14 Day Rule Frequently Asked Questions

What is the “14 Day Rule”?

The “14 Day Rule” (Medicare Date of Service Regulation 42 C.F.R. §414.510) outlines whether or not a laboratory, such as Caris Life Sciences® (Caris), can bill Medicare for clinical laboratory services (i.e. Caris Molecular Intelligence®) based on when a Medicare patient was discharged, including outpatient discharge.

Why does Medicare enforce the 14 Day Rule?

If laboratory tests are ordered within 14 days of patient discharge, Medicare has determined that the date of service (see reverse side for calculation) overlaps with the claim submitted by the hospital or hospital-owned facility, and is therefore considered to be part of the diagnosis related group (DRG) payment for inpatients. Medicare considers any claim made by the laboratory to be a duplicate claim.

Who is affected by the 14 Day Rule?

Hospitals and hospital-owned facilities that collected the specimen submitted to an independent lab for testing.

How does the 14 Day Rule impact the facility?

Laboratories are required by Medicare to bill the hospital or hospital-owned facility for testing ordered within 14 days of patient discharge. Certain outpatient services can be submitted by the facility to Medicare for reimbursement.

What if Caris Molecular Intelligence testing is not ordered until 14 days after discharge?

The 14 Day Rule is triggered by the date the testing was ordered by the physician. Therefore, for any tumor profiling order placed within 14 days of discharge, regardless of when Caris starts testing, the hospital or hospital-owned facility will receive a bill.

What if the specimen is collected during the hospital stay or outpatient procedure, but I order Caris Molecular Intelligence more than 14 days after discharge?

Caris will bill Medicare, not the hospital or hospital-owned facility, for any tumor profiling order placed more than 14 days after the patient is discharged.

Will the hospital get a bill if Caris Molecular Intelligence testing is canceled?

The decision to cancel a test should be guided by the clinical judgement of the ordering physician and should not be based on the application of any billing rules. If an order is canceled prior to the start of testing, neither Medicare or the hospital/hospital-owned facility will receive a bill. The appropriate time for testing is patient specific and should be determined by the patient’s physician. Caris follows applicable billing guidelines for patients and payors.
14 Day Rule Calculation

The below information is based on the Centers for Medicare and Medicaid Services (CMS) regulation, “Laboratory date of service for clinical laboratory and pathology specimens” (42 C.F.R. §414.510). Please review the regulation for complete details.*

The “14 Day Rule” is a regulation set by CMS that requires laboratories, including Caris Life Sciences, to bill the hospital for clinical laboratory services and the technical component of pathology services provided to Medicare patients when services are ordered less than 14 days after the patient was discharged.

1. Was the specimen acquired at a hospital or hospital-owned facility?
   - NO

2. Is this a Medicare patient?
   - NO

3. Was the physician order made less than 14 days after discharge*?
   - NO

   Hospital will not receive a bill.

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   (Clinical Lab Services & TC)