

EOM CLINICAL DATA ELEMENTS GUIDE

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Revision History

Revision #	Revision Date	Description of Change
1.0	June 1, 2023	Initial Version
1.1	July 20, 2023	<p>Section 4.2 Updated the section title from “EOM-PGP-ID” to “EOM-ID.”</p> <p>Section 4.3.4 Updated the section title and data element name from “Beneficiary Date of Birth” to “Date of Birth.”</p> <p>Section 4.3.5 Updated the section title from “Beneficiary Gender” to “Beneficiary Sex” and renamed the data element label name from “beneficiary_gender” to “sex_assigned_at_birth.”</p> <p>Section 4.8.3 Metastasis (M): updated the example noted within the data element description.</p> <p>Section 4.8.4 Result of Estrogen Receptor (ER) Test: removed response option, “Not Performed (Not Tested).”</p> <p>Section 4.8.5 Result of Progesterone Receptor (PR) Test: removed response option, “Not Performed (Not Tested).”</p> <p>Section 4.8.6 Result of HER2 Test: removed the response option, “Not Performed (Not Tested).”</p>
2.0	January 8, 2024	<p>Introduction: Updated content to align with EOM Payment Methodology verbiage and EOM guides.</p> <p>Section 1 EOM CDE Overview - Episodes and Performance Periods: Updated verbiage to include reporting of PP2 in Spring 2025 in current reporting cycle.</p> <p>Section 2.2 Identifying EOM-Attributed Beneficiaries: Updated name of section; updated location of new list of EOM initiating therapies.</p> <p>Section 3:Renamed Excel template to CDE Data Submission Template.</p> <p>Table 2: Updated Current or History of Metastatic Disease and added new CDE, History of Metastatic Cancer.</p> <p>Section 3.3 EOM Health Data Reporting (HDR) Application: Updated description of the EOM HDR Application.</p>

Revision #	Revision Date	Description of Change
		<p>Table 3: Updated content to reflect naming of CDEs to be consistent with naming in CDE Data Submission Template.</p> <p>Section 4.7.3 Recurrence or Relapse Clinical Status: Updated responses for both reporting options.</p> <p>Section 4.7.4 Current Clinical Status Trend: Added new responses for both reporting options; added SNOMED CT codes for FHIR API; Added information regarding clinical adjusters.</p> <p>Section 4.7.5 Current or History of Metastatic Disease (PP1 CDE Data Submission Template Only) and History of Metastatic Cancer (all Performance Periods): included new content to reflect reporting for PP1 and PP2; added information regarding clinical adjusters.</p> <p>Section 4.8.3 Metastasis (M): Added information regarding clinical adjusters.</p> <p>Section 4.8.4 Result of Estrogen Receptor (ER) Test: Updated to include guidance of qualitative and quantitative test codes and values for both reporting options.</p> <p>Added Subsection 4.8.4.1 Estrogen Receptor (ER) Test Specified.</p> <p>Added Subsection 4.8.4.2 Estrogen Receptor (ER) Test Quantity.</p> <p>Section 4.8.5 Result of Progesterone Receptor (PR) Test: Updated to include guidance of qualitative and quantitative test codes and values for both reporting options.</p> <p>Added Subsection 4.8.5.1 Progesterone Receptor (PR) Test Specified</p> <p>Added Subsection 4.8.5.2 Progesterone Receptor (PR) Test Quantity</p> <p>Section 4.8.6 Result of HER2 Test: Updated to include guidance of qualitative and quantitative test codes and values for both reporting options.</p> <p>Added Subsection 4.8.6.1 HER2 Test Specified</p> <p>Added Subsection 4.8.6.2 HER2 Test Quantity</p> <p>Section 4.8.7 Histology: Added guidance and referenced a list of histology descriptions and ICD-O-3 codes by cancer type for the CDE Data Submission Template reporting option.</p>

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Introduction

This document is designed to guide Enhancing Oncology Model (EOM) participants in the collection and reporting of clinical data for specific cancer types as part of the strategic goals of EOM.

EOM is a Center for Medicare & Medicaid Innovation (Innovation Center) alternative payment model designed to promote high quality, person-centered care, advance health equity, encourage better care coordination, improve access to care, reduce costs, and improve outcomes for Medicare fee-for-service (FFS) beneficiaries with cancer who receive cancer treatment. EOM builds on lessons from the Oncology Care Model (OCM) and shares certain features with OCM, including episode-based payments that financially incentivize physician group practices (PGPs) to improve care and lower costs. EOM participants are oncology PGPs that prescribe and administer chemotherapy for cancer, and the model is centered on 6-month episodes of care triggered by receipt of a qualifying initiating cancer therapy for an included cancer type. Seven cancer types are included in the model:

- Breast Cancer¹
- Chronic Leukemia
- Lung Cancer
- Lymphoma
- Multiple Myeloma
- Prostate Cancer¹
- Small Intestine/Colorectal Cancer

This document provides guidance on the details, terminologies, and definitions necessary for collection and reporting of EOM Clinical Data Elements (CDE) for the seven cancer types that the Centers for Medicare & Medicaid Services (CMS) requires to be reported by EOM participants to the Innovation Support Platform (ISP) EOM Health Data Reporting (HDR) application. In addition, this document highlights two reporting options generally in alignment with minimal Common Oncology Data Elements (mCODE) including, 1) a ‘low-tech’ reporting approach utilizing a standardized Excel template, referred to as the CDE Data Submission Template throughout this document, and 2) a ‘high-tech’ FHIR-based reporting approach leveraging the appropriate mCODE standards for PGPs planning to engage in mCODE as the data mappings will already be established.

