2018

Centers for Medicare & Medicaid Services (CMS) Frequently Asked Questions

OUTPATIENT QUALITY REPORTING PROGRAM

ADMISSIONS AND EMERGENCY DEPARTMENT (ED) VISITS FOR PATIENTS RECEIVING OUTPATIENT CHEMOTHERAPY MEASURE

(OP-35)

(CHEMOTHERAPY MEASURE)

SEPTEMBER 2018

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Contents

List of Commonly used Acronyms and Abbreviations

CCN – CMS Certification Number

CY – Calendar Year

ED – Emergency Department

FFS – Fee-For-Service

FSR – Facility Specific Report

FY – Fiscal Year

OQR – Hospital Outpatient Quality Reporting

PCHQR – Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting

Measure Performance Period and Public Reporting

1. What is the performance period for the calendar year (CY) 2020 payment determination under the Outpatient Quality Reporting (OQR) program for the Chemotherapy measure?

Results for the chemotherapy measure for CY 2020 payment determination are calculated based on eligible outpatient chemotherapy treatments that were performed from January 1, 2018 through December 31, 2018.

2. When will CMS publicly report my facility's measure performance scores for OQR?

Public reporting for the chemotherapy measure will begin on or after January 1, 2020 for CY2020 payment determination (calculated using data from CY 2018).

CMS announced the addition of the chemotherapy measure in the OQR program beginning with CY 2020 payment determination in the CY 2017 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Final Rule [81 FR 79562 (Nov. 14, 2016)],(see CY 2017 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule [81 FR 79562 (November 14, 2016)]: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html).

3. Where will my facility's results be publicly reported?

This measure will be publicly reported on Hospital Compare (See https://www.medicare.gov/hospitalcompare/search.html) on or after January 2020.

4. Were any changes made to the chemotherapy measure in 2018?

CMS conducts annual measure reevaluations that often result in minor changes to the measure. Information about changes made to the chemotherapy measure in 2018 can be found in the 2018 Chemotherapy Measure Updates and Specifications Report available on *QualityNet* at: www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Measure Methodology. Changes made to the measure in 2018 will apply to the CY 2018 performance period. No changes were made to the measure in 2017 during the dry run year.

5. How does performance on this measure effect hospital reimbursement?

Facilities paid by Medicare under the Outpatient Prospective Payment System (OPPS) participate in the OQR Program by submitting data on measures of outpatient quality of care. Facilities that meet OQR Program requirements during a given calendar year receive a full OPPS payment update, also called the Outpatient Department (OPD) fee schedule (FS) increase factor, for the upcoming calendar year. The OPD FS increase factor is calculated using the hospital market basket update. Eligible hospitals that do not participate, or participate but fail to meet program requirements, receive a 2 percentage point reduction of their payment update for the applicable payment year. Thus, there is no penalty linked to performance on the measure but there is a penalty if the data are not properly reported.

Background

6. Why measure hospital visits following outpatient chemotherapy?

Chemotherapy treatment can have severe, predictable side effects, which, if inappropriately managed, can reduce patients' quality of life and increase healthcare utilization and costs. Improved management of these potentially preventable clinical conditions that are frequent side effects of chemotherapy treatment—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—could reduce admissions and ED visits and increase patients' quality of care and quality of life.

This measure aims to:

- Assess the care provided to cancer patients;
- Encourage quality improvement efforts to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in a hospital outpatient setting;
- Encourage hospitals to use guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies to integrate and promote use of evidence-based interventions to prevent and treat common side effects and complications of chemotherapy; and
- Increase transparency in the quality of care cancer patients receive and to provide information to help physicians and hospitals mitigate patients' need for acute care, which can be a burden on patients, and increase patients' quality of life.

7. Why measure admissions and ED visits for patients receiving their chemotherapy treatment at hospital outpatient departments (HOPDs)?

Cancer is an increasingly prevalent condition associated with considerable morbidity and mortality and therefore a priority area for outcome measurement. In 2015, there were more than 1.6 million new cases of cancer in the United States. About 22% of cancer patients receive chemotherapy each year with Medicare payments for cancer treatment totaling $34.4 billion in 2011, which is almost 10% of Medicare fee-for-service (FFS) dollars.[1] With an increasing number of cancer patients receiving chemotherapy in an HOPD, a growing body of peer-reviewed literature identifies unmet needs in the care provided to these patients. This gap in care may be due to reasons including: (1) the large burden and delayed onset of chemotherapy side effects that patients must manage at home, (2) patients' assumption that little can be done about their symptoms, which leads them to not seek outpatient medical assistance, allowing symptoms to worsen, and (3) limited access to providers in the outpatient setting who can manage care for these individuals. As a result, cancer patients who receive chemotherapy in an HOPD

[1] Guillory K, Sockdale H. Lifeline: why cancer patients depend on Medicare for critical coverage. Washington (DC): American Cancer Society Cancer Action Network; 2013 Jan 1. 19 p.

require more frequent acute care in the hospital setting and experience more adverse events than cancer patients who are not receiving chemotherapy.[2]

