

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 DX® or OncoExTra™ 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. There is a broad exception for molecular pathology tests. When a specimen is collected for a molecular pathology test during a hospital outpatient encounter, the date of service is the date of performance, even if the test is ordered within 14 days of discharge. The laboratory bills Medicare (not the hospital) in such cases.

ONCOTYPE AND ONCOEXTRA TEST SCENARIOS



These tables show how the Medicare date of service rules apply to specific scenarios for our 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 of the Precision Oncology portfolio of tests

HISTOPATHOLOGY SERVICES

| 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.

[†]The hospital status and other information used to calculate the Medicare date of service is based on the tissue specimen used in the processing of the OncoExTra test. The date of collection of the normal or germline specimen is not used in that calculation.

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 their tumor biopsied 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 DX® or OncoExTra™ 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 Oncotype DX® and OncoExTra™ 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

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