The EOM FHIR-based data collection is a primary focus, and initial use case, of the US Core Data for Interoperability (USCDI) + Cancer initiative² in support of the White House Cancer Moonshot. The EOM FHIR-based CDE data collection is an early opportunity to support this important initiative and the White House call to action.

Note: All documents referenced within this guide are located on [EOM Connect](#).

¹ Low-risk breast cancer and low-intensity prostate cancer are not included in EOM. For the purposes of EOM, low-risk breast cancer is defined as breast cancer treated with only long-term oral endocrine chemotherapy; and low-intensity prostate cancer is defined as prostate cancer treated with either androgen deprivation and/or anti-androgen therapy without any other chemotherapy.

² <https://www.healthit.gov/topic/interoperability/uscdi-plus>

Section 1: EOM CDE Overview - Episodes and Performance Periods

EOM participants are required to report CDEs for EOM-attributed beneficiaries on a semi-annual basis, within 30 days of attribution data being made available in the EOM HDR application for each performance period.

The receipt of a qualifying initiating cancer therapy by an eligible beneficiary for an included cancer type will trigger the start of an episode, as long as the beneficiary receives a qualifying E&M service during the episode.

For the purposes of EOM, a qualifying E&M service means the evaluation and management of a new or established patient, furnished to an eligible beneficiary with an included cancer type and with a Current Procedural Terminology (CPT®) code in the ranges 99201-99205 or 99211-99215.

Episodes will last for 6 months. If a beneficiary continues to receive a qualifying initiating cancer therapy after completing the 6-month episode, a new episode of care will begin. If the beneficiary entered hospice or died during the 6-month episode, the episode will still continue for the full 6 months, and it will include hospice costs or claims for care that occurred around the time of death but were not processed until after the beneficiary’s death.

EOM participants will be required to report clinical data on beneficiaries attributed to their PGP for each performance period. EOM participants will be required to report data during Performance Period 1 in Fall 2024 and for Performance Period 2 in Spring 2025. Specific due dates will be communicated to EOM participants in a timely manner. Each performance period consists of the episode initiation date and end date as shown in Table 1.

Table 1: Performance Periods and Episodes

Performance Period	Episode Initiation Dates	Episode End Dates
1	7/1/2023 - 12/31/2023	12/31/2023 - 6/29/2024
2	1/1/2024 - 6/30/2024	6/30/2024 - 12/29/2024
3	7/1/2024 - 12/31/2024	12/31/2024 - 6/29/2025
4	1/1/2025 - 6/30/2025	6/30/2025 - 12/29/2025
5	7/1/2025 - 12/31/2025	12/31/2025 - 6/29/2026
6	1/1/2026 - 6/30/2026	6/30/2026 - 12/29/2026
7	7/1/2026 - 12/31/2026	12/31/2026 - 6/29/2027
8	1/1/2027 - 6/30/2027	6/30/2027 - 12/29/2027
9	7/1/2027 - 12/31/2027	12/31/2027 - 6/29/2028

Section 2: CDE Reporting Requirements

EOM participants are required to report complete clinical data for at least 90% of their attributed beneficiaries in the performance period. That is, **at least 90%** of attributed beneficiaries must have complete and valid clinical data reported by EOM participants to qualify for the clinical adjusters for episodes involving certain cancer types.

Note: For additional information and criteria regarding clinical adjusters for episodes involving certain cancer types, refer to Section 4.1.3, “Clinical Adjusters”, in the EOM Payment Methodology document on the [EOM website](#).

2.1 EOM Participant Reporting Criteria

- The EOM participant to which the episode was attributed is the same as the EOM participant reporting the clinical data for that episode.
- The cancer type assigned to the episode is the same as the cancer type associated with the diagnosis code reported to the EOM HDR application.
- The reported records are “complete,” i.e., all clinical data elements required for the cancer type were reported to the EOM HDR application or via a FHIR-based API.
- The relevant data was reported to the EOM HDR application by the deadline specified for the performance period.
- In accordance with Article VIII of the EOM Participation Agreement, EOM participants are required to report beneficiary-level clinical data elements on a semi-annual basis to CMS on at least a minimum of 90% of attributed episodes in a given performance period for seven cancer types included in the model.

The criteria used to identify potential EOM-attributed beneficiaries can be found in **Section 2.2**. EOM participants are required to report clinical data for the attributed cancer type at the EOM-attributed beneficiary level into the EOM HDR application for each performance period in which the beneficiary is attributed.

2.2 Identifying EOM-Attributed Beneficiaries

EOM participants are required to report clinical data elements for EOM-attributed beneficiaries on a semi-annual basis, within 30 days of attribution data being made available in the EOM HDR Application for each performance period. Since attribution is retrospective, CMS identification of which beneficiaries require clinical data reporting will occur after episodes have completed. It is recommended that participants collect clinical data during the course of care delivery to be prepared for reporting later. The criteria below can help practices identify potential EOM-attributed beneficiaries prior to attribution.

