessment of chromosome number and structure. Primary use in Medicare population is cancer diagnosis, evaluation of prognosis, and monitoring response to treatment.	16	6.2
Cancer antigens 15.3 and 27.29. Used to monitor response to treatment and recurrence.	16	6.2
Antibodies to Ro-bound RNA. Used in the evaluation of autoimmune disease.	15	5.8
Antibodies to La-bound RNA. Used in the evaluation of autoimmune disease.	14	5.4

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5.4 Quality of Care

We will assess the relationship of complex testing and quality of care in the chapters focused on specific conditions.

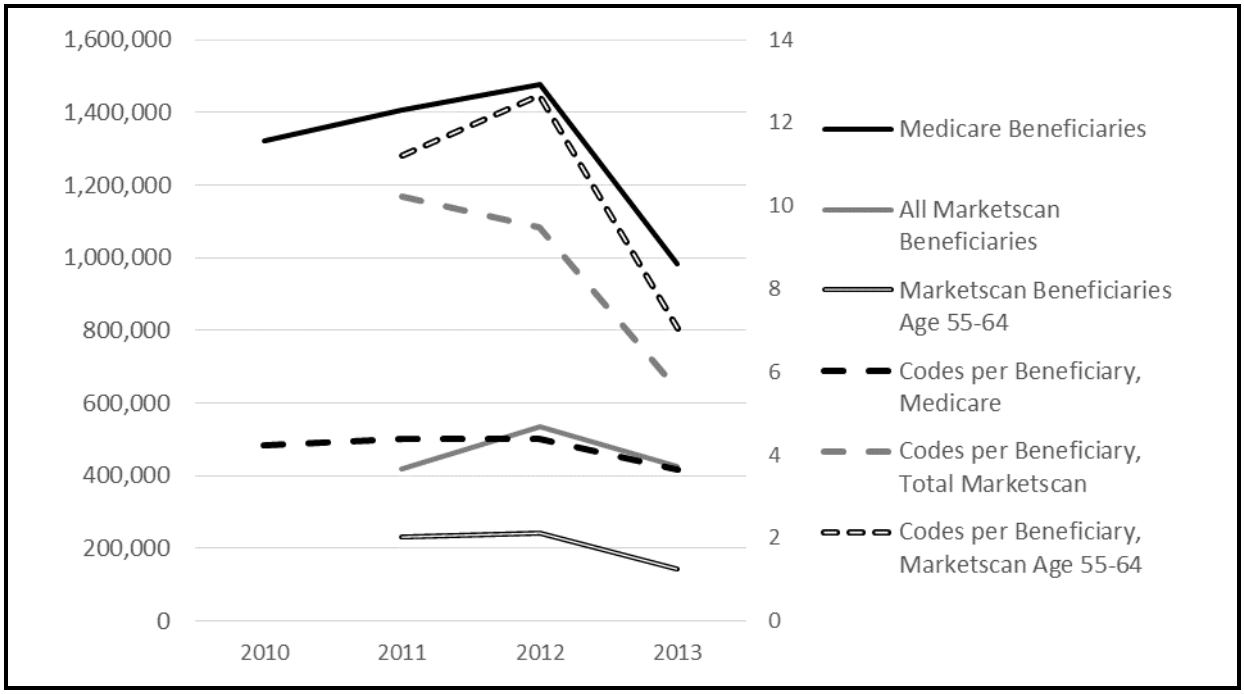
5.5 Health Outcomes

Among the 258 beneficiaries with abstracted medical records data, 69% of those who had received a complex test were alive, compared to 59% of those who had not (p-value = 0.052). More in-depth analyses of the relationship between complex tests and health outcomes are presented in the following chapters on specific conditions.

5.6 Health Care Utilization and Expenditures

The total number of codes billed to Medicare increased each year from 2010 to 2012, then decreased sharply in 2013. The number of codes billed to commercial payers also increased from 2011 to 2012, and decreased in 2013, both for all beneficiaries and for beneficiaries age 55 to 64 (***Figure 6***, ***Table 16***). The overall utilization and expenditures for each type of code (Demonstration, Tier 1/2, NOC) are presented in Table 16.

Figure 6
Total codes billed in Medicare and private insurance, 2010–2013



The decrease in the overall number of codes between 2012 and 2013 correlates with the introduction of the new Tier 1 and Tier 2 codes, which were adopted by private payers at various times during 2012 and by Medicare on January 1, 2013. At the same time, a number of original

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Table 16
Complex tests utilization and expenditures among Medicare beneficiaries and privately insured beneficiaries [1]

	Demonstration		New		Not otherwise classified codes		Total	
Year	Medicare	MarketScan	Medicare	MarketScan	Medicare	MarketScan	Medicare	MarketScan
Codes								
2010	5,446,471	*	—	*	148,772	*	5,595,243	*
2011	5,997,755	4,144,484	—	—	179,925	149,600	6,177,680	4,294,084
2012	6,258,884	4,833,921	—	78,322	211,200	166,365	6,470,084	5,078,608
2013	1,598,329	1,071,070	1,832,279	1,067,060	516,905	231,283	3,580,708	2,369,413
Patients								
2010	1,320,576	*	—	*	—	*	1,320,576	*
2011	1,406,747	419,545	—	—	—	—	1,406,747	419,545
2012	1,476,216	487,710	—	47,347	—	—	1,476,216	535,057
2013	982,492	4,436	527,404	422,385	—	—	1,509,896	426,821
Payments								
2010	194,206,484	*	—	*	54,809,680	*	249,016,164	*
2011	239,962,383	275,917,760	—	—	70,679,936	110,548,667	310,642,318	386,466,427
2012	404,897,012	372,707,868	—	78,986,283	84,184,585	69,070,165	489,081,596	520,764,316
2013	76,903,528	48,320,196	256,242,345	381,436,408	114,891,522	93,741,382	448,037,395	523,497,986

* Data not available for analysis
— = not available.

[1] May not include all private payer claims; reporting is voluntary.

methodology-based codes were eliminated. Because Tier 1 codes are gene-specific, only one code is used per test, eliminating code stacking and reducing the average number of codes per patient. Although the number of codes billed per Medicare beneficiary decreased significantly in 2013 ($p < 0.0001$), the decrease was less than 1 code per patient (Figure 6). In contrast the number of codes billed per private insurer beneficiary declined 3.9 codes per patient for all beneficiaries and 5.6 codes for beneficiaries age 55 to 64.

5.6.1 Demonstration-eligible HCPCS Codes

The most frequently billed methodology-based Demonstration code in both Medicare and MarketScan was 83912, Genetic examination (or Molecular diagnostics, interpretation and report), which was found in 526,148 Medicare claims in 2010, in 627,867 claims in 2011, and in 782,015 claims in 2012. This code was used once per test to bill for pathologists' services with many tests billed with stacking codes. The number of Medicare claims with this code increased from 2011 to 2012 by 24.6%, and the number of private payer claims in MarketScan increased by 18.7%. The frequencies of individual 36 Demonstration test codes and patients who had claims with these codes between 2011 and 2013 in the Medicare and MarketScan files are summarized in Appendix C, Tables C.1 and C.2, respectively.

Several of the 36 Demonstration codes were analyte-specific (i.e., they indicated what markers were tested). Of these, the most frequently billed codes were the following:

- immunoassay for the cancer antigen CA 15-3 (86300), used to monitor breast cancer patients and most frequently associated with a line diagnosis of breast cancer;

- assays for nuclear antigen antibody (86235) and anti-DNA antibody (86225), used in the diagnosis of systemic lupus erythematosus (SLE) and other autoimmune diseases, and most frequently associated with a line diagnosis of rheumatoid arthritis, other joint disorders, and SLE; and

- immunoassay for the cancer antigen CA 125 (86304), used in the diagnosis and management of ovarian and other female genital cancers, and most frequently associated with a line diagnosis of ovarian and uterine cancer.

The most frequently billed analyte-specific code in MarketScan was 86235, nuclear antigen antibody for SLE, reflecting the fact that this condition is commonly diagnosed between age 15 and 45 (Estes & Christian, 1971). Assays for CA 15-3 and CA 125 were billed less frequently in MarketScan, consistent with the younger age, and therefore, lower prevalence of breast cancer in this population.

5.6.2 Tier 1 and Tier 2 Molecular Pathology Codes

In 2013, Medicare was billed for 1,832,279 Tier1 or Tier2 codes for 527,404 Medicare beneficiaries (3.5 codes per beneficiary), compared to 1,067,060 codes for 422,385 patients in MarketScan (2.5 codes per beneficiary) (***Tables 17*** and ***18***). There were 1,558,071 Tier 1 (gene-specific) codes billed in Medicare in 2013 (***Table 17***), compared to 900,013 Tier 1 codes in MarketScan (***Table 18***). The Tier 1 gene-specific codes most frequently billed to Medicare were

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CYP (28.3%) Factor 5 (11.2%), Factor 2 (10.6%), and MTHFR (10.0%). Nine tests (***Table 18***) accounted for 89% of Tier 1 tests billed to Medicare, and 91% of Medicare payments for Tier 1 tests, in 2013. Four of these nine tests (Factor 5, Factor 2, MTHFR, and VKORC1), and a CYP gene (CYP2C9) are used in the diagnosis, treatment, or monitoring of venous thrombosis or other cardiovascular disease. The remaining four gene-specific tests (BCR-ABL1, HLA, BRCA1/BRCA2, and JAK2) are used in the diagnosis, treatment, or monitoring of one or more forms of cancer.

Table 17
Most utilized tier 1 billing codes among Medicare beneficiaries in 2013

		2013				
		Tests			Payments	
HCPCS	Gene/Test	Number	Percent	Beneficiaries	Amount	Percent
Total		1,558,071	100.0	527,404	249,525,679	100.0
81225–81227	CYP (germ line mutations in cytochrome genes). Used to determine rate at which drugs are metabolized and recommend for or against specific drugs or for dosing guidance. Example drug types: antidepressants, warfarin.	519,340	28.3	468,494	117,845,531	46.0
81241	Factor 5 (germ line mutations in Factor 5 (Leiden)). Used to identify patients at increased risk of venous thrombosis. Oral contraception is contraindicated for individuals with 1691 G > A mutation. Weaker risk factor for arterial thrombosis and pregnancy complications.	205,082	11.2	190,142	13,187,524	5.1
81240	Factor 2 (germ line mutations in prothrombin). Used to identify patients at increased risk of venous thrombosis. Weaker risk factor for arterial thrombosis.	193,436	10.6	178,282	7,633,652	3.0
81291	MTHFR (germ line mutations in methylenetetrahydrofolate reductase). May be ordered as follow-up to elevated blood homocysteine or with other cardiovascular risk markers.	182,358	10.0	170,781	12,414,445	4.8
81355	VKORC1 (germ line mutations in vitamin K epoxide reductase. Used to determine appropriate dose for the anticoagulant warfarin).	91,859	5.0	82,966	4,188,876	1.6
81206–81208	BCR-ABL1 translocation (somatic alteration in blood cancers). Used in diagnosis of certain types of leukemia and to monitor response to treatment.	62,647	3.4	40,124	5,039,299	2.0
81370–81383	HLA (variants in histocompatibility genes). Used to match organ or bone marrow transplant recipients.	47,082	2.6	39,871	7,591,724	3.0

(continued)

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Table 17
Most utilized tier 1 billing codes among Medicare beneficiaries in 2013 (continued)

		2013				
		Tests			Payments	
HCPCS	Gene/Test	Number	Percent	Beneficiaries	Amount	Percent
81211–81217	BRCA1/BRCA2 (germ line or somatic mutations in breast cancer genes). Used to diagnose familial breast and ovarian cancer syndromes. Somatic mutations provide treatment and prognosis information.	44,762	2.4	42,209	56,763,760	22.2
81270	JAK2 (somatic mutations in janus kinase 2 gene). Used to diagnose and monitor myeloproliferative neoplasms.	40,225	2.2	36,464	2,625,106	1.0

SOURCE: RTI Analysis of Medicare claims. Programming requests JL19, JL20.

The most frequently used Tier 1 codes among the entire MarketScan population were CFTR (13.3%), Factor 5 (6.9%), BRCA (6.7%), and Factor 2 (6.4%) (***Table 18***). The differences in age distribution of Medicare beneficiaries and private-payer beneficiaries in the MarketScan dataset explain the differences in the volume of certain tests. A large proportion of private-payer beneficiaries are of reproductive age, which is reflected in the frequency of tests such as (e.g., CFTR for cystic fibrosis or FMR1 for fragile X syndrome) that are often done to determine carrier status, for prenatal diagnosis, or for the diagnosis of fertility issues. Tests for inherited cancer syndromes (e.g., BRCA for hereditary breast and ovarian cancer) are frequently done in early adulthood to allow intensive screening and prophylactic genetic susceptibility to cancer. Pharmacogenetic tests for adjusting medication dosage (e.g., CYP and VKORC1) and tests that guide cancer treatment (e.g., BCR-ABL, JAK2, and EGFR) are more frequently found in Medicare claims. Both databases revealed high volume of billing with codes for genes implicated in vascular disease, such as Factor 5, Factor 2, and MTHFR, the latter despite clinical guidelines discouraging use of this test for a number of conditions, including pregnancy. See ***Table 19*** for most frequently used Tier 1 codes among the age 55-64 Marketscan population.

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Table 18
Most commonly utilized [1] tier 1 billing codes among privately insured patients in 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
Total		78,322	100.0	47,347	78,986,283	100.0	1,067,060	100.0	422,385	381,436,408	100.0
81220–81224	CFTR (germ line mutations in cystic fibrosis transmembrane conductance regulator). Used for carrier or diagnostic testing for cystic fibrosis; diagnostic testing for male infertility and hereditary pancreatitis.	8,238	10.5	8,034	3,164,924	4.0	141,683	13.3	132,791	83,513,351	21.9
81241	Factor 5 (germ line mutations in Factor 5 (Leiden)). Used to identify patients at increased risk of venous thrombosis. Oral contraception is contraindicated for individuals with 1691 G > A mutation. Weaker risk factor for arterial thrombosis and pregnancy complications.	3,739	4.8	3,599	214,328	0.3	73,179	6.9	69,842	6,228,996	1.6
81211–81217	BRCA1/BRCA2 (germ line or somatic mutations in breast cancer genes). Used to diagnose familial breast and ovarian cancer syndromes. Somatic mutations provide treatment and prognosis information.	32,988	42.1	32,395	66,949,522	84.8	71,920	6.7	69,965	120,968,509	31.7

[1] May not include all private payer claims; reporting is voluntary.

(continued)

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Table 18 (continued)
Most commonly utilized [1] tier 1 billing codes among privately insured [2] patients in 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
81240	Factor 2 (germ line mutations in prothrombin). Used to identify patients at increased risk of venous thrombosis. Weaker risk factor for arterial thrombosis.	2,693	3.4	2,570	151,783	0.2	68,317	6.4	65,341	5,772,103	1.5
81291	MTHFR (germ line mutations in methylenetetrahydrofolate reductase). May be ordered as follow-up to elevated blood homocysteine or with other cardiovascular risk markers.	2,578	3.3	2,508	157,262	0.2	61,698	5.8	58,720	7,210,645	1.9
81225–81227	CYP (germ line mutations in cytochrome genes). Used to determine rate at which drugs are metabolized and recommend for or against specific drugs or for dosing guidance. Example drug types: antidepressants, warfarin.	420	0.5	402	27,211	0.0	53,356	5.0	50,866	11,468,445	3.0
81370–81383	HLA (variants in histocompatibility genes). Used to match organ or bone marrow transplant recipients.	5,008	6.4	4,446	759,841	1.0	49,022	4.6	42,273	14,663,401	3.8

[1] May not include all private payer claims; reporting is voluntary.
[2] Defined as more than 30,000 tests in 2013.

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Table 18 (continued)
Most commonly utilized [1] tier 1 billing codes among MarketScan [2] patients in 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
81243–81244	FMR1 (germline mutations in the fragile X mental retardation protein). Used for carrier or diagnostic testing for fragile X syndrome, premature ovarian failure, and fragile X associated tremor/ataxia syndrome.	1,269	1.6	1,237	74,844	0.1	48,597	4.6	46,421	6,168,173	1.6
81292–81301	MMR (germ line mutations in mismatch repair genes). Used to confirm Lynch syndrome, a hereditary colorectal cancer syndrome.	11,830	15.1	11,397	5,631,037	7.1	31,372	2.9	30,367	14,939,572	3.9

[1] May not include all private payer claims; reporting is voluntary.
[2] Defined as more than 30,000 tests in 2013.

SOURCE: RTI analysis of MarketScan data 2011–2013. JL_EVAL_012_MarketScan

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Table 19
Most commonly utilized [1] tier 1 billing codes among privately insured patients age 55–64, 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/Test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
Total		32,781	100.0	To be provided in final report	36,838,867	100.0	369,103	100.00	To be provided in final report	137,741,182	100.00
81240	Factor 2 (germ line mutations in prothrombin). Used to identify patients at increased risk of venous thrombosis. Weaker risk factor for arterial thrombosis.	1,434	4.37		81,397	0.22	54,000	14.63		4,519,921	3.28
81241	Factor 5 (germ line mutations in Factor 5 (Leiden)). Used to identify patients at increased risk of venous thrombosis. Oral contraception is contraindicated for individuals with 1691 G > A mutation. Weaker risk factor for arterial thrombosis and pregnancy complications.	1,246	3.80		81,203	0.22	36,938	10.01		3,162,984	2.30
81211–81217	BRCA1/BRCA2 (germ line or somatic mutations in breast cancer genes.) Used to diagnose familial breast and ovarian cancer syndromes. Somatic mutations provide treatment and prognosis information.	16,132	49.21		32,310,937	87.71	36,314	9.84		60,371,145	43.83
81225–81227	CYP (germ line mutations in cytochrome genes). Used to determine rate at which drugs are metabolized and recommend for or against specific drugs or for dosing guidance. Example drug types: antidepressants, warfarin.	162	0.49		20,616	0.06	33,516	9.08		7,236,511	5.25

(continued)

Table 19 (continued)
Most commonly utilized [1] tier 1 billing codes among privately insured [2] patients age 55–64, 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/Test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
81291	MTHFR (germ line mutations in methylenetetrahydrofolate reductase). May be ordered as follow-up to elevated blood homocysteine or with other cardiovascular risk markers.	826	2.52		49,941	0.14	32,026	8.68		3,914,399	2.84
81370–81383	HLA (variants in histocompatibility genes). Used to match organ or bone marrow transplant recipients.	2,690	8.21		598,773	1.63	23,837	6.46		9,351,027	6.79

[1] Defined as more than 20,000 tests in 2013.
[2] May not include all private payer claims; reporting is voluntary.

SOURCE: RTI analysis of MarketScan data 2011–2013. JL_EVAL_012_MarketScan

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Tier 2 (methodology-based) codes were extensively used in 2013 both in Medicare claims and in claims to commercial payers (***Table 20***). We identified 274,208 Tier 2 codes billed to Medicare in 2013, which corresponds to 15.0% of all claims with the new codes. In MarketScan, we identified 167,047 Tier 2 codes, which constituted 15.7% of all new codes billed in 2013. The frequencies of all the new Tier1/Tier2 codes and patients with claims with these codes in 2013 in Medicare and in 2012-2013 in MarketScan is summarized in Appendix C, Tables C.3 and C.4, respectively.

Table 20
Billing for molecular pathology methodology codes (Tier 2 codes, level 1-9), 2012–2013

Population	Number	Percent	Beneficiaries	Amount	Percent
Medicare, 2013	274,208	15.0	189,504	6,716,666	2.6
Privately insured [1], All, 2012	1,642	2.1	1,532	353,560	0.4
Privately insured [1] All, 2013	167,047	15.7	151,024	53,568,336	14.0
Privately insured [1] 55–64, 2012	819	2.50		187,148	0.51
Privately insured [1] 55–64, 2013	64,132	17.38		19,103,338	13.87

[1] May not include all private payer claims; reporting is voluntary.

SOURCE: RTI analysis of Medicare and MarketScan data 2011–2013.
JL_EVAL_012_MarketScan

This analysis illustrates the challenges in comparing test utilization between Medicare beneficiaries and privately insured populations, and the benefits of limiting analysis of the MarketScan data to beneficiaries age 55 to 64 years. First, the timing of introduction of the new billing codes was different for Medicare and commercial payers. Second, coding for several large-volume tests was not consistent across payers. For example, before the introduction of the new gene-specific Tier 1 billing codes, BRCA testing was billed to Medicare using methodology-based codes, while commercial payers used mostly the S-codes, which were also used by Medicaid, but not by Medicare. The new codes were adopted by commercial payers in 2012, and by Medicare in 2013, hence in 2012 BRCA testing in MarketScan was billed with three sets of codes. Third, despite AMA predictions, Tier 2 codes were used extensively, representing 15.0% of codes billed to Medicare and 15.7% of those in MarketScan. As with the old methodology-based codes, Tier 2 codes identify laboratory methods rather than the gene/protein analyzed. Therefore, some gene-specific tests are included in Tier 2 claims. For example, the three most clinically relevant variants of the KRAS gene, mutations in codons 12 and 13, are reported with a gene-specific code 81275, while testing for KRAS codon 61 is included in the Tier 2 level 4 code 81403 and full gene sequencing of KRAS is included in the Tier 2 level 6 code 81405. This issue is further complicated by laboratories moving toward multigene panels that can be billed with Tier 2 codes, requiring researchers to verify if the gene of interest is included in the panel.

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Further, while some proprietary tests billed with methodology-based codes can be identified in Medicare claims using laboratory-specific CLIA numbers, but provider numbers in the MarketScan database are de-identified.

5.5.3 Not Otherwise Classified (NOC) Codes

We also analyzed utilization and expenditures for tests billed with the following Not Otherwise Classified (NOC) codes:

Code	Description
81479	Unlisted molecular pathology procedure
84999	Unlisted chemistry procedure
87799	Infectious agent detection by nucleic acid
87999	Unlisted microbiology procedure
88399	Unlisted surgical pathology procedure

The purpose of NOC codes is to report services that cannot be described with other HCPCS codes. The laboratories who bill these codes were generally eligible to apply for a G code as part of the Demonstration. We summarized Medicare expenditures for claims with each NOC code in 2010–2013, identified the laboratories that billed most claims with each code, and the most frequent line item diagnosis codes associated with each code. We then used the line item diagnosis codes and the information on specific products from these laboratories to identify the most likely tests that were billed with these NOC codes.

Table 21 summarizes utilization and payments for these codes in Medicare and MarketScan. We included in this comparison the S codes S3818-S3823 and S3854, which were used to bill private payers for breast cancer tests, because these types of tests were also billed with NOC codes to Medicare. ***Table 22*** shows the summary of allowed line items and payments from Medicare for Part B claims with these five NOC codes, ranked by the highest billing laboratories in 2013. The total payments in 2013 were $104,721,056, of which 54,551,148 (52.3%) was to Genomic Health, which specializes in genomic tests for breast and prostate cancer. Other top-billing laboratories included Crescendo Bioscience, CardioDx, Veracyte, and Agendia. The most frequent line item diagnosis codes associated with each NOC code and the description of tests most likely billed with each code are provided in the Appendix C, Tables C.5 and C.6.

