Section 3113: Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration

Request for Temporary G-code—Supporting Information

Section I

A. BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) published a *Federal Register* notice (CMS-5058-N) informing interested parties of an opportunity to participate in the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration mandated by section 3113 of the Affordable Care Act (Pub. L. 111-148). This Demonstration will allow a separate 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 begins January 1, 2012. The Demonstration will be conducted for two years subject to a $100 million payment limit. Thereafter, payment for these tests will be made under the existing non-demonstration process. 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.

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 by the hospital or CAH, either directly or under arrangement. Under the date of service 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, a laboratory may bill Medicare directly for a complex clinical laboratory test which is 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 the Demonstration must submit a claim with a Project Identifier 56. For purposes of the Demonstration, in addition to the tests that already meet the requirements at section 3113(a)(2) (see "Demonstration Test List" at http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611), we will assign temporary codes based on the supporting information provided to CMS for diagnostic laboratory tests defined in section 3113(a)(2) but currently billed using NOC codes.

B. SECTION 3113 DEMONSTRATION TEMPORARY G-CODES

For purposes of the Demonstration, tests that would meet the criteria for being complex diagnostic laboratory tests except that they are billed under Medicare using NOC codes and where the current payment rate setting method of gap filling and cross walking is not applicable, test manufacturers/developers may request a temporary G-code. We have developed an approach that incorporates 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.

Matrix: G-Codes Based on Method and Clinical Utility

	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

The method refers to the definition of a complex diagnostic test specified in section 3113a(2) of the statute (see Section A). The clinical utility captures the reason why the test is used or its importance in treating a patient by resolving diagnostic discrepancies, differentiating stages of disease, assessing prognosis or risk, or assessing a patient's response to treatment.

C. REQUESTING A SECTION 3113 DEMONSTRATION TEMPORARY G-CODE

As discussed in Section B, under the Demonstration, a test manufacturer/developer may request a temporary G-code for a test that would meet the criteria for being a complex diagnostic laboratory test except that it is billed under Medicare using a NOC code. In general, the test manufacturer/developer must submit to CMS information about utilization; the Clinical Laboratory Improvement Amendment certificate number of the laboratory(ies) performing the test; current billing practices and cost and other information. The supporting information (see template provided below) is due to CMS no later than August 1, 2011. If necessary, test manufacturers/developers will be asked to complete, clarify, or verify supporting information provided to CMS. Manufacturers/developers must fill out section II for each test for which they are requesting for a temporary G-code under the Demonstration.

Section II

For CMS Use Only	
Name of Manufacturer or Developer	Date Received

A. TEST DEVELOPER INFORMATION

1. Business Information

Developer's Name		
Mailing Address *(Number, Street)*		
City	State	Zip Code
Telephone Number *(Include Area Code)*	Fax Number *(Include Area Code)*	

2. Federal Tax Identification Number (TIN)

_____

3. What is the name of the test for which you are requesting a G-code under the demonstration?

4. Is this a laboratory developed test? _____Yes _____No

Name of the laboratory: _____

Clinical Laboratory Improvement Amendment (CLIA) Certificate Number

_____

5. Demonstration Contact Information: Please provide contact information for CMS in case more information or clarification is necessary.

Name		
Title/Position:		
Mailing Address *(Number, Street)*		
City	State	Zip Code
Telephone Number *(Include Area Code)*	Fax Number *(Include Area Code)*	

B. SUPPORTING INFORMATION ON COMPLEX LABORATORY TEST(S)

Please answer all the following questions to the best of your knowledge.

1. With reference to Section 3113a(2), is this test a/an (please check the appropriate box)

- **a. Analysis of gene protein expression?** ☐
- **b. Topographic genotyping test?** ☐
- c. **Cancer chemotherapy sensitivity assay?** ☐

2. Please indicate the clinical utility of the test. Does this test (check the appropriate box/boxes)

- **a. Resolve diagnostic discrepancies?** ☐
- **b. Differentiate states of the disease?** ☐
- **c. Assess the prognosis or risk?** ☐
- **d. Assess the patient's response to treatment?** ☐

PLEASE ATTACH A SAMPLE PATIENT REPORT

3. Please briefly state the demographic and clinical features of patients for whom this test would typically provide important information for diagnosis or treatment planning. If appropriate, please indicate how (if at all) the results of this test are typically expected to 1) guide therapy; 2) indicate whether other diagnostic studies are necessary; and/or 3) depend on family history for interpretation.

4. Please describe how this test is obtained by laboratories performing the test:

Specifically,

a. Is this test marketed as a test kit? ☐ **Yes** ☐ **No**

b. If this test is marketed as a test kit, then for the most recent fiscal/calendar year (please identify year), what is the:

(i) cost of producing one test kit?

(ii) list price to laboratories for one test kit (please note if there are any volume or other discounts provided to laboratories)?

(iii) number of tests a laboratory can provide using one test kit (note: one unit of the test provided by a laboratory is defined as the testing for one patient's reportable results)?

