

# Laboratory Date of Service billing rule

Impact on Medicare  
patients receiving Natera  
oncology testing



When providing services to Medicare beneficiaries, laboratories, including Natera, must adhere to billing regulations from the Centers for Medicare & Medicaid Services (CMS), including the “Date of Service” regulation (42 C.F.R. §414.510). The following clarifies how this regulation determines whom Natera bills for your Altera and Signatera orders for Medicare patients.

## Who is impacted by the Date of Service rule?

The Date of Service rule impacts who must bill for a test. The laboratory that performs the test or the healthcare facility (e.g., hospitals and certain hospital-owned facilities) where the test is ordered and the specimen is collected (e.g., tissue for Altera, blood for Signatera, blood for Empower). To see the comprehensive list of services subject to this policy, please refer to the code list on the CMS website (link: <https://go.cms.gov/3e9OeQu>).

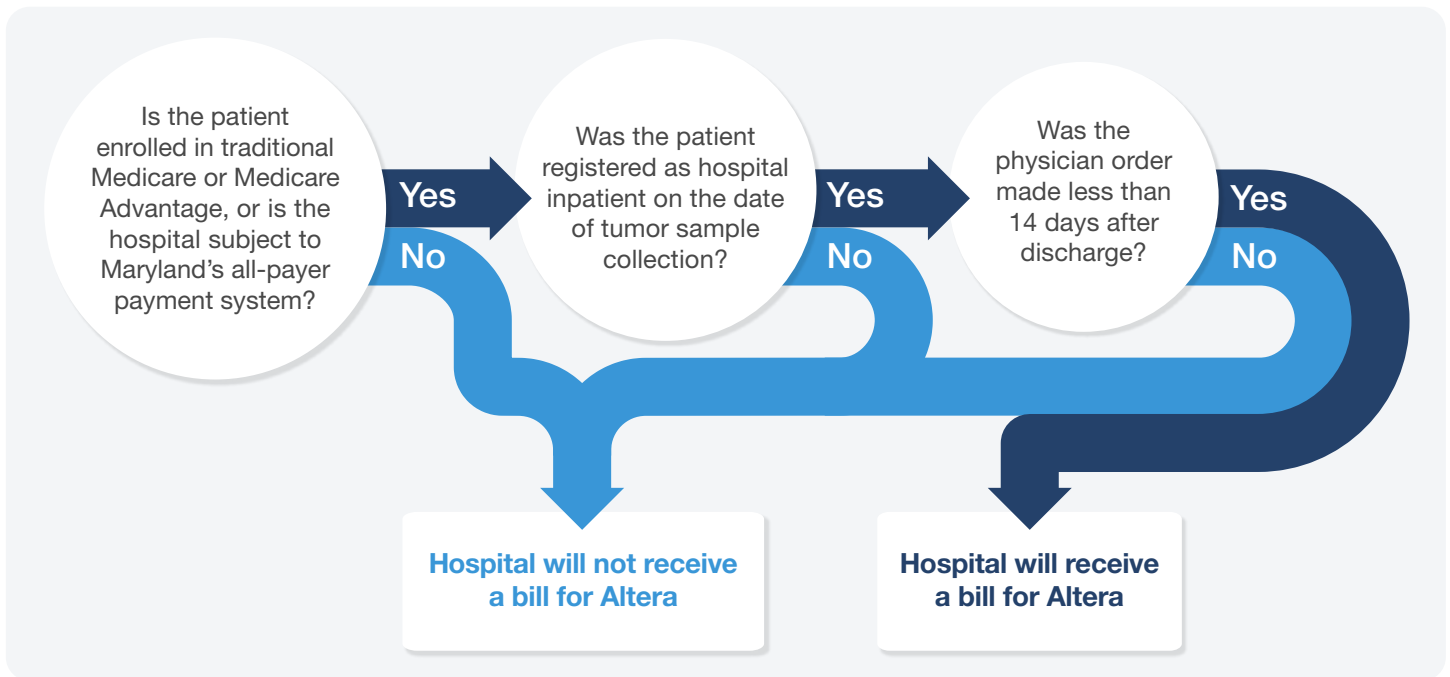
Effective January 1st, 2018, Medicare requires Natera to bill Medicare directly for certain tests on specimens collected during an outpatient encounter and performed following discharge from that encounter.

Does the Date of Service rule require Natera to bill the hospital for your order?