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Table 21
Expenditures for tests billed with NOC codes 81479, 84999, 87799, 88399, and S codes S3818-S3823 and S3854

		Codes				Payments				Percent change from 2011 to 2013	
Code	Description	2010	2011	2012	2013	2010	2011	2012	2013	Tests	Payments
MarketScan	Total	—	149,600	166,365	231,283	—	110,548,667	69,070,165	93,741,382	54.6	(15.2)
81479	Unlisted molecular pathology procedure	—	—	10	82,128	—	—	2,926	46,221,509	—	—
84999	Unlisted chemistry procedure	—	53,455	57,073	47,012	—	4,404,010	9,624,863	12,082,768	(12.1)	174.4
87799	Infectious agent detection by nucleic acid	—	57,162	84,159	82,563	—	7,055,996	9,459,669	9,148,553	44.4	29.7
87999	Unlisted microbiology procedure	—	2,527	7,291	11,166	—	932,282	852,567	821,134	341.9	(11.9)
88399	Unlisted surgical pathology procedure	—	1,924	2,185	1,309	—	720,588	537,321	63,779	(32.0)	(91.1)
S3818-S3823	BRCA1/BRCA2	—	27,059	7,573	21		70,871,586	19,993,202	77,235	(99.9)	(99.9)
S3854	Oncotype DX Breast Cancer Assay	—	7,473	8,074	7,084		26,564,206	28,599,616	25,326,403	(5.2)	(4.7)
Medicare	Total	148,772	179,925	211,200	516,905	54,809,680	70,679,936	84,184,585	114,891,522	(16.6)	62.6
81479	Unlisted molecular pathology procedure	—	—	4	213,728	—		—	3,869,889	—	—
84999	Unlisted chemistry procedure	27,300	27,935	34,341	73,740	43,837,570	57,422,614	69,954,706	96,545,633	(90.1)	68.1
87799	Infectious agent detection by nucleic acid	117,598	148,286	173,742	224,636	7,924,077	9,563,044	11,193,035	12,137,375	(11.0)	26.9
87999	Unlisted microbiology procedure	2,473	2,671	2,120	3,303	3,016,340	3,630,867	3,018,602	2,320,676	(84.7)	(36.1)
88399	Unlisted surgical pathology procedure	1,401	1,033	993	1,498	31,692	63,410	18,241	17,950	(25.8)	(71.7)

— = not available.

SOURCE: RTI analysis of Medicare claims 2010–2013. JL19; JL_EVAL_012_MarketScan; JL_Eval_25; JL_Eval_27

Table 22
Top 12 laboratories billing Medicare using NOC codes 81479, 84999, 87799, 87999, and 88399

	Lines				Medicare payments			
Laboratory	2010	2011	2012	2013	2010	2011	2012	2013
Total	64,813	94,432	130,747	135,439	47,164,821	62,191,408	74,876,496	104,303,013
Genomic Health	11,640	13,956	15,135	16,333	37,399,492	45,351,168	49,449,568	54,551,148
Crescendo	—	90	6,579	24,748	—	—	3,700,000	14,295,787
CardioDx	25	2,790	3,245	5,829	1,195	575	1,800,000	6,000,000
Veracyte	—	—	1,050	1,779	—	—	3,100,000	5,625,152
Agendia	341	444	1,305	1,328	1,000,000	1,416,800	3,045,416	4,542,231
RedPath	1,068	1,587	1,487	1,477	2,727,907	4,737,209	3,052,713	4,430,863
LabCorp	8,330	9,504	12,150	15,016	3,167,302	3,878,245	3,283,875	3,389,793
Biotheranostics	835	852	793	1,115	970,201	2,215,270	1,911,600	3,017,117
Quest	16,072	30,352	46,088	39,005	777,553	1,221,594	1,904,290	2,308,173
Biodesix	208	912	1,104	1,605	—	80,140	234,798	1,900,195
Novartis	—	—	47	3,381	—	—	8,525	823,400
Ambry	—	—	—	362	—	—	—	762,484
All others	26,294	33,945	41,764	23,461	1,121,172	3,290,407	3,385,711	2,656,670

— = not available.

SOURCE: RTI analysis of Medicare claims. JL19

5.6.4 Medicare Expenditures and Receipt of Complex Testing

We matched 227 of 258 medical records abstractions to the Medicare Summary File to obtain information on the annual payments for each beneficiary's medical care. Thirty-one of the beneficiaries did not match to the file: 29 heart transplant patients, one lupus patient, and one patient with leukemia. Nine of the heart transplant beneficiaries received AlloMap and one received Anti-Ro(SSA) RNA antibody test. The lupus patient received an antinuclear antibody test. The remaining 20 nonmatched patients did not receive tests. These 31 patients are not included in the analyses below.

Of the 227 patients with medical records abstraction data who could be linked to the Medicare Summary File, 131 received at least one genetic test. ***Table 23*** presents the mean Medicare payments for beneficiaries by the number of genetic tests received. There was little difference in annualized payments for those receiving two or three genetic tests ($30,053) and those receiving one genetic test ($29,451). Beneficiaries not receiving genetic tests had the lowest mean payments ($21,451). Hospital inpatient and outpatient and Medicare Part B payments were the main drivers of annual Medicare costs for beneficiaries with genetic tests. Notably, beneficiaries without genetic test had substantially lower inpatient hospital payments compared to beneficiaries with genetic tests.

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Table 23
Medicare payments by total number of genetic tests for the abstracted sample

Total number of tests	Count	Total annualized	Total non-annualized	DME	HHA	Hospice	Inpatient acute hospital	Outpatient hospital	Part B	SNF
0	96	$25,715	$21,451	$1,090	$1,072	$598	$1,926	$5,233	$9,220	$2,312
1	71	$39,589	$29,451	$1,484	$1,145	$31	$7,364	$11,028	$8,027	$372
2 or 3	60	$46,844	$30,053	$1,274	$1,229	$425	$8,682	$8,501	$8,818	$1,125

The annualized Medicare payments for patient care differed greatly by primary disease ranging from $18,164 for breast cancer to $73,637 for leukemia as shown in ***Table 24***. Payments for inpatient hospitalizations for breast cancer and SLE patients were less than $1,000 per beneficiary per year. For the remaining diseases, hospital inpatient and outpatient costs and independent provider costs payments were the main drivers of annual Medicare costs. Except for lung cancer, patients with genetic tests had higher costs than those without genetic tests. Appendix Table C6 presents a detailed cost breakdown for beneficiaries with and without genetic tests by primary disease.

Table 24
Medicare payments by primary disease for the abstracted sample, by receipt of complex tests

		Overall		Received complex tests		Did not receive complex tests	
Primary disease	Total	Total annualized	Total non-annualized	Total annualized	Total non-annualized	Total annualized	Total non-annualized
Breast cancer	61	$18,164	$15,344	$22,028	$16,935	$13,901	$13,588
Leukemia	58	$73,637	$42,747	$81,126	$47,606	$47,715	$25,928
Lung cancer	59	$26,319	$23,631	$23,594	$21,518	$27,716	$24,715
SLE	38	$19,062	$18,841	$20,386	$20,097	—	—

— = not available.

NOTE. Diseases with fewer than 10 observations are not shown.

Lastly, we look at the average annual Medicare payments by genetic test. As with primary disease, the annualized Medicare payments for patient care differed greatly by genetic test. Annualized payments for beneficiaries with other unspecified genetic tests were the highest at $113,417 while payments for known tests ranged from $16,580 for the anti-dsDNA antibodies test and to $101,344 for a FISH test as shown in ***Table 25***. Of interest is that payments for inpatient hospitalizations for CA 27.29 and CA 15-3, which are used for monitoring for recurrence, were $0, indicating no inpatient stays. For the remaining tests a combination of hospital inpatient and outpatient and Medicare Part B payments were the main drivers of annual Medicare costs. Inpatient and Part B payments were substantially higher for beneficiaries with FISH, karyotype, and other genetic tests compared to most other genetic tests.

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Table 25
Medicare payments by test for the abstracted sample, overall

Test	Count	Total annualized	Total non-annualized	DME	HHA	Hospice	Inpatient acute hospital	Outpatient hospital	Part B	SNF
Anti-dsDNA Antibodies	18	$16,580	$16,172	$2,350	$221	$0	$901	$8,734	$3,967	$0
Antinuclear antibody	26	$23,898	$23,346	$4,413	$450	$0	$1,199	$11,834	$4,765	$685
CA 27.29	17	$17,884	$13,909	$1,096	$752	$0	$0	$7,853	$3,374	$834
CA15-3	15	$19,353	$14,847	$1,242	$852	$0	$0	$8,309	$3,499	$945
EGFR	18	$27,538	$25,133	$664	$1,010	$855	$1,264	$9,074	$12,267	$0
FISH	21	$101,344	$53,722	$476	$1,765	$252	$18,963	$13,508	$16,253	$2,504
HER 2/neu	16	$31,068	$21,495	$502	$1,085	$169	$2,167	$9,586	$7,100	$886
Karyotype	10	$78,638	$54,716	$52	$1,352	$1,278	$23,362	$10,751	$15,890	$2,031
Other genetic test	14	$113,417	$44,252	$466	$2,463	$411	$20,423	$8,019	$11,720	$750
No genetic tests	96	$25,715	$21,451	$1,090	$1,072	$598	$1,926	$5,233	$9,220	$2,312

NOTE. A beneficiary may have more than one test; tests with fewer than 10 observations are not shown.

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CHAPTER 6
COMPLEX LABORATORY TESTING IN BREAST CANCER PATIENTS

In this and the following five chapters, we explore the questions of access, utilization, and expenditures related to complex testing and the impact of such testing on quality of care and health outcomes for six specific conditions in which complex testing is used in diagnosis or treatment. The six conditions are breast cancer, lung cancer, ovarian cancer, hematologic malignancies, heart transplantation, and systemic lupus erythematosus (SLE).

The list of ICD-9 diagnosis codes used to identify each cohort is provided in Appendix B. Of note, the cohort of patients with each disease identified in 2010 includes those who had the corresponding diagnosis code before that year, while patients identified in 2011-2013 had claims with the diagnosis code in the given year, but not in the years prior. Therefore, the 2010 Medicare cohort represents prevalent cases, while the 2011-2013 cohorts represent incident cases for the respective years. We analyzed the demographic and clinical characteristics of beneficiaries 55 years of age and older who underwent complex tests specifically for each condition (i.e., when the test was billed with a line item diagnosis code for that condition). We compared the characteristics of the total cohorts of all patients with a given condition and those who underwent testing. We compared Medicare beneficiaries to the corresponding cohort of patients aged 55 or older who had claims billed to private payers in MarketScan.

6.1 The Use of Complex Tests in Breast Cancer

Breast cancer can affect both females and males. Compared to other cancers, female breast cancer is fairly common. In 2013, there were an estimated 3,053,450 women living with breast cancer in the United States (National Cancer Institute). Female breast cancer is most frequently diagnosed among women aged 55–64, with median age at diagnosis at 62 years. Since the introduction of routine mammography screening, the majority of patients (61%) are diagnosed before the cancer has spread to lymph nodes and other organs, and the prognosis is good. However, because of high incidence, female breast cancer remains the fourth leading cause of cancer death in the United States (National Cancer Institute).

For most patients, breast cancer is diagnosed through a biopsy of a suspicious lesion either palpable or detected through screening mammography. If cancer is present, standard treatments include surgery, radiation therapy, and various pharmacological interventions (chemotherapy or targeted drugs). Laboratory complex tests for breast cancer fall into two categories: molecular tests characterizing gene expression in the tumor tissue for prognosis and choosing treatment (tests for hormone receptors and HER2, and proprietary gene expression tests) and genetic tests identifying an inherited cancer susceptibility (BRCA1/2 and other genetic markers).

Testing for expression of three markers—estrogen receptor (ER) and progesterone receptor (PR), collectively referred to as “hormone receptors,” and HER2—constitutes the established standard of care in breast cancer. Clinical practice guidelines issued by the National Comprehensive Cancer Network (NCCN) recommend testing for these markers in all new invasive breast cancers and in breast cancer recurrences (National Comprehensive Cancer Network). There is no National Coverage Determination covering these tests within Medicare,

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but local coverage based on medical necessity has been in effect since 2004. The results of these tests determine which targeted treatments (hormonal or monoclonal antibody therapies) will likely be effective. Additionally, several proprietary tests have been developed, such as Oncotype DX Breast Cancer Assay, Mammostrat, MammaPrint, and others, which estimate the risk of recurrence after surgery and predict if the patient with an early breast cancer will benefit from standard cytotoxic chemotherapy in addition to targeted therapy. These tests measure expression of many biomarkers at once, and the result is arrived at through a proprietary algorithm. Among these tests, Oncotype DX has been used most often to guide management of hormone receptor-positive early breast cancer, and has been included in NCCN guidelines. Additionally, another variant of the Oncotype DX test estimates the risk of recurrence of in situ cancer and the risk of progression to invasive disease in patients with ductal carcinoma in situ. Local Medicare coverage for Oncotype DX has been in effect since 2008.

Hereditary mutations in a number of genes increase an individual's susceptibility to breast and ovarian cancer, a condition called hereditary breast-ovarian cancer (HBOC) syndrome. The most common are mutations in BRCA1 and BRCA2 genes. According to the NCCN guidelines, female breast cancer patients with early onset (less than 50 years) and family history of cancer, and all males with breast cancer, should be tested for BRCA1/2 mutations. During the Demonstration period, Medicare coverage for BRCA testing was in effect for beneficiaries under 67 years of age (CMS.gov). Upon positive diagnosis of HBOC (i.e., positive BRCA1/2 test result), management options include increased surveillance (annual mammography or MRI, annual or semiannual transvaginal ultrasound, monitoring of CA-125 levels) and risk-reducing medications (e.g., tamoxifen and oral contraceptives) and surgery (oophorectomy or mastectomy).

Tests for inherited genetic markers among individuals who do not have cancer are usually done on blood samples. Such samples are collected in outpatient settings and would not be subject to the date of service rule or participation in the Demonstration, as defined by Section 3113(a)(2). Tumor tissue may be tested in individuals with cancer, however.

6.2 Access to Care

Several laboratory tests used for breast cancer patients met the requirements for participation in the Demonstration, as defined by Section 3113(a)(2). In addition, some met all requirements except they were billed under an NOC code. We conducted an in-depth analysis of laboratory testing for the diagnosis and treatment of breast cancer.

We identified 1,638,562 beneficiaries with the diagnosis of breast cancer from 2010 to 2013, of whom 472,912 (28.9%) received molecular testing for this condition (***Table 26***). Even though breast cancer affects both males and females, there was a substantial difference in the proportion of tested beneficiaries between men and women: only 16.9% of male beneficiaries received testing compared to 29.1% of female beneficiaries. Gender distribution of tested patients was similar among privately insured patients. For Medicare beneficiaries, we also found differences in testing frequency depending on race/ethnicity. Hispanic beneficiaries were the most likely to be tested for breast cancer, and Black beneficiaries were the least likely. Patients with complex testing had higher risk scores, on average, but were less likely to be in end stage renal disease (ESRD).

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Table 26
Counts and percentages of breast cancer beneficiaries (N) [1] receiving at least one breast cancer-related complex test (n) [2] as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Total	1,638,562	472,912	28.9		218,384	58,665	26.9	
Age				<0.0001				<0.0001
55–59	46,203	15,649	33.9		106,475	29,374	27.6	
60–64	165,732	56,438	34.1		111,909	29,291	26.2	
65–69	399,248	126,713	31.7		—	—	—	
70–74	326,435	100,411	30.8		—	—	—	
75+	700,944	173,701	24.8		—	—	—	
Age (SD)	73.66(8.48)	72.37(7.87)			59.5 (2.8)	59.5(2.8)		
Gender				<0.0001				<0.0001
Female	1,607,286	467,624	29.1		215,943	58,254	27.0	
Male	31,276	5,288	16.9		2,441	411	16.8	
Race/Ethnicity				<0.0001				
White	1,419,145	411,622	29.0		—	—	—	
Black	146,885	39,282	26.7		—	—	—	
Asian/Pacific Islander	20,875	6,226	29.8		—	—	—	
Hispanic	19,904	6,542	32.9		—	—	—	
North American/Native	4,985	1,266	25.4		—	—	—	
Other	20,726	6,170	29.8		—	—	—	
Unknown	6,042	1,804	29.9		—	—	—	
Medicaid Status				<0.0001				
No Medicaid	1,407,010	408,846	29.1		—	—	—	
Medicaid	231,552	64,066	27.7		—	—	—	
Risk Score	1.23 (1.04)	1.30 (1.09)		<0.0001				
ESRD [3]				<0.0001				
No	1,628,743	470,971	28.9		—	—	—	
Yes	9,819	1,941	19.8		—	—	—	

[1] As identified by having ICD9 codes 174.0-174.9, 175.0, or 175.9 anywhere in MedPAR, Part B, or Outpatient for these years.
[2] Any Demonstration test code if billed with breast cancer as a principal diagnosis.
[3] Not provided for MarketScan at this time.

SOURCE: RTI analysis. Programs jl44; MKTSCN_JL_EVAL_SignificanceTests55

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6.2.1 Case Study: Utilization of Oncotype Dx in 2011 Incident Breast Cancer Cases

We examined test eligibility and utilization for breast cancer patients first treated for breast cancer in 2011 to better understand the impact of the DOS rule on access to complex diagnostic laboratory tests before the Demonstration. The analysis included a case study of the impact of the DOS rule for the Oncotype DX breast cancer assay, a leading proprietary test used to guide treatment and predict prognosis for breast cancer patients. If the majority of Oncotype DX tests were ordered on tissue obtained from outpatient procedures conducted outside of the hospital setting (e.g., in a physician's office), the DOS rule would have no meaningful impact on access.

Table 27 illustrates the results of that analysis, which revealed that 75% of Oncotype DX tests paid by Medicare were conducted on biopsy tissue obtained during a nonhospital outpatient procedure, and 17% were conducted on biopsy tissue obtained during inpatient breast surgery. For the Medicare beneficiaries for whom the tests were conducted on biopsy tissue obtained as an inpatient, the mean number of days the test was ordered after surgery was 19 , and 56% were ordered within 14 days. Thus, of the 11,879 Oncotype DX tests ordered in 2011, the timing of only 8% could have been affected by the DOS rule.

Table 27
Date of service analysis for Oncotype Dx breast test orders

				Days test ordered							
	Observations			<15		15-30		31-60		61 or more	
Test order in relation to procedure	#	%	Mean	#	%	#	%	#	%	#	%
Following breast surgery in hospital inpatient	2,175	16.8	18.8	1,217	56.0	269	12.4	556	25.6	133	6.2
After pathology analysis in Part B physician	9,647	74.7	37.3	2,344	24.3	2,510	26.0	3,029	31.4	1,764	18.2
After pathology analysis in hospital outpatient	57	0.4	30.6	18	32.7	12	21.8	17	29.1	10	16.4
Prior to 2011 or no biopsy or surgery in claims	1,037	8.0	—	—	—	—	—	—	—	—	—

SOURCE: RTI analysis of 2011 Medicare administrative data.

6.3 Quality of Care

We examined quality of care using abstracted medical records data from 61 patients with breast cancer. Orders for complex laboratory tests were documented for 32 of 63 (52%) patients. These tests were used as follows:

- ***Diagnosis of Genetic Cancer Syndrome:*** Two patients had had BRCA testing. One patient was tested 19 months prior to her cancer diagnosis. The other patient was tested in 2012 when she was diagnosed with ovarian cancer. The patient had had breast cancer 10 years prior to her ovarian cancer diagnosis.

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- ***Treatment Planning:*** Fifteen patients had HER2/neu testing. This test is used initially in new or recurrent cases of breast cancer to determine suitability for Trastuzumob monoclonal antibody therapy (must be HER2 + for this therapy) and determine prognosis and risk of recurrence. In two cases, the specific therapeutic agent used was documented and it aligned with the recorded laboratory results.

- ***Monitoring for Recurrence.*** Thirty patients received serial testing to monitor for response to treatment and cancer recurrence. Sixteen patients were monitored using serum markers; 14 patients with cancer antigens CA15.3 and CA27.29 and two with CA27.29 alone. The timing of the testing seemed to align with usual clinical practice. Serial HER2/neu testing was used to monitor response to treatment in 14 patients. Quantitative HER2/neu testing can either measure the amount of HER2 protein or the number of copies of the gene. Testing is expensive and may cause cardiac toxicity. The timing of testing seemed to align with clinical practice.

A lack of documented testing does not necessarily mean that the patients did not have appropriate testing. The 29 cases which had no record of testing in the abstracted information were cases of recurrent breast cancer or metastatic breast cancer. The admissions for which we received medical records were admissions for therapy or complications and did not include records for the initial admission for diagnosis or care. A few of these cases had recorded estrogen receptor status. In general, these patients' care was being overseen by physicians classified as general practitioners or "other." The patient may have received their specialty care elsewhere (e.g., at an oncology office). Records were not requested from other hospitals or clinics.

6.4 Health Outcomes

Seventy-two percent of the 32 breast cancer patients who had a complex tests were alive at the end of 2013, compared to 66% of the 29 patients who did not have a complex test. The difference was not statistically significant (p = 0.7824).

Of the 61 breast cancer patients with medical record abstractions, the records of 43 had information on treatment response. Twenty-one percent of the patients with complex testing declined after treatment, compared to 8% of those with no complex tests. The difference was not statistically significant. (Table X)

Table 28
Response to treatment for breast patients who did and did not receive complex tests.

Complex Tests	Treatment Response			Total
	Declined	Improved	Stable	
No	2 (8.3)	14 (58.3)	8 (33.3)	24 (55.8)
Yes	4 (21.1)	8 (42.1)	7 (36.8)	19 (44.2)
Total	6 (14.0)	22 (51.1)	15 (34.9)	43 (100)

p-value: 0.48, Fisher's exact test

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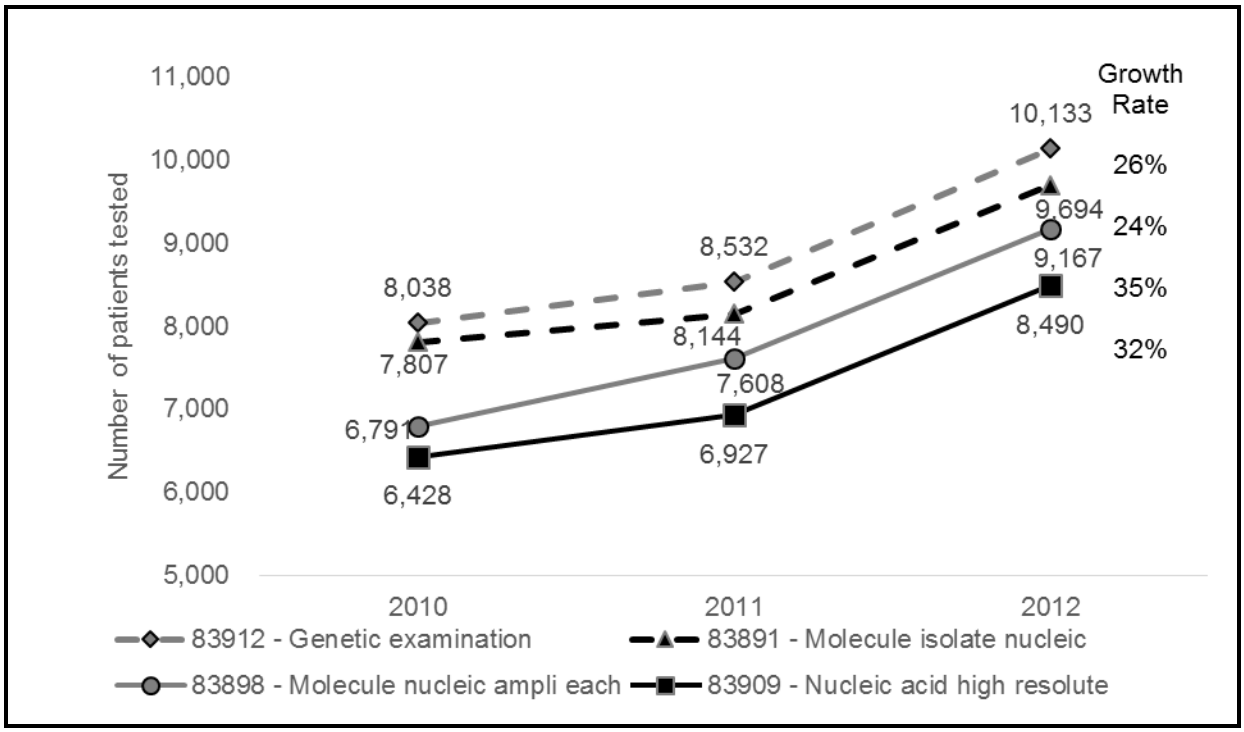
6.5 Health Care Utilization

Even though complex laboratory testing for breast cancer is well established in clinical practice, its utilization continued to increase between 2010 and 2012. The use of four selected Demonstration-eligible codes increased 24% to 35% during this period.

