

Considerations for **Biomarker Testing Reimbursement**

14-DAY RULE EXPLANATION

The goal of this chapter is to provide educational information regarding reimbursement for biomarker testing. It is being provided for informational purposes only. It is the sole responsibility of the health care provider to select the proper codes and to ensure the accuracy of all statements used in seeking coverage and reimbursement for the care of individual patients.

The **14-day rule** dictates who may be billed for diagnostic tests based on a patient's status and the specific biomarker test(s).¹

Laboratories are required to bill the hospital for some test(s) ordered <14 days after an inpatient discharge or outpatient visit¹

- In the **outpatient** setting, exempted tests may be billed to Medicare within the 14-day window¹



Many tests used to identify genes relevant in cancer are exempt from the 14-day rule¹⁻³

14-DAY RULE EXPLANATION (CONTINUED)

Essential definitions



INPATIENT: formally admitted to a hospital with a physician's order⁴

- The last inpatient day is the day before discharge



OUTPATIENT: visits the hospital for services, treatment or tests, but does not have a physician's formal admission order⁴



NONHOSPITAL PATIENT: has sample(s) collected at a private physician's office or commercial laboratory⁵

- There is no hospital visit on the date of collection

Billing by the lab for hospital outpatients depends on whether the testing is exempt from the 14-day rule, unlike hospital inpatients and nonhospital patients^{1,6}

Types of biomarker tests that may be exempt^{1,7}



Molecular pathology tests*



Advanced diagnostic laboratory tests (ADLTs)



Cancer-related protein-based multi-analyte algorithmic assays (MAAAs)

*IHC, FISH, and immunoassay are not exempt from the 14-day rule and must be billed to the hospital if performed less than 14 days from outpatient discharge

WHAT ARE THE MOST FREQUENT SCENARIOS OF THE 14-DAY RULE?

	Days from Discharge	For EXEMPT Tests, Lab Bills:	For NON-EXEMPT Tests, Lab Bills
HOSPITAL INPATIENTS have been formally admitted to a hospital with a physician's order ¹	<14	Hospital	Hospital
	≥14	Medicare	Medicare
HOSPITAL OUTPATIENTS visit the hospital for services, treatment or tests but have not received a physician's formal admission order ¹	<14	Medicare	Hospital
	≥14	Medicare	Medicare
NONHOSPITAL PATIENTS are patients whose samples are collected at a private physician's office or commercial laboratory with no hospital visit on the date of collection ⁶	<14	Medicare	Medicare
	≥14	Medicare	Medicare