(iv) total annual number of test kits sold?

c. Is this test a laboratory developed test performed *exclusively* by the laboratory?
☐ **Yes** ☐ **No**

d. Is this test both marketed as a test kit and performed by the laboratory?
☐ **Yes** ☐ **No**

5. For all laboratories performing this test (including you, the developer, and any laboratories that purchased the test kit), please provide in the table below the total annual patient test volume and the corresponding annual patient test payments (revenues) for the most recent fiscal or calendar year.

Please provide annual volume and annual payments in total and also separately by source of reimbursement (payer).

Please note the time period of the fiscal/calendar year.

Note: One unit (volume = 1) of the test is defined as the testing for one patient's reportable results.

Source of reimbursement	Annual patient test volume	Annual patient test payments
Hospitals under arrangement		
Medicare Fee-For-Service		
Medicare Advantage		
Medicaid		
Commercial Insurers		
Self-Pay		
Other Payers		
TOTAL		

6. For all laboratories performing this test (including you, the developer, and any laboratories that purchased the test kit), please provide in the table below the current prices paid to the laboratories by payer (source of reimbursement) for testing for one patient's reportable results.

Payer	Minimum Price	Maximum Price	Mean Price
Hospitals under arrangement			
Medicare Fee-For-Service			
Medicare Advantage			
Medicaid			
Commercial Insurers			
Self-Pay			
Other Payers			

7. Please name and describe the sequence of laboratory steps (methods) involved in performing the test. For example, molecular isolation or extraction, enzymatic digestion, DNA amplification, gene amplification, etc. You may attach your test procedure to answer this question.

8. Please provide the current cost breakdown for the steps identified in question 7.

Definitions and Instructions for Cost Information

a. Definitions

Direct Costs: non-labor costs which are directly identifiable with a test (e.g., equipment, reagents, disposable supply costs)

Indirect Costs: the common laboratory costs shared by all tests (overhead) (e.g., administration, facility costs, licensure/certification costs, regulatory costs)

Labor Costs: the costs associated with employee/s actually performing the test (please identify skill level)

For **labor category**, please select the labor skill level needed for the task. Skill level categories are: MD, PhD, MT, MLT, and other.

b. Instructions

To submit the Cost Breakdown Information, please complete the recommended template (in excel table format). **To obtain an electronic copy of the template, please send an email request to Section3113LabDemo@rti.org.**

NOTE: *PLEASE PROVIDE ALL COST INFORMATION FOR TESTING FOR ONE PATIENT'S REPORTABLE RESULTS*

9. Please describe how often the test may be ordered for each patient. For example, is it appropriate to order this test on a periodic basis?
10. Please identify (by HCPCS code and short description) other tests commonly ordered in combination with or as follow-up to this test:

11. Please describe current billing practices for this test– identifying all HCPCS codes and short descriptions, used to bill for this test including any and all accompanying technical and/or professional component codes:
12. Does this test have one or more patents? If so, what are the patent numbers, country the patents were obtained from, and dates the patents were obtained? What were the research and development costs associated with developing the test?

Section III

A. CERTIFYING STATEMENT

I, the undersigned, certify to the following:

1. I attest that the Supporting Information submitted to CMS for purposes of this Demonstration is accurate and complete.

2. I attest on behalf of the organization and agree that the organization will notify CMS in writing and within 15 days should the organization become aware at any time during the review of the Supporting Information by CMS or any time during the Demonstration period that any information provided to CMS is not true, correct, or complete.

3. I understand that, in accordance with 18 U.S.C. § 1001, any omission, misrepresentation, or falsification of any information communicated to CMS for purposes of the Demonstration may be punishable by criminal, civil, or administrative actions including revocation of approval, fines, and/or imprisonment.

4. I certify that I am a legal representative of the organization and am authorized to submit and certify this request for a temporary Demonstration G-code under the Section 3113: Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration on behalf of the organization.

Authorized Official Name (First, Middle, Last)	**Title/Position**
Signature	**Date**
Name of Developer/Manufacturer	

B. SUBMITTING INFORMATION

The Freedom of Information Act (FOIA) does not require a state or local government or a private organization or business to release any records directly to the public, whether such records have been submitted to the federal government or not. However, records submitted to the federal government by such organizations or companies may be available through a FOIA request if it is not protected by a FOIA exemption, such as the one covering trade secrets and confidential business information.

To be considered by CMS for a temporary Demonstration G-code, supporting information must be received by CMS not later than August 1, 2011. Supporting information must include an electronic copy and 3 hard copies. Please submit the electronic copy to

Section3113LabDemo@rti.org**.** The 3 hard copies of the supporting information should be mailed or delivered to the following address:

Linda R. Lebovic
Centers of Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Medicare Demonstrations Program Group
7500 Security Blvd
Mailstop C4-14-15
Baltimore, MD 21244
410.786.3402

For further information regarding the supporting information requested and/or questions, please send an email to Section3113LabDemo@rti.org.