Figure 7
Number of patients by year undergoing specific Demonstration test codes for breast cancer



Overall, 23 of 61 breast cancer patients with medical record abstractions had documentation of treatment for breast cancer in their medical record. Among the 32 patients who received at least one complex test, 14 received treatment and 5 of these patients received chemotherapy **(*Table 29*)**. No statistical difference was observed for the receipt of treatment among patients who received complex tests compared to patients who did not (P = 0.39 for Fisher's exact test).

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Table 29
Treatment approaches for breast cancer among beneficiaries who did and who did not receive complex tests

	Treatment approach					
Complex test	Chemotherapy	Radiation	Surgery	Combined therapy [1]	No treatment	Total
No	4 (13.8)	0 (0.0)	3 (10.3)	1 (3.5)	21 (72.4)	29 (47.5)
Yes	5 (15.6)	3 (9.4)	6 (18.8)	1 (3.1)	17 (53.1)	32 (52.5)
Total	9 (14.8)	3 (4.9)	9 (14.8)	2 (3.3)	38 (62.3)	61 (100)

p-value: 0.39, Fisher's exact test

[1] Combined therapy includes any two or three types of therapy approaches of chemotherapy, radiation, or surgery.

6.6 Medicare Expenditures

Average overall Medicare expenditures for breast cancer patients who received a complex test were $2,572 higher per patient than average per patient expenditures for breast cancer patients who did not receive a complex test (***Table 30***). Payments were higher for all payment categories except for payments for inpatient hospital care (Inpatient payments). The difference in mean payments was greater for services provided for physicians and other health care practitioners (Part B payments) than for services provided in the outpatient department of a hospital (outpatient payments). Annual mean expenditures for all privately insured breast cancer patients age 55–64 and for those who received complex tests were higher than those for Medicare beneficiaries for each year. (Appendix C, Table C7).

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Table 30
Payment summaries for breast cancer patients covered by Medicare (2010–2013)

	Medicare				
	Did not receive a complex test for breast cancer		Received a complex test for breast cancer		
Description	Mean	SD	Mean	SD	p-value
Inpatient facility payments	832	5,374	555	3,919	<0.0001
Outpatient facility payments	2,789	6,491	3,642	7,763	<0.0001
Physician/Supplier payments	4,422	7,363	7,226	11,162	<0.0001
Total Payments	10,694	16,247	13,266	17,493	<0.0001
Annualized total payments	22,549	25,249	14,675	20,858	<0.0001

SOURCE: RTI analysis of Medicare data. jl36_(cancer)_table2_yr10-13, jl44

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CHAPTER 7
COMPLEX LABORATORY TESTING IN LUNG CANCER PATIENTS

7.1 Introduction on Use of Complex Tests in Lung Cancer

Lung cancer is the leading cause of cancer death in the United States, with more than 415,000 people living with the disease in 2013 and an estimated 160,000 deaths (National Cancer Institute). Approximately 57% of lung cancer patients are diagnosed at a late stage with distant metastases, and less than 18% of patients live for 5 years or longer after diagnosis. The average age of diagnosis is about 70 years. The most common form of the disease is non-small cell lung cancer (NSCLC), representing 85%-90% of all lung cancer cases (American Cancer Society). Because lung cancer is predominantly a disease of the elderly, it represents a major health issue in the Medicare population.

Treatment is a combination of surgical resection (if the tumor is operable), radiation therapy, and pharmacological treatments, mostly chemotherapy. Drugs that target tumor blood vessels can be used with or without chemotherapy. Also, for the subset of patients with specific alterations in the EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genes, targeted therapies against those biomarkers are appropriate (erlotinib for EGFR mutations and crizotinib for ALK). Targeted treatments have less severe side effects than traditional chemotherapy and can be more effective against specific subtypes of lung cancer. Therefore, molecular testing for EGFR and ALK is essential for NSCLC therapy planning. It is estimated that in the United States, about 15% of patients with NSCLC have EGFR mutations (up to 35% in patients of East Asian descent), and about 5% carry rearrangements of the ALK gene.

As of 2011, clinical practice guidelines issued by the NCCN recommended EGFR testing for all newly diagnosed patients with metastatic NSCLC except squamous cell carcinoma (a subtype of lung cancer where EGFR mutations are very rare) (National Comprehensive Cancer Network). By 2013, NCCN also recommended routine testing of ALK in the same subset of patients. Additionally, it has been demonstrated that patients with mutations in another biomarker, KRAS, have poor survival and do not benefit from anti-EGFR therapy. However, there are no therapies targeted against KRAS, and in patients with known EGFR mutations, KRAS testing does not provide additional predictive information, so routine KRAS testing of lung cancer patients is not recommended.

7.2 Access to Care

In total, 6.2% of Medicare beneficiaries with lung cancer received a complex laboratory test (***Table 31***). This was lower than the percentage (9%) of private insurance patients receiving such tests. Private insurance patients are more likely to receive complex testing than Medicare beneficiaries of the same age or sex.

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Table 31
Counts and percentages of lung cancer beneficiaries (N) [1] receiving at least one lung cancer-related complex test (n) [2] covered by Medicare (2010–2013) and MarketScan (2011–2013)

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Total	1,135,178	70,352	6.2		48,808	4,392	9.0	
Age				<0.0001				<0.0001
55–59	39,311	1,888	4.8		21,156	2,026	9.6	
60–64	90,711	5,319	5.9		27,652	2,366	8.6	
65–69	242,231	17,085	7.1		—	—	—	
70–74	243,003	17,123	7.0		—	—	—	
75+	519,922	28,937	5.6		—	—	—	
Age (SD)	73.96 (8.21)	73.11(7.28)			59.9(2.8)	59.7(2.8)		
Gender				<0.0001				
Female	562,894	39,451	7.0		24,420	2,552	10.5	<0.0001
Male	572,284	30,901	5.4		24,388	1,840	7.5	
Race/Ethnicity				<0.0001				
White	980,773	61,530	6.3		—	—	—	
Black	104,918	4,983	4.7		—	—	—	
Asian/Pacific Islander	16,526	1,628	9.9		—	—	—	
Hispanic	12,661	622	4.9		—	—	—	
North American/Native	4,268	220	5.2		—	—	—	
Other	12,804	1,160	9.1		—	—	—	
Unknown	3,228	209	6.5		—	—	—	
Medicaid Status				<0.0001				
No Medicaid	925,542	60,300	6.5		—	—	—	
Medicaid	209,636	10,052	4.8		—	—	—	
Clinical Characteristics								
Risk Score (SD) [3]	1.87(1.45)	1.74(1.40)		<0.0001				
Risk score	1.87 (1.45)							
ESRD [3]				<0.0001				
No	1,122,764	69,921	6.2		—	—	—	
Yes	12,414	431	3.5		—	—	—	

[1] As identified by having ICD9 codes 162.0-162.9 anywhere in MedPAR, Part B, or Outpatient for these years.
[2] Any Demonstration test code if billed with lung cancer as a principal diagnosis.
[3] Not provided for MarketScan at this time.

SOURCE: jl44; MKTSCN_JL_EVAL_SignificanceTests55

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We observed significant differences in the probability of receiving a complex test among Medicare beneficiaries depending on their gender and race/ethnicity. Male beneficiaries were less likely to be tested than females (5.4% vs. 7.0%) and beneficiaries of Asian descent were over twice as likely to be tested as Black beneficiaries and 1.6 times more likely than Whites. Although some of this may reflect genuine disparity in access, these numbers also correspond to known gender and racial differences in the probability of finding clinically actionable somatic mutations in the tumors of various groups of lung cancer patients. These mutations are much less frequent in smokers, who are more likely to be male. Also, the frequency of mutations in Asians in much higher than in the general U.S. population (35% vs. 15%).

7.3 Quality of Care

The prevalence of complex testing was much higher among the 59 lung cancer patients for whom we had medical record abstractions: 19 cases, 32%, had documented complex testing. The most common test was genetic analysis of EGFR (15 cases), followed by genetic analysis of ALK (9 cases). Four patients had tests that are not currently recommended by guidelines. These included KRAS testing (2 patients); Foundation One, a next generation sequencing profile that is used to target therapy (1 patient), and karyotyping (1 patient), which has been replaced by molecular analysis. Six patients received tests that were referenced only by methodology, FISH, sequencing, or flow cytometry.

7.4 Health Outcomes

Of the 59 lung cancer patients for whom we had medical record abstractions, 33 (56%) had died by the end of 2013. Among patients who had a documented complex test, 9 (47%) had died, compared to 24 (60%) patients who had no documented tests. The difference was not statistically significant, however.

Information on treatment response was available for 36 of the 59 lung cancer patients with medical records data. Among the 12 patients who had received at least one complex test, 3 (25%) had improved after treatment, 1 (8.3%) remained stable after treatment, and 8 (66.7) declined or worsened after treatment. Among 24 patients who did not receive complex tests, 50% (12) improved after treatment, eight (33.3%) remained stable, and four (16.7%) declined **(*Table 32*).** Patients who received complex tests were less likely to respond to treatment, and the difference was statistically significant (p = 0.01).

Table 32
Response to treatment for lung cancer patients who did and did not receive complex tests.

	Treatment response			
Complex tests	Declined	Improved	Stable	Total
No	4 (16.7)	12 (50.0)	8 (33.3)	24 (66.7)
Yes	8 (66.7)	3 (25.0)	1 (8.3)	12 (33.3)
Total	12 (33.3)	15 (41.7)	9 (25.0)	36 (100)

p-value: 0.01, Fisher's exact test

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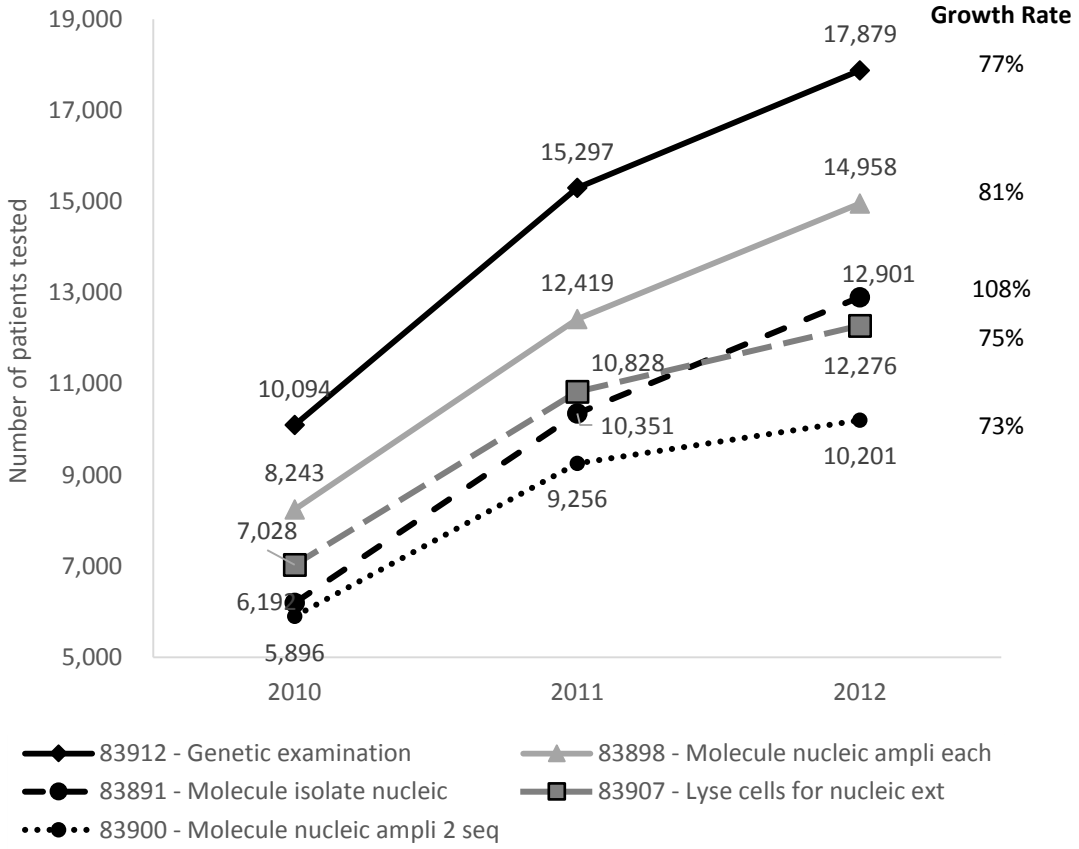
7.5 Health Care Utilization

The utilization of complex testing in the management of lung cancer patients increased dramatically between 2010 and 2012 (***Figure 8***). Billing for five selected Demonstration-eligible HCPCS codes that are required for most complex testing increased 73% to 108% during this period.

Figure 8
Number of patients by year undergoing specific Demonstration test codes for lung cancer



Treatment information was available for 21 of 59 lung cancer patients with medical record abstractions. Patients who received complex laboratory tests were also more likely to have received treatment for lung cancer: 85% of those who had no documented complex laboratory tests also had no documented treatment ($p = 0.007$). This finding is not surprising; the primary purpose of lung cancer complex tests is to guide treatment decisions.

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Table 33
Treatment approaches for lung cancer among patients who did and who did not have complex laboratory tests.

	Treatment					
Complex test	Chemotherapy	Radiation	Surgery	Combined [1] treatment	No treatment	Total
No	2 (5.0)	2 (5.0)	2 (5.0)	0 (0.0)	34 (85.0)	40 (67.8)
Yes	3 (15.8)	1 (5.3)	3 (15.8)	3 (15.8)	9 (47.4)	19 (32.2)

p-value: 0.007, Fisher's exact test

[1] Combined therapy includes any two or three types of therapy approaches of chemotherapy, radiation, or surgery.

7.6 Medicare and Beneficiary Expenditures

Average Medicare expenditures for lung cancer patients who received a complex test were $8,465 higher per patient than the average for lung cancer patients who did not receive a complex test (***Table 34***). Only for inpatient acute hospital care (inpatient payments) was the average expenditure for lung cancer patients who received complex testing lower than for lung cancer patients overall. As with breast cancer patients, the difference in mean payments between patients who received testing and the overall population of patients with lung cancer was larger for Part B payments, $6,247, than for outpatient payments, $4,311. Expenditures were higher for privately insured patients than for breast cancer patients for each year between 2011 to 2013. (Appendix C, table C.8).

Table 34
Payment summaries for lung cancer patients covered by Medicare (2010–2013)

	Medicare				
	Did not receive a complex test for lung cancer		Received a complex test for lung cancer		
Description	Mean	SD	Mean	SD	p-value
Inpatient facility payments	3,372	10,637	2,864	9,466	<0.0001
Outpatient facility payments	4,320	9,328	8,631	14,382	<0.0001
Physician/supplier payments	7,506	11,722	13,753	17,321	<0.0001
Total payments	20,147	23,081	28,613	26,052	<0.0001
Annualized total payments	29,576	47,338	33,620	35,321	<0.0001

SOURCE: Medicare: jl36, JL44.

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CHAPTER 8
COMPLEX LABORATORY TESTING IN OVARIAN CANCER PATIENTS

8.1 Use of Complex Tests in Ovarian Cancer

Ovarian cancer is the leading cause of death from gynecologic cancer and the fifth leading cause of cancer-related death among women overall. It is most commonly diagnosed between the ages of 60 and 64 (National Comprehensive Cancer Network). The highest incidence is found in white, non-Hispanic women (Centers for Disease Control and Prevention, 2015a).

Early stages of ovarian cancer are often asymptomatic; therefore, most ovarian cancers are diagnosed late. Approximately 70% of epithelial ovarian cancers are not found until the disease is in an advanced stage and has spread to other parts of the body, most commonly the abdomen (National Comprehensive Cancer Network).

Clinical practice guidelines for management of adnexal masses have been issued by the American College of Obstetricians and Gynecologists (American College of Obstetricians and Gynecologists, 2007) and the NCCN (National Comprehensive Cancer Network). If the abdominal/pelvic exam or the set of symptoms suggest ovarian cancer, a test for the cancer marker CA 125 is performed (Medeiros, Rosa, da Rosa, & Bozzetti, 2009). This marker is not ovarian-cancer specific, as it is also elevated in several other cancers and in some in noncancerous conditions. Furthermore, CA 125 is not very sensitive at detecting early-stage ovarian cancer, as approximately 50% of stage I ovarian cancer patients have a normal CA 125 level. Recently, a new marker, human epididymis protein 4 (HE4) has been increasingly used in conjunction with CA 125 for differential diagnosis between benign gynecologic disease and ovarian cancer. The definitive diagnosis of ovarian cancer is based on pathologic evaluation of tissue and abdominal fluid from a biopsy or surgery.

Standard treatment of ovarian cancer involves surgical removal of the ovaries and, if needed, fallopian tubes, combined with taxane- and platinum-based systemic chemotherapy (Rutten, Leeflang, Kenter, Mol, & Buist, 2014). Targeted treatments against tumor blood vessels, and various anti-estrogen treatments, are also used. Testing of the CA 125 marker is often used to monitor the effectiveness of therapy.

When multiple, apparently equivalent chemotherapy options are available, in vitro chemosensitivity/resistance assays can be used to determine which chemotherapy drugs are best suited for a particular patient(Grendys et al., 2014). As of 2013, both the American Society of Clinical Oncology and the NCCN, while recognizing the potential importance of chemosensitivity testing, had determined that there was insufficient evidence that those tests improved survival and thus recommended that their use be limited to patients participating in clinical trials. However, during the Demonstration time period, clinicians treating ovarian cancer patients frequently ordered chemosensitivity assays, most notably ChemoFx (Precision Therapeutics, Pittsburgh, PA) (Brower, Fensterer, & Bush, 2008).

According to the NCCN guidelines, personal history of epithelial ovarian cancer or fallopian tube cancer is a sufficient indication for genetic counseling and testing for mutations in

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BRCA1 and BRCA2 genes, to detect the HBOC syndrome (National Comprehensive Cancer Network). Ovarian cancer is also a component of another hereditary condition, known as Lynch syndrome or hereditary non-polyposis colorectal cancer (HNPCC) (Toss et al., 2015), which is caused by mutations in the mismatch repair genes MLH1, MSH2, MSH6, and PMS2. NCCN guidelines recommend that these markers be tested if there are clinical indications of HNPCC (National Comprehensive Cancer Network).

8.2 Access to Care

There were 213,255 patients with ovarian cancer diagnosis in 2010–2013 and almost half of them (48.3%) received ovarian cancer-related testing (***Table 35***). This high rate of testing is not surprising, given that the cancer marker CA 125 is routinely used both in diagnosis and in monitoring of this cancer. The proportion of patients tested was even greater in MarketScan (56.8%), which may be partly explained by a much lower mean age of private payer patients. Black and Native American Medicare beneficiaries were much less likely to be tested compared to beneficiaries of Asian descent and Whites (39.0% and 39.9% vs. 51.6% and 49.2%, respectively). Of note, 1.3% of ovarian cancer patients in Medicare and 0.6% in MarketScan were erroneously coded as male.

Table 35
Counts and percentages of ovarian cancer beneficiaries (N) [1] receiving at least one ovarian cancer-related complex test (n) [2] as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Total	213,255	103,098	48.3		21,253	12,066	56.8	
Age				<0.0001				0.5333
55–59	8,233	3,977	48.3		10,608	6,000	56.6	
60–64	21,407	11,886	55.5		10,645	6,066	57.0	
65–69	53,438	27,639	51.7		—	—	—	
70–74	44,310	22,468	50.7		—	—	—	
75+	85,867	37,128	43.2		—	—	—	
Age (SD)	73.06 (8.36)	72.17 (7.80)			59.5 (2.8)	59.5 (2.8)		
Gender				<0.0001				<0.0001
Female	210,486	102,811	48.8		21,130	12,051	57.0	
Male	2,769	287	10.4		123	15	12.2	

(continued)

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Table 35 (continued)
Counts and percentages of ovarian cancer beneficiaries (N) [1] receiving at least one ovarian cancer-related complex test (n) [2] as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Race/Ethnicity				<0.0001				
White	180,449	88,776	49.2		—	—	—	
Black	19,701	7,690	39.0		—	—	—	
Asian/Pacific Islander	3,910	2,016	51.6		—	—	—	
Hispanic	4,275	2,105	49.2		—	—	—	
North American/Native	747	298	39.9		—	—	—	
Other	3,272	1,698	51.9		—	—	—	
Unknown	901	515	57.2		—	—	—	
Medicaid Status				<0.0001	—	—	—	
No Medicaid	175,296	87,517	49.9		—	—	—	
Medicaid	37,959	15,581	41.0		—	—	—	
Clinical Characteristics								
Risk Score (SD) [3]	1.55 (1.32)	1.56 (1.31)		<0.0001	—	—	—	
ESRD [3]								
No	211,704	102,702	48.5	<0.0001	—	—	—	
Yes	1,551	396	25.5		—	—	—	

— = not available.

[1] As identified by having ICD9 codes 183.0-183.9 anywhere in MedPAR, Part B, or Outpatient for these years.
[2] Any Demonstration test code if billed with ovarian cancer as a principal diagnosis.
[3] Not provided for MarketScan at this time.

SOURCE: jl44 (Medicare); MKTSCN_JL_EVAL_SignificanceTests55 (MarketScan).

8.3 Quality of Care

We sampled two cases of ovarian cancer for medical records abstraction. In addition, five cases sampled for breast cancer and one sampled for lung cancer had or had previously had ovarian cancer. One of the cases sampled for breast cancer actually had no mention of breast cancer in the chart, but did have a history of ovarian cancer. One patient had complex testing for monitoring (CA15-3/ CA27.29) and one for tumor characterization (HER2/neu). Surprisingly, of six cases with a history of both breast and ovarian cancer, only one had documented BRCA testing.

8.4 Health Outcomes

Two of the eight cases (25%) of ovarian cancer had died by the end of 2013. The number of records was insufficient for other analyses.

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8.5 Health Care Utilization

The utilization of complex testing in the management of ovarian cancer patients increased sharply between 2010 and 2012 (***Figure 9***). Billing for four selected Demonstration-eligible HCPCS codes that are required for most complex testing increased 32% to 57% during this period.

No abstracted medical records data on treatment utilization are available for patients with ovarian cancer.

8.6 Medicare and Beneficiary Expenditures

Mean Medicare expenditures for ovarian cancer patients who received a complex test were only slightly higher, $259, than the mean for ovarian cancer patients who did not receive a complex test (***Table 36***), and annualized expenditures were $4,111 lower among patients who received a complex test. As with other cancer types, the difference in mean payments between patients who received testing and those who did not was larger for Part B payments, $2,487, than for outpatient payments, $1,121. Mean per patient expenditures for privately insured ovarian cancer patients age 55–64 were higher than those for Medicare patients for every year between 2011 and 2013 (Appendix C, table C.9).

