

Oncotype® Tests and Medicare’s 14-Day Rule



What is the 14-Day Rule?

Medicare has specific date of service reporting requirements for clinical laboratory tests and the technical component (TC) of physician pathology services (commonly known as the “14-Day Rule”). Because of these requirements, an Oncotype test’s date of service may overlap with a hospital patient’s inpatient or outpatient visit, where the specimen was collected for testing. In these situations, unless an exception is met, the laboratory must bill the hospital for payment.

How does it work?

Medicare’s general rule is that the date of service for laboratory testing is the date the specimen was collected. However, the 14-Day Rule states that if the test is ordered by the patient’s physician at least 14 days following the patient’s discharge from the hospital (where the specimen was collected), the date of service must be the date the test was performed. Using this later date means that the test is unlikely to overlap with the patient’s inpatient or outpatient visit, allowing Exact Sciences to bill Medicare directly. For molecular pathology testing, Medicare created an even broader exception requiring the date of service for these tests to be the date of performance when the specimen was collected from a hospital outpatient – even if the patient’s physician orders the test less than 14 days from the patient’s outpatient discharge. Most Oncotype testing components are molecular pathology.



These tables show how the Medicare date of service rules apply to specific scenarios for Oncotype tests

MOLECULAR PATHOLOGY TESTS

Status at Specimen Collection	Medicare Billing*
Nonpatient	Exact Sciences bills Medicare
Outpatient	
Inpatient - ordered ≥ 14 days after date of discharge	
Inpatient - ordered < 14 days after date of discharge	Exact Sciences bills hospital

This covers most Oncotype testing components

IMMUNOHISTOCHEMISTRY (IHC) TESTING

Status at Specimen Collection	Medicare Billing*
Nonpatient	Exact Sciences bills Medicare
Inpatient - ordered ≥ 14 days after date of discharge	
Outpatient - ordered ≥ 14 days after date of discharge	
Inpatient - ordered < 14 days after date of discharge	Exact Sciences bills hospital
Outpatient - ordered < 14 days after date of discharge	

*Original Medicare administered by the federal government. Does not include Medicare Advantage health plans administered by private insurers. Oncotype is a trademark of Genomic Health, Inc. Exact Sciences is a registered trademark of Exact Sciences Corporation. ©2021 Genomic Health, Inc. All rights reserved. EXS12924_0521

HOSPITAL BILLING SCENARIOS



SCENARIO 1

- A patient has their tumor biopsied as an outpatient in a hospital-based physician clinic and leaves that same day.
- The treating physician orders immunohistochemistry stains from an independent laboratory **7 days** after the outpatient visit where the tumor specimen was collected.
- Because the test was ordered less than **14 days** from outpatient discharge, the date of service for the TC component of physician pathology services must be the date of collection (i.e., overlap with outpatient visit).



The laboratory must bill the hospital.

SCENARIO 2

- A hospital inpatient with advanced cancer has blood collected during their stay and sent to an independent laboratory for molecular testing.
- The treating physician orders a genomic profiling test **10 days** after the patient's inpatient discharge to identify other potential therapy options.
- Because the test was ordered less than **14 days** from discharge, the date of service for the laboratory test is the date of collection (i.e., overlap with inpatient stay).



The laboratory must bill the hospital.

What should hospitals do if they receive an invoice for Oncotype® testing?

After remitting payment, hospitals should contact their revenue cycle departments for guidance on reporting laboratory and/or physician pathology services under arrangements. Even if Medicare requires the laboratory to bill the hospital, reimbursement rules for inpatient and outpatient services may allow the hospital to report these charges on the claims it submits to Medicare.

Exact Sciences processes test orders as they are received from providers. Clinical judgment should be the determining factor for test ordering.

About Exact Sciences

A leading provider of cancer screening and diagnostic tests, Exact Sciences helps people get the answers they need to make more informed decisions across the cancer continuum. Building on the success of the Cologuard® and Oncotype DX® tests, Exact Sciences is investing in its product pipeline to take on some of the deadliest cancers and improve patient care. Through an innovative, rigorous approach, and with the support of visionary collaborators, we're helping advance the fight against cancer.

References:

- Medicare Benefit Policy Manual, Ch. 1, sec. 50.3 ("Diagnostic Services Furnished to an Inpatient by an Independent Clinical Laboratory Under Arrangements With the Hospital")
- Medicare Benefit Policy Manual, Ch. 6, sec. 20.4.5 ("Outpatient Diagnostic Services Under Arrangements")
- 42 CFR 414.510, 42 CFR 410.28, 42 CFR 410.42, 42 CFR 412.50, 42 CFR 409.16

Oncotype MAP, Oncotype MAP Pan-Cancer Tissue Test, Oncotype DX, Oncotype DX Breast Recurrence Score, Oncotype DX Breast DCIS Score, Oncotype DX Genomic Prostate Score, Oncotype DX Colon Recurrence Score, and Oncotype DX AR-V7 Nucleus Detect are trademarks of Genomic Health, Inc. Exact Sciences is a registered trademark of Exact Sciences Corporation. ©2021 Genomic Health, Inc. All rights reserved. EXS12924_0521

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