FOUNDATION MEDICINE®

14-Day Rule Billing Requirements for Foundation Medicine® Tests

The Medicare date of service rules (commonly known as the “14-day rule”) provide billing requirements for diagnostic tests ordered for Medicare patients. These rules determine whether the clinical laboratory performing the test will directly bill Medicare or bill the hospital where the specimen was collected.[1]

Effective on January 1, 2018, the Centers for Medicare & Medicaid Services (CMS) issued changes to the laboratory date of service rules. As a result, molecular pathology tests (including Foundation Medicine’s tests) performed on specimens collected from a hospital outpatient are now billed by the performing lab as long as the test is performed after the patient is discharged.

The tables below outline the scenarios under which the Medicare date of service rules will apply to Foundation Medicine tests.

MOLECULAR PATHOLOGY TESTS

Status at Specimen Collection	Medicare Billing*
Outpatient	Foundation Medicine Bills Medicare
Nonpatient	
Inpatient – ordered ≥ 14 days after date of discharge	
Inpatient – ordered < 14 days after date of discharge	Foundation Medicine Bills Hospital

IMMUNOHISTOCHEMISTRY (IHC) TESTING - PD-L1

Status at Specimen Collection	Medicare Billing*
Nonpatient	Foundation Medicine 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	Foundation Medicine 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 timing of a test order must be based on a clinical judgment and not on the Medicare billing rules. Foundation Medicine is not involved in determining the appropriate clinical timing for any patient.

Scenario 1

Patient has a routine appointment with a clinician whose practice is owned by the hospital and has been designated as "provider-based," and the patient is registered as a hospital outpatient. During the visit, a blood draw is performed and the clinician orders FoundationOne®Liquid CDx.

Foundation Medicine bills Medicare because the test is a molecular pathology test performed following a hospital outpatient discharge.

Scenario 2

Patient is registered as a hospital outpatient for a biopsy. The patient leaves on the same day. FoundationOne®CDx is ordered a few days later by the medical oncologist.

Foundation Medicine bills Medicare because the test is a molecular pathology test performed following a hospital outpatient discharge.

Scenario 3

A patient has a bone marrow biopsy at their hematologic oncologist's office. The patient is admitted to the hospital the next day for something related to the patient diagnosis, no specimen was collected, and discharged the following day. The oncologist orders testing and the specimen from days earlier is sent to Foundation Medicine for testing.

Foundation Medicine bills Medicare because the patient is considered a non-hospital patient at the time of specimen collection.

Scenario 4

Patient is admitted to the hospital as an inpatient and a biopsy is performed during the inpatient stay. The patient is discharged from the hospital after 5 days, and the next day, the oncologist orders Foundation Medicine testing on the sample collected a few days prior.

Foundation Medicine bills the hospital because the sample was collected during an inpatient visit and the test was ordered less than 14 days following the patient's discharge date.

Scenario 5

Patient is registered as a hospital outpatient for a biopsy. The patient leaves on the same day. FoundationOne®CDx and IHC testing are ordered a few days later by the medical oncologist.

Foundation Medicine bills Medicare for FoundationOne®CDx because the test is a molecular pathology test performed following a hospital outpatient discharge. Foundation Medicine bills the hospital for the technical component of the IHC test because the test was ordered less than 14 days following a hospital outpatient discharge.

Reference

[1] For the performing lab to bill Medicare for a molecular pathology test the following must be met: 1) It was medically appropriate to have collected the sample from the hospital outpatient during the encounter; 2) the results of the test do not guide treatment provided during the hospital outpatient encounter; and 3) the test was reasonable and medically necessary for the treatment of an illness.

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