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Figure 9
Number of patients by year undergoing specific Demonstration test codes for ovarian cancer

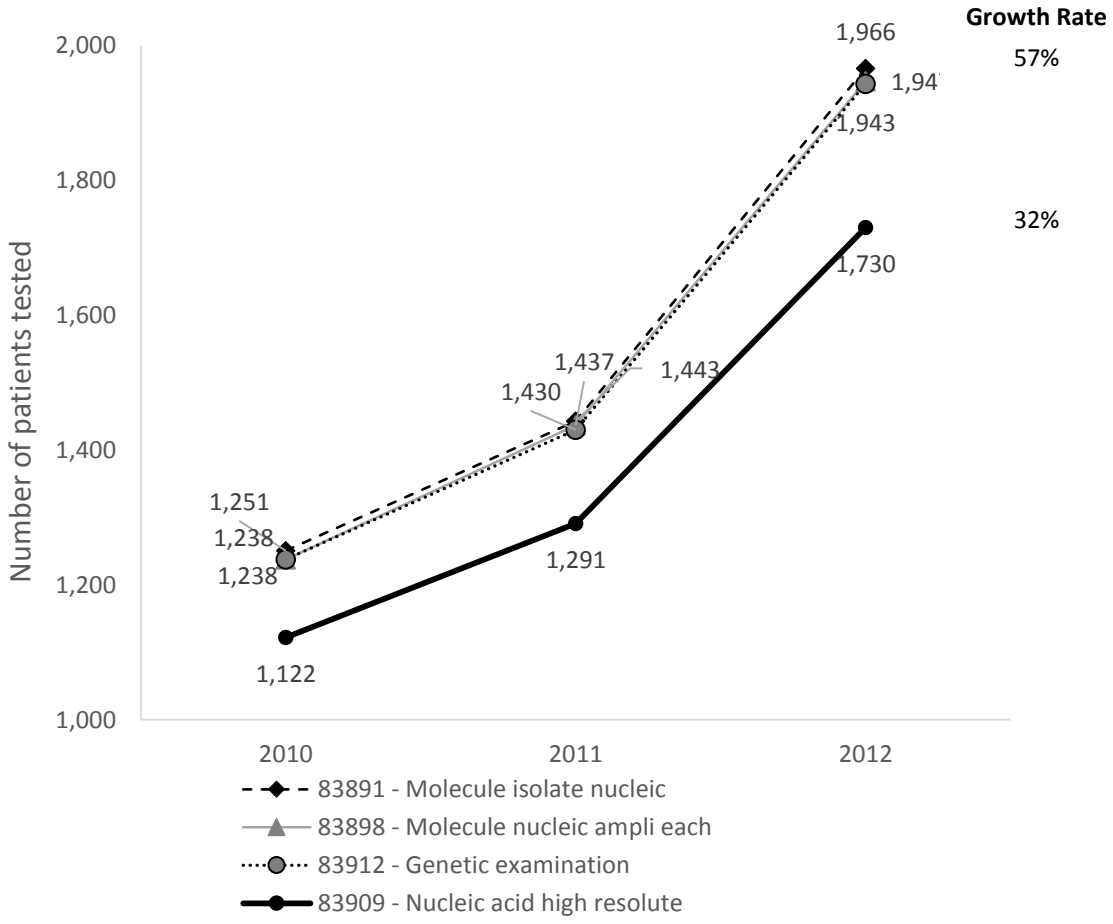

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Table 36
Payment summaries for ovarian cancer patients covered by Medicare (2010–2013)

	Medicare					MarketScan				
	Did not receive a complex test for ovarian cancer		Received a complex test for ovarian cancer			Did not receive a complex test for ovarian cancer		Received a complex test for ovarian cancer		
Description	Mean	SD	Mean	SD	p-value	Mean	SD	Mean	SD	p-value
Inpatient facility payments	2,685	10,080	1,345	6,342	<0.0001	11,903	36,424	10,429	27,808	0.0012
Outpatient facility payments	3,397	7,862	4,518	9,718	<0.0001	12,030	27,121	16,172	37,849	<0.0001
Physician/supplier payments	5,826	9,225	8,313	11,867	<0.0001	9,246	16,173	12,279	19,775	<0.0001
Total payments	16,597	21,715	16,857	20,449	0.0045	33,179	57,416	38,880	60,081	<0.0001
Annualized total payments	23,833	46,646	19,722	26,699	<0.0001	45,473	99,949	50,612	92,096	<0.0001

SOURCE: RTI analysis of Medicare claims data. Programs jl44.

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CHAPTER 9
COMPLEX LABORATORY TESTING IN HEMATOLOGIC CANCER PATIENTS

9.1 Use of Complex Tests in Hematologic Cancers

Hematologic malignancies (bone marrow–derived proliferative disorders) are cancers of blood and lymphatic system cells. They represent a wide array of diseases and can be classified by several overlapping criteria, including the cell type of origin (myeloid vs. lymphocytic malignancies) or the site of origin of malignancy (leukemias vs. lymphomas). Leukemias originate in bone marrow and lymphomas originate in lymph nodes. However, leukemias and lymphomas involving the same cell type often can have very similar presentation and course. The most common leukemias and lymphomas are summarized in ***Table 37***.

Table 37
Common leukemias and lymphomas

Malignancy	Age at diagnosis	Notes
Chronic lymphocytic leukemia (CLL)	>50 y; extremely rare in children; median age at diagnosis 72 y	Most common leukemia in the Western world
Acute lymphoblastic or lymphocytic leukemia (ALL)	Bimodal age distribution (highest in children younger than 5, another peak in incidence above 50 y)	Most cases occur in children, but most deaths (about 4 of 5) occur in adults
Chronic myelogenous leukemia (CML)	More common in the elderly; median age at diagnosis 65 y	First use of targeted tyrosine kinase inhibitor (TKI) treatment (imatinib)
Acute myelogenous leukemia (AML)	>45 y; median age at diagnosis 67 y	Most common acute leukemia affecting adults
Non-Hodgkin lymphoma (a diverse group of disease)	Median age at diagnosis: 66 y. Can occur at any age, but >95% of cases occur in adults	More common in men than in women

In 2013, there were an estimated 569,536 people living with non-Hodgkin lymphoma and 333,975 people living with leukemia in the United States (National Cancer Institute; National Cancer Institute). Age of onset and overall survival vary greatly depending on the particular disease type.

Most hematologic cancer cases are initially asymptomatic or associated with unspecific symptoms; they are often identified incidentally in a routine physical exam. The first step in diagnosis is a complete blood count and peripheral blood smear. If malignancy-associated abnormalities are detected, additional tests are used for differential diagnosis. These include laboratory tests (bone marrow morphology, immunological phenotyping, cytogenetic analysis,

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molecular testing) and imaging techniques that provide information about the extent of cancer in the body (X-ray, CT scan, PET scan, MRI, ultrasound).

Hematologic malignancies are treated with a variety of methods, sometimes in combinations, including chemotherapy, radiation, targeted pharmacological treatments (e.g., monoclonal antibodies and tyrosine kinase inhibitors), and bone marrow transplantation. Lymph node surgery is sometimes used in certain types of lymphoma, and splenectomy (partial or complete spleen removal) is applied in certain types of lymphoid malignancies, in particular when the spleen is enlarged.

In addition to supporting diagnosis, cytogenetic and molecular tests are used for determining prognosis, selecting treatment, and assessment of potential disease relapse during and after treatment. These tests are performed on blood samples or on biopsy material from bone marrow, lymph nodes, or, less commonly, spleen.

Testing for clonal rearrangements in immunoglobulin genes (IGH and IGK) is used to identify lymphoid neoplasms. It can also be used also for identification of residual disease or early recurrence after treatment in patients with a previous diagnosis. Also, several hematologic malignancies have unique molecular signatures which are used for both diagnosis and targeted treatment planning. For example, the hallmark of chronic myelogenous leukemia (CML) is the presence of a chromosomal translocation (Philadelphia chromosome) resulting in the BCR-ABL1 gene fusion. Testing for BCR-ABL1 is an essential part of differential diagnosis of CML and allows for selecting patients for treatment with tyrosine kinase inhibitors, such as imatinib, that specifically target BCR-ABL1. Targeted treatments have greatly improved CML survival, as illustrated by increasing prevalence of the disease. Other markers that have been targeted by specific inhibitors include JAK2, which is mutated in myeloproliferative neoplasms other than CML, and Bruton's tyrosine kinase (BTK), which plays a role in B-cell malignancies (National Comprehensive Cancer Network). Monitoring targeted therapies with molecular tests is important, because over time some patients develop drug-resistant mutations. Also, chemotherapy can cause further genetic alterations, not present at initial diagnosis. Therefore, the same test often needs to be administered multiple times over the course of the disease.

Molecular tests such as histocompatibility antigens (HLA) and chimerism are also crucial in bone marrow transplantation, for determining suitability of potential donors and for post-transplantation monitoring. Immunosuppressed patients after transplantation are also closely monitored for possible infections using molecular methods. During the time of the Demonstration, these infection tests were often billed with the NOC code 87799 (Infectious agent detection by nucleic acid). Molecular testing guidelines for hematologic malignancies have been outlined by several professional organizations, including the NCCN (National Comprehensive Cancer Network).

9.2 Access to Care

We identified 512,210 beneficiaries who had claims with hematologic malignancies in 2010–2013, of whom 7.9% were tested (***Table 38***). The probability of testing was strongly reversely correlated with age, the frequency of testing among patients aged 75 and older being less than half that among patients aged 65-69 years (5.4% vs. 12.1%, respectively). There was a

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less strong correlation with ethnicity/race, although we observed lower frequency of testing among Black and Hispanic beneficiaries (6.8% and 7.1%), respectively, than among White beneficiaries (8.0%). Privately insured patients were slightly more likely (1.2 percentage points) to receive a complex test than Medicare beneficiaries.

Table 38
Counts and percentages of hematologic cancer beneficiaries (N) [1] receiving at least one hematologic cancer-related complex test (n) [2] as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
	N	n			N	n		
Description	Total	Tested	%	p-value	Total	Tested	%	p-value
Total	512,210	40,351	7.9		88,241	7,710	8.7	
Age				<0.0001				<0.0001
55–59	15,101	1,815	12.0		41,799	3,899	9.3	
60–64	30,131	3,547	11.8		46,442	3,811	8.2	
65–69	88,669	10,769	12.1		—	—	—	
70–74	93,517	8,887	9.5		—	—	—	
75+	284,792	15,333	5.4		—	—	—	
Age (SD)	75.94 (8.74)	72.52 (7.96)			59.6 (2.8)	59.4 (2.8)	—	
Gender				0.0007				0.0072
Female	240,284	18,604	7.7		40,238	3,628	9.0	
Male	271,926	21,747	8.0		48,003	4,082	8.5	
Race/Ethnicity				<0.0001				
White	445,818	35,511	8.0		—	—	—	
Black	44,323	3,025	6.8		—	—	—	
Asian/Pacific Islander	5,223	407	7.8		—	—	—	
Hispanic	7,814	552	7.1		—	—	—	
North American/Native	1,558	115	7.4		—	—	—	
Other	5,948	559	9.4		—	—	—	
Unknown	1,526	182	11.9		—	—	—	
Medicaid Status				<0.0001				
No Medicaid	441,881	35,479	8.0		—	—	—	
Medicaid	70,329	4,872	6.9		—	—	—	
Clinical Characteristics								
Risk Score (SD) [3]	2.12 (1.53)	2.26 (1.71)		<0.0001	—	—	—	
ESRD [3]				<0.0001				
No	499,253	39,739	8.0		—	—	—	
Yes	12,957	612	4.7		—	—	—	

— = not available.

[1] As identified by having ICD9 codes 200.00-208.92 anywhere in MedPAR, Part B, or Outpatient for these years.
[2] Any Demonstration test code if billed with hematologic cancer as a principal diagnosis.
[3] Not provided for MarketScan at this time.

SOURCE: RTI analysis of Medicare and Marketscan claims. jl44; MKTSCN_JL_EVAL_SignificanceTests55

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9.3 Quality of Care

We abstracted medical records for 59 leukemia cases, of which 45 (76%) had documented complex testing and 14 (24%) did not (***Table 39***). The majority of the cases (29 of 59) had AML. Karyotyping and FISH analyses were used in the management of all types of hematologic malignancy. Molecular analyses were done to identify the presence of chromosome rearrangements or the product of the fused genes or for acquired mutations associated with specific cancer types. For example, of the 14 cases of CML, all 10 cases with documented complex testing had molecular testing specifically for the BCR-ABL chromosome rearrangement or had karyotyping or FISH analysis that could detect the rearrangement. The 14 cases that did not have documented complex testing fell into three categories: the patients hematologic malignancy was in remission and the index admission was for a different medical reason, the patient was very ill and no further treatment was planned, or the medical records we received were limited and incomplete.

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Table 39
Complex testing by type of hematologic malignancy

Type of blood malignancy	Number of cases	Type and number of complex tests
Chronic lymphocytic leukemia (CLL)	9	FISH for chromosome rearrangements, 3 Karyotype, 1 ZAP70, 1 None documented (5)
Acute lymphoblastic or lymphocytic leukemia (ALL)	4	FISH for chromosome rearrangements 2, BCR-ABL, 3 Karotyping, 3 CEBPA, 1
Chronic myelogenous leukemia (CML)	14	BCR-ABL, 7 Karyotype, 2 FISH, 1 ANA and double strand DNA AB, 1 PDGFRB/TEL, 1 MDS, 1 None documented, 4
Acute myelogenous leukemia (AML)	29	FLT3, 14 NPM1, 9 JAK2, 2 Karyotype, 16 FISH, 6 CEBPA, 6 AML1-ETO, 1 PML-RARA, 1 None documented, 5
Acute Promyelocytic Leukemia, myelodysplastic syndrome	1	FISH, 1 Karyotype, 1
Plasma cell leukemia	1	FISH, 1 Karyotype, 1
Multiple myeloma	1	FISH, 1 Karyotype, 1

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9.4 Health Outcomes

Of the patients with hematologic malignancies who had documentation of one or more complex tests, 56% were alive at the end of 2013, compared to 36% of those for whom there was no documented testing.

Information on treatment response was present in 40 of the 59 hematologic cancer patients with medical records data. Among the 32 patients who had received at least one complex test, 11 (34%) had improved response after treatment, 10 (31%) had stable response after treatment, and 11 (34%) had declined or worsened treatment response. Among eight patients who did not receive complex tests, two had improved response after treatment, two had stable response, and four declined after treatment **(*Table 40*).** The difference was not statistically significant.

Table 40
Response to treatment for hematologic cancer patients who did and did not receive complex tests

	Treatment response			
Complex tests	Declined	Improved	Stable	Total
No	4 (50.0)	2 (25.0)	2 (25.0)	8 (20.0)
Yes	11 (34.4)	11 (34.4)	10 (31.3)	32 (80.0)
Total	15 (37.5)	13 (32.5)	12 (30.0)	40 (100)

p-value: 0.78, Fisher's exact test

9.5 Health Care Utilization

The utilization of complex testing in the management of hematologic cancers patients increased only slightly between 2010 and 2012 (***Figure 10***). Billing for five selected Demonstration-eligible HCPCS codes that are required for most complex testing only increased 7% to 18% during this period. The slow growth likely reflects the longstanding and widespread use of complex testing in the management of these cancers: the Philadelphia chromosome was first discovered in cases of CML in 1960 (Nowell, 2007).

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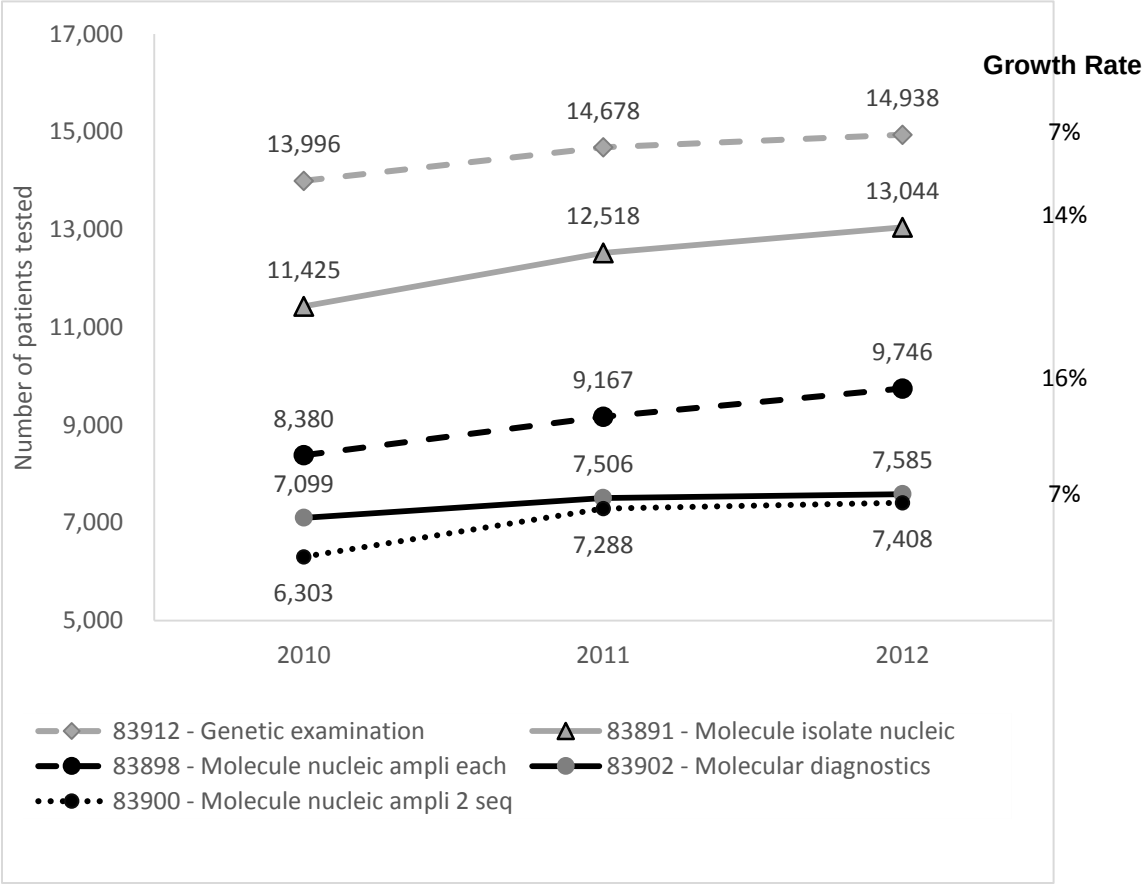
Figure 10
Number of patients by year undergoing specific Demonstration test codes for hematologic cancer



Information on treatment was available for 39 of the 59 patients with medical abstractions. Eighty percent of patients who did not receive treatment also did not receive complex tests. Three patients who did not have documented receipt of any complex test received chemotherapy **(*Table 41*).** Most (59%) of the patients who received complex tests also received chemotherapy. Four patients received stem cell treatments. The difference in treatment among patients who received complex tests and patients who did not received complex tests was statistically significant (p = 0.005).

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Table 41
Treatment approaches for patients with hematologic cancer who did and who did not receive complex tests

Complex Testing	Treatment				
	Chemotherapy	Radiation Therapy	Stem Cell Therapy	No Treatment	Total
	N(%)	N(%)	N(%)	N(%)	N(%)
No	3 (20.0)	0 (0)	0 (0)	12 (80.0)	15 (25.4)
Yes	26 (59.1)	1 (2.3)	4 (9.1)	13 (29.6)	44 (74.6)
Total	29	1	4	25	39

p-value: 0.005, Fisher's exact test

9.6 Medicare and Beneficiary Expenditures

Mean per patient Medicare expenditures for hematologic cancer patients who received a complex test were 57% higher than the mean for patients who did not receive a complex test, $39,498 compared to $25,109 (***Table 42***). Patients who received complex laboratory tests had higher payments than patients who did not for all payment types. Mean per patient expenditures for privately insured hematologic cancer patients age 55–64 were higher than the mean for Medicare patients for each of the three years for which we had data (Appendix C, Table C10).

Table 42
Payment summaries for hematologic cancer patients covered by Medicare (2010–2013)

Description	Medicare				p-value
	Did not receive a complex test for hematologic cancer		Received a complex test for hematologic cancer		
	Mean	SD	Mean	SD	
Inpatient facility payments	5,100	14,853	7,867	22,308	<0.0001
Outpatient facility payments	5,270	11,861	12,328	20,505	<0.0001
Physician/supplier payments	9,348	14,479	15,275	17,727	<0.0001
Total payments	25,109	28,899	39,498	37,327	<0.0001
Annualized total payments	37,137	65,353	50,362	70,840	<0.0001

SOURCE: RTI analysis of Medicare claims data. Programs jl44.

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CHAPTER 10
COMPLEX TESTING IN HEART TRANSPLANT PATIENTS

10.1 Use of Complex Tests in Heart Transplant Follow-up

Heart transplantation is performed for selected patients with end-stage congestive heart failure who have estimated less than 1 year survival without the transplant and who are not candidates for conventional therapy or other surgical options (Botta & Mancini, 2016). The criteria for evaluation and management of cardiac transplantation candidates have been outlined by the International Society for Heart and Lung Transplantation (ISHLT) (Mehra et al., 2006). The ISHLT has also provided clinical guidelines for the care of heart transplant recipients and patient risk stratification (Costanzo et al., 2010). A fundamental concern in the follow-up care of these patients is the risk for rejection of the new heart. Acute rejection accounts for 12% of deaths among patients who undergo heart transplantation (Taylor et al., 2009). Patients have traditionally been monitored for rejection through serial endomyocardial biopsies (EMB). Despite its usefulness, EMB remains an invasive procedure associated with rare but potentially serious complications and substantial cost.

In recent years, gene expression profiling has emerged as a noninvasive tool to identify patients at low risk for rejection, thereby potentially obviating the need for biopsies (Deng et al., 2006). A commercial genetic test named AlloMap became available in 2005 and was cleared by the Food & Drug Administration in 2008 (FDA, 2008, August 27). It is currently the only commercially available, validated assay to measure risk for cardiac rejection. Because it is a blood test, it is more readily obtained than an EMB and is more convenient and less risk to the patient. The ISHLT guidelines state that the AlloMap blood test (ABT) can be used to rule out the presence of transplant rejection in appropriate low-risk patients (Costanzo et al., 2010). AlloMap has been covered by Medicare and by a number of major commercial insurers since 2006.

10.2 Methods

The population of the heart transplant analyses was all beneficiaries receiving a heart transplant within claims of years 2010 to 2013 for Medicare and within claims of years 2011 to 2013 for MarketScan. The population is restricted to incident cases. The analysis of complex testing for heart transplant are facilitated because the a single complex test (ABT) and single competing procedure (i.e., EMB) used for management are readily identified in claims. If a beneficiary had two transplant events during the cohort time period, the second transplant and associated tests were dropped from the analysis, leaving a dataset with one transplant per individual. Some analyses were restricting to transplant recipients aged 55 years and older to increase comparability between the Medicare and MarketScan populations.

Logistic regression was used to evaluate the patient and provider characteristics that predicted whether AlloMap or biopsy was used to monitor for rejection and to evaluate the relationship of complex testing to mortality within the first year after transplant. Survival analysis was used to determine the length of time to a second AlloMap test among those who had received an initial AlloMap test. These analyses were limited to the following populations

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- ***Factors predicting receipt of an AlloMap test:*** Patients with a transplant prior to December 31, 2012, who had received at least one AlloMap or biopsy and who had survived for at least 1 year post-transplant.

- ***Time between first and second AlloMap tests:*** Patients with a transplant prior to December 31, 2012, who had received at least one AlloMap and who had survived for at least 1 year post-transplant.

- ***Relationship of AlloMap testing to mortality within 1 year of transplant:*** Patients with a transplant prior to December 31, 2012, who had survived for at least 55 days post-transplant and whose vital status at 1 year post-transplant was known.

