



Laboratory Date of Service and Billing Rules for Molecular Pathology Tests

Site of Specimen Collection	Date Specimen Removed from Storage	Order Date	Date of Service	Medicare Billing
<u>Outpatient</u>	Any	Any	Performance date (As long as test performed after encounter discharge)	FMI bills Medicare
<u>Nonpatient</u> (Patient does not receive any other hospital services on that day)	Any	Any	Any	FMI bills Medicare
<u>Inpatient</u>	≤ 30 days from date of specimen collection	< 14 days after date of discharge	Specimen collection date	FMI bills Hospital (Test bundled into DRG and not billed separately)
		≥ 14 days after date of discharge	Performance date	FMI bills Medicare
	> 30 days from date of specimen collection	Any	Date specimen obtained from storage	FMI bills Medicare



Scenarios:

Scenario 1: Patient has a routine appointment with a clinician whose practice is owned by the hospital, and the patient is registered in the system as an outpatient. During the visit, a blood draw is performed and the clinician orders FACT.

FMI bills Medicare. Specimen collected from hospital outpatient. Date of service is date of test performance regardless of order date under new exception so long as the test is performed after the patient's discharge from the outpatient encounter.

Scenario 2: Patient is registered at an outpatient surgery center for a lung (or other) biopsy. Patient leaves same day. F1 is ordered a few days later by the medical oncologist.

FMI bills Medicare. Specimen collected from hospital outpatient. Date of service is date of test performance.

Scenario 3: Similar to Scenario 1, but the patient is sent across the street to the hospital to have the blood draw performed at the hospital lab, because the med onc does not have a phlebotomist in office. The patient is registered in the hospital system as an outpatient for the blood draw.

FMI bills Medicare. See Scenario 1. If patient registered as hospital outpatient, performance of blood draw at hospital does not affect date of service under new exception.

Scenario 4: A patient is admitted to the hospital with an acute blood disease or cancer (AML, MDS, MPN). They are discharged and follow up with their heme onc the next week, where an additional bone marrow biopsy or blood draw is performed. That specimen is sent to FMI for F1H testing.

FMI bills Medicare. Patient is a hospital outpatient at the time of specimen collection. Under the new exception the date of service is the date of test performance. It does not matter that the patient was previously a hospital inpatient because the specimen collection took place when they were an outpatient.

If the specimen had been collected during the inpatient stay, the "14 Day Rule" would apply.

Clarification on applicability of new date of service exception to F1CDx if it is designated an ADLT as an FDA cleared or approved test.

As a molecular pathology test, F1CDx should fall within the new exception to the date of service policy regardless of ADLT status. Following assignment of a PLA code for F1CDx, we will confirm with CMS that the new code is status indicator "A", and excluded from the outpatient packaging policy.