Inpatient admissions and ED visits among cancer patients receiving chemotherapy are often caused by predictable, and manageable, side effects from treatment. Recent studies of patients receiving chemotherapy in the outpatient setting show the most commonly cited symptoms and reasons for hospital visits are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression.[3] These hospital visits may be due to conditions related to the cancer itself or to side effects of chemotherapy. However, treatment plans and guidelines exist to support the management of these conditions. Appropriate outpatient care should curb potentially avoidable inpatient admissions and ED visits for these issues and improve cancer patients' quality of life. Publicly reporting potentially avoidable inpatient admissions and ED visits will encourage providers to improve their quality of care and lower rates of adverse events that lead to inpatient admissions or ED visits after outpatient chemotherapy (CY 2017 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule [81 FR 79562 (November 14, 2016)]: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html

8. What facilities are included in measure calculation?

Under the OQR program, the chemotherapy measure (OP-35) includes all non-federal acute care HOPDs that provided qualifying chemotherapy services during the performance period. Prospective Payment System (PPS)-exempt cancer hospitals are not included in calculations for OP-35, since they are included in separate calculations under the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) program.

9. What data sources and years are used for measure calculation?

CMS uses Medicare enrollment and claims data to identify:

- Chemotherapy treatments performed in the outpatient setting and subsequent hospital visits; and
- Patients' histories in the 12 months prior to any chemotherapy treatment during the measurement period

HOPDs do not need to submit any additional data for the measure because CMS uses paid FFS claims that are already routinely provided to the agency.

CMS uses the CMS Certification Number (CCN) to attribute patients to facilities. All necessary data elements (patient demographics, diagnoses, procedures, and dates) are included in standard claims files (inpatient, outpatient, and physician claims) for calculation of risk-adjusted performance rates.

The measure calculations for CY 2020 payment determination include patients receiving chemotherapy in any HOPD during a one-year period from January 1, 2018, through December 31, 2018.

---

[2] McKenzie H, Hayes L, White K, et al. Chemotherapy outpatients' unplanned presentations to hospital: a retrospective study. Support Care Cancer. 2011;19:963-969.

[3] Hassett MJ, O'Malley J, Pakes JR, Newhouse JP, Earle CC. Frequency and cost of chemotherapy-related serious adverse effects in a population sample of women with breast cancer. J Natl Cancer Inst. 2006;98(16):1108-1117.

10. Which quality reporting programs are implementing this measure?

CMS added the chemotherapy measure to the OQR and PCHQR programs and plans to calculate the measure separately for each program's facilities. For more information on the OQR program, see the calendar year (CY) 2017 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule [81 FR 79562 (Nov. 14, 2016)]). http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html

Facility-Specific Reports and Claims-Detail Reports

11. What information is included in my CDR and FSR?

Prior to publicly reporting the chemotherapy measure, CMS will provide two different types of confidential reports to Hospital Outpatient Departments (HOPDs):

- Claims-Detail Reports (CDRs); and
- Facility-Specific Reports (FSRs).

These reports are provided to facilities with the goal of supporting them in reviewing and understanding the measure's methodology and their specific results, and providing them with an opportunity to preview measure results and patient prior to public reporting.

For CY 2020 payment determination, CMS will distribute:

- Two CDRs; and
- One FSR.

The purpose and content included in each report is described below.

Claims-Detail Report

The CDRs provide facilities with information on their chemotherapy cases included in the measure calculation. Prior to the final measure calculation and public reporting of the measure in January 2020, CMS will provide facilities with:

- The first CDR in September 2018 with detailed information on outpatient chemotherapy treatments performed during the first 5 months of 2018 (January 1 – May 31, 2018).
- The second CDR in March 2019 with detailed information on outpatient chemotherapy treatments performed during the first 11 months of 2018 (January 1 - November 30, 2018).

The CDRs are Microsoft Excel files that contain patient-level information (for example, qualifying cases for the measure cohort, applied inclusion and exclusion criteria, and outcome information) for patients who underwent qualifying chemotherapy treatments at your facility. The CDRs contain no measure rate calculations.

An example mock CDR with simulated facility-specific data is available on *QualityNet* at www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Reports. The CDR is accompanied by a User Guide which includes an overview of the measure methodology and

instructions about how to interpret the measure and patient-level data in the CDR. The user guide is available on *QualityNet* at www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Claims-Detail Reports.

Facility-Specific Report

In Fall 2019, CMS will distribute FSRs to facilities subject to the measure with final calculations based on the full 2018 performance period (January 1 – December 31, 2018). Performance results in the FSR will be publicly reported in January 2020 and used for payment determination under the OQR program in CY 2020.

The FSR is a Microsoft Excel file that contains measure performance results and patient data for the chemotherapy measure. It includes your facility's results, along with the information on measure performance for other facilities in your state and the nation. The FSR also provides patient-level information for patients who underwent qualifying chemotherapy treatments at your facility, including information on hospital visits (ED visits and unplanned inpatient admissions) following an outpatient chemotherapy treatment. Finally, the FSR includes a table that summarizes your facility's case mix compared with all facilities in your state and the nation, and information on the effect of each risk factor in the statistical model.