10.3 Access to Care

A total of 3,236 heart transplants were identified within the 2010–2013 CMS claim populations, after dropping 6 second transplant events. Of these 3,236 beneficiaries, 2,250 were aged 55 and over, among whom 736 (33%) had at least one ABT (***Table 43***). Similarly, for MarketScan 285 transplant events were identified in the 2011–2013 period with only 16% of these having received at least one ABT. There was little variation in receipt of testing among different groups of patients, although substantially more men than women received heart transplants (1,783 vs. 467).

Table 43
Counts and percentages of heart transplant recipients (N) receiving at least one AlloMap test (n) as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Total	2,250	736	33		285	46	16	
Age				0.11				0.80
55–59	486	147	30		135	21	16	
60–64	584	195	33		150	25	17	
65–69	964	310	32		—	—	—	
70–74	205	82	40		—	—	—	
75+	11	2	18		—	—	—	
Missing	—	—	—		—	—	—	
Age (SD)	64.4 (4.6)	64.7 (4.6)	—	0.03	59.7 (2.9)	60.2 (2.7)	—	0.16
Gender				0.18				0.59
Female	467	165	35		71	10	14	
Male	1,783	571	32		214	36	17	
Missing	—	—	—		—	—	—	

(continued)

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Table 43 (continued)
Counts and percentages of heart transplant recipients (N) receiving at least one AlloMap test (n) as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Race/Ethnicity								
White	1,735	580	33		—	—	—	
Black	357	116	32		—	—	—	
Asian/Pacific Islander	35	11	31		—	—	—	
Hispanic	43	7	16		—	—	—	
North American/Native	4	0	0		—	—	—	
Other	61	17	28		—	—	—	
Unknown	15	5	33		—	—	—	
Missing	—	—	—		—	—	—	
Medicaid Status				0.69				
No Medicaid	1,890	615	33		—	—	—	
Medicaid	360	121	34		—	—	—	
Missing	—	—	—		—	—	—	
Clinical Characteristics				0.40				
Risk Score (SD)	2.8 (2.1)	2.9 (2.0)	—		—	—	—	
ESRD				0.04				
No	2,156	714	33		—	—	—	
Yes	94	22	23		—	—	—	

— = not available.

The hospital where the transplant was performed and patient's race and age at transplant predict whether a patient received an AlloMap test. The hospital random effect was $\hat{\sigma}_h$ = 2.23, 95% CI: (1.85, 2.75). The probability of a white patient receiving an AlloMap test was 0.37, while it was .33 for African American patients and .26 for other races. The probability of receiving an AlloMap test increased by 1% for each year of age at transplant. Hospital of transplant and age at transplant were also related to the time between the first and second AlloMap test, which was also predicted by the timing of the first AlloMap test (***Figure 11***).

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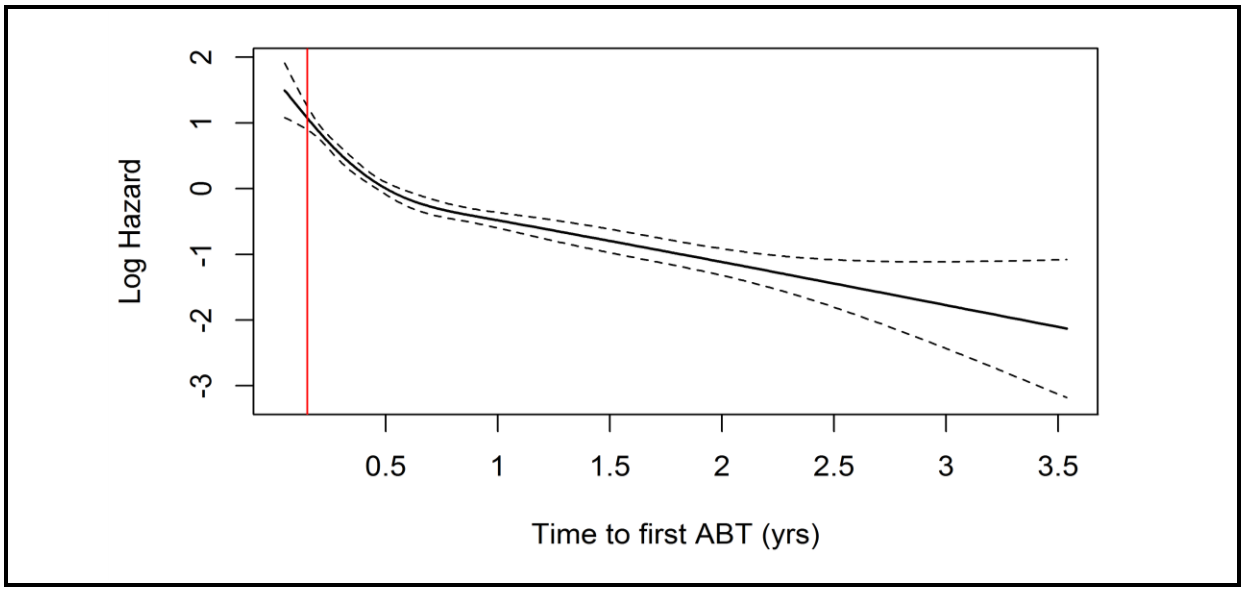
Figure 11
Time to receiving second AlloMap test by time of first test



10.4 Quality of Care

We abstracted medical records for 37 heart transplant patients. Twelve of these patients had documented receipt of at least one AlloMap test and 21 of at least one endomyocardial biopsy. The majority of the patients with AlloMap had more than one test. In the few patients for whom we had dates for all of the series of tests, the time between testing was 1 to 2 months.

Four patients had documented receipt of both tests. For these patients, the biopsy was performed either within 1 to 3 weeks of the transplant to evaluate initial acceptance of the transplant or in response to an AlloMap test that indicated rejection of the transplant (***Figure 12***).

Eight patients had neither test documented in the medical records that we received. Some of these cases were post-transplant patients who had received their transplant more than 5 years previously and were admitted in 2012 for evaluation and treatment of complications of anti-rejection medications or comorbidities, which may account for the lack of documented tests for rejection. For at least one of these cases, the physician wanted to use AlloMap but could not get it covered by insurance (Figure 14). Other cases, however, were recent transplant recipients who were being monitored for rejection using clinical examination and echocardiograms only.

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Figure 12
Use of AlloMap in management of heart transplant patients; case studies

Barriers to use	Use in management
▪ Note dated 2.28: AlloMap (if insurance allows) noted in clinic note of 2/28/13. ▪ Note dated 7/11/13: Unable to get an AlloMap, therefore we will follow him with echocardiograms and clinical exam." [Transplant done: 11/2007]	▪ 12/17/2012. AlloMap test indicates rejection ▪ 12/19. Endomyocardial biopsy showed mild acute cellular rejection, Grade 1R. Findings consistent with anti-body mediated rejection grade 1, Cytomegalovirus positive. ▪ 12/19–12/21. Change in treatment: High dose steroids x 3 days, started antibacterial and antifungal medications, continued on antiviral medications. ▪ 12/22/2012. Discharged to home.

10.5 Health Outcomes

Among the heart transplant patients with medical record abstractions, 93% of those who had received a complex test were alive, compared to 79% of those who had not received a complex test. The difference was not statistically significant (p = 0.2155).

Among Medicare beneficiaries who had survived for at least 55 days after their heart transplant, 0.6% of patients who had received an AlloMap testing died within a year post-transplant, compared to 2.7% of those who had received only biopsies and 6.2% of patients who did not receive any test for monitoring rejection. These results control for the presence or absence of complications; no other patient characteristics predicted mortality.

Information on treatment response was available for 32 of 38 heart transplant patients with medical records abstractions. Among the 11 patients who received at least one AlloMap test, three (27%) improved after treatment, six (55%) were stable after treatment, and two (18%) declined after treatment. Among the 21 patients who did not receive an AlloMap test, 13 (62%) improved after treatment and 7 (33%) were stable. One (5%) patient declined after treatment **(*Table 44*).** The differences in response were not statistically significant.

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Table 44
Response to treatment for heart transplant patients who did and did not receive complex tests

	Treatment Response			
Complex Tests	Declined	Improved	Stable	Total
No	1 (4.8)	13 (61.9)	7 (33.3)	21 (65.6)
Yes	2 (18.2)	3 (27.3)	6 (54.6)	11 (34.4)
Total	3 (9.4)	16 (50.0)	13 (40.6)	32 (100)

p-value: 0.12, Fisher's exact test

10.6 Health Care Utilization

Treatment information was available for 34 of 38 patients with a heart transplant. Twelve patients (31.6%) received an endomyocardial biopsy alone or in combination with medications. Twelve patients had documentation of medications such as IV antibiotics, transplant medications such as tacrolimus, prednisone, cellcept, and vorinconazole. Thirteen patients received routine follow up without biopsy, including procedures such as echocardiogram (EKG), PET scan, CT chest, heart catheterization, office visit, and lab work (***Table 45***).

Table 45
Treatment approach for heart transplant in beneficiaries who received and who did not receive complex tests.

	Treatment					
Complex testing	Biopsy+Medication N(%)	Biopsy N(%)	Routine follow-up +biopsy N(%)	Routine follow-up +medication N(%)	Routine follow-up N(%)	Total N(%)
No	3 (14.3)	5 (23.8)	1 (4.8)	6 (28.6)	6 (28.6)	21 (61.8)
Yes	0 (0.0)	4 (30.8)	1 (7.7)	3 (23.1)	5 (45.5)	13 (38.2)
Total	3 (8.8)	9 (26.5)	2 (5.9)	9 (26.5)	11 (32.4)	34 (100)

p-value: 0.72, Fisher's exact test

The difference in costs between mean per patient Medicare expenditures for heart transplant patients who received a complex test and for patients who did not receive a complex test was only $248 (0.3%) and was not statistically significant (***Table 46***). Inpatient expenditures were much higher for patients who did not receive an AlloMap test, while outpatient facility and physician payments were higher for patients who received an AlloMap test. Mean per patient expenditures for privately insured heart transplant patients age 55–64 were higher than the mean for Medicare patients for each year from 2011 to 2013.

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Table 46
Payment summaries for heart transplant patients age 55 and older covered by Medicare (2010–2013)

	Medicare				
	Did not receive an AlloMap test		Received an AlloMap test		
Description	Mean	SD	Mean	SD	p-value
Inpatient facility payments	37,794	100,460	15,466	56,826	<0.001
Outpatient facility payments	11,817	13,624	18,808	12,790	<0.001
Physician/supplier payments	17,268	16,525	25,484	13,809	<0.001
Total payments	77,406	110,735	77,654	66,869	0.95
Annualized total payments	126,849	341,540	83,552	98,177	<0.001

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CHAPTER 11
COMPLEX TESTING FOR SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS

11.1 Use of Complex Tests in Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an autoimmune disease, in which antigen-antibody complexes form in the bloodstream and deposit in tissues, leading to chronic inflammation and eventually to tissue damage. SLE affect joints, skin, brain, lungs, kidneys, and blood vessels. The usual onset is in young adults, but it may manifest at any age, including childhood. The reported incidence rates of SLE range from approximately 1 to 10 per 100,000 person-years, and prevalence rates range from 20 to 70 per 100,000 (Pons-Estel, Alarcon, Scofield, Reinlib, & Cooper, 2010). Similar to other autoimmune diseases, it is much more common in females, affecting 1 in approximately 700 women of childbearing age. It is also more common and more severe in African Americans, and possibly in Hispanics, Asians, and Native Americans than in Caucasians (Centers for Disease Control and Prevention, 2015b).

The clinical presentation of SLE varies greatly and also overlaps with several other autoimmune diseases (e.g., rheumatoid arthritis). Comprehensive SLE diagnosis involves clinical evaluation of physical signs and symptoms in combination with an array of blood tests (Yu, Gershwin, & Chang, 2014). The initial screen is an immunofluorescence assay for the presence of generic antinuclear antibodies (ANAs). This test is sensitive, but not very specific to SLE. If the result is positive, more specific tests need to be performed that detect other antibodies, mainly anti-dsDNA, anti-Smith (Sm) antigen, anti-histone, and anti-RNP. In particular, the presence of anti-histone antibodies is indicative of drug-induced SLE. These tests are also used for monitoring the disease during treatment.

Because SLE may lead to damage of various tissues and organs, other tests may be applied to evaluate the patient's condition. Kidney inflammation (lupus nephritis) is of particular concern, with renal failure being the most common cause of lupus-related deaths. Central nervous system (CNS) involvement is also quite common; therefore, in addition to blood serum, cerebrospinal fluid can be tested for the presence of ANAs.

The American College of Rheumatology (ACR) last updated the clinical classification criteria for SLE diagnosis in 1997, and the guidelines for management of SLE in 1999 (Guidelines, 1999). Specific guidelines for screening, treatment, and management of SLE patients with kidney involvement were issued by ACR in 2012 (Hahn et al., 2012). In August 2011, ACR issued the Position Statement on the Methodology of Testing for Antinuclear Antibodies (American College of Rheumatology). It emphasized the importance of immunofluorescence for ANA as the gold standard for ANA testing in SLE and specified standards for detecting ANAs and anti-DNA, anti-Sm, anti-RNP, and other antibodies involved in SLE diagnostics.

The Systemic Lupus International Collaborating Clinics revised the SLE classification criteria in 2012 (Petri et al., 2012). In 2014, an international task force formulated recommendations aimed at improving the management of SLE in clinical practice through target-based approaches (van Vollenhoven et al., 2014).

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11.2 Methods

The SLE population was defined as all beneficiaries with an SLE diagnosis within claims of years 2010 to 2013 for Medicare and within claims of years 2011 to 2013 for MarketScan. The resulting population thus contains both incident and prevalent cases. We restricted comparison of Medicare and MarketScan beneficiaries with an SLE diagnosis to those aged 55 years and older to increase comparability among the populations.

11.3 Access to Care

A total of 316,419 individuals aged 55 and over with a SLE diagnosis were identified in the Medicare data, among whom 139,433 or 44% received at least one of the three diagnostic tests (***Table 47***). Medicare beneficiaries were more likely to have received a complex test during the study period than privately insured patients in the MarketScan population, among whom 30% of 45,790 SLE cases received one of the three lupus tests.

Testing was relatively constant between age groups until age 75+, when the proportion of beneficiaries who received testing declined from 47% for ages 70–74 to 39% for ages 79 and older. The likelihood of an SLE patient receiving a complex test also varied by sex, race and ethnicity, and end-stage renal disease status (ESRD). As expected, SLE patients were more likely to be women than men. Medicare beneficiaries who were women were more likely than men to receive a complex test for lupus (45% vs. 38%); the difference among privately insured patients was smaller (31% vs. 29%). Asian/Pacific Islanders (54%) and Hispanics (50%) were more likely than whites (44%) or blacks (43%) to receive a complex test, and American Indians/Alaska Natives were least likely to receive a complex test (30%). SLE cases with ESRD were much less likely to have a complex test than those without ESRD (26% vs. 44%, respectively).

Table 47
Counts and percentages of SLE beneficiaries (N) [1] receiving at least one lupus-related complex test (n) [2] as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Total	316,419	139,433	44		45,790	13,790	30	
Age				<0.001				<0.001
55–59	34,093	15,256	45		26,194	8,125	31	
60–64	34,692	15,157	44		19,596	5,659	29	
65–69	89,214	42,430	48		—	—	—	
70–74	60,593	28,273	47		—	—	—	
75+	97,827	38,317	39		—	—	—	
Missing	—	—	—		—	—	—	
Age (SD)	70.5 (8.6)	69.9 (8.0)	—	<0.001	59.0 (3.0)	58.9 (2.9)	—	<0.001

(continued)

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Table 47 (continued)
Counts and percentages of SLE beneficiaries (N) [1] receiving at least one lupus-related complex test (n) [2] as identified in Medicare (2010–2013) and MarketScan (2011–2013) data

	Medicare				MarketScan			
Description	N Total	n Tested	%	p-value	N Total	n Tested	%	p-value
Gender								<0.001
Female	260,414	118,323	45	< 0.001	39,535	12,102	31	
Male	56,005	21,110	38		6,255	1,682	27	
Missing	—	—	—		—	—	—	
Race/Ethnicity				< 0.001				
White	251,902	110,333	44		—	—	—	
Black	44,057	19,031	43		—	—	—	
Asian/Pacific Islander	4,776	2,569	54		—	—	—	
Hispanic	7,835	3,956	50		—	—	—	
North American/Native	1,776	541	30		—	—	—	
Other	4,949	2,471	50		—	—	—	
Unknown	1,124	532	47		—	—	—	
Missing	—	—	—					
Medicaid Status				< 0.001				
No Medicaid	251,484	111,924	45		—	—	—	
Medicaid	64,932	27,507	42		—	—	—	
Missing	3	2	67		—	—	—	
Clinical Characteristics								
Risk Score (SD)	1.5 (1.1)	1.4 (1.0)	—	< 0.001	—	—	—	
ESRD								
No	309,812	137,721	44	< 0.001	—	—	—	
Yes	6,604	1,710	26		—	—	—	
Missing	3	2	67		—	—	—	

— = not available.

[1] As identified by have ICD9 code 710.0 anywhere in MedPAR, Part B, or Outpatient for these years.
[2] HCPCS code 86225 (dsDNA), 86226 (ssDNA) or 86235 (ENA).

11.4 Quality of Care

We abstracted medical records for 39 Medicare beneficiaries with SLE, of whom 30 (77%) cases had documentation of one or more complex tests. Seventy-two percent of SLE patients had received anti-ds DNA tests, 21 as the first test documented within the abstracted records. Sixteen (41%) had received an antinuclear antibody test (ANA), and 27 (69%) had received a test for antibodies to RNA. Eleven of 39 cases (28%) had two or more anti-ds DNA tests. SLE cases who did not have documented complex testing were those receiving clinical care for complications of SLE.

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11.5 Health Outcomes

Information on treatment response was available for 29 of 39 SLE patients with medical records abstractions. Among the 22 patients who received at least one complex test, 18 (82%) improved after treatment, 1 (5%) was stable, and 3 (14%) declined after treatment. Among the seven patients who did not receive complex tests, five (71%) improved after treatment, five (71%) were stable, and one (14%) declined. ***(Table 48)***. The difference, which was highly significant (p = 0.0006), may be because of better diagnosis, or patients with complex tests may be more recently diagnosed and have access to improved treatments.

Table 48
Response to treatment for systemic lupus erythematosus among beneficiaries who received and did not receive complex tests

	Treatment Response			
Complex Tests	Declined	Improved	Stable	Total
No	1 (14.3)	1 (14.3)	5 (71.4)	7 (24.1)
Yes	3 (13.4)	18 (81.8)	1 (4.6)	22 (75.9)
Total	4 (13.8)	19 (65.5)	6 (20.7)	29 (100)

p-value: 0.0006, Fisher's exact test

11.6 Health Care Utilization

Information on treatment was available for 24 of the 39 patients with systemic lupus erythematosus for whom we had medical records abstractions. Of the 19 patients who had at least one documented complex test, 2 received dialysis and 17 received immunosuppressant or steroid treatment ***(Table 49)***. All five of the patients who did not have a documented complex test received immunosuppressant or steroid treatment; none received dialysis. The difference was not statistically significant. We should note that the Medicare population of SLE patients overrepresents patients with severe disease, as end-stage renal disease is an outcome of severe SLE and a qualifying condition for Medicare.

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Table 49
Treatment approach for systemic lupus erythematosus in beneficiaries who received and who did not receive complex tests

Complex testing	Dialysis	Immunosuppressant and/or steroid treatment	Total
No	0	5 (100)	5 (20.8)
Yes	2 (10.5)	17 (89.5)	19 (79.2)
Total	2 (8.3)	22 (91.7)	24 (100)

p= 0.72, Fisher's exact test

11.7 Expenditures

Mean per patient Medicare expenditures for SLE who received a complex test (***Table 50***) were $1,472 lower than per patient expenditures for patients who did not receive a complex test. Expenditures in every category were lower for patients who received a complex test. Mean per patient expenditures for privately insured SLE patients age 55–64 were lower than the mean for Medicare beneficiaries for each year from 2011 to 2013 (Appendix C, Table 11).

Table 50
Payment summaries for systemic lupus erythematosus patients age 55 and older covered by Medicare (2010–2013) by receipt of complex tests

	Medicare				
	Did not receive a complex test		Received a complex test		
Description	Mean	SD	Mean	SD	p-value
Inpatient facility payments	1,490	8,676	757	5,482	<0.001
Outpatient facility payments	2,323	6,045	2,241	5,225	<0.001
Physician/supplier payments	4,387	7,661	5,050	5,917	<0.001
Total payments	11,588	19,705	10,116	14,472	<0.001
Annualized total payments	14,174	34,183	10,797	17,645	<0.001

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CHAPTER 12
DISCUSSION AND RECOMMENDATIONS

12.1 Participation

The Demonstration was implemented in the midst of multiple known and proposed billing and regulatory changes for molecular diagnostics 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 reimbursement. The AMA also began reviewing molecular diagnostic CPT codes, developed new codes, and effective January 1, 2013, deleted 21 codes eligible for the Demonstration. The new codes were not included in the eligible Demonstration codes, so many previously eligible tests could no longer be billed under the Demonstration.

The technological environment for molecular diagnostics 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 pricing and reduced applicability of the date-of-service rule to complex testing contributed to the lack of applications for G-codes, and therefore, to the low uptake of the Demonstration.

The effort and cost required to modify electronic medical record and billing systems was a major contributor to lack of uptake of the Demonstration for tests billed using HCPCS codes among the hospital and clinical laboratories we interviewed. This concern was noted even by the clinical laboratory that did bill the Demonstration for tests; it participated in the Demonstration at its clients' request. The hospital laboratories, which did not participate, were uncertain whether the benefits of participation to their patients or themselves would surpass the cost of participation. The increased use of specimens obtained from outpatient biopsies for complex testing may have also contributed to the lack of Demonstration uptake for tests billed using HCPCS codes.

12.2 Impact of the Demonstration

Given the extremely low participation in the Demonstration, it clearly 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 those beneficiaries who had a test billed under the Demonstration.

Most of the beneficiaries who had a laboratory test billed under the Demonstration had a cancer diagnosis, with lung cancer and colon cancer the most common diagnoses. The reasons for the selection of the tests of these few hundred patients for billing under the Demonstration are not clear. 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, which was noticeably absent from Demonstration claims. Although oncology is heavily reliant on molecular

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pathology and complex laboratory tests, Demonstration-eligible laboratory tests were associated with a wide variety of diagnoses.

12.3 Relationship of the Outcomes of Interest to the Date-of-Service Rule and Complex Testing

12.3.1 Access to Care

Our findings suggest that many Medicare beneficiaries receive complex tests appropriate for their diagnoses and clinical status. With the exception of hematologic cancers, Medicare beneficiaries were more likely to receive complex testing than privately insured patients with the same diagnosis. Our findings suggest that the date-of-service rule or other coverage issues may delay testing for some patients, however. Although healthcare providers uniformly say clinical requirements drive the ordering and timing of testing, some providers have policies to hold testing until 14 days after discharge, when the date-of-service rule no longer applies. In addition, the finding that over 60% of Demonstration-billed claims that could be linked to an inpatient stay were done ≤ 14 days after the stay suggests that in at least some cases, providers would prefer to order tests before 14 days after the stay. One of the oncologists interviewed noted that date-of-service rule delays treatment decisions and creates anxiety for some patients facing emotional diagnoses (e.g., breast cancer), but that the rule was only one of many factors that delay care.

Some patient characteristics affected the likelihood of receiving complex tests for multiple diagnosis. Tested patients were overall younger and healthier, as measured by their risk score and the proportion of beneficiaries with end stage renal disease (ESRD). This was expected, as testing of beneficiaries with a shorter expected survival and those receiving palliative care is less likely to impact treatment. The race and ethnicity of beneficiaries affects either their access to or uptake of complex tests. Although patterns varied somewhat by diagnosis, African Americans were less likely to receive complex tests for any diagnosis. Among heart transplant recipients, the disparity was statistically significant after controlling for the presence of complications. Although for some conditions (e.g., lung cancer) the decreased frequency of testing among African Americans can be partly explained by clinical differences between races, most differences in the frequency of testing probably reflect genuine disparities in access and warrant further investigation.