1. Identify patients that have a qualifying cancer diagnosis code.
 - a. A list of qualifying ICD-10-CM diagnosis codes utilized within EOM for episode identification is located in the “[EOM Technical Payment Resources](#)” document on the “Cancer Type Mapping” tab.
 - b. Of the patients identified with a qualifying cancer diagnosis code, identify those that have a qualifying initiating cancer therapy code.
 - i. A list of qualifying initial cancer therapies and codes can be found in the “EOM Initiating

Therapies List” document (available on the [EOM website](#)) associated with the relevant performance period in the HCPCS Codes or NDC Codes tabs.

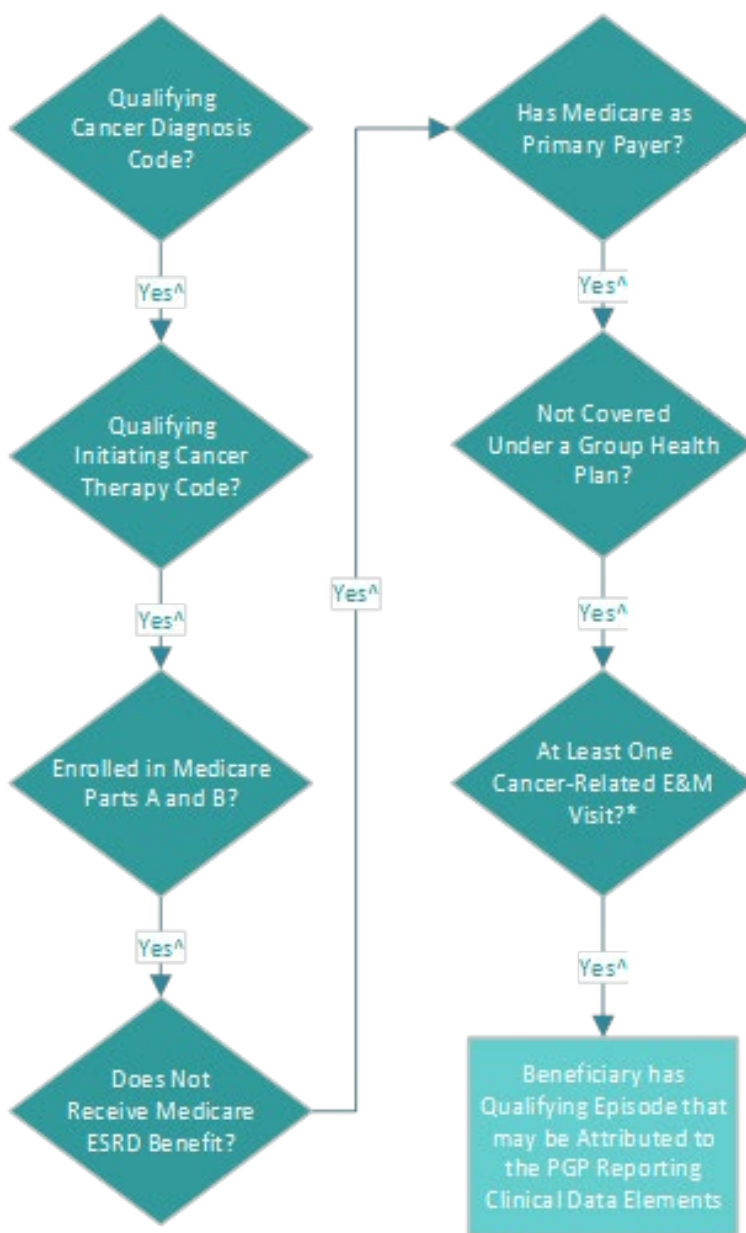
Note: Receipt of this qualifying initiating cancer therapy code triggers the beginning of an episode. Once an episode has begun, it will last for 6 calendar months.

2. Of the patients identified above with a qualifying cancer diagnosis code, a beneficiary must meet the following requirements for all six months of the episode (or in the event the beneficiary dies during the episode, until the beneficiary’s death) for that episode to be eligible for inclusion in EOM:
 - a. Beneficiary is enrolled in Medicare Parts A and B, AND
 - b. Beneficiary does not receive the Medicare End Stage Renal Disease (ESRD) benefit,³ AND
 - c. Beneficiary has Medicare as his or her primary payer, AND
 - d. Beneficiary is not covered under Medicare Advantage or any other group health program, AND
 - e. Beneficiary received an initiating cancer treatment for cancer AND
 - f. Beneficiary has at least one qualifying E&M visit during the 6 months of the episode.
 - i. A qualifying E&M visit is defined as having a HCPCS code in the ranges 99201-99205 or 99211-99215, a cancer diagnosis included in the “[EOM Technical Payment Resources](#)” document on the “Cancer Type Mapping” tab available on the [EOM website](#), and billed by a TIN with at least one oncology provider during the performance period.
 - ii. Oncology providers are those with a specialty code of Hematology/Oncology or Medical Oncology as described in **Section 1.1.** in the [EOM Payment Methodology](#) document.