Beginning with Fall 2019, an example mock FSR with simulated facility- and state-specific and actual national data will be available on QualityNet at www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Reports from Fall 2019. The FSR is accompanied by a User Guide, which includes an overview of the measure methodology, a summary of national results, and instructions about how to interpret the measure and each table in the FSR.

See Table 1 below for a summary of the differences between CDRs and FSRs.

Table 1. Comparison of data elements in chemotherapy FSRs and CDRs

Data element	CDR	FSR
Performance period	Each of the two CDRs will contain data from less than a full calendar year of claims (5 and 11 months)	Calendar year performance period used for measure calculation and public reporting (12 months)
Patient-level data (included and excluded chemotherapy cases)	Yes	Yes
State and National measure results	No	Yes
Facility-level distribution of measure risk factors	No	Yes
Facility-level measure rate and performance category	No	Yes

12. Why is CMS distributing CDRs throughout the year?

The intent of distributing two CDRs is to allow facilities to:

- Observe and correct coding errors in the claims used to calculate the measure;
- Increase transparency about the way patients are chosen for inclusion in the measure; and
- Provide facilities with an opportunity to improve the quality of care provided to patients receiving outpatient chemotherapy treatments prior to final measure calculation.

13. How can my facility access our reports?

Facilities will be able to access their FSRs and CDRs via the QualityNet Secure Portal. You should utilize your QualityNet Secure Portal user account with the two designated roles of "File Exchange & Search" (to receive the report) and "View QNet Content" (to download the report from the QualityNet Secure Portal).

14. Why didn't my facility receive a report?

If your facility did not receive a FSR or CDR, it could be due to any of the following reasons:

- Your facility was not open during the performance period for the current report;
- Your facility did not have any eligible patients for the measure during the report timeframe; and/or
- Your facility did not have a QualityNet Secure Portal user account with the roles described in Question 13;

If you do not have access to a FSR or CDR, you may access a mock report on QualityNet by visiting www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Reports. These mock reports contain real national information and simulated state and hospital data.

If you have questions about your QualityNet Secure Portal registration status, please contact the QualityNet Help Desk at qnetsupport@hcqis.org. If you would like to confirm whether a report is available or was sent to your facility, please submit a question using the QualityNet Question and Answer Tool: https://cms-ocsq.custhelp.com/. Please provide the name of your facility and the facility's CCN.

15. My facility is not yet registered for *QualityNet* Secure Portal. How do we register?

Your facility can register for a *QualityNet* account by visiting the *QualityNet* website (www.qualitynet.org) and selecting "Portal Resources." Under "Portal User Training and Guides," select the "Non-QualityNet account holders" link to the PDF which will contain further instructions.

To gain *Secure Portal* access after a *QualityNet* account is established, visit the *QualityNet* website (www.qualitynet.org), select "Portal Resources," and then, under "Portal User Training and Guides," select the "QualityNet account holders" link to the PDF which will contain further instructions.

After you register and have a *QualityNet Secure Portal* inbox with the designated roles (see Question 12), you must request an upload of your report using the *QualityNet* Question and Answer Tool: https://cms-ocsq.custhelp.com/. Please provide the name of your facility and the CCN assigned by CMS (for HOPDs) or your Vendor ID (for vendors).

Cohort Inclusion and Exclusion Criteria

16. What are the inclusion and exclusion criteria for the measure?

Inclusion Criteria

The chemotherapy measure includes Medicare Fee-for-Service (FFS) patients age 18 and older with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting.

Exclusion Criteria

The chemotherapy measure excludes:

- Patients with a diagnosis of leukemia at any time during the performance period.
- Patients who were not enrolled in 12 months of continuous in Medicare FFS Parts A and B prior to any chemotherapy treatment during performance period.
- Patient was not enrolled in Medicare FFS Parts A and B for the 30 days following any chemotherapy treatment during the performance period.
- Cases in which patients receive chemotherapy to treat a qualifying autoimmune condition, rather than to treat cancer. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

For additional information on inclusion and exclusion criteria for the measure, please visit www.qualitynet.org > Outpatient > Measures > Chemotherapy Measure Methodology.

17. Does the measure include patients receiving oral chemotherapy treatment?

No, the measure does not include patients receiving only oral chemotherapy. The decision to not include patients receiving only oral chemotherapy was made during development for several reasons, including attribution and timing. Attributing a prescription to a hospital-based outpatient setting is challenging. Not all claims for an individual provider are attributable to the hospital since patients are likely to receive care from multiple physicians, in multiple settings, and not all physicians are employed by the hospital. In addition, identifying the correct index date on which the patient started oral chemotherapy is not feasible using claims data. Claims data only includes information on the date the prescription was filled, without information on what day the patient started taking the medication. However, patients receiving oral chemotherapy in combination with infusion-based chemotherapy are included in the cohort.