12.3.2 Quality of Care

The physicians we interviewed noted that complex tests are increasingly standard of care, and that they allow physicians to better anticipate an individual patient's prognosis and target treatment accordingly. Case studies from the medical records abstraction demonstrate that these tests are widely used for clinical management and that they can allow rapid identification of clinical problems and appropriate follow-up and treatment.

These physicians felt the impact of the date-of-service rule on the quality of care their patients receive depends heavily on the specific diagnosis and test: Some test results are needed quickly to make treatment decisions, but others, such as AlloMap, are performed on samples collected after discharge for long-term monitoring. Our analysis of the procedures associated

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with Oncotype Dx Breast tests suggests that some complex tests that used to be associated with an inpatient stay are now performed on biopsy samples obtained at outpatient clinics.

12.3.3 Health Outcomes

Receipt of complex testing was associated with increased survival among Medicare beneficiaries with a heart transplant in 2010–2012. Beneficiaries who received AlloMap testing were 89% less likely to have died than those who did not receive either AlloMap or biopsy, and 21% less likely to have died than those who only received biopsy.

Among the patients who had abstracted medical records data and a diagnosis of breast cancer, lung cancer, hematologic cancer, or heart transplant, more patients who received a complex test were alive at the end of 2013 than those who did not receive a complex test. The difference was not statistically significant and was likely related to differences in patient characteristics, however. Patients who were older, with a greater time since diagnosis, and who had more complications were less likely to have received a complex test.

The purpose of many complex tests is to guide treatment, with the expectation of improved outcomes with tailored treatment. We found that receiving a complex test was significantly associated with an improved treatment response for SLE patients, but not for other conditions. For lung cancer, receipt of a complex test was significantly associated with poorer response to treatment. There was no significant relationship between treatment response and the receipt of other complex laboratory tests.

12.3.4 Health Care Utilization and Expenditures

The use of complex tests for cancer diagnosis and treatment rose throughout 2010–2013 and will likely continue to increase, although the change in coding between 2012 and 2013 makes it difficult to analyze trends across those years. Of the six conditions we examined, the greatest increase between 2010 and 2012 was in complex tests used in the diagnosis or monitoring of ovarian cancer. The most frequently billed analyte-specific Demonstration codes were those used for breast and ovarian cancers and autoimmune diseases. In 2013, the most frequently billed Tier 1 (gene-specific) codes were pharmacogenomics tests for long-term use of medications and tests for markers associated with vascular disease and cancer markers.

The costs of such tests is substantial: In 2012, Medicare spent almost $405 million on Demonstration-eligible tests. Although the high costs of these tests is often justified by expected savings in overall expenditures, mean annualized expenditures for beneficiaries with breast, lung, and hematologic cancers who received a Demonstration test were higher than expenditures for patients who did not receive complex testing. Receipt of complex testing was associated with treatment approach among patients with hematologic cancer, lung cancer, and SLE, but not among patients with breast cancer or heart transplants. These findings should be interpreted with caution, given the small number of medical records available, however.

12.4 Limitations

These analyses have some important limitations. Information from the claims does not allow us to identify the exact denominator for calculating access (i.e., a number of patients in

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each cohort whose clinical features made them eligible for a particular test). For example, lung cancer testing for EGFR is recommended for late-stage patients with a particular histological type of lung cancer (non-squamous adenocarcinoma), not for other lung cancer patients. Furthermore, testing is covered by Medicare only for those patients for whom test results would impact clinical decisions, and this excludes patients with certain comorbidities. Thus, albeit informative for comparisons, the proportion of patients with each disease who were tested does not directly reflect access to guideline-recommended testing. Further, our MarketScan dataset included patients 64 years of age and younger, so a comprehensive comparison of testing for all age groups between Medicare and MarketScan was not possible. Information on race/ethnicity, Medicaid status, and clinical characteristics such as risk score or ESRD are not available from the MarketScan database.

The limitations of claims data can be partially addressed by the analysis of the medical records data. The small number of cases for any given diagnosis and the fact that the patients in our medical records abstraction sample were found to be older and sicker than the overall population of Medicare beneficiaries with the diagnoses of interest limits the interpretation of findings from the medical records. Similarly, the stakeholder interviews provide context to the analytic findings that is otherwise unobtainable, but the very limited number of interviews prohibits wider generalization of the findings.

12.5 Recommendations and Next Steps

The low participation rates preclude a thorough assessment of the effect of the date-of-service 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, however. Therefore, we are unable to make recommendations for Medicare policy in this area.

Some of our findings suggest that the date-of-service rule delays or impedes access to complex testing, and we clearly demonstrate that African Americans are less likely to receive complex testing. The data available do not elucidate the reasons for the lower rate of testing among African Americans. We recommend additional research to investigate origins of the racial disparity in complex testing.

Any recommendations related to the date-of-service rule would have been rendered moot by the passage of the Protecting Access to Medicare Act of 2014, which mandated substantial changes to current reimbursement policies for laboratory tests, and specified separate policies for complex tests such as those considered in this Demonstration. Future research to examine whether these new policies achieved their objectives is recommended.

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APPENDIX A:
INTERVIEW GUIDES

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INTERVIEW GUIDE
— LABORATORY —

Thank you for taking the time to meet with us today. We are from RTI International, an independent, nonprofit research institute headquartered in Research Triangle Park, North Carolina. We are currently working with the Centers for Medicare & Medicaid Services (CMS) to evaluate a demonstration regarding the payment for certain complex diagnostic laboratory tests. As part of the evaluation, we are conducting interviews with select stakeholders to understand varying experiences with orders and reimbursement for complex laboratory tests.

Mandated by the Patient Protection and Affordable Care Act of 2010, the Medicare demonstration allowed separate payments for certain complex diagnostic laboratory tests. The law defines a complex diagnostic laboratory tests as diagnostic laboratory tests that involve (1) analysis of gene or protein expression, (2) topographic genotyping, or (3) cancer chemotherapy sensitivity assay. I will refer to this as the Section 3113 Payment Demonstration.

Under the current Medicare payment system, payment to a laboratory for a test ordered within 14 days of discharge must be made under arrangement from the hospital through the diagnosis-related group (DRG) payment or outpatient prospective payment system (OPPS) rather than directly from Medicare. This policy is known as the date-of-service rule. The demonstration changed this payment rule for a set of 36 specific complex tests by allowing direct payment from Medicare to independent and hospital laboratories even when ordered within 14 days of discharge. The demonstration ran from Jan 1, 2012, to Dec 31, 2013.

In this interview, we will be primarily focus on how the change in payments mandated by the Demonstration may have impacted access to care, quality of care, health outcomes, and expenditures.

Please do your best to answer each question. There are no right or wrong answers, and it is okay to say, "I don't know." Your participation is completely voluntary; you may end the interview at any time; and if we ask a question that you would prefer not to answer, just tell us, and we will skip over it.

RTI considers issues of privacy and confidentiality to be very important. We will report our findings in an aggregate report to CMS and Congress, and your name will not be identified in our reports. When we speak, we would like to record the interview to ensure that we capture your responses correctly and completely. Once the notes are cleaned, we will delete the recording. Is it OK to record our interview?
____Yes ___No

[IF THE INTERVIEE RESPONDS "YES."] Thank you.

[IF THE INTERVIEWEE RESPONDS "NO."] That is fine. We will take extra care to capture your responses. I may speak slower, ask you to repeat some information, and restate some key points.

Do you have any questions for us before we begin the interview? (Answer questions, if any).

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OVERVIEW

During the interview, my reference to "laboratory" includes all locations that are part of the laboratory firm. To get started, I would like an overview of your laboratory and position at the laboratory.

1. To start, could you tell us your name and role within [INSTITUTION]?

PARTICIPATION

My next set of questions are about your decisions regarding participation in the Section 3113 Demonstration. These questions refers to period just before and during the demonstration. Demonstration tests refer to tests wholly or partially billed using any of the 36 HCPCS codes.

2. Please describe your role in the laboratory's decision regarding participation in the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration.

- PROBE: In what way were you involved in implementing processes for receiving payments under the demonstration?

3. Based on your knowledge, why did this institution decide to (participate / not participate) in the payment demonstration?

- PROBE: How did payment practice influence this laboratory's decision to participate in the demonstration?
- PROBE: What impact did input from hospitals or physicians have on the laboratory's decision on whether or not to participate in the demonstration?

4. What laboratory tests does your laboratory perform that would have been billed using any of these HCPCS codes (provide list of HCPCS codes)?

5. How did you decide whether to bill a specific test or test component under the demonstration or through the regular billing system?

Under Medicare's date of service rule, a laboratory that performs a test on a specimen collected during a hospital stay and ordered within 14 days after discharge is paid through its diagnosis-related group (DRG) or outpatient payment system (OPPS).

6. How does the date of service rule impact your ability to perform complex laboratory tests or the timing relative to discharge of performing those tests?

- PROBE: Prior to January 1, 2012, which of the demonstration tests or test components did you perform within 14 days post-discharge?

7. How did the demonstration effect which tests you performed within the 14-day window?

- PROBE: What tests, if any, did you perform within the 14 day period that you had previously only performed more than 14 after discharge?

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SPECIMEN ACCESS

The next set of questions focus on your experiences obtaining specimens from hospitals or other providers and on sharing specimens with other laboratories.

8. What has been your experience in obtaining specimens for complex laboratory testing?

- PROBE: Have you ever had difficulty obtaining specimens from hospitals for requested tests?
    - What caused the difficulty in getting specimens?

9. During the demonstration, how did your experience accessing specimens for tests change?

PROBES:

- How did the time between when the specimen was collected and when it was received by laboratory for testing change during 2012-2013?
- Specifically for tests billed using the 36 HCPCS codes, how did the time between specimen collection and laboratory receipt change during the demonstration?
- How did the quality of the specimens change during the demonstration?
    - From your perspective, what factors affected this change?

TEST ORDERS

10. During the demonstration period, how did tests ordered for Medicare patients change?

PROBES:

- What factors seemed to drive this change?
    - How did these factors affect the change in the number of tests ordered for Medicare patients?
        - Payment arrangements with hospitals?
        - Time since discharge or specimen collection?

11. How did the physicians or hospitals that used your services change during the demonstration?

PROBES:

- Were any of the changes you described unexpected? If so, please explain.

12. From your perspective, what factors motivated physicians or hospitals to order tests from your laboratory during the demonstration period?

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13. How did you measure or monitor quality assurance before January 1, 2012?

14. How was quality assurance measured during the demonstration (after January 1, 2012)?

15. In what ways did the demonstration impact test accuracy?

PROBE:

- Has test accuracy improved since January 1, 2012? If so, please explain this further.

PAYMENTS

The following questions refer to your Medicare FFS business.

16. Do you have formal contracts in place with hospitals for payment ("under arrangement") for laboratory tests performed?

17. In general, how does payment under arrangement (or ad hoc payment) for laboratory tests performed within the 14-day window compare with payment from the Medicare Administrative Contractor (MAC) under the Clinical Laboratory Fee Schedule (CLFS)?

18. How does the timeliness of payments from hospitals for tests performed within the 14-day window compare with payment from the MAC under the CLFS?

19. For the tests on the demonstration test list provided, did payments per test increase, decrease, or remain the same during the demonstration period?

20. For tests that do not have a single specific HCPCS code, how do you determine what code or codes to use to bill for a test?

- PROBE: What characteristics of the test or clinical application affect the decision?

21. How did the demonstration affect how the hospitals you work with reimburse you for tests billed using the demonstration tests codes?

22. Prior to the demonstration (January 1, 2012), what strategies did this laboratory use to market complex tests?

PROBES:

- Who was your primary audience?
- Describe any changes in the laboratory's marketing strategies or audience during the demonstration period. Was this in response to the demonstration or other factors?
- If a permanent change in the date of service rule, similar to that mandated by the demonstration, were implemented, how might the change affect marketing strategies long term?

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FOR LABORATORIES THAT PARTICIPATED IN THE DEMONSTRATION

23. How did the payment process for complex laboratory tests under the demonstration compare to payments made under arrangement with a hospital?

PROBE:

- To what extent did the demonstration's effect on payment process differ by test code?

24. Describe any differences in the amount of time it took to receive payments prior to and during the Demonstration (before and after January 1, 2012).

25. Describe any disagreements or complications the laboratory experienced with receiving payments under the demonstration.

PROBE:

- How were these complications resolved?

26. During the demonstration period, how did you choose which tests or test codes to bill using the demonstration identifier "56"?

COST IMPACTS

Now, my questions will focus on laboratory costs.

27. Overall, how does the current Medicare payment policy regarding the date-of-service impact internal laboratory costs?

28. How did the demonstration impact laboratory costs?

PROBES:

(1) What were the unexpected changes in costs?

(2) What internal changes in behavior or processes had the most impact on costs? Why has this been the case?

(3) Please describe any efficiency gains resulting from the demonstration.

SUMMARY

My last few questions focus on the overall impact of the demonstration and date-of-service rule on this laboratory.

29. How would you describe the impact of the payment demonstration on this laboratory, its staff, and the physicians who use its services?

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PROBES:

- What challenges did this laboratory encounter during the demonstration period?
- What unexpected benefits did this laboratory experience?

30. What is your overall view of changing the payment rule so that independent and hospital laboratories can bill Medicare directly for complex laboratory tests?

PROBES:

(1) How would this change affect beneficiary access?

(2) How would it affect the quality or cost of care?

31. From the laboratories' standpoint, how would you modify the demonstration overall or as implemented at this laboratory?

32. Are there any topics related to the demonstration that we have not covered that you would like to discuss today?

CLOSING

We appreciate your participating in this interview and providing this important information.

THANK YOU FOR YOUR TIME.

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INTERVIEW GUIDE
— HOSPITAL —

Good (morning/afternoon/evening) I am **<name>** and this is **<name>**. Thank you for taking the time to meet with us today. We are from RTI International, an independent, nonprofit research institute headquartered in Research Triangle Park, North Carolina. We are currently working with the Centers for Medicare and Medicaid Services (CMS) to evaluate a demonstration regarding the payment for certain complex diagnostic laboratory tests. As part of the evaluation, we are conducting interviews with select stakeholders to gain an understanding of varying experiences with complex laboratory tests used during the demonstration period.

The Affordable Care Act of 2010 mandates a Medicare demonstration under which separate payments are made for certain complex diagnostic laboratory tests. The law defines a complex diagnostic laboratory tests as diagnostic laboratory tests that involve: 1) analysis of gene protein expression, 2) topographic genotyping, or 3) cancer chemotherapy sensitivity assay.

Under the current Medicare payment system, payment to a laboratory performing the test within 14 days of discharge must come under arrangement from the hospital through its existing diagnosis-related group (DRG) or outpatient prospective payment system (OPPS) payment, rather than as a direct payment from Medicare. The Demonstration changes this payment rule by allowing for direct payments from Medicare to independent and hospital laboratories for a set of 36 specific complex tests. As such independent laboratories and hospital labs can bill Medicare directly for laboratory tests provided within the 14 days of discharge.

RTI considers issues of privacy and confidentiality to be very important. We will be asking you a series of questions and recording the information in order to correctly and completely capture your responses. Is it OK that we audiotape our interview? ____Yes ___No

There are no right or wrong answers; and it is okay to say, “I don’t know.” Please know that your name will not be identified in our reports. Your participation is completely voluntary; you may end the interview at any time; and if we ask a question that you would prefer not to answer, just tell us, and we will skip over it. However, please try your best to answer each question.

In this interview, we will be primarily focus on how the change in payments mandated by the Demonstration impacted access to care, quality of care, health outcomes, and expenditures during the demonstration period, January 1, 2012 to December 31, 2013.

Do you have any questions for us before we begin? (Answer questions, if any.)

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OVERVIEW

1. Please describe your role in the hospital.

2. What is your hospital's usual policy in specimen collection? For instance, how long is the specimen stored?

3. What is your hospital's usual policy for sharing specimens with independent laboratories for testing?

4. Since the demonstration started, have any of your hospital's policies regarding specimen collection, storage, or sharing with independent laboratories changed? If so, when were the changes made? Please describe the changes.

5. What type of physicians at your hospital are hospitalists?

COST/REVENUE IMPACT

6. Prior to the demonstration, describe any contracts or other arrangements this hospital had in place with independent laboratories for lab tests performed within 14 days of discharge.

- *Ask if formal or if just usual and customary charges?*
- *If they have contracts, are they just with certain laboratories?*

7. (a)Were the negotiated rates for inpatient laboratory tests paid under arrangement (discussed above) generally higher or lower than the amount on the Medicare Clinical Laboratory Fee Schedule?

(b) Were the negotiated rates for outpatient laboratory tests paid under arrangement (discussed above) generally higher or lower than the amount on the Medicare Clinical Laboratory Fee Schedule?

8. Has the hospital monitored changes in costs and revenues as a result of the demonstration?

- *If yes, probe: Overall, how did the Demonstration impact internal hospital costs and revenues? Which departments were most affected? Were these impacts expected?*
- *Specifically, which internal changes (as a result of the Demonstration) in physician, hospitalist and other staff (e.g. billing personnel) behavior and changes in processes of care had the most impact on costs and revenues during the Demonstration period? Why do you believe this was the case?*
- *Which changes in physician/other staff behavior or processes of care (as a result of the Demonstration*) did not result in anticipated cost and revenue impacts? Why?
- *Can you trace an increase/decrease in revenue to any one of the 36 test codes (on the demonstration test list provided) or group of test codes*?

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ACCESS TO AND QUALITY OF CARE

9. Describe any major concerns the hospital had over changes in quality of care when allowing certain clinical laboratory tests to be billed directly to Medicare by the laboratory performing the test. Describe any changes in quality of care your institution experienced during the demonstration period (e.g. turnaround time for these tests, error rates).

10. Does this hospital incorporate any information from internal or external sources into quality control measures?

11. What knowledge do you have of tests ordered using specimens obtained at your hospital that were ordered under the demonstration, but not previously?

- *If yes, probe if the Demonstration was the reason.*

12. Were there any tests that your hospital performed at an internal laboratory that would have been sent to a reference or other independent laboratory prior to the Demonstration?

- *If yes, probe:* Which tests? Why did your institution decide to perform the tests internally? How did this affect the treatment plans for patients?

13. Were there any tests that your hospital sent to a reference or independent laboratory that would have been performed at an internal laboratory prior to the Demonstration?

- *If yes, probe:* Which tests? Why did your institution decide to send these tests to a reference laboratory? How did this affect the treatment plans for patients?

14. (a) Compared to before the Demonstration (January 2012), did physicians order the laboratory tests closer to the date the specimen was acquired (within 14 days) during the Demonstration period? Why?

(b) Compared to before the Demonstration (January 2012), did hospitalists order the laboratory tests closer to the date the specimen was acquired (within 14 days) during the Demonstration period? Why?

PATIENT SATISFACTION

15. Do you feel that provisions of laboratory tests under the Demonstration altered the course of care for your institution's patient(s)? If yes, please describe.

16. Do you know whether patient satisfaction has changed as a result of the Demonstration? What element of the payment Demonstration do you believe had a positive impact (if any) on patient satisfaction/quality of care received? Why? Were there any negative impacts? If so, please describe.

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SUMMARY

17. How has the Demonstration impacted quality of care where improvement was needed?

18. How would you describe the impact of the Demonstration on this hospital, and its affiliated physicians?

19. What is your overall view of the Demonstration? Does it hold promise as a policy tool to improve quality of care, access to care, outcomes and/or reduce costs? Why or why not?

20. How would you improve or otherwise modify the demonstration and how it was implemented?

21. Are there any topics related to the demonstration that we have not covered that you would like to discuss today?

THANK YOU FOR YOUR TIME.

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APPENDIX B:
ICD-9 DIAGNOSIS CODES FOR APPENDIX

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Table B.1
ICD-9 diagnosis codes used to identify disease-specific patient cohorts in Medicare and MarketScan claims data

Condition	ICD-9 code	Description
Breast cancer	174	Malignant neoplasm of female breast
	174.0	Malignant neoplasm of nipple and areola of female breast
	174.1	Malignant neoplasm of central portion of female breast
	174.2	Malignant neoplasm of upper-inner quadrant of female breast
	174.3	Malignant neoplasm of lower-inner quadrant of female breast
	174.4	Malignant neoplasm of upper-outer quadrant of female breast
	174.5	Malignant neoplasm of lower-outer quadrant of female breast
	174.6	Malignant neoplasm of axillary tail of female breast
	174.8	Malignant neoplasm of other specified sites of female breast
	174.9	Malignant neoplasm of breast (female), unspecified
	175	Malignant neoplasm of male breast
	175.0	Malignant neoplasm of nipple and areola of male breast
	175.9	Malignant neoplasm of other and unspecified sites of male breast
Lung cancer	162	Malignant neoplasm of trachea, bronchus and lung
	162.0	Malignant neoplasm of trachea
	162.2	Malignant neoplasm of main bronchus
	162.3	Malignant neoplasm of upper lobe, bronchus or lung
	162.4	Malignant neoplasm of middle lobe, bronchus or lung
	162.5	Malignant neoplasm of lower lobe, bronchus or lung
	162.8	Malignant neoplasm of other parts of bronchus or lung
	162.9	Malignant neoplasm of bronchus and lung, unspecified

(continued)

Table B.1 (continued)
ICD-9 diagnosis codes used to identify disease-specific patient cohorts in Medicare and MarketScan claims data

Condition	ICD-9 code	Description
Ovarian cancer	183	Malignant neoplasm of ovary and other uterine adnexa
	183.0	Malignant neoplasm of ovary
	183.2	Malignant neoplasm of fallopian tube
	183.3	Malignant neoplasm of broad ligament of uterus
	183.4	Malignant neoplasm of parametrium
	183.5	Malignant neoplasm of round ligament of uterus
	183.8	Malignant neoplasm of other specified sites of uterine adnexa
	183.9	Malignant neoplasm of uterine adnexa, unspecified
Hematologic malignancies	200.00-200.88	Lymphosarcoma and reticulosarcoma and other specified malignant tumors of lymphatic tissue
	201.00-201.98	Hodgkin's disease
	202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue
	203.00-202.82	Multiple myeloma and immunoproliferative neoplasms
	204.00-204.92	Lymphoid leukemia
	205.00-205.92	Myeloid leukemia
	206.00-206.92	Monocytic leukemia
	207.00-207.82	Other specified leukemia
	208.00-208.92	Leukemia of unspecified cell type
Lupus erythematosus	710.0	Syst Lupus Erythematosus
	695.4	Lupus Erythematosus
Heart transplantation	996.83	Complications of transplanted heart
	V421	Heart replaced by transplant

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APPENDIX C:
DETAILED TABLES

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Table C.1
Utilization of 36 Demonstration billing codes among Medicare beneficiaries from 2010 through 2013