 **75% of possible scenarios can be billed to Medicare^{1,6}**

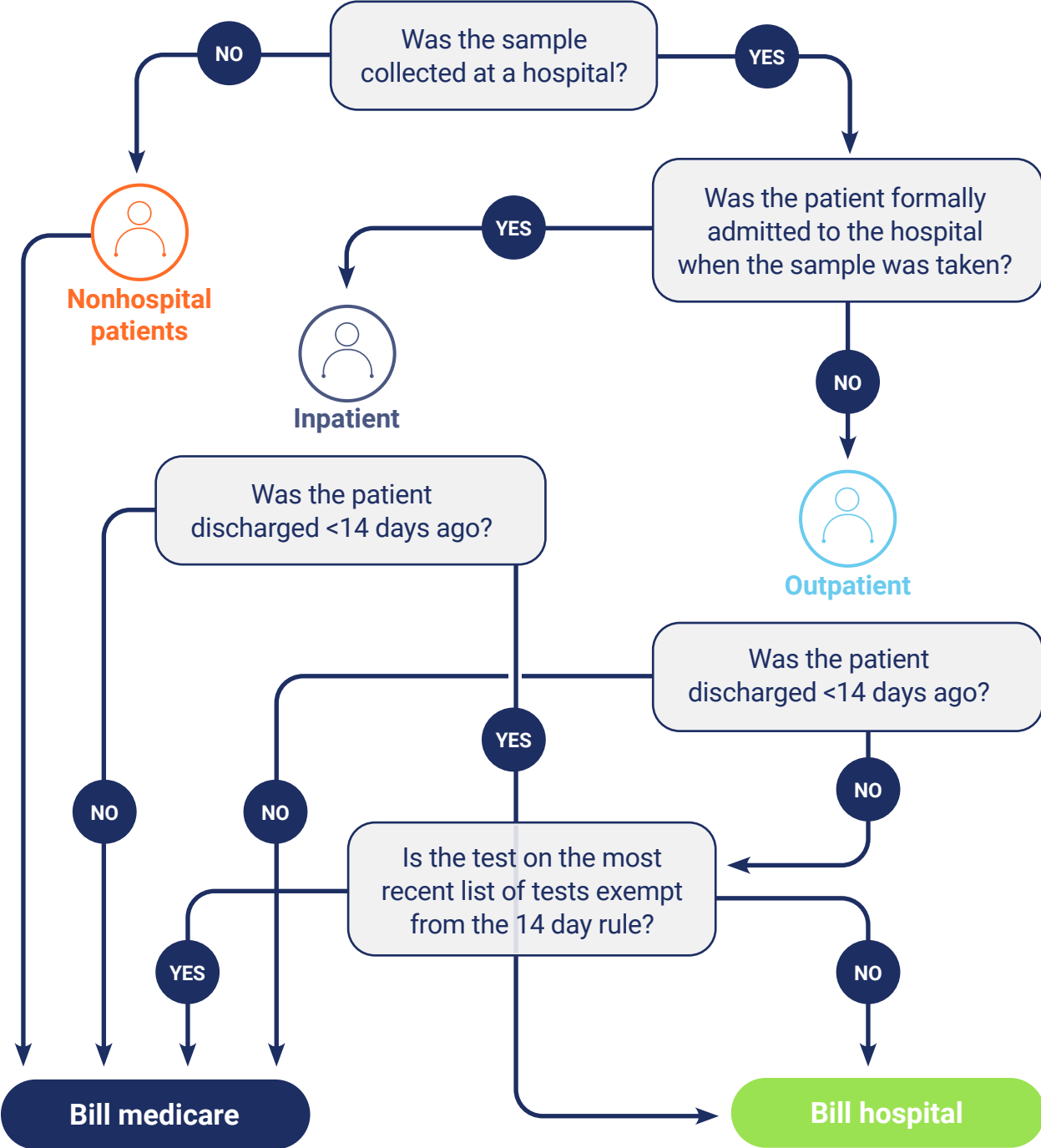
SELECT BIOMARKER TESTS IN ONCOLOGY THAT ARE EXEMPT FROM THE 14-DAY RULE^{2,8}

Test Name	CPT / PLA code(s)
FOUNDATIONONE® CDX	0037U
MI PROFILE™	0211U
GUARDANT360® CDX	0242U
TEMPUS XF	81479, 81455
NEOTYPE® PRECISION PROFILE FOR SOLID TUMORS (NGS)	81479
MSK IMPACT™	0048U
PENN PRECISION PANEL 2.0	81479, 81445
MOFFITT STAR™ (TRUSIGHT® TUMOR 170)	81455
HOPESEQ SOLID TUMOR COMPLETE	81479, 81455
JOHNS HOPKINS UNIVERSITY SOLID TUMOR PANEL V6	81455
EMPOWER™ CANCER TEST	81479, 81455
STANFORD SOLID TUMOR ACTIONABLE MUTATION PANEL (STAMP)	81479, 81455
ONCOPANEL (POPV3)	81455
ONCOTYPE MAP™ PAN-CANCER TISSUE TEST	0244U
CLEVELAND CLINIC PAN-SOLID TUMOR NGS PANEL	81445
MYCHOICE® CDX	0172U
PCMP - PERSONALIZED CANCER MUTATION PANEL (ION AMPLISEQ™ CANCER HOTSPOT PANEL V2)	81445
STRATANGS®	81479, 81455
ION AMPLISEQ™ CANCER HOTSPOT PANEL V2	81445, 81450, 81455, 81479
TRUSIGHT™ ONCOLOGY 500	81445, 81479
OncoPrint™ Focus Assay	81445

Tests performed by dedicated, external laboratories
 Tests that can be ordered as kits by independent laboratories

The select tests listed above represent the top 20 NGS solid tissue cancer tests by market share in Q1 2022. This information is not exhaustive and is not intended to endorse a particular test. When testing for therapy selection, please consult product prescribing information and FDA-approved companion diagnostics. It is the sole responsibility of the health care provider to select the proper codes and to ensure the accuracy of all statements used in seeking coverage and reimbursement for the care of individual patients.

QUESTIONS TO CONSIDER WHEN DETERMINING WHO MAY BE BILLED FOR A TEST:



REFERENCES

1. CMS. Laboratory Date of Service Policy. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy>. Accessed May 16, 2022.
2. Centers for Medicare and Medicaid Services. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Test-Codes-DOS-Exception.zip>. Accessed May 25, 2022.
3. Colomer R, et al. *EClinicalMedicine*. 2020;25:100487.
4. Medicare. Are You a Hospital Inpatient or Outpatient. <https://www.medicare.gov/sites/default/files/2018-09/11435-Are-You-an-Inpatient-or-Outpatient.pdf>. Accessed May 16, 2022.
5. CMS Manual System. Pub 100-04 Medicare Claims Processing Transmittal 2971. <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2971cp.pdf>. Accessed May 16, 2022.
6. CMS. Frequently Asked Questions Revised Laboratory Date of Service Exception Policy. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-DOS-FAQs.pdf>. Accessed May 16, 2022.
7. CMS. Laboratory Date of Service Policy. <https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf>. Accessed August 1, 2022.
8. Data on File. Novartis Pharmaceuticals Corp; 2022.

SUMMARY



The 14-day rule instructs laboratories to bill the hospital for tests ordered <14 days after an inpatient discharge or outpatient visit¹



The 14-day rule only applies in certain situations

- In the inpatient setting, the rule always applies¹
- In the outpatient setting, the rule **only applies to nonexempt tests**¹
- In the nonpatient setting, the rule **does not apply**⁶



In oncology, numerous biomarker tests are exempt from the 14-day rule¹



Do you have the **Knowledge Check** that goes with this chapter?



Are you interested in learning more about **Precision Medicine**?

GO TO OUR WEBSITE!



You'll find knowledge checks, additional resources, a digital version of this and other chapters, and more

www.hcp.novartis.com/precision-medicine



Looking to speak to a Precision Medicine Liaison? Scan this QR code

www.hcp.novartis.com/precision-medicine/contact-us