18. Does the measure capture services subject to the CMS 3-day payment window policy?

Yes, the measure does account for the 3-day payment window policy. The policy states that outpatient services, including some non-diagnostic services such as chemotherapy, provided by a hospital or any Part B entity wholly owned or wholly operated by a hospital (such as an HOPD) in the three calendar days before a patient's inpatient admission are considered related to the admission. For outpatient chemotherapy treatments subject to the 3-day payment policy, the outpatient chemotherapy service should be bundled and billed with the inpatient claim.

As a result of the 3-day payment window, steps are taken to ensure the inclusion of all HOPD-based chemotherapies. Specifically, the measure first identifies all chemotherapy treatments during the performance period and then supplements this cohort by identifying chemotherapy treatments included on inpatient claims with a date of service prior to or equal to the date of admission on the inpatient claim. CMS will continue to assess this approach to identifying chemotherapy treatments subject to CMS 3-day payment window billing.

19. Why are only patients with leukemia excluded and not those with other hematologic cancers?

CMS specified the measure to be as inclusive as possible; therefore, CMS excluded only those patient groups for which hospital visits were not typically a quality signal or for which risk adjustment would not be adequate. CMS decided during development to limit the exclusion criteria to only those patients with leukemia based on feedback from earlier public comments suggesting that exclusion of all patients with a hematologic malignancy would be too broad. Analyses showed that patients with lymphoma and multiple myeloma have similar rates of admission and ED visits when compared with patients with other non-leukemia cancer types.

20. Why does the measure not exclude patients receiving palliative care?

CMS does not exclude patients receiving palliative care because published literature shows that all patients receiving outpatient chemotherapy, regardless of the reason for chemotherapy (palliative or curative), may experience a gap in care that leads to acute, potentially preventable hospitalizations. Improving quality of life by keeping patients out of the hospital is a priority of cancer care, especially at the end of life.

21. Can the same patient be included in the cohort of more than one facility?

If an eligible patient received chemotherapy at more than one facility during the performance year, the patient is included within the cohort of eligible patients for each facility. The measure attributes the outcome to the facility (or facilities) where the patient received chemotherapy treatment during the 30 days before the qualifying outcome event. The measure will attribute the outcome to both facilities if a patient received outpatient chemotherapy treatment from more than one facility in the 30 days before a qualifying outcome event.

For example:

> If a patient received an outpatient chemotherapy treatment at Facility A on January 1 and a second treatment at Facility B on January 10, and then experienced a qualifying admission on January 15, the measure would count this outcome for both Facility A and Facility B. This is because both hospitals provided outpatient chemotherapy treatment to the patient within the 30-day window.
>
> However, if a patient received an outpatient chemotherapy treatment from Facility A on January 1 and a second treatment from Facility B on March 1, and then experienced a qualifying outcome on March 3, the measure would attribute this outcome only to Facility B. This is because both only Facility B provided outpatient chemotherapy treatment to the patient within the 30-day window.

Defining Hospital Visits Outcome

22. How does the measure define a qualifying admission or ED visit following chemotherapy in an HOPD?

The measure calculates two separate but related rates, the first for inpatient admissions and the second for ED visits. A qualifying inpatient admission is considered to be any inpatient acute care admission within 30 days of any outpatient chemotherapy treatment during the performance period with either:

- A primary discharge diagnosis of one of the ten potentially preventable diagnoses (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis), or
- A primary discharge diagnosis of cancer and a secondary diagnosis of any one of the ten diagnoses listed as secondary on the same claim.

Only unplanned inpatient admissions qualify for the measure.

Similarly, for patients in the cohort who do not have a qualifying inpatient admission outcome, the measure defines a qualifying ED visit outcome as a standalone ED visit within 30 days of any outpatient chemotherapy treatment during the performance period with either:

- A primary discharge diagnosis of one of the ten potentially preventable diagnoses (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis), or
- A primary discharge diagnosis of cancer and a secondary diagnosis of any one of those ten diagnoses listed as secondary on the same claim.

These ten conditions are seen as potentially preventable through appropriately managed outpatient care.

23. Does the outcome include observation stays?

No, the outcome does not include observation stays. CMS did not include observation stays in the outcome for two reasons.

1. Patients admitted for observation stays, predominately, first seek care at an ED and are therefore captured within the ED outcome of the measure. Similarly, if a patient is first admitted into observation care and later gets admitted to the hospital, the patient is captured within the inpatient admission outcome.
2. Second, the measure is calculated separately for the PCHQR and Hospital OQR programs, and including observation stays as a third, separately reported rate may bias the outcome measure in favor of one type of billing practice over another due to differences among PCHs capabilities and billing practices. Several PCHs do not have emergency departments, requiring them to treat observation stays and inpatient admissions differently from other PCHs.

CMS recognizes that other CMS outcome measures are beginning to incorporate observation stays within the outcome of interest and will continue to reassess this decision in future measure reevaluation.

24. How does CMS define a 'planned' admission for this measure?

Planned admissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. The chemotherapy measure does not count "planned" hospital visits as an outcome because these are not a signal of quality of care.