		Codes [1]				Beneficiaries				Payments				Percent change from 2010 to 2012		
Code	Description	2010	2011	2012	2013	2010	2011	2012	2013	2010	2011	2012	2013	Codes	Patients	Payments
Total		5,595,243	6,177,680	6,470,084	3,580,708	1,320,576	1,406,747	1,476,216	1,455,162	249,016,164.02	310,642,318.15	489,081,596.26	448,037,394.70	15.64	11.79	96.41
Demonstration test codes		5,446,471	5,997,755	6,258,884	1,598,329	1,320,576	1,406,747	1,476,216	982,492	194,206,484.48	239,962,382.55	404,897,011.52	76,903,527.83	14.92	11.79	108.49
83890	Molecule isolate	69,985	80,739	61,780	7	54,876	65,263	80,453	—	454,432.18	521,290.24	629,227.15		(11.72)	46.61	38.46
83891	Molecule isolate nucleic	345,798	453,728	655,290	23	271,265	340,237	434,166	—	2,540,562.48	2,964,421.78	3,765,789.58		89.50	60.05	48.23
83892	Molecular diagnostics	231,654	250,236	216,953	4	161,996	184,324	201,921	—	3,625,208.59	4,131,556.53	2,089,925.16		(6.35)	24.65	(42.35)
83893	Molecule dot/slot/blot	56,102	40,086	22,507	—	11,194	12,931	13,908	—	344,235.64	436,324.26	495,713.37		(59.88)	24.25	44.00
83894	Molecule gel electrophor	70,576	78,599	53,483	11	47,532	53,908	64,052	—	544,541.73	656,681.57	804,029.75		(24.22)	34.76	47.65
83896	Molecular diagnostics	456,173	460,291	525,617	3	198,736	258,697	320,718	—	9,506,538.65	14,159,357.42	19,316,023.47		15.22	61.38	103.19
83897	Molecule nucleic transfer	1,443	1,687	2,583	—	1,211	1,316	2,681	—	8,545.92	9,449.19	17,119.17		79.00	121.39	100.32
83898	Molecule nucleic ampli each	305,023	359,201	415,077	11	211,872	242,285	285,371	—	27,686,834.31	33,939,217.70	43,750,100.22		36.08	34.69	58.02
83900	Molecule nucleic ampli 2 seq	116,453	158,992	291,491	8	88,413	118,203	166,669	—	4,647,940.52	6,565,172.25	11,039,554.08		150.31	88.51	137.51
83901	Molecule nucleic ampli addon	131,076	200,258	353,795	11	53,655	79,349	129,430	—	10,133,160.89	16,337,564.43	35,922,686.85		169.92	141.23	254.51
83902	Molecular diagnostics	66,671	76,192	55,526	—	44,864	51,005	54,663	—	1,426,607.13	1,585,020.51	1,682,175.86		(16.72)	21.84	17.91
83903	Molecule mutation scan	128,730	155,330	208,303	—	101,960	124,572	138,221	—	9,136,988.71	12,281,815.05	12,560,492.82		61.81	35.56	37.47
83904	Molecule mutation identify	61,772	86,606	154,821	2	43,772	64,829	151,060	—	16,480,878.49	22,608,753.18	45,464,394.11		150.63	245.11	175.86
83905	Molecule mutation identify	2,009	1,598	336	—	1,719	1,342	1,162	—	68,617.07	53,878.03	59,339.85		(83.28)	(32.40)	(13.52)
83906	Molecule mutation identify	184	221	38	—	112	128	116	—	4,894.10	4,822.13	5,097.81		(79.35)	3.57	4.16

(continued)

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Table C.1 (continued)
Utilization of 36 Demonstration billing codes among Medicare beneficiaries from 2010 through 2013

		Codes [1]				Beneficiaries				Payments				Percent change from 2010 to 2012		
Code	Description	2010	2011	2012	2013	2010	2011	2012	2013	2010	2011	2012	2013	Codes	Patients	Payments
83907	Lyse cells for nucleic ext	45,325	72,493	84,144	4	32,019	49,565	69,945	—	829,021.59	1,268,582.36	1,853,594.53		85.65	118.45	123.59
83908	Nucleic acid signal ampli	76,932	132,215	206,090	5	53,196	95,373	135,338	—	3,773,896.39	6,214,716.50	9,747,261.03		167.89	154.41	158.28
83909	Nucleic acid high resolute	160,905	121,330	125,292	8	77,086	88,642	116,886	—	16,056,486.68	19,541,973.14	26,228,790.39		(22.13)	51.63	63.35
83912	Genetic examination	526,148	627,867	782,015	17	320,053	395,934	492,437	—	3,712,048.92	4,255,146.53	5,111,578.94		48.63	53.86	37.70
83913	Molecular RNA stabilization	17,357	18,174	17,208	1	14,929	16,047	17,541	—	296,849.32	311,589.42	350,576.14		(0.86)	17.50	18.10
83914	Mutation ident ola/sbce/aspe	73,804	115,372	404,940	—	38,802	70,292	182,476	—	5,301,741.51	14,586,852.91	104,214,740.88		448.67	370.27	1,865.67)
83950	Oncoprotein her-2/neu	1,075	906	664	149	424	339	354	161	96,636.05	80,710.25	78,181.40	27,330.61	(38.23)	(16.51)	(19.10)
83951	Oncoprotein dcp	668	745	342	562	527	582	948	995	59,028.55	64,966.55	129,748.50	114,516.52	(48.80)	79.89	119.81
86215	Deoxyribonuclease antibody	2,460	2,732	1,709	2,393	2,226	2,499	2,991	2,342	45,798.22	50,143.19	61,013.11	75,647.56	(30.53)	34.37	33.22
86225	DNA antibody	353,333	336,362	255,682	262,296	259,115	267,854	284,246	113,951	6,172,588.90	6,237,138.12	6,666,031.35	6,550,341.38	(27.64)	9.70	7.99
86226	DNA antibody single strand	23,437	22,367	23,133	25,067	19,745	19,323	20,773	4,380	372,350.22	370,313.43	415,041.43	430,528.03	(1.30)	5.21	11.47
86235	Nuclear antigen antibody	591,782	589,942	439,994	451,022	288,515	297,231	311,943	264,155	33,460,823.28	33,002,910.28	35,048,431.28	33,878,308.28	(25.65)	8.12	4.74
86294	Immunoassay tumor qual	98,196	87,462	23,098	15,734	72,219	64,454	17,641	10,678	2,381,208.74	2,064,904.96	549,727.88	366,540.56	(76.48)	(75.57)	(76.91)
86300	Immunoassay tumor ca 15-3	692,026	705,282	454,467	430,220	288,941	294,159	293,653	266,924	19,605,629.29	19,762,446.01	20,070,484.85	18,888,676.51	(34.33)	1.63	2.37
86301	Immunoassay tumor ca 19-9	216,003	229,320	133,142	132,890	109,355	113,359	116,990	94,963	3,968,460.36	4,240,121.37	4,641,256.82	4,745,885.16	(38.36)	6.98	16.95
86304	Immunoassay tumor ca 125	445,744	448,306	244,946	233,749	207,150	202,717	195,765	170,298	9,421,117.65	9,478,884.27	9,687,012.59	9,372,437.59	(45.05)	(5.50)	2.82
86305	Human epididymis protein 4	3,475	5,400	4,028	4,032	2,022	2,783	3,765	2,489	102,497.74	156,737.82	213,523.18	186,941.58	15.91	86.20	108.32

(continued)

Table C.1 (continued)
Utilization of 36 Demonstration billing codes among Medicare beneficiaries from 2010 through 2013

		Codes				Beneficiaries				Payments				Percent change from 2010 to 2012		
Code	Description	2010	2011	2012	2013	2010	2011	2012	2013	2010	2011	2012	2013	Codes	Patients	Payments
86316	Immunoassay tumor other	63,009	65,428	34,103	33,854	34,022	33,347	37,648	35,591	1,585,501.63	1,629,798.97	1,823,387.97	1,807,722.28	(45.88)	10.66	15.00
87149	DNA/RNA direct probe	11,010	12,201	6,200	6,181	8,190	8,824	9,674	9,772	352,078.56	387,021.68	402,023.42	456,944.98	(43.69)	18.12	14.19
88371	Protein western blot tissue	15	14	—	2	12	12	6	5	330.39	230.56	206.94	55.48	(100.00)	(50.00)	(37.36)
88372	Protein analysis w/probe	118	73	87	63	82	60	64	62	2,404.08	1,869.96	2,729.64	1,651.31	(26.27)	(21.95)	13.54
NOC codes: 81479, 84999, 87799, 87999, 88399		148,772	179,925	211,200	150,100	—	—	—	—	54,809,679.54	70,679,935.60	84,184,584.74	114,891,521.79	41.96	—	53.59
New codes: 81225-81408		-	—	—	1,832,279	—	—	—	527,404	—	—	—	256,242,345.08			

— = not available.

SOURCE: Programs jl01frq1_07JUN14; JL21_table_2010_12FEB16; jl09_table_2011_16JUL14

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Table C.2
Utilization of 36 Demonstration billing codes among MarketScan patients from 2011 through 2013

		Codes			Patients			Payments			Percent change from 2011 to 2012		
Code	Description	2011	2012	2013	2011	2012	2013	2011	2012	2013	Tests	Patients	Payments
Total Demonstration test codes		4,144,484	4,833,921	1,071,070	419,545	487,710	4,436	275,917,759.77	372,707,868.15	48,320,195.94	18.53	16.25	35.08
83890	Moleculeisolate	73,218	80,209	342	63,591	69,271	295	2,258,043.12	2,421,509.71	21,036.42	9.55	8.93	7.24
83891	Moleculeisolatenucleic	395,264	476,104	2,329	331,141	382,135	2,065	7,569,305.60	8,269,926.48	95,791.77	20.45	15.40	9.26
83892	Moleculardiagnostics	221,204	248,605	1,286	181,778	206,193	921	6,262,285.24	6,660,127.95	15,894.96	12.39	13.43	6.35
83893	Moleculedot/slot/blot	24,528	27,059	234	21,333	23,802	193	1,040,968.32	1,009,300.70	3,383.64	10.32	11.57	(3.04)
83894	Moleculegelelectrophor	99,819	102,019	812	82,778	85,213	729	3,053,463.21	2,992,217.27	7,892.64	2.20	2.94	(2.01)
83896	Moleculardiagnostics	253,499	300,101	1,228	182,287	220,872	804	19,866,716.63	23,786,005.26	27,715.96	18.38	21.17	19.73
83897	Moleculenucleictransfer	19,411	25,236	476	18,237	17,900	251	338,527.84	369,959.76	6,173.72	30.01	(1.85)	9.28
83898	Moleculenucleicamplieach	206,967	244,549	1,366	163,000	178,770	1,191	25,208,580.60	29,878,996.82	76,099.86	18.16	9.67	18.53
83900	Moleculenucleicampli2seq	242,416	289,591	1,604	201,918	228,213	1,414	12,702,598.40	15,047,148.36	55,145.52	19.46	13.02	18.46
83901	Moleculenucleicampliaddon	242,854	296,016	2,998	166,971	196,665	2,007	39,077,637.14	64,238,432.16	446,582.08	21.89	17.78	64.39
83902	Moleculardiagnostics	24,692	26,670	117	16,949	18,370	84	943,728.24	993,190.80	2,610.27	8.01	8.38	5.24
83903	Moleculemutationscan	87,342	102,690	61	73,714	90,193	57	9,042,517.26	9,651,833.10	2,078.27	17.57	22.36	6.74
83904	Moleculemutationidentify	39,774	115,264	975	30,968	95,516	446	12,667,223.52	31,747,163.52	134,355.00	189.80	208.43	150.62
83905	Moleculemutationidentify	1,316	1,267	2	1,107	1,137	2	72,064.16	63,692.09	17.38	(3.72)	2.71	(11.62)
83906	Moleculemutationidentify	144	130	—	111	94	—	10,111.68	10,511.80	—	(9.72)	(15.32)	3.96
83907	Lysecellsfornucleicext	23,258	35,567	50	18,638	29,763	42	668,667.50	1,004,767.75	497.5	52.92	59.69	50.26
83908	Nucleicacidsignalampli	88,757	134,091	565	71,216	105,251	330	7,166,240.18	10,797,007.32	29,685.10	51.08	47.79	50.66
83909	Nucleicacidhighresolute	181,178	190,622	909	156,988	160,567	807	12,200,526.52	15,693,909.26	29,078.91	5.21	2.28	28.63
83912	Geneticexamination	464,275	550,853	2,558	370,781	421,294	2,162	9,661,562.75	10,075,101.37	28,521.70	18.65	13.62	4.28
83913	Molecularrnastabilization	5,714	6,713	25	4,950	5,898	20	123,022.42	153,861.96	679	17.48	19.15	25.07
83914	Mutationidentola/sbce/aspe	239,264	320,510	1,573	156,170	220,463	933	49,293,169.28	79,063,406.80	211,568.50	33.96	41.17	60.39
83950	Oncoproteinher-2/neu	300	223	149	166	130	97	37,545.00	38,616.91	38,145.49	(25.67)	(21.69)	2.86
83951	Oncoproteindcp	361	723	767	281	600	665	36,803.95	77,158.56	79,169.74	100.28	113.52	109.65
86215	Deoxyribonucleaseantibody	8,917	10,241	9,002	7,649	8,433	7,274	252,975.29	285,621.49	229,280.94	14.85	10.25	12.90
86225	DNAantibody	238,159	256,878	220,651	188,975	202,278	174,128	5,899,198.43	6,439,931.46	5,258,113.33	7.86	7.04	9.17
86226	Dnaantibodysinglestrand	11,429	13,157	9,807	10,250	11,350	8,697	217,036.71	246,299.04	183,096.69	15.12	10.73	13.48

(continued)

Table C.2 (continued)
Utilization of 36 Demonstration billing codes among MarketScan patients from 2011 through 2013

		Codes			Patients			Payments			Percent change from 2011 to 2012		
Code	Description	2011	2012	2013	2011	2012	2013	2011	2012	2013	Tests	Patients	Payments
86235	Nuclearantigenantibody	339,404	366,598	308,351	207,512	222,178	185,949	25,367,054.96	27,190,573.66	21,612,321.59	8.01	7.07	7.19
86294	Immunoassaytumorqual	13,613	3,409	1,717	11,830	3,027	1,460	331,204.29	83,725.04	47,286.18	(74.96)	(74.41)	(74.72)
86300	Immunoassaytumorca15-3	193,742	199,032	161,820	83,707	84,251	69,448	8,203,036.28	8,339,440.80	6,624,910.80	2.73	0.65	1.66
86301	Immunoassaytumorca19-9	48,541	52,999	48,053	26,104	27,677	25,816	2,221,236.16	2,430,004.15	2,148,449.63	9.18	6.03	9.40
86304	Immunoassaytumorca125	215,693	209,406	167,423	145,206	136,779	110,322	8,705,369.48	8,725,948.02	6,732,078.83	(2.91)	(5.80)	0.24
86305	Humanepididymisprotein4	2,744	3,523	3,243	1,951	2,574	2,316	138,379.92	167,624.34	169,641.33	28.39	31.93	21.13
86316	Immunoassaytumorother	36,979	36,040	30,781	27,101	25,690	22,012	2,551,181.21	2,005,986.40	1,740,665.55	(2.54)	(5.21)	(21.37)
87149	DNA/rnadirectprobe	99,180	107,536	89,604	95,761	102,774	85,592	2,457,680.40	2,577,637.92	2,174,689.08	8.43	7.32	4.88
88371	Proteinwesternblottissue	480	274	174	67	52	33	263,246.40	166,531.72	87,375.84	(42.92)	(22.39)	(36.74)
88372	Proteinanalysisw/probe	48	16	18	34	16	18	8,851.68	4,698.40	162.72	(66.67)	(52.94)	(46.92)
81225-81408, new codes		—	78,322	1,067,060	—	47,441	423,296	—	78,986,283.32	381,470,958.57	—	—	—

— = not available.

SOURCE: RTI analysis of MarketScan data 2011–2013. JL_EVAL_012_MarketScan

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Table C.3
Utilization of Tier 1/Tier 2 billing codes among Medicare beneficiaries in 2013

		2013				
		Tests			Payments	
HCPCS	Gene/Test	Number	Percent	Beneficiaries	Amount	Percent
Total		1,832,279	100.0	527,404	256,242,345	100.0
81161	DMD	24	0.0	23	—	—
81200	ASPA	258	0.0	193	1,915	0.0
81201-81203	APC	3,423	0.2	2,843	658,797	0.3
81205	BCKDHB	157	0.0	126	245	0.0
81206-81208	BCR-ABL1 translocation	62,647	3.4	40,124	5,039,299	2.0
81209	BLM	182	0.0	135	213	0.0
81210	BRAF	12,650	0.7	11,327	966,070	0.4
81211-81217	BRCA1/BRCA2	44,762	2.4	42,209	56,763,760	22.2
81220-81224	CFTR	6,647	0.4	5,880	195,855	0.1
81225-81227	CYP	519,340	28.3	468,494	117,845,531	46.0
81228-81229	Cytogenomic tests	2,805	0.2	2,383	55,487	0.0
81235	EGFR	22,581	1.2	20,941	3,820,761	1.5
81240	Factor 2	193,436	10.6	178,282	7,633,652	3.0
81241	Factor 5	205,082	11.2	190,142	13,187,524	5.1
81242	FANCC	207	0.0	189	7,516	0.0
81243-81244	FMR1	1,595	0.1	1,357	4,106	0.0
81245	FLT3	4,033	0.2	3,507	434,060	0.2
81250	G6PC	124	0.0	112	4,797	0.0
81251	GBA	218	0.0	173	5,337	0.0
81252-81254	GJB2/GJB6	41	0.0	40	924	0.0
81255	HEXA	175	0.0	154	6,128	0.0
81256	HFE	18,633	1.0	17,609	882,451	0.3
81257	HBA1/HBA2	1,708	0.1	1,572	98,295	0.0

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Table C.3 (continued)
Utilization of Tier 1/Tier 2 billing codes among Medicare beneficiaries in 2013

		2013				
		Tests			Payments	
HCPCS	Gene/Test	Number	Percent	Beneficiaries	Amount	Percent
81260	IKBKAP	273	0.0	223	12,139	0.0
81261-81262	IGH@ gene rearrangement	6,388	0.3	5,458	794,359	0.3
81263	IGH@, omatic mutations	3,457	0.2	3,175	687,368	0.3
81264	IGK@, gene rearrangement	1,874	0.1	1,564	243,746	0.1
81265-81266	Short Tandem Repeat (STR)	8,277	0.5	7,637	1,296,089	0.5
81267-81268	Chimerism	10,449	0.6	5,221	1,661,200	0.6
81270	JAK2	40,225	2.2	36,464	2,625,106	1.0
81275	KRAS codons 12 and 13	19,909	1.1	17,858	2,920,758	1.1
81280-81282	Long QT	209	0.0	188	246	0.0
81290	MCOLN1	118	0.0	104	5,097	0.0
81291	MTHFR	182,358	10.0	170,781	12,414,445	4.8
81292-81301 81317-81319	MMR (mismatch repair)	20,118	1.1	18,376	5,225,342	2.0
81302-81304	MECP2 (Rett syndrome)	67	0.0	62	3,133	0.0
81310	NPM1	2,955	0.2	2,618	224,394	0.1
81315-81316	PML/RARalpha translocation	2,208	0.1	1,370	214,130	0.1
81321-81322	PTEN	2,387	0.1	2,117	193,503	0.1
81324-81326	PMP22	639	0.0	569	19,391	0.0
81330	SMPD1	178	0.0	132	213	0.0
81331	SNRPN/UBE3A methylation	83	0.0	73	493	0.0
81332	SERPINA1	3,830	0.2	3,709	177,549	0.1
81340-81341	TRB@ gene rearrangement	3,433	0.2	2,962	430,122	0.2
81342	TRG@ gene rearrangement	7,513	0.4	6,462	979,225	0.4
81350	UGT1A1	1,454	0.1	1,233	4,309	0.0
81355	VKORC1	91,859	5.0	82,966	4,188,876	1.6

(continued)

Table C.3 (continued)
Utilization of Tier 1/Tier 2 billing codes among Medicare beneficiaries in 2013

		2013				
		Tests			Payments	
HCPCS	Gene/Test	Number	Percent	Beneficiaries	Amount	Percent
81370-81383	HLA (histocompatibility genes)	47,082	2.6	39,871	7,591,724	3.0
81400-81408	Tier 2 codes (Level 1-9)	274,208	15.0	189,504	6,716,666	2.6

— = not available.

SOURCE: JL19, JL20

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Table C.4
Utilization of Tier 1/Tier 2 billing codes among MarketScan patients in 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/Test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
Total		78,322	100.0	47,347	78,986,283	100.0	1,067,060	100.0	422,385	381,436,408	100.0
81161	DMD	—	0.0	—	—	—	63	0.0	51	50,343	0.0
81200	ASPA	241	0.3	235	30,550	0.0	22,800	2.1	21,712	2,488,392	0.7
81201-81203	APC	1	0.0	1	20	0.0	2,238	0.2	2,112	1,325,569	0.3
81205	BCKDHB	131	0.2	129	9,618	0.0	16,003	1.5	15,458	1,717,602	0.5
81206-81208	BCR-ABL1 translocation	1,441	1.8	964	178,584	0.2	19,632	1.8	11,484	3,465,930	0.9
81209	BLM	154	0.2	151	5,031	0.0	21,308	2.0	20,566	1,573,596	0.4
81210	BRAF	138	0.2	135	20,324	0.0	3,116	0.3	2,843	1,031,116	0.3
81211-81217	BRCA1/BRCA2	32,988	42.1	32,395	66,949,522	84.8	71,920	6.7	69,965	120,968,509	31.7
81220-81224	CFTR	8,238	10.5	8,034	3,164,924	4.0	141,683	13.3	132,791	83,513,351	21.9
81225-81227	CYP	420	0.5	402	27,211	0.0	53,356	5.0	50,866	11,468,445	3.0
81228-81229	Cytogenomic tests	595	0.8	562	251,149	0.3	6,781	0.6	6,230	7,990,993	2.1
81235	EGFR	1	0.0	1	—	—	3,211	0.3	2,893	1,697,174	0.4
81240	Factor 2	2,693	3.4	2,570	151,783	0.2	68,317	6.4	65,341	5,772,103	1.5
81241	Factor 5	3,739	4.8	3,599	214,328	0.3	73,179	6.9	69,842	6,228,996	1.6
81242	FANCC	145	0.2	141	7,582	0.0	21,137	2.0	20,423	1,618,037	0.4
81243-81244	FMR1	1,269	1.6	1,237	74,844	0.1	48,597	4.6	46,421	6,168,173	1.6
81245	FLT3	20	0.0	16	7,264	0.0	1,550	0.1	1,294	251,224	0.1
81250	G6PC	113	0.1	111	6,226	0.0	13,468	1.3	12,998	1,102,356	0.3
81251	GBA	194	0.2	187	33,991	0.0	20,590	1.9	19,922	2,617,813	0.7
81252-81254	GJB2/GJB6	—	0.0	—	—	—	849	0.1	797	173,142	0.0
81255	HEXA	355	0.5	344	69,148	0.1	21,926	2.1	21,163	3,296,136	0.9
81256	HFE	1,242	1.6	1,219	103,443	0.1	13,311	1.2	12,598	1,555,657	0.4
81257	HBA1/HBA2	205	0.3	197	31,734	0.0	4,984	0.5	4,722	2,383,698	0.6
81260	IKBKAP	180	0.2	176	15,125	0.0	20,113	1.9	19,433	1,546,287	0.4
81261-81262	IGH@ gene rearrangement	149	0.2	135	42,512	0.1	1,831	0.2	1,468	643,003	0.2
81263	IGH@ somatic mutations	16	0.0	14	5,029	0.0	487	0.0	446	193,933	0.1
81264	IGK@ gene rearrangement	114	0.1	84	46,397	0.1	523	0.0	403	176,947	0.0
81265-81266	Short Tandem Repeat (STR)	220	0.3	207	111,109	0.1	4,964	0.5	3,989	3,554,349	0.9
81267-81268	Chimerism	409	0.5	142	152,643	0.2	5,886	0.6	2,213	4,161,751	1.1

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Table C.4 (continued)
Utilization of Tier 1/Tier 2 billing codes among MarketScan patients in 2012–2013

		Year 2012					Year 2013				
		Codes		Patients	Payments		Codes		Patients	Payments	
HCPCS	Gene/Test	Number	Percent	Number	Amount	Percent	Number	Percent	Number	Amount	Percent
81270	JAK2	809	1.0	777	79,380	0.1	10,405	1.0	9,442	1,464,088	0.4
81275	KRAS codons 12 and 13	159	0.2	153	33,723	0.0	3,844	0.4	3,510	1,415,745	0.4
81280-81282	Long QT	58	0.1	57	180,332	0.2	1,428	0.1	1,372	1,073,291	0.3
81290	MCOLN1	135	0.2	131	7,709	0.0	19,359	1.8	18,710	1,509,421	0.4
81291	MTHFR	2,578	3.3	2,508	157,262	0.2	61,698	5.8	58,720	7,210,645	1.9
81292-81301 81317-81319	MMR (mismatch repair)	11,830	15.1	11,397	5,631,037	7.1	31,372	2.9	30,367	14,939,572	3.9
81302-81304	MECP2 (Rett syndrome)	10	0.0	10	13	0.0	744	0.1	664	465,849	0.1
81310	NPM1	20	0.0	16	6,162	0.0	1,368	0.1	1,196	212,409	0.1
81315-81316	PML/RARalpha translocation	58	0.1	36	7,804	0.0	1,782	0.2	1,166	323,449	0.1
81321-81322	PTEN	—	0.0	—	—	—	3,628	0.3	3,428	2,109,763	0.6
81324-81326	PMP22	—	0.0	—	—	—	284	0.0	271	207,539	0.1
81330	SMPD1	172	0.2	167	18,786	0.0	19,644	1.8	18,966	1,661,686	0.4
81331	SNRPN/UBE3A methylation	19	0.0	19	2,383	0.0	354	0.0	323	71,023	0.0
81332	SERPINA1	219	0.3	212	14,270	0.0	2,044	0.2	1,967	233,854	0.1
81340-81341	TRB@ gene rearrangement	63	0.1	52	7,753	0.0	974	0.1	787	396,737	0.1
81342	TRG@ gene rearrangement	114	0.1	102	15,585	0.0	2,037	0.2	1,649	603,991	0.2
81350	UGT1A1	7	0.0	7	386	0.0	224	0.0	215	30,780	0.0
81355	VKORC1	10	0.0	10	207	0.0	5,979	0.6	5,732	540,203	0.1
81370-81383	HLA (histocompatibility genes)	5,008	6.4	4,446	759,841	1.0	49,022	4.6	42,273	14,663,401	3.8
81400-81408	Tier 2 codes (Level 1-9)	1,642	2.1	1,532	353,560	0.4	167,047	15.7	151,024	53,568,336	14.0

— = not available.