**Our flowcharts and examples will help you determine the billing rule that applies to each patient and order**

Next page

# Altera testing



## Medicare case examples

### Altera case 1

A biopsy sample is collected from the patient registered as a hospital outpatient. The oncologist orders Altera the next day.

**Natera bills Medicare. Reason: specimen was collected when the patient was a hospital outpatient, and test was performed following discharge.**

### Altera case 2

Outside of a hospital (or hospital-owned) setting, the patient undergoes a biopsy procedure. The next day, the patient is admitted to the hospital for care related to the patient's diagnosis. During the inpatient stay, specimens are not collected. The patient is discharged after a 1 day stay. After discharge, the oncologist orders Altera and sends the biopsy sample that was collected before inpatient admission.

**Natera bills Medicare. Reason: specimen was collected when the patient was a non-hospital patient.**

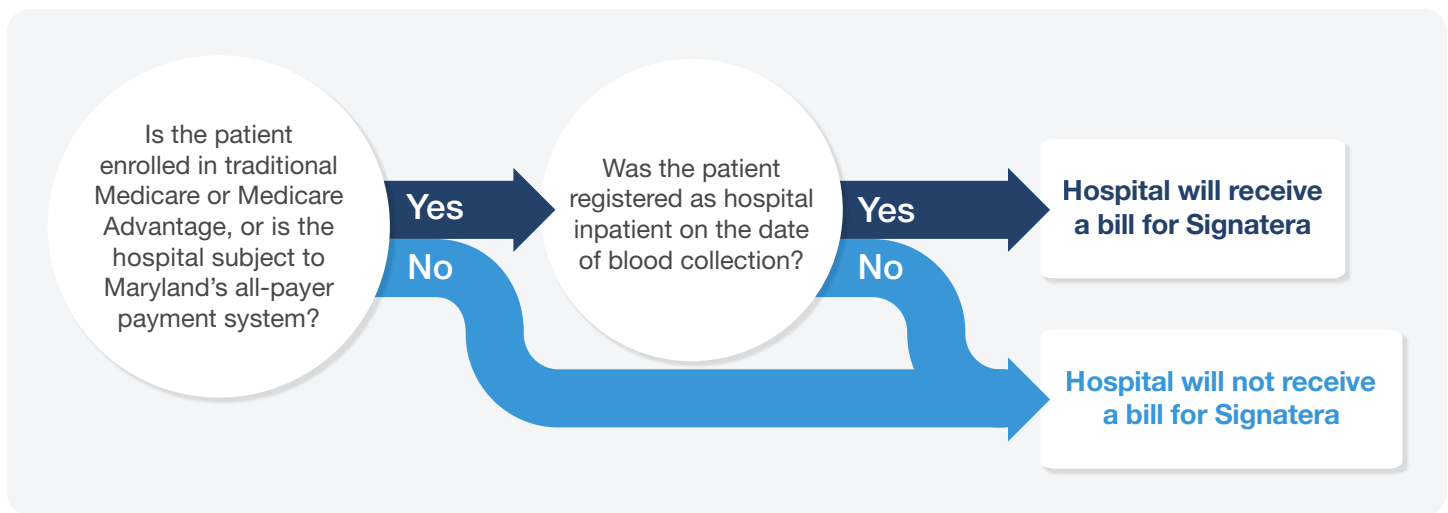
### Altera case 3

The hospital admits the patient as an inpatient. The patient receives a biopsy during the inpatient stay. The patient is discharged after 4 days. The day after discharge, the oncologist orders Altera testing based on the sample collected 5 days prior.

**Natera bills the hospital. Reason: Altera was ordered fewer than 14 days following the patient's discharge date, and the sample was collected during an inpatient stay.**



# Signatera testing



## Medicare case examples

### Signatera case 1

The hospital admits the patient as an inpatient. The patient undergoes a biopsy during the inpatient stay. The patient is discharged after 3 days. The day after discharge, the oncologist orders Signatera testing, and the patient's blood sample is collected after discharge.

**Natera bills Medicare. Reason: the blood sample was collected after patient discharge.**

### Signatera case 2

The patient undergoes a biopsy while registered as a hospital outpatient. The oncologist orders Signatera, which is performed following the patient's discharge from the outpatient encounter.