For the chemotherapy measure, inpatient hospital admissions with the following Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) procedures or diagnoses are considered always planned and do not qualify for the measure outcome. These procedure and diagnosis categories are shown in the "Always Planned Procedure Definition" and "Always Planned Diagnosis Definition" tabs of the 2018 Chemotherapy Measure Data Dictionary.

<u>Procedure Diagnosis Categories</u>

- AHRQ CCS 64 – Bone marrow transplant
- AHRQ CCS 105 – Kidney transplant
- AHRQ CCS 176 – Other organ transplantation (other than bone marrow corneal or kidney)

<u>Diagnoses</u>

- AHRQ CCS 45 – Maintenance chemotherapy; radiotherapy
- AHRQ CCS 254 – Rehabilitation care; fitting of prostheses; and adjustment of devices

More information about AHRQ's CCS algorithm is available at http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp.

25. How does the measure account for same-day admissions or ED visits?

Qualifying admissions or ED visits occurring on the same day as the outpatient chemotherapy treatment, whether at the same facility or different facilities, are counted in the outcome. CMS assumes that patients who received chemotherapy treatment were subsequently admitted or seen in the ED for one of the ten qualifying conditions. It is unlikely that a patient admitted to the hospital or visited the ED for one of the ten conditions would then receive outpatient chemotherapy treatment on the same day.

26. If a patient is seen in the ED with a qualifying condition and then admitted to the hospital, does this count in the measure as an ED visit or an admission?

Outcomes are identified separately for the inpatient admissions and ED categories. A patient can only qualify for an outcome once. Patients who experience both a qualifying inpatient admission and a qualifying ED visit during the performance period are counted towards the inpatient admission outcome. Among those with no qualifying inpatient admissions, qualifying ED visits will be counted.

For example:

> If a patient is seen in the ED for a qualifying reason and is then admitted for a qualifying reason, the measures counts the patient as an inpatient admission outcome.
>
> Similarly, if the patient experiences a qualifying ED visit following the first treatment at a given facility and a qualifying inpatient admission following the second treatment, the patient qualifies only for the inpatient admission outcome since it is the most severe and costly outcome.

27. If a patient has more than one qualifying admission and/or ED visit within 30 days, does the measure count the outcome twice?

No, a patient can experience only one qualifying outcome event. The outcomes are defined as one or more qualifying inpatient admissions, or one or more qualifying ED visits for patients who do not have a qualifying inpatient admission.

28. My facility does not have an ED. How can the measure capture ED visits for patients receiving chemotherapy in my HOPD?

Patients receiving outpatient chemotherapy at your facility are not required to visit your ED in order to be captured in the outcome; chemotherapy patients at your facility who visit any ED for a qualifying diagnosis within 30 days of chemotherapy will be counted in the outcome. Using Medicare FFS claims CMS is able to review the patient experience across all facilities.

29. Why does the measure use a 30-day outcome timeframe?

The measure limits the outcome time frame to 30 days following each chemotherapy treatment (including the date of treatment) in an outpatient setting for the following four reasons:

- First, existing literature[4,5,6] suggests that the vast majority of adverse events occur within 30 days after treatment, indicating that a 30-day period is a reasonable time frame to observe the side effects of treatment;
- Second, we observed in our own data that the highest rates of hospital visits occur within 30 days after chemotherapy treatment;
- Third, restricting the time frame links patients' experiences more closely to the HOPDs that provided their recent chemotherapy while accounting for variations in duration between outpatient treatments; and
- Fourth, relating the time frame to a specific chemotherapy administration supports the idea that the admission stems from the management of side effects of treatment and ongoing care, rather than progression of the disease or other unrelated events.

30. Why does the measure focus on admissions and ED visits for only ten conditions?

This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in a HOPD setting.

The ten conditions that the measure captures—including **anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis**—are commonly cited reasons for hospital visits among cancer outpatients, and are potentially preventable through appropriately managed outpatient care and increased communication with the patient.

By focusing the measure on these potentially preventable hospital visits, the measure aims to:

- Provide more useful and actionable information to facilities, patients, and other stakeholders; and
- Improve hospital management of these potentially preventable symptoms, which could reduce admissions and ED visits and increase patients' quality of care and quality of life.

We acknowledge that not all of the identified outcomes for each patient may be preventable. The goal of this measure is not to avert all admissions and ED visits and achieve a rate of zero, but to focus on acute care visits that are potentially avoidable by characterizing relative performance across hospitals, identifying clear opportunities for improvement.

[4] McKenzie H, Hayes L, White K, et al. Chemotherapy outpatients' unplanned presentations to hospital: a retrospective study. Support Care Cancer. 2011;19:963-969

[5]Aprile G, Pisa FE, Follador A, et al. Unplanned presentations of cancer outpatients: a retrospective cohort study. Support Care Cancer. 2013;21(2):397-404.

[6] Foltran L, Aprile G, Pisa FE, et al. Risk of unplanned visits for colorectal cancer outpatients receiving chemotherapy: a case-crossover study. Support Care Cancer. 2014;22(9):2527-2533.