SOURCE: RTI analysis of MarketScan data 2011–2013. JL_EVAL_012_MarketScan

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Table C.5
Most frequent line item diagnoses for claims billed with NOC codes

Code number and description		Frequency	Percent
Code 81479, Unlisted molecular pathology procedure			
ICD-9	HCPCS description		
	Total	199,486	100.0
V58.69	Long-term (current) use of other medications	20,847	10.5
272.4	Other and unspecified hyperlipidemia	11,576	5.8
311	Depressive disorder, not elsewhere classified	10,260	5.1
790.93	Elevated prostate specific antigen (PSA)	9,310	4.7
272.2	Mixed hyperlipidemia	5,897	3.0
Code 84999, Unlisted chemistry procedure			
ICD-9	HCPCS description		
	Total	70,970	100.0
714	Rheumatoid arthritis	27,304	38.5
174.9	Malignant neoplasm of breast (female), unspecified	13,062	18.4
780.79	Other malaise and fatigue	2,405	3.4
790.93	Elevated prostate specific antigen (PSA)	2,079	2.9
174.4	Malignant neoplasm of upper-outer quadrant of female breast	1,821	2.6
Code 87799, Infectious agent detection by nucleic acid			
ICD-9	HCPCS description		
	Total	92,723	100.0
V42.0	Kidney replaced by transplant	21,425	23.1
616.10	Vaginitis and vulvovaginitis, unspecified	16,102	17.4
V58.44	Aftercare following organ transplant	5,318	5.7
623.5	Leukorrhea, not specified as infective	4,818	5.2
V58.69	Long-term (current) use of other medications	3,096	3.3

(continued)

Table C.5 (continued)
Most frequent line item diagnoses for claims billed with NOC codes

Code number and description		Frequency	Percent
Code 87999, Unlisted microbiology procedure			
ICD-9	HCPCS description		
	Total	2,895	100.0
042	Human immunodeficiency virus [HIV] disease	1,242	42.9
599.0	Urinary tract infection, site not specified	149	5.1
487.1	Influenza with other respiratory manifestations	131	4.5
780.60	Fever, unspecified	88	3.0
V08	Asymptomatic human immunodeficiency virus [HIV] infection status	79	2.7
Code 88399, Unlisted surgical pathology procedure			
ICD-9	HCPCS description		
	Total	731	100.0
702.0	Actinic keratosis	62	8.5
174.9	Malignant neoplasm of breast (female), unspecified	28	3.8
216.5	Benign neoplasm of skin of trunk, except scrotum	27	3.7
996.81	Complications of transplanted kidney	25	3.4
429.89	Other ill-defined heart diseases	24	3.3

SOURCE: jl19

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Table C.6
Complex tests most likely billed with NOC codes (based on line item diagnoses in claims and laboratory profile)

Laboratory	Test	Biological material	Intended use
81479 (Unlisted molecular pathology procedure)			
Assurex Health	GeneSight	Oral swab	Pharmacogenomic test for ADHD, depression, and other psychiatric disorders
Caris	Several tumor profiling tests	Tumor tissue (from biopsy or surgery)	To personalize cancer treatment based on the biology of their patient's tumor
PGXL Laboratories	PGXL Multi-Drug Sensitivity Panel	Blood Oral swab	Pharmacogenomic information for patients treated with various medications, including antidepressants and statins. Helps establish the dose and predict adverse drug reactions.
Berkeley Heart Lab (now part of Quest Diagnostics)	Cardio IQ (includes testing for the SLCO1B1 gene)	Blood	Assess inherited risk for cardiovascular disease Identify genotypes that affect statin metabolism for statin dose adjustment
Millennium Health	Millennium PGT	Saliva Oral swab	Pharmacogenomic testing for pain management and addiction treatment
Boston Heart Diagnostics	SLCO1B1	Blood	Identify genotypes that affect statin metabolism for statin dose adjustment; Identify patients at higher risk for statin induced myopathy
Prometheus Laboratories	PROMETHEUS IBD sgi Diagnostic	Blood	Assist in diagnosing inflammatory bowel disease (IBD) and differentiate between Crohn's Disease and Ulcerative Colitis.
ITT Laboratories	GenoPATH	Oral swab	Individualized pharmacogenomic testing
Dianon (LabCorp)	PCA3	Urine	Prostate cancer assay to determine the need for biopsy
Ambry	Sequencing analysis of over 200 genes	Blood Saliva	Used in various conditions
Genoptics (Novartis)	CALR gene mutation analysis	Blood Bone marrow aspirate	To specify the diagnosis of a myeloproliferative neoplasm when JAK2 and MPL testing are negative. It also has prognostic value.
Genoptics (Novartis)	Partial tandem duplications in the MLL gene (MLL-PTD)	Blood Bone marrow aspirate	The MLL-PTD status is a prognostic factor for remission duration in acute myeloid leukemia (AML).
Multiple laboratories	PCA3	Urine	The test is offered by a number of reference laboratories including ARUP, Mayo Medical Laboratories, and LabCorp
84999 (Unlisted chemistry procedure)			
Crescendo Bioscience	Vectra DA	Blood	For use in adults diagnosed with rheumatoid arthritis (RA) for the assessment of disease activity when used in conjunction with standard clinical assessment (not for diagnosis)
Genomic Health	Oncotype DX Breast Cancer Assay	Tumor tissue (from biopsy or surgery)	To predict risk of recurrence and chemotherapy benefit in early breast cancer
CardioDx	Corus CAD	Blood	Coronary artery disease risk assessment
Agendia	MammaPrint	Tumor tissue (from biopsy or surgery)	To predict risk of recurrence and chemotherapy benefit in early breast cancer

(continued)

Table C.6 (continued)
Complex tests most likely billed with NOC codes (based on line item diagnoses in claims and laboratory profile)

Laboratory	Test	Biological material	Intended use
Quest Diagnostics	Several lymphocyte clonality tests	Blood Bone marrow aspirate	Identification of minimal residual disease or early recurrence in patients with a previous diagnosis of hematologic malignancy
Veracyte	Afirma Thyroid FNA Analysis	Thyroid fine needle aspirate	Thyroid cancer diagnosis; helps avoid unnecessary surgery
Biodesix	VeriStrat	Blood	Predicts benefit from anti-EGFR drugs (erlotinib) for lung cancer patients
87799 (Infectious agent detection by nucleic acid)			
Quest Diagnostics	Multiple	Blood Urine Vaginal swab	Detection of infectious agents, including Varicella-Zoster virus (VZV), which causes chickenpox and shingles, polyomavirus BK associated with an increased risk of graft rejection in renal recipients, and Toxoplasma gondii, an intracellular parasite of immunosuppressed patients and pregnant women. To diagnose bacterial vaginosis and concomitant infection with Chlamydia trachomatis and/or Neisseria gonorrhoeae. Detection of JC Polyoma Virus (JCV) in cerebrospinal fluid (CSF) to confirm diagnosis of progressive multifocal leukoencephalopathy (PML).
LabCorp	Multiple	Blood Urine	Quantitation of several viruses, including polyomavirus BK associated with an increased risk of graft rejection in renal recipients

SOURCE: jl19 and analysis of manufacturers' data

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Table C7a
Payments by primary disease among beneficiaries with and without complex laboratory tests

Table A. Payments by primary disease for the abstracted sample, with genetic tests

Primary disease	Count	Total annualized	Total non-annualized	DME	HHA	Hospice	Inpatient acute hospital	Outpatient hospital	Part B	SNF
Breast cancer	32	$22,028	$16,935	$851	$942	$84	$1,083	$8,320	$5,211	$443
Leukemia	45	$81,126	$47,606	$306	$1,454	$382	$20,670	$11,193	$12,225	$1,376
Lung cancer	20	$23,594	$21,518	$306	$930	$390	$2,569	$7,254	$9,178	$891
Lupus	29	$20,386	$20,097	$3,992	$1,319	$0	$90	$10,264	$4,432	$0

NOTE. Diseases with fewer than 10 observations are not shown. Output nc_ 14 Jul 2016 13_32_09.

Table B. Payments by primary disease for the abstracted sample, without genetic tests

Primary disease	Count	Total annualized	Total non-annualized	DME	HHA	Hospice	Inpatient acute hospital	Outpatient hospital	Part B	SNF
Breast Cancer	29	$13,901	$13,588	$530	$915	$193	$92	$3,936	$6,031	$1,891
Leukemia	13	$47,715	$25,928	$662	$582	$232	$3,565	$6,191	$14,695	$0
Lung Cancer	39	$27,716	$24,715	$385	$757	$1,251	$3,349	$5,196	$9,886	$3,891

NOTE. Diseases with fewer than 10 observations are not shown. Output nc_ 14 Jul 2016 13_32_09.

Table C. Payments by primary disease for the abstracted sample, overall

Primary disease	Count	Total annualized	Total non-annualized	DME	HHA	Hospice	Inpatient acute hospital	Outpatient hospital	Part B	SNF
Breast Cancer	61	$18,164	$15,344	$699	$929	$136	$612	$6,236	$5,601	$1,131
Leukemia	58	$73,637	$42,747	$386	$1,258	$348	$16,836	$10,072	$12,779	$1,068
Lung Cancer	59	$26,319	$23,631	$359	$815	$959	$3,084	$5,894	$9,646	$2,874
Lupus	38	$19,062	$18,841	$3,187	$1,513	$0	$207	$8,716	$4,813	$405

NOTE. Diseases with fewer than 10 observations are not shown. Output nc_ 14 Jul 2016 13_32_09.

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Table C.7b
Payments for breast cancer patients by year recorded in Medicare and MarketScan

	Medicare															
	2010				2011				2012				2013			
	All patients		Tested for breast cancer		All patients		Tested for breast cancer		All patients		Tested for breast cancer		All patients		Tested for breast cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	716	4,897	625	4,301	837	5,218	591	3,939	815	5,207	557	3,874	729	4,901	583	4,241
Outpatient payments	2,480	6,216	2,898	7,119	3,371	6,957	4,905	8,348	3,785	7,547	5,506	8,934	4,111	8,367	6,114	10,460
Part B payments	4,936	8,724	6,894	11,672	5,599	8,804	9,365	12,009	5,691	8,806	9,641	11,939	5,493	8,492	9,294	11,638
Payments overall	10,465	16,102	12,461	17,892	12,500	17,248	16,801	18,338	12,857	17,367	17,512	18,391	12,578	17,104	17,740	19,145
Annualized payments	12,087	24,122	13,674	21,524	14,519	23,657	18,992	22,322	14,952	24,094	19,733	22,142	14,685	24,166	20,006	22,732

	MarketScan											
	2011				2012				2013			
	All patients		Tested for breast cancer		All patients		Tested for breast cancer		All patients		Tested for breast cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	2,842	16,300	3,806.18	18164.29	3,038	19,607	4,978	20,188	3,125	18,805	4,612	18,368
Outpatient payments	7,259	22,977	11,291.4	30818.93	7,632	23,945	17,048	34,006	8,642	26,947	16,550	38,257
Part B payments	6,945	15,354	11,643.25	21771.23	6,798	15,166	15,532	23,155	7,298	16,193	14,425	24,765
Payments overall	17,047	38,210	26,741	48,872	17,468	40,698	37,558	53,017	19,065	43,289	35,587	55,708
Annualized payments	19,627	48,211	30,341	57,548	20,592	51,239	43,078	65,346	22,616	57,155	41,946	80,838

SOURCE: Medicare: jl36, JL44; MarketScan: MKTSCN_JL_EVAL35

Table C.8
Payments for lung cancer patients by year recorded in Medicare and MarketScan

	Medicare															
	2010				2011				2012				2013			
	All patients		Tested for lung cancer		All patients		Tested for lung cancer		All patients		Tested for lung cancer		All patients		Tested for lung cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	2,976	9,979	3,184	10,578	3,595	10,787	3,842	11,091	3,671	11,198	3,923	11,281	3,535	10,910	3,330	9,648
Outpatient payments	4,107	8,961	8,741	14,263	4,567	9,512	9,413	14,061	4,997	10,477	10,272	15,817	5,271	10,945	11,011	16,708
Part B payments	8,052	12,761	15,972	19,259	8,021	11,972	15,219	16,926	7,864	12,043	14,859	16,643	7,415	11,483	14,172	16,930
Annualized payments	29,546	50,076	38,024	38,959	29,681	42,241	38,314	35,062	30,394	44,752	40,971	39,851	30,033	45,503	38,984	35,243
Payments overall	19,872	22,802	31,831	27,416	21,208	23,539	32,347	25,651	21,460	23,970	33,272	26,388	21,057	23,731	32,619	26,331

	MarketScan											
	2011				2012				2013			
	All patients		Tested for lung cancer		All patients		Tested for lung cancer		All patients		Tested for lung cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	14,487	45,296	25,393.99	41,904.24	15,841	40,195	29,987	44,880	18,236	44,021	27,436	42,525
Outpatient payments	17,274	45,324	43,025.54	67,385.96	20,000	46,642	48,681	69,870	22,888	49,195	41,627	60,797
Part B payments	14,109	25,432	33,897.73	37,097.96	15,126	27,070	32,753	35,169	16,784	29,286	32,126	36,554
Annualized payments	61,509	115,498	120,588	108,327	70,232	119,238	137,950	119,910	81,325	136,712	120,136	105,288
Payments overall	45,871	78,597	102,317	88,738	50,967	77,497	111,421	89,831	57,908	83,073	101,189	87,387

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Table C.9
Payments for ovarian cancer patients by year recorded in Medicare and MarketScan

	Medicare															
	2010				2011				2012				2013			
	All patients		Tested for ovarian cancer		All patients		Tested for ovarian cancer		All patients		Tested for ovarian cancer		All patients		Tested for ovarian cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	1,748	7,676	1,284	6,343	2,277	9,083	1,357	6,408	2,318	9,372	1,330	6,243	2,266	9,021	1,408	6,411
Outpatient payments	3,914	9,393	4,648	10,740	3,631	7,858	4,191	8,543	3,944	8,264	4,871	8,834	4,385	8,848	5,496	9,547
Part B payments	7,402	11,727	8,974	13,522	6,922	9,878	8,498	10,777	6,717	9,755	8,591	10,823	6,420	9,129	8,413	10,356
Annualized payments	21,366	36,767	20,802	28,446	22,060	36,498	19,880	25,335	22,276	37,807	20,867	25,926	22,497	45,227	21,411	26,676
Payments overall	16,520	21,250	17,761	21,983	16,831	21,116	16,914	19,608	16,966	21,042	17,686	19,493	16,907	20,780	18,122	19,685

	MarketScan											
	2011				2012				2013			
	All patients		Tested for ovarian cancer		All patients		Tested for ovarian cancer		All patients		Tested for ovarian cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	9,272	32,954	11,404.15	33,562.47	9,899	33,733	15,519	32,582	10,927	37,267	15,618	37,248
Outpatient payments	12,013	33,765	17,776.17	44,281.15	13,556	38,108	18,799	41,435	15,385	43,966	20,894	42,833
Part B payments	10,468	20,574	15,153.03	25,443.4	10,244	20,638	15,009	22,438	10,652	20,450	14,462	20,460
Annualized payments	38,812	88,038	52,905	91,940	42,345	91,090	58,127	91,433	48,205	110,794	63,210	111,112
Payments overall	31,753	61,534	44,333	71,526	33,699	65,492	49,326	68,916	36,964	71,686	50,974	71,592

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Table C.10
Payments for hematologic cancer patients by year recorded in Medicare and MarketScan

	Medicare															
	2010				2011				2012				2013			
	All patients		Tested for hematologic cancer		All patients		Tested for hematologic cancer		All patients		Tested for hematologic cancer		All patients		Tested for hematologic cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	5,163	14,650	9,422	25,152	5,294	15,111	9,526	25,194	5,443	15,751	10,818	26,260	5,478	17,431	9,648	25,020
Outpatient payments	5,495	11,880	13,021	20,177	5,550	12,185	13,140	20,486	6,003	13,448	14,762	21,717	6,532	14,650	16,944	24,835
Part B payments	10,180	14,470	16,097	16,860	9,960	15,419	16,536	18,424	9,592	14,741	16,806	18,060	9,253	14,889	16,593	18,447
Annualized payments	39,640	67,721	55,500	73,668	37,320	65,695	54,561	68,535	37,339	62,572	59,474	72,936	37,585	66,416	56,439	59,081
Payments overall	26,456	28,739	43,017	39,293	26,112	29,553	43,383	38,530	26,207	30,067	46,382	39,754	26,066	32,029	46,971	41,131

	MarketScan											
	2011				2012				2013			
	All patients		Tested for hematologic cancer		All patients		Tested for hematologic cancer		All patients		Tested for hematologic cancer	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	12,149	54,788	44,619.5	11,8637.8	12,894	56,837	58,427	142,128	13,931	57,039	16,855	44,418
Outpatient payments	11,838	36,015	32,860.04	66,190.46	13,108	38,131	31,910	57,657	14,199	39,705	26,118	47,152
Part B payments	10,063	21,136	20,324.49	29,423.95	10,167	21,617	21,048	27,395	10,965	22,780	19,386	24,172
Annualized payments	42,122	123,801	116,171	220,257	45,527	121,177	128,769	214,798	49,888	135,038	73,624	100,604
Payments overall	34,050	82,114	97,804	165,295	36,169	85,540	111,385	177,119	39,096	87,478	62,359	79,895

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Table C.11
Payments for heart transplant patients by year recorded in Medicare and MarketScan

	Medicare															
	2010				2011				2012				2013			
	All patients		Tested for heart transplant		All patients		Tested for heart transplant		All patients		Tested for heart transplant		All patients		Tested for heart transplant	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	33,501	101,544	16,486	60,530	24,575	74,924	14,556	61,324	33,089	90,149	23,933	62,778	30,920	88,688	449	2,184
Outpatient payments	13,642	13,166	17,159	11,446	14,978	15,087	18,575	13,888	14,302	13,523	19,109	12,552	13,508	13,129	21,480	12,994
Part B payments	19,131	15,851	23,318	13,447	20,366	16,383	24,777	14,439	19,760	15,853	25,274	12,932	20,499	16,486	30,768	13,587
Payments overall	79,551	110,887	76,165	74,123	75,059	86,086	78,149	73,168	79,463	98,801	84,599	68,034	76,056	97,626	67,037	28,106
Annualized payments	120,782	320,416	78,054	76,896	114,505	359,180	79,371	72,689	114,544	236,672	101,476	149,118	101,852	208,487	68,706	29,036

	MarketScan											
	2011				2012				2013			
	All patients		Tested for heart transplant		All patients		Tested for heart transplant		All patients		Tested for heart transplant	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	314,041	257,243	322,450	236,782	297,991	290,699	217,467	113,722	329,921	307,560	243,269	200,533
Outpatient payments	46,739	37,110	49,718	27,191	51,742	51,290	62,663	51,382	48,018	34,710	49,278	25,559
Part B payments	49,328	31,828	61,095	40,222	49,216	40,861	48,093	34,018	53,702	61,020	69,913	61,812
Total payments	410,108	269,245	433,263	273,745	398,948	302,390	328,223	162,399	441,642	329,601	362,660	220,781
Annualized total payments	481,369	395,427	456,066	275,183	526,283	736,957	350,770	172,817	521,254	451,296	379,398	295,034

PROGRAMS: Medicare Heart Transplant and Demographics and Payment Tables.sas
Marketscan Heart Transplant Demographics and Payment Tables.sas

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Table C.11
Payments for Lupus patients by year recorded in Medicare and MarketScan

	Medicare															
	2010				2011				2012				2013			
	All patients		Tested for lupus		All patients		Tested for lupus		All patients		Tested for lupus		All patients		Tested for lupus	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	1,178	7,293	703	5,099	1,174	7,353	790	5,934	1,173	7,999	774	5,317	1,124	7,307	846	6,064
Outpatient payments	2,273	5,638	2,188	5,178	2,197	5,482	2,126	5,151	2,338	5,741	2,322	5,181	2,375	6,051	2,440	5,488
Part B payments	4,695	7,366	4,866	5,696	4,706	6,719	5,122	5,929	4,669	6,712	5,170	6,086	4,619	6,462	5,332	6,279
Annualized payments	12,868	28,359	10,327	16,343	12,677	28,700	10,783	17,522	12,615	26,806	11,265	18,525	12,335	28,511	11,590	20,057
Payments overall	11,106	17,793	9,860	14,019	10,919	17,349	10,005	14,527	10,869	17,812	10,338	14,700	10,640	17,237	10,721	15,331

	MarketScan											
	2011				2012				2013			
	All patients		Tested for lupus		All patients		Tested for lupus		All patients		Tested for lupus	
Description	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Inpatient payments	2,291	13,956	463	4,348	2,377	16,793	444	5,234	2,523	15,170	345	3,630
Outpatient payments	2,142	12,986	686	4,348	2,305	16,093	675	5,248	2,388	14,051	533	3,649
Part B payments	984	4,961	471	1,210	1,126	4,859	486	1,467	1,260	670	441	914
Annualized payments	5,416	28,790	1,619	9,554	5,807	34,680	1,605	11,703	6,171	31,420	1,320	7,872
Payments overall	6,421	37,184	1,726	9,722	6,815	40,553	1,768	12,261	7,509	49,054	1,496	9,500

PROGRAMS: Medicare Lupus Demographics and Payment Tables.sas
Marketscan Lupus Demographics and Payment Tables.sas