Note: When determining attribution, each episode is attributed to the TIN that provided the first qualifying E&M service during the episode if this TIN also provided at least 25% of the total qualifying E&M services for the episode. If the TIN that provided the first qualifying E&M service did not render at least 25% of the total qualifying E&M services, then the attribution is based on E&M plurality and the episode is attributed to the TIN providing the largest proportion of qualifying E&M services during the performance period. Participants are only required to report on beneficiaries attributed to their TIN.

³ ESRD status is determined using information in the Medicare Enrollment Database.

Figure 1: Identification of Potential EOM-Attributed Beneficiaries



* Each episode is attributed to the TIN that provided the first qualifying E&M service in the episode if this TIN also provided at least 25% of the total qualifying E&M services for the episode. If the TIN that provided the first qualifying E&M service did not render at least 25% of the total qualifying E&M services, then the attribution is based on E&M plurality and the episode is attributed to the TIN providing the largest proportion of qualifying E&M services during the performance period. Participants are only required to report on beneficiaries attributed to their TIN. ^ If any of these criteria is answered "No," the patient does not qualify as a potential EOM-attributed beneficiary.

Section 3: Data Collection and Reporting Options

This section illustrates the data collection and reporting options for each of the CDEs to be reported by EOM participants for their attributed beneficiaries each performance period. Provided within each subsection is a description of the data element applicable for the attributed cancer type, as well as the values accepted for reporting data, and how the CDEs and the data element values that can be reported via the EOM HDR application map to the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)® minimal Common Oncology Data Elements (mCODE) standard, and ultimately the USCDI + Cancer Implementation Guide (IG). All clinical data elements applicable to the ICD-10 diagnosis for the cancer type are required to be reported.

3.1 Pre-populated Data Elements Available in the CDE Data Submission Template

EOM participants will have access to a template within the EOM HDR application which will be pre-populated with key information for each attributed beneficiary for the performance period. This template can be used for participants using the “low-tech” option to complete reporting for attributed beneficiaries or as a reference for those using the “high-tech” FHIR API option. The data elements which will be pre-populated for each EOM participant and EOM-attributed beneficiary include the following:

- Model ID
- EOM-ID
- MBI
- Beneficiary First Name
- Beneficiary Last Name
- Date of Birth
- Beneficiary Sex
- Attributed Cancer Type
- Episode Start Date
- Episode End Date

Note: Beneficiary Date of Birth and Sex Assigned at Birth are pre-populated in the CDE Data Submission Template based on Medicare enrollment data and are provided for reference to help EOM participants match attributed beneficiaries to the clinical record when reporting CDEs. Participants must still gather sociodemographic data directly from beneficiaries and report the accurate data as identified by the beneficiary as part of the submission of the Sociodemographic Data Elements (SDE). These data are collected via a separate SDE Data Submission Template or via a FHIR-based API leveraging the US Core IG Patient Resource. If the Beneficiary Date of Birth or Sex Assigned at Birth pre-populated in the CDE Data Submission Template are not accurate, (e.g., inaccurate information was in claims data), it is not necessary to change or update this in the CDE Data Submission Template, but please be sure accurate information is included when reporting the SDE data for that beneficiary. The EOM Sociodemographic Data Collection Guide (SDE) is located on the [EOM website](#).

IMPORTANT: Do not include non-attributed beneficiaries in the CDE Data Submission Template for reporting to the HDR application as the file will be rejected.⁴

3.2 Clinical Data Elements

The following high-level clinical data elements* are required to be reported (as applicable for the attributed cancer type) by the participant for each attributed beneficiary. Note, the subsequent sections provide additional details regarding how reporting occurs for these data elements using the CDE Data Submission Template or the HL7 FHIR API and mCODE/USCDI + Cancer IG.

Table 2: Clinical Data Elements

Data Element Concepts	Data Element Names	Applicable Cancer Types	Reporting Options
Attributed Cancer Diagnosis	ICD-10-CM Diagnosis Code	All Cancer Types	CDE Data Submission Template or HL7 FHIR API
	Initial Date of Diagnosis	All Cancer Types	CDE Data Submission Template or HL7 FHIR API
Current Clinical Status	Patient Deceased	All Cancer Types	CDE Data Submission Template or HL7 FHIR API
	Date Patient Died	All Cancer Types	CDE Data Submission Template or HL7 FHIR API
	Recurrence or Relapse Clinical Status	All Cancer Types	CDE Data Submission Template or HL7 FHIR API
	Current Clinical Status Trend	All Cancer Types	CDE Data Submission Template or HL7 FHIR API
	Current or History of Metastatic Disease	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE Data Submission Template ^{**} (PP1 only)
	History of Metastatic Cancer	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE Data Submission Template beginning with PP2 or HL7 FHIR API beginning with PP1 ^{**}
	Current Clinical Status Date	All Cancer Types	CDE Data Submission Template or HL7 FHIR API

⁴ A CDE “Sample” Template will be made available that does not include any prefilled data. This will further support you as you prepare for your data submission. If you choose to submit data via HDR, be sure to submit the official CDE Data Submission Template you download from HDR with the prefilled data as this official copy has all the necessary metadata to ensure successful validation and submission. The CDE Sample Template is for reference only.