Measure Calculation and Risk Adjustment

31. Is the measure risk adjusted?

Yes, the measure adjusts for each of the two mutually exclusive outcomes using two separate risk adjustment models both of which include patient-level variables, including age, clinical comorbidities, and cancer diagnosis categories. We limited our selection of candidate variables for the risk-adjustment models to variables with a strong clinical rationale for inclusion as identified in the literature and through clinical expert input.

- The risk-adjustment model for inpatient admissions has 21 patient-level variables (age, sex, 2 exposure variables, 9 comorbidity variables, and 8 cancer diagnosis categories).
- The risk-adjustment model for ED visits has 16 patient-level variables (age, sex, 2 exposure variables, 6 comorbidity variables, and 6 cancer diagnosis categories). The ED visit model does not include the variables for renal disease, diabetes, metabolic disorder, lymphoma, or prostate cancer that the inpatient admission model includes because these variables were not predictive of risk for this outcome.

The list of risk factors is shown in Table 4 (Case Mix Comparison) of your FSR and the mock FSR posted on the chemotherapy measure page at: www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Facility-Specific Reports. The mock FSR contains actual national-level results and simulated hospital and state-level data. The Case Mix Comparison table shows the prevalence of each risk factor among your hospital's patients compared to state and national averages. The diagnosis codes for each risk factor for the measure are grouped into CMS Condition Categories (CCs). These correspond to thousands of ICD-10-CM codes. Crosswalks mapping ICD-10-CM codes to CCs are also posted on the surgery measure pages of QualityNet: www.qualitynet.org > Hospitals – Outpatient > Measures > Surgery Measure > Resources."

32. How does CMS account for differences in the patient characteristics of HOPDs and PCHs?

The measure uses risk-standardized rates of hospital visits to account for the fact that patient characteristics may vary by facility type. The risk-adjustment models account for patient-level factors that affect the probability of a having a hospital visit, and ensures fair treatment of all facilities that see different kinds of patients, regardless of whether they are a HOPD or PCH facility. Furthermore, since the measure calculation is separate for HOPDs and PCHs, the risk-adjustment models also have different coefficients for the identified risk factors. Therefore, while the same set of risk factors are applied in both programs, only information from the patients seen at HOPDs are used to determine the numerical value of the risk factor coefficients used for the OQR program.

33. Does the measure adjust for sociodemographic (SDS) factors?

The measure does not currently adjust for sociodemographic status (SDS) factors beyond those that are accounted for by age, gender and clinical variables. As part of measure development, the relationship between the measure outcomes and SDS factors were assessed in accordance with National Quality Forum (NQF) measure development guidelines. CMS used three variables that are available within or

link directly to Medicare administrative claims data for analysis: race, Medicaid dual-eligible status, and the Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) Index score.[7]

At the hospital-level, there was no clear relationship between median risk-standardized rates and hospitals' case mix by these three SDS factors, and the distributions of risk-standardized rates suggested that hospitals caring for a greater percentage of dual eligible, black, or low SES index patients have similar rates of inpatient admission and ED visits within 30 days of hospital-based outpatient chemotherapy. Based on these findings, CMS did not include these SDS factors in the final measure specifications. CMS understands the important role that SDS plays in the care of patients. However, CMS continues to have concerns about holding facilities to different standards for the outcomes of their patients of diverse SDS because CMS does not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. However, CMS will continue to assess the appropriateness of including SDS factors in risk adjustment.

34. How is the risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR) calculated?

The measure calculates and reports the two mutually exclusive outcome rates—RSAR and RSEDR—separately using the same methodology for each.

RSAR:

The RSAR is calculated as the ratio of the number of "predicted" qualifying inpatient admissions to the number of "expected" qualifying inpatient admissions multiplied by the national observed qualifying inpatient admission rate. CMS estimates the expected number of qualifying inpatient admission outcomes for each facility using the facility's patient mix and the average facility-specific intercept (that is, the average intercept among all facilities in the sample).

To calculate a facility RSAR, the measure uses a two-level hierarchical logistic regression model. CMS models the log-odds of the outcome following outpatient chemotherapy as a function of the patient demographic and clinical characteristics, and a random facility-specific intercept. This strategy accounts for within-facility correlation of the observed outcome and sample size differences, and it accommodates the assumption that underlying differences in quality across facilities lead to systematic differences in outcomes. For fairness, the model adjusts for demographic variables and clinical comorbidities that vary across patient populations, are unrelated to quality, and influence the outcome to help ensure that differences in the measure score do not reflect differences in case mix across facilities.

RSEDR:

Similarly, the RSEDR is calculated as the ratio of the number of "predicted" qualifying ED visits to the number of "expected" qualifying ED visits multiplied by the national observed qualifying ED visit rate. The measure follows this same methodology described above for the RSAR, using a separate

[7] Agency for Healthcare Research and Quality. Chapter 3: Creating and validating an index of socioeconomic status. In: Creation of New Race-Ethnicity Codes and SES Indicators for Medicare Beneficiaries. Rockville, MD: Agency for Healthcare Research and Quality; 2008 Jan. Rockville, MD. http://archive.ahrq.gov/research/findings/final-reports/medicareindicators/medicareindicators3.html.

two-level hierarchical logistical regression model specified for that outcome and adjusted for appropriate demographic variables and clinical comorbidities.