**Natera bills Medicare. Reason: the test was performed after the patient's discharge on a specimen collected during an outpatient encounter.**

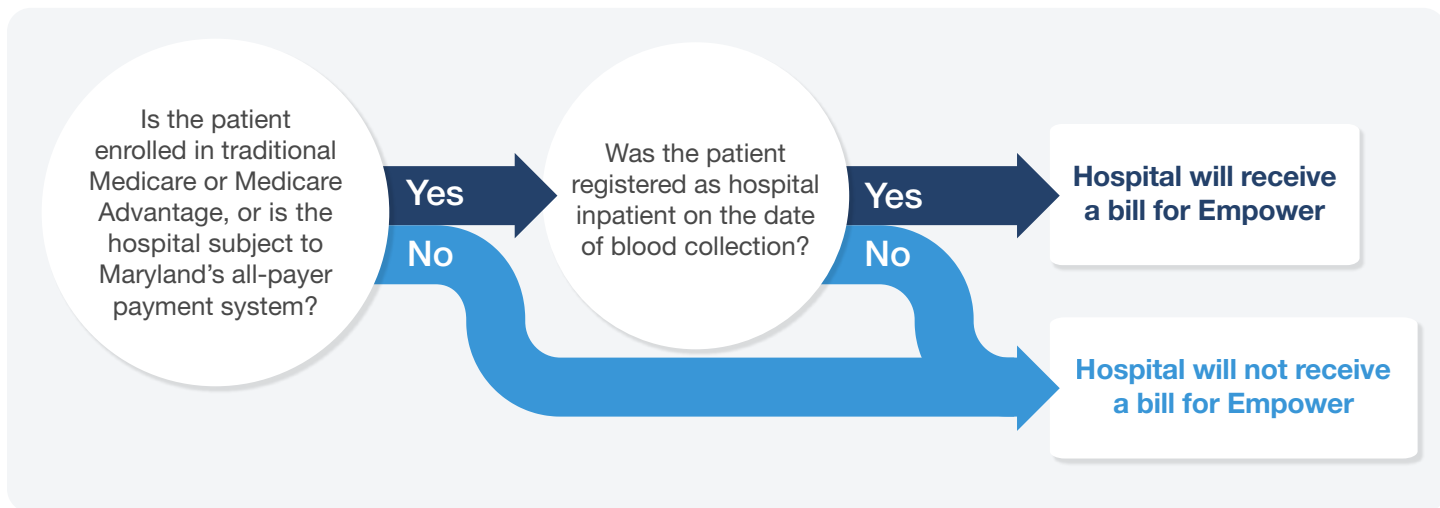
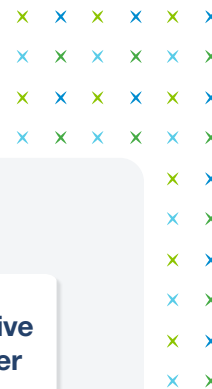
### Signatera case 3

The patient is admitted to the hospital and is registered as hospital inpatient to undergo curative intent surgery. The oncologist orders Signatera on the date of surgery and the patient is discharged. The patient is readmitted as a hospital inpatient due to complications related to the primary diagnosis. During the second hospital stay, the Signatera blood sample is collected in the hospital facility. The patient is discharged 2 days after the Signatera blood sample collection.

**Natera bills the hospital. Reason: the patient was registered as a hospital inpatient on the date of blood sample collection.**



# Empower testing



## Medicare case examples

### Empower case 1

The hospital admits the patient as a hospital inpatient. The patient is discharged after 2 days. The day after discharge, the oncologist orders Empower testing, and the patient's blood sample is collected after discharge.

**Natera bills Medicare. Reason: the blood sample was collected after patient discharge.**

### Empower case 2

The patient is admitted to the hospital and is registered as hospital inpatient. The oncologist orders Empower and the Empower blood sample is collected in the hospital facility. The patient is discharged 4 days after the Empower blood sample collection.

**Natera bills the hospital. Reason: the patient was registered as a hospital inpatient on the date of blood sample collection.**



## Questions about hospital billing? Contact us

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The test described has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). Although FDA is exercising enforcement discretion of premarket review and other regulations for laboratory-developed tests in the US, certification of the laboratory is required under CLIA to ensure the quality and validity of the tests. CAP accredited, ISO 13485 certified, and CLIA certified. © 2021 Natera, Inc. All Rights Reserved. [ONC\\_BR\\_Billing\\_20210728\\_NAT-8020545](#)