Data Element Concepts	Data Element Names	Applicable Cancer Types	Reporting Options
TNM Staging	Primary Tumor (T)	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE Data Submission Template or HL7 FHIR API
	Nodal Disease (N)	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE Data Submission Template or HL7 FHIR API
	Metastasis (M)	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE Data Submission Template or HL7 FHIR API
Tumor Markers	Result of Estrogen Receptor (ER) Test Estrogen Receptor (ER) Test Specified Estrogen Receptor (ER) Test Quantity	Breast Cancer	CDE Data Submission Template or HL7 FHIR API
	Result of Progesterone Receptor (PR) Test Progesterone Receptor (PR) Test Specified Progesterone Receptor (PR) Test Quantity	Breast Cancer	CDE Data Submission Template or HL7 FHIR API
	Result of HER2 Test HER2 Test Specified HER2 Test Quantity	Breast Cancer	CDE Data Submission Template or HL7 FHIR API
Histology	Histology	All Cancer Types	CDE Data Submission Template or HL7 FHIR API

*List shown of current data elements; CMS reserves the right to modify data elements throughout the duration of the model. This list represents the minimum data elements that CMS may collect. CMS continues to explore ways to further align with other reporting standards (e.g., mCODE; USCDI).

****IMPORTANT NOTE:** EOM participants utilizing the FHIR-based API reporting option are able to report “History of Metastatic Cancer” beginning with PP1 as this data element was recently added to the mCODE IG. EOM participants using the CDE Data Submission Template will report “Current or History of Metastatic Disease” for PP1. Beginning with PP2, the CDE Data Submission Template will replace the “Current or History of Metastatic Disease” with “History of Metastatic Cancer” to align data elements across reporting methods.

3.3 EOM Health Data Reporting (HDR) Application

EOM participants will use a centralized reporting platform, the Innovation Support Platform (ISP). The EOM HDR application, part of the ISP, is a web-based data submission and collection tool that EOM participants will use to submit data, including practice-level quality measures, beneficiary-specific clinical data elements, and beneficiary-specific SDEs. A separate user manual for the EOM HDR application will be available on the Resource page of the IC Portal and EOM Connect for EOM participants in the future.

EOM participants are required to report all clinical data elements applicable to the ICD-10 diagnosis for the attributed cancer type associated with EOM-attributed beneficiaries via the HDR application or a FHIR-based API.

Two reporting options are available for EOM participants to utilize for reporting data to the EOM:

- **Option 1 - CDE Data Submission Template via EOM HDR Application:** This reporting option allows EOM participants to leverage (through the HDR Application) a standardized Excel template pre-populated with the list of attributed beneficiaries for reporting cancer-specific clinical data elements. The template is designed for EOM participants who may not have the ability to send CDE data conformant with the mCODE/USCDI + Cancer IG via a FHIR-based API. The Excel template will be available via download from the HDR application.
- **Option 2 - HL7 Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (API):** This reporting option allows for the reporting of CDEs directly from the EOM participants Electronic Health Record (EHR) system via a FHIR-based API. Reporting via this method will leverage HL7 FHIR mCODE standard and HL7 United States Core Data for Interoperability (USCDI) and specifically the HL7 FHIR US Core and USCDI + Cancer Implementation Guides (IGs).

Table 3 displays how the data element names in the CDE Data Submission Template are related to the corresponding data element names utilized in mCODE/USCDI + Cancer. This is important as the data submitted via the CDE Data Submission Template will be stored in a FHIR server together with the data collected via HL7 FHIR-based API reporting to ensure that there is one unified analytic data set for all mCODE-aligned EOM CDEs. Additional information regarding the terminologies, definitions, and reporting details of the EOM CDEs to be reported by EOM participants to the HDR application is provided in [Section 4](#) of this guide. Additional information to support FHIR-based data submission is forthcoming.

Table 3: EOM CDE Names by Reporting Option

CDE Data Submission Template Data Element Name	HL7 FHIR-Based API Data Element Name (mCODE)
ICD-10 Diagnosis Code	Primary (Initial) Cancer Condition Code
Initial Date of Diagnosis	Primary (Initial) Cancer Condition Extension: Asserted Date
Patient Deceased	Patient Deceased [Boolean]
Date Patient Died	Patient Deceased [Date Time]
Recurrence or Relapse Clinical Status	Condition Clinical Status
	Condition Verification Status

