

Biomarker Testing, Medicare Billing, and CMS Laboratory Date of Service Policy (the "14-Day Rule")

Updated as of January 1, 2020



What is the policy?

CMS Laboratory Date of Service Policy (sometimes referred to as the "14-day rule") affects diagnostic tests ordered less than 14 days after an inpatient or outpatient discharge. The policy requires laboratories to bill the hospital for tests performed for Medicare patients within this 14-day window. The updated policy requires laboratories to bill Medicare directly for exempted tests performed within the 14-day window.



How does the updated policy affect biomarker testing?

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

The policy still applies in the inpatient setting. Laboratories are required to contact the hospital for payment.

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

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.

Which tests are exempt from the policy?

In the *outpatient setting*, the following tests are exempt:



Molecular pathology tests



Certain Advanced Diagnostic Laboratory Tests (ADLTs)

Certain test methodologies, such as IHC or FISH testing, are not exempt from the Laboratory Date of Service Policy and would be billed to the hospital if <14 days from discharge.

In the inpatient setting, the policy still applies.



Examples of inpatient vs outpatient billing

Scenario 1



Inpatient sample collected and test ordered <14 days from discharge



Lab bills hospital

Scenario 2



Inpatient sample collected but test ordered ≥ 14 days from discharge (**outpatient status**)



Lab bills Medicare (Nonexempt codes, such as IHC and FISH, are billed to the hospital)

Scenario 3



Outpatient sample* collected and test ordered <14 days from discharge



Lab bills Medicare (Nonexempt codes, such as IHC and FISH, are billed to the hospital)

*Outpatient samples in this scenario would include exempt outpatient molecular pathology tests or ADLTs.

Scenario 4



Outpatient sample collected and test ordered ≥ 14 days from discharge



Lab bills Medicare



What are some current* CPT and PLA codes for exempt lung, breast, ovarian, and prostate cancer biomarker testing?

| | |
|---------------------------------------|---|
| 81432 | Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary prostate cancer, hereditary pancreatic cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53 |
| 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 genes |
| 81235 | EGFR gene variants, for example, PCR cobas® EGFR Mutation Test v2 |
| 0022U | Oncomine™ Dx Target Test (ThermoFisher Scientific), which evaluates non-small cell lung cancer (NSCLC) tumor tissue |
| 0037U | FoundationOne®CDx (F1CDx®) test from Foundation Medicine, Inc, a companion diagnostic (CDx) test for melanoma, NSCLC, and breast, ovarian, prostate, and colorectal cancer |
| 0048U | MSK-IMPACT™ (Integrated Mutation Profiling of Actionable Cancer Targets), Memorial Sloan Kettering Cancer Center, a targeted DNA-sequencing panel for somatic mutations in formalin-fixed, paraffin-embedded tumor tissues of solid organ tumors |
| 81479 | Unlisted molecular pathology |
| 81162-81167, 81212, 81215-81217 | <i>BRCA1</i> and/or <i>BRCA2</i> testing, including Sanger Sequencing |

*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 August 13, 2020.



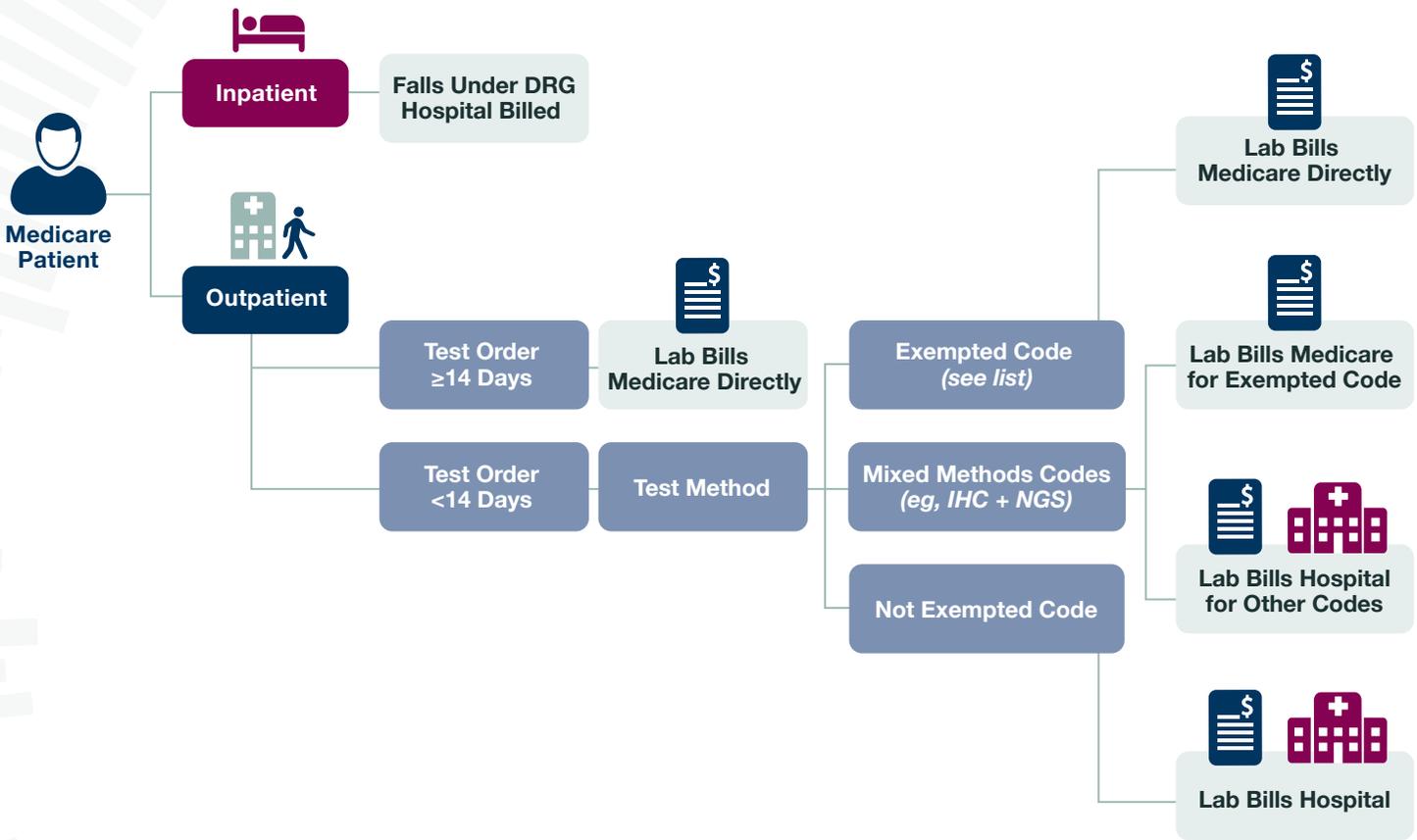
When eligible, laboratories may bill Medicare for direct payment using the above (CPT) codes.

See the full list:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>



Medicare Laboratory Date of Service Policy ("14-Day Rule")



See the full list of codes:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>

Oncomine™ Dx is a trademark of Thermo Fisher Scientific Inc.; cobas® is a registered trademark of Roche Diagnostics, Inc.; FoundationOne®CDx is a registered trademark of Foundation Medicine, Inc.; MSK-IMPACT™ is a trademark of Memorial Sloan Kettering Cancer Center; Guardant360® is a registered trademark of Guardant Health, Inc.