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 table below outlines the scenarios under which the Medicare date of service rules will apply to Foundation Medicine 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

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 the patient is registered as an outpatient. During the visit, a blood draw is performed and the clinician orders FoundationOne®Liquid.

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

Scenario 2

Patient is registered at an outpatient surgery center 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 is admitted to the hospital with an acute blood disease or cancer (AML, MDS, MPN). Patient is discharged and follows up with his/her hematologic oncologist the next week, where an additional bone marrow biopsy or blood draw is performed. That specimen is sent to Foundation Medicine for testing.

Foundation Medicine bills Medicare because the patient is considered an outpatient at time of specimen collection and the molecular pathology test is performed after discharge.

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.

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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