CDE Data Submission Template Data Element Name	HL7 FHIR-Based API Data Element Name (mCODE)
Current Clinical Status Trend	Current Clinical Status Trend Observation Value [Codeable Concept]
	Current Clinical Status Trend Observation Status
Current or History of Metastatic Disease*	Data Element for CDE Data Submission Template only – not used for FHIR-based reporting*
History of Metastatic Cancer	History of Metastatic Cancer Observation Value [Boolean]
	History of Metastatic Cancer Observation Status
	History of Metastatic Cancer Observation Code
Current Clinical Status Date	Current Clinical Status Observation Effective [Date Time]
Primary Tumor (T)	Primary Tumor Staging Observation Status
	Primary Tumor Staging Observation Code
	Primary Tumor Staging Observation Value [Codeable Concept]
	Primary Tumor Staging Observation Method
Nodal Disease (N)	Nodal Disease Observation Status
	Nodal Disease Observation Code
	Nodal Disease Observation Value [Codeable Concept]
	Nodal Disease Observation Method
Metastasis (M)	Distant Metastases Observation Status
	Distant Metastases Observation Code
	Distant Metastases Observation Value [Codeable Concept]
	Distant Metastases Observation Method
Result of Estrogen Receptor (ER) Test**	Tumor Marker - Estrogen Receptor Observation Value [Codeable Concept]
Estrogen Receptor (ER) Test Specified	Tumor Marker - Estrogen Receptor Observation Status
	Tumor Marker - Estrogen Receptor Observation Code
	Tumor Marker - Estrogen Receptor Observation Data Absent Reason
Estrogen Receptor (ER) Test Quantity	Tumor Marker – Estrogen Receptor Observation Value [Quantity]
Result of Progesterone Receptor (PR) Test**	Tumor Marker - Progesterone Receptor Observation Value [Codeable Concept]
Progesterone Receptor (PR) Test Specified	Tumor Marker - Progesterone Receptor Observation Status
	Tumor Marker - Progesterone Receptor Observation Code
	Tumor Marker - Progesterone Receptor Observation Data Absent Reason
Progesterone Receptor (PR) Test Quantity	Tumor Marker - Progesterone Receptor Observation Value [Quantity]

CDE Data Submission Template Data Element Name	HL7 FHIR-Based API Data Element Name (mCODE)
Result of HER2 Test**	Tumor Marker - HER2 Observation Value [Codeable Concept]
HER2 Test Specified	Tumor Marker - HER2 Observation Status
	Tumor Marker - HER2 Observation Code
	Tumor Marker - HER2 Observation Data Absent Reason
HER2 Test Quantity	Tumor Marker - HER2 Observation Value [Quantity]
Histology	Condition Extension: Histology Morphology Behavior

***IMPORTANT NOTE** EOM participants utilizing the FHIR-based API reporting option are able to report “History of Metastatic Cancer” beginning with PP1 as this data element was recently added to the mCODE IG. EOM participants using the CDE Data Submission Template will report “Current or History of Metastatic Disease” for PP1. Beginning with PP2, the CDE Data Submission Template will replace the “Current or History of Metastatic Disease” with “History of Metastatic Cancer” to align data elements across reporting methods.

****Note:** Either qualitative or quantitative values are acceptable for reporting the Result of Estrogen Receptor (ER) Test (see Section 4.8.4), Result of Progesterone Receptor (PR) Test (see Section 4.8.5), and results of specific HER2 tests (see Section 4.8.6). Quantitative results are optional to report for PP1.

Section 4: CDE Terms and Definitions

This section describes the terminologies and definitions for the CDEs to be reported by EOM participants for their attributed beneficiaries each performance period. Each subsection provides a description of the data collected, the values accepted for reporting data, and how the CDEs and the data element values that can be reported via the HDR application map to the HL7 FHIR mCODE standard. All clinical data elements applicable to the ICD-10 diagnosis for the cancer type are required to be reported via the HDR application or a FHIR-based API.

4.1 Model ID

The Model ID refers to the Enhancing Oncology Model developed by CMS. The Model ID will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): model_id
- Pre-populated: EOM

4.2 EOM-ID

The EOM-ID (EOM-PGP-ID) Physician Group Practice (PGP) identification number is a unique number assigned by CMS for each EOM participant and will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): entity_id

- Pre-populated: EOM-ID (format = EOM-PGP-XXX)

4.3 EOM Beneficiary-Level Demographic Data

This subsection lists the EOM-attributed beneficiary-level demographic data that will be pre-populated in the CDE Data Submission Template for EOM participants each performance period based on claims data as determined by CMS.

4.3.1 Medicare Beneficiary Identifier (MBI)

This data element reflects the attributed beneficiary's current Medicare Beneficiary Identifier (MBI) number. The MBI for the EOM-attributed beneficiary will be pre-populated in the CDE Data Submission Template for the EOM participant.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): mbi
- Pre-populated: Medicare Beneficiary Identifiers must be 11 characters. The 1st, 4th, 7th, 10th, and 11th characters will always be numbers. The 2nd, 5th, 8th, and 9th characters will always be upper-case letters, except for S, L, O, I, B, and Z. The 3rd and 6th characters will be letters or numbers.

In the FHIR-based API (mCODE), this data element maps to the following:

- FHIR Data Elements:
 - i. Patient.identifier.system (URI - <http://hl7.org/fhir/sid/us-mbi>)
 - ii. Patient.identifier.value
- mCODE Profile: Cancer Patient

4.3.2 Beneficiary First Name

The first name of the EOM-attributed beneficiary will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): first_name
- Pre-populated: First Name

In the FHIR-based API (mCODE), this data element maps to the following:

- FHIR Data Element: Patient.name.given
- mCODE Profile: Cancer Patient

4.3.3 Beneficiary Last Name

The last name of the EOM-attributed beneficiary will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): last_name
- Pre-populated: Last Name

In the FHIR-based API (mCODE), this data element maps to the following:

