US-35227 ONC Unbranded Dx 14-day Rule Leave Behind

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UPDATED

Biomarker testing, Medicare billing, and the 14-day rule*

Labs should continue to bill Medicare directly for outpatient biomarker testing, regardless of sample collection date

WHAT IS THE 14-DAY RULE?

The Centers for Medicare & Medicaid Services (CMS) 14-day rule affects diagnostic tests ordered less than 14 days after an inpatient or outpatient discharge. The rule requires laboratories to bill the hospital for tests performed for Medicare patients within this 14-day window.

HOW DOES THE 14-DAY RULE AFFECT BIOMARKER TESTING?

In the outpatient setting, CMS has created exemptions to the 14-day rule for molecular pathology and certain other test categories, so laboratories can bill Medicare directly for biomarker testing, regardless of how many days have elapsed since discharge.

In the inpatient setting, the 14-day rule still applies. For tests ordered less than 14 days from an inpatient discharge, laboratories are required to contact the hospital for payment.

In the nonpatient setting, tests are billed directly to Medicare.

HIGHLIGHTS OF CURRENT POLICY

- For Medicare patients in the outpatient setting, laboratories should bill Medicare directly for molecular pathology and other tests exempted from the 14-day rule
  - For example, outpatient breast and lung biomarker testing, such as *BRCA*- and EGFR-mutation tests, may be billed by labs to Medicare directly for separate payment
- Laboratories should work with their hospital partners to ensure that they do not both bill Medicare for the same test
- The date of service (DOS) rule, currently enforced with discretion, is set to be enforced starting January 2, 2020

INPATIENTS, OUTPATIENTS, AND NONPATIENTS: INS AND OUTS

Inpatients have been formally admitted to a hospital with a physician's order. The day before they are discharged is their last inpatient day.

Outpatients visit the hospital for services, treatments, or tests, but they have not received a physician's formal admission order.

Nonpatients are patients whose samples are collected at a private physician's office or commercial laboratory with no hospital visit on the date of collection.

*Centers for Medicare and Medicaid Services Laboratory Date of Service Policy.

BRCA, breast cancer susceptibility gene; CPT, current procedural terminology; EGFR, epidermal growth factor receptor.

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WHICH TESTS ARE EXEMPT FROM THE 14-DAY RULE?

In the outpatient setting, the following tests are exempt:

- Molecular pathology tests
- Certain Advanced Diagnostic Laboratory Tests (ADLTs)
- Preventative tests

In the inpatient setting, the 14-day rule still applies.

HOW DOES THE 14-DAY RULE APPLY FOR INPATIENTS VS OUTPATIENTS?

SCENARIO 1

Inpatient sample taken and test ordered **<14 days** from discharge → Lab bills hospital

SCENARIO 2

Inpatient sample taken and test ordered **≥14 days** from discharge → Lab bills Medicare

SCENARIO 3

Outpatient sample* taken and test ordered **<14 days** from discharge → Lab bills Medicare†

SCENARIO 4

Outpatient sample taken and test ordered **≥14 days** from discharge → Lab bills Medicare

*Outpatient samples in this scenario would include exempt outpatient molecular pathology tests, ADLTs, or preventative tests.
†During the enforcement discretion period, which ends on January 2, 2020, either the lab or the hospital may bill Medicare.

WHAT IS THE NONENFORCEMENT PERIOD?

Since 2014, CMS has exempted certain outpatient tests from the 14-day rule, including molecular tests and ADLTs.

This time of exemption is known as the nonenforcement period. Enforcement of the 14-day rule for outpatient samples is scheduled to begin on January 2, 2020.

WHAT ADDITIONAL RULE CHANGES ARE EXPECTED?

The DOS, currently defined as the date the sample was collected, is used to determine whether a test falls within the 14-day period. But this definition is set to change. An as-yet-unenforced 2018 rule affecting DOS is scheduled for enforcement starting January 2, 2020:

For outpatient testing currently exempted from the 14-day rule, the DOS must be the date that the test was performed, instead of the date the specimen was obtained, provided the following conditions are met:

1. The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department
2. The specimen was collected from a hospital outpatient during an outpatient encounter
3. It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter
4. The results of the test do not guide treatment provided during the hospital outpatient encounter
5. The test was reasonable and medically necessary for the treatment of an illness

What this means: If all the requirements are met, **the laboratory performing the test must bill Medicare directly for the test**, instead of seeking payment from the hospital.

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WHAT ARE THE CURRENT* CPT CODES FOR EXEMPT LUNG AND BREAST CANCER BIOMARKER TESTING?

When eligible, laboratories may bill Medicare for direct payment using these Current Procedural Terminology (CPT) codes:

81445	Solid Organ Neoplasm: Targeted Genome Sequencing 5-50 genes
81450	Hematological Neoplasm: Targeted Genome Sequencing 5-50 genes
81455	Solid or Hematological Neoplasm: Targeted Genome Sequencing 51 or greater genes
81235	EGFR gene variants, **cobas® EGFR Mutation Test v2**
0022U	Targeted genomic sequence analysis panel, non–small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider, **Oncomine™ Dx Target Test**
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden, **FOUNDATIONONE®CDx**
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s), **MSK-IMPACT™**
81479	Unlisted molecular pathology, such as **Guardant360®** and **BRACAnalysis CDx®**
81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217	*BRCA*1 and/or *BRCA*2 testing

**Source:* Laboratory date of service policy. Centers for Medicare & Medicaid Services Web site. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html. Accessed September 6, 2019.

WANT TO LEARN MORE?

For more information, see the Centers for Medicare & Medicaid Services "Laboratory Date of Service Policy" page at: **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html**

For any concerns about the 14-day rule, please contact your AstraZeneca representative.

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