For each rate, this approach is analogous to a ratio of "observed" to "expected" outcomes used in other types of statistical analyses. It conceptually allows for a comparison of a particular facility's performance given its case mix to an average facility's performance with the same case mix. Thus, a predicted/expected ratio of less than one indicates a lower-than-expected visit rate (or better quality), and a ratio of greater than one indicates a higher-than-expected visit rate (or worse quality).

Figure 1. Equation for Risk-Standardized Hospital Visit Rate Calculation

$$\text{Rate} = \frac{\text{Predicted Outcomes}}{\text{Expected Outcomes}} \times \text{National Observed Rate}$$

The best source of information on the risk-adjustment model is the methodology technical report posted at www.qualitynet.org > Hospitals – Outpatient > Measures > Chemotherapy Measure > Measure Methodology.

Additional references on hierarchical generalized linear modeling, which is also used for CMS's inpatient outcome measures, can be found in the published literature section for related inpatient outcome measures on the QualityNet website (www.qualitynet.org > Hospitals - Inpatient > Claims-Based and Hybrid Measures).

35. Patients undergoing chemotherapy treatment at my HOPD had zero qualifying admissions but my hospital has a RSAR greater than 1. Why is this?

Your facility can have an observed (unadjusted) rate of zero but a non-zero RSAR (or RSEDR) because the RSAR (or RSEDR) is based on the ratio of the "predicted" number of outcomes to "expected" number of outcomes multiplied by the national observed outcome rate. The model adjusts for demographic variables, clinical comorbidities, and the number of outpatient chemotherapy administrations during the performance period (exposure) to account for differences among patients that may influence the outcome in ways that do not relate to the quality of outpatient chemotherapy care. This ratio will always be greater than zero, but a ratio of less than one indicates a better-than-expected hospital visit rate relative to an average facility with the same case mix, whereas a ratio of greater than one indicates a worse-than-expected hospital visit rate relative to an average facility with the same case mix. In addition, the occurrence of zero hospital visits is typically associated with relatively low case size. Estimated outcome rates for smaller facilities will likely be closer to the national observed outcome rate because the limited number of eligible patients receiving outpatient chemotherapy in the facility tells little about that facility's true outcome rate.

36. Will facilities be able to replicate the RSAR and RSEDR for the purpose of validation?

No, facilities will not be able to replicate the RSAR or RSEDR independently. The models require use of patient longitudinal data across care settings and data from the entire national sample for all eligible patients to estimate the facility-specific effects used in measure calculations. However, your facility can validate the patient cohort used to calculate your facility's RSAR and RSEDR rates using the discharge-level information contained in your FSR, available via the QualityNet Secure Portal.

To ensure transparency in calculating the RSAR and RSEDR rates, CMS posted the measure calculation methodology, including the condition category algorithm, on the QualityNet website (www.qualitynet.org). Facilities may also request a copy of the SAS program used to estimate the RSAR and RSEDR rates by emailing CMSChemotherapyMeasure@yale.edu. However, please note that CMS does not provide training, consultations, or technical assistance for using the program or obtaining the needed data.

37. How do I interpret the RSAR and RSEDR into an overall picture of my facility's performance?

The measure assesses two mutually exclusive outcomes for each patient in the cohort; the ED visit outcome is assessed only for patients who do not qualify for the inpatient admission outcome. In addition, a patient can only qualify for an outcome once. The measure calculates the two rates separately because the severity and cost of an inpatient admission differ from those of an ED visit, but both adverse events are important signals of quality and represent outcomes of care that are important to patients. As a result, the rates can be viewed as additive to provide a comprehensive performance estimate of patients' quality of care following outpatient chemotherapy treatment at the facility.