- FHIR Data Element: Patient.name.family
- mCODE Profile: Cancer Patient

4.3.4 Date of Birth

The EOM-attributed beneficiary date of birth will be pre-populated in the CDE Data Submission Template for EOM participants based on Medicare claims data. If the beneficiary date of birth pre-populated in the CDE Data Submission Template is not accurate, (e.g., inaccurate information was in claims data), it is not necessary to change or update this in the CDE Data Submission Template, but please be sure accurate information is included when reporting the SDE data for that beneficiary.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): date_of_birth
- Pre-populated: YYYY-MM-DD

In the FHIR-based API (mCODE), this data element maps to the following:

- FHIR Data Element: Patient.birthDate
- mCODE Profile: Cancer Patient

4.3.5 Beneficiary Sex

The EOM-attributed beneficiary sex assigned at birth will be pre-populated in the CDE Data Submission Template for EOM participants based on Medicare claims data. If the beneficiary sex assigned at birth pre-populated in the CDE Data Submission Template is not accurate (e.g., inaccurate information was in claims data), it is not necessary to change or update this in the CDE Data Submission Template, but please be sure accurate information is included when reporting the SDE data for that beneficiary.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): sex_assigned_at_birth
- Pre-populated: Beneficiary Sex

In the FHIR-based API (mCODE), this data element maps to the following:

- FHIR Data Element: patient.extension:birthsex
- mCODE Profile: Cancer Patient

4.4 EOM Attribution Data

This subsection describes the data applicable for the cancer type assigned by CMS based on claims data pertaining to the EOM-attributed beneficiary.

4.4.1 Attributed Cancer Type

The attributed cancer type is assigned by CMS based on claims data for beneficiaries who had at least one E&M code with an included cancer diagnosis and received an initiating cancer therapy billed by the EOM participant during a given episode. Refer to [Section 2.2](#) for additional details on identifying potential attributed beneficiaries and also within the EOM Payment Methodology document. Seven cancer types are included in the model and can be an attributed cancer type: Breast Cancer; Chronic Leukemia; Lung Cancer; Lymphoma; Multiple Myeloma; Prostate Cancer; and Small Intestine/Colorectal Cancer. The attributed cancer type will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): `attributed_cancer_type`
- Pre-populated: Attributed Cancer Type for the beneficiary

4.4.2 Episode Start Date

The episode start date refers to the receipt of a qualifying initiating cancer therapy identified by the date of service listed on the claim with a cancer diagnosis that triggers the beginning of an episode. Each episode must include a qualifying E&M service. Once an episode has begun, it will last for six calendar months. The episode start date will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): `episode_start_date`
- Pre-populated: Episode Start Date (Numeric YYYY-MM-DD)

4.4.3 Episode End Date

The episode end date refers to the six months after the date on which an episode initiated. The Episode End Date will be pre-populated in the CDE Data Submission Template for EOM participants.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): `episode_end_date`
- Pre-populated: Episode End Date (Numeric YYYY-MM-DD)

4.5 ICD-10 Diagnosis Code

The ICD-10 diagnosis code is the attributed cancer type diagnosis for the attributed beneficiary. The ICD-10 diagnosis code is required to be reported for all attributed beneficiaries.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
ICD-10_diagnosis_code
 - i. The ICD-10 diagnosis code and description is available in the CDE Data Submission Template allowing users to select the valid primary cancer diagnosis.

In the FHIR-based API (mCODE), this data element maps to Condition.code in the mCODE Primary Cancer Condition Profile. Of note, while this data element maps to the Primary Cancer Condition, for EOM, the data must reflect the attributed cancer type.

- FHIR-based API (mCODE):
 - i. Code System: ICD-10 Diagnosis Code or SNOMED CT
 - The diagnosis code is based on ICD-10 codes if no appropriate SNOMED CT code is available for the seven cancer types included in EOM.
 - ii. FHIR Data Element: Condition.code
 - iii. mCODE Profile: Primary Cancer Condition

4.6 Initial Date of Diagnosis

The initial date of diagnosis data element is the date of diagnosis for the attributed cancer type. The date format must be numeric YYYY-MM-DD. The initial date of diagnosis is to be reported for all attributed beneficiaries.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): initial_date_diagnosis
- Format: Numeric YYYY-MM-DD

In the FHIR-based API (mCODE), this data element maps to Condition.extension:assertedDate in the mCODE Primary Cancer Condition Profile:

- FHIR-based API (mCODE):
 - i. Format: Numeric YYYY-MM-DD
 - ii. FHIR Data Element: Condition.extension:assertedDate
 - iii. mCODE Profile: Primary Cancer Condition

4.7 Current Clinical Status Data

The clinical status describes the patient's disease status or condition assessed by the clinician that summarizes all currently available information about the patient during the episode. **That is, the data reported for the current clinical status data elements should be reflective of the beneficiary's status within the episode date range for the attributed beneficiary. The current clinical status date must be within the beneficiary's episode date range.** The data collected for clinical status includes several elements involving the patient's disease status or condition comprised of the following: deceased status and date of death if applicable; recurrence or relapse clinical status; current clinical status trend; current or history of

metastatic disease; and the most recent date corresponding to the clinical status response during the episode.

4.7.1 Patient Deceased

The patient deceased data element is required to be reported for all attributed beneficiaries.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): patient_deceased
- Response: True or False

In the FHIR-based API (mCODE), this data element maps to patient.deceased[boolean] in the mCODE Cancer Patient Profile.

- FHIR-based API (mCODE):
 - i. Value: True or False
 - ii. FHIR Data Element: patient.deceased[boolean]
 - iii. mCODE Profile: Cancer Patient

4.7.2 Date Patient Died

If the 'Patient Deceased' response is reported as "True," the date the patient died is required to be reported.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): patient_deceased_date
- Format: Numeric YYYY-MM-DD (if applicable)

In the FHIR-based API (mCODE), this data element maps to patient.deceased[dateTime] in the mCODE Cancer Patient Profile.

- FHIR-based API (mCODE):
 - i. Format: YYYY-MM-DD
 - ii. FHIR Data Element: patient.deceased[dateTime]
 - iii. mCODE Profile: Cancer Patient

4.7.3 Recurrence or Relapse Clinical Status

Recurrence is the return of a solid tumor cancer after a clinically disease-free interval (even after a previous relapse); this includes local or regional recurrence. The term relapse is used to describe the return of a leukemia, lymphoma, or other hematopoietic malignancy that was not previously clinically apparent or symptomatic. This data element is related to the attributed cancer type and episode dates and is required to be reported for all attributed beneficiaries. The most complete final clinical status as noted in their medical record system should be reported by the EOM participant.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): recurrence_relapse_clinical_status
- Response:
 - i. Yes (Active Recurrence or Active Relapse)
 - ii. No (Inactive Recurrence or Inactive Recurrence)

In the FHIR-based API (mCODE), this data element maps to condition.clinicalStatus in the mCODE Primary Cancer Condition Profile. Each condition.clinicalStatus must have a corresponding condition.verificationStatus. For the purposes of EOM reporting, the corresponding condition.verificationStatus must be equal to “confirmed.”

- FHIR-based API (mCODE):
 - i. Response:
 - active (Yes)
 - recurrence (Yes)
 - relapse (Yes)
 - inactive (No)
 - remission (No)
 - resolved (No)
 - unknown (value not known)
- FHIR Data Element: condition.clinicalStatus with the condition.verificationStatus = “confirmed”
- mCODE Profile: Primary Cancer Condition

4.7.4 Current Clinical Status Trend

The Current Clinical Status Trend data element describes the patient’s current cancer condition during an episode. This data element is related to the attributed cancer type and episode dates and is required to be reported for all attributed beneficiaries. The most complete Current Clinical Status Trend data element response is required to be populated in the CDE Data Submission Template by EOM participants.

The CDE Data Submission Template has a drop-down field allowing users to select any of the following options for the Current Clinical Status Trend value.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): current_clinical_status_trend
- Response:
 - i. Patient’s condition improved
 - Cancer in a patient that is decreasing in extent or severity in response to current treatment
 - ii. Patient's condition stable
 - Cancer in a patient that is neither decreasing nor increasing in extent or severity
 - iii. Patient’s condition worsened

- Cancer in a patient that continues to grow or spread since initial diagnosis. This option should not be selected solely based on the patient having metastatic disease at diagnosis.
- iv. Patient's condition undetermined
 - Cancer in a patient that is pending clinician evaluation and/or assessment
- v. In full remission.
 - No evidence of cancer in a patient who is being or has been treated for cancer (including a previous recurrence/relapse); or there is no morphological evidence of leukemia.
- vi. In partial remission
 - Cancer in a patient that partly responded to treatment though still present.
- vii. Distant metastasis present
 - Cancer in a patient that has migrated and spread to one or more organs or lymph nodes distant from the primary tumor site.

Note: Reporting of attributed beneficiaries with 'Distant metastasis present' will be considered in the clinical adjusters for episodes involving certain cancer types. For additional information and criteria regarding clinical adjusters for episodes involving certain cancer types, refer to Section 4.1.3, "Clinical Adjusters", in the EOM Payment Methodology document on the [EOM website](#).

In the FHIR-based API (mCODE), this data element maps to `observation.value[CodeableConcept]` in the mCODE Cancer Disease Status Profile. Each `observation.value[CodeableConcept]` must have a corresponding `observation.status`. For the purposes of EOM reporting, the corresponding `observation.status` must be equal to "final."

- FHIR-based API (mCODE):
 - i. Response: SNOMED code (for the following trends)*
 - 268910001 Patient's condition improved (finding)
 - 359746009 Patient's condition stable (finding)
 - 271299001 Patient's condition worsened (finding)
 - 709137006 Patient's condition undetermined (finding)
 - 103338009 In full remission (qualifier value)
 - 103337004 In partial remission (qualifier value)
 - 399409002 Distant metastasis present (finding)

*The expansion set with the disorder codes are not included above; use of the base set of codes listed for the purposes of EOM CDE requirements is encouraged.

- ii. FHIR Data Element: `observation.value[CodeableConcept]` with `observation.status = final`
- iii. mCODE Profile: Cancer Disease Status

4.7.5 Current or History of Metastatic Disease (PP1 CDE Data Submission Template Only) and History of Metastatic Cancer (all Performance Periods)

Metastatic disease occurs when there is evidence of cancer in a different site other than the primary tumor site that was not present at initial diagnosis. Reporting of