38. How does CMS categorize facility performance for the measure?

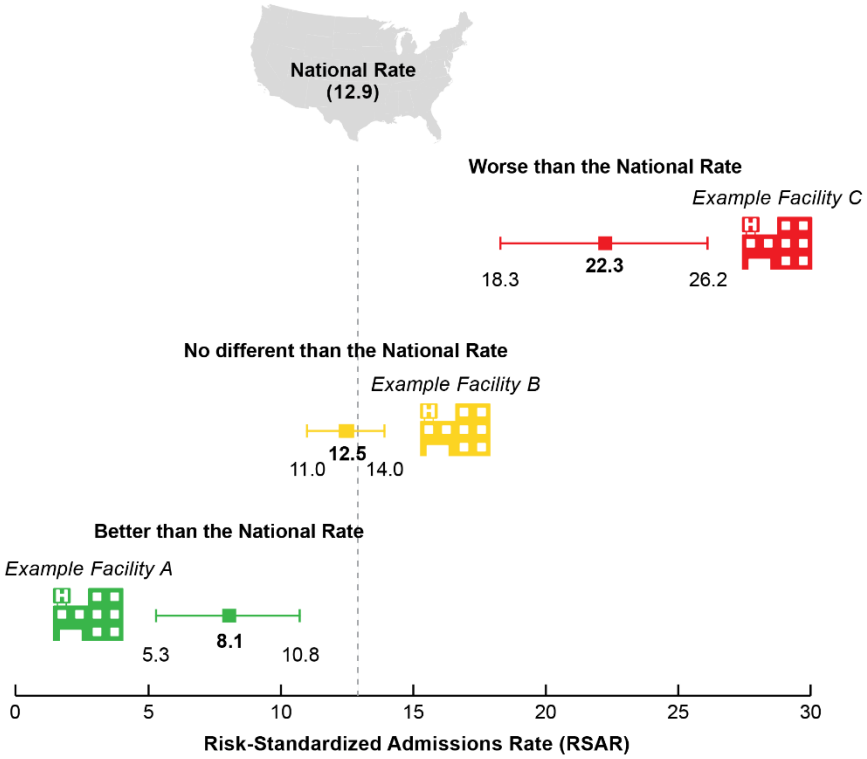
CMS categorizes each facility's performance separately for the RSAR and RSEDR by comparing each facility's 95% interval estimate with the national observed hospital visit rate. For the OQR program, all participating hospitals are compared with the observed rate among all non-PCHs. The interval estimate represents the range of probable values of the RSAR and RSEDR. A 95% interval estimate indicates that there is 95% probability that the true value of the RSAR and RSEDR lies between the lower limit and the upper limit of the interval.

CMS assigns the performance categories as follows:

- "Worse than national rate" if the entire 95% interval estimate of the facility's rate is higher than the national observed hospital visit rate.
- "No different from the national rate" if the 95% interval estimate of the facility's rate includes the national observed hospital visit rate.
- "Better than national rate" if the entire 95% interval estimate of the facility's rate is lower than the national observed hospital visit rate.

If an HOPD does not have the minimum number of eligible patients to qualify for the measure (N=25), CMS cannot reliably tell how well the facility is performing, and assigns the facility a separate category of "Number of cases too small."

Figure 2. Example Performance Category Assignment for the Chemotherapy Measure



39. What performance information will be provided to small-volume facilities?

CMS is providing a confidential FSR and the FSR User Guide to all open facilities that have at least one eligible patient with a qualifying chemotherapy treatment for the measure during the performance period. RSAR and RSEDR rates will be calculated for every facility with at least one eligible patient wtih a qualifying chemotherapy and included in the FSR. However, if a facility has fewer than 25 patients eligible for inclusion in the measure, its performance will be categorized as, "Number of cases too small." Small-volume facilities will receive comparative performance data (for example, state-level results) and patient information.

Using Measure Results for Quality Improvement

40. My facility is interested in conducting a quality improvement program to understand and reduce our hospital visits for patients receiving chemotherapy treatment in the outpatient setting. How can I best track my facility's performance on the chemotherapy outcome measure, including for time periods not reported in my FSR?

CMS's risk-standardized outcome rates are not designed for facilities' internal quality tracking purposes since they are measures of each facility's performance relative to the national rate during a given time period. However, your facility may choose to track its observed rates for quality improvement purposes. To obtain your facility's observed rate, you will need to calculate the proportion of patients receiving outpatient chemotherapy that experience an admission or ED visit for a qualifying diagnosis during your

time period of interest. You will also need to obtain data on inpatient admissions and ED visits to other facilities. Eligible patients should be selected based on the inclusion and exclusion criteria listed in the response to Question 16. Please note that your facility's observed rate may change over time due to changes in case mix as well as to changes in quality. However, if your facility's case mix is stable over time, your observed rate can be used to track internal improvement over time.

Although you can calculate your facility's observed rate for more recent timeframes than the data included in your FSR, it is difficult to predict how this may translate into a risk-standardized inpatient admission rate or risk-standardized ED visits rate, since the risk-standardized rates are measures for each facility's performance relative to the national rate.

However, facilities that provide outpatient chemotherapy should proactively implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy.

Accounting for Patient Behavior and Compliance

41. My facility provides post-treatment care planning and education, but we cannot ensure patients will follow recommended care plans when they go home. Why doesn't the chemotherapy outcome measure account for patient behavior or compliance?

Reducing adverse outcomes is the joint responsibility of HOPDs and other clinicians. Measuring hospital visits will create incentives to invest in interventions to improve outpatient chemotherapy care and improved symptom management. CMS recognizes that some patients who receive education may not follow post-chemotherapy care instructions. However, all facilities have the opportunity to reduce the rate of hospital and ED visits following chemotherapy, particularly for these ten potentially preventable diagnoses.

Contact

42. Who do I contact if I have more questions?

Facilities can submit questions about the chemotherapy measure to the Outpatient Question and Answer tool: https://cms-ocsq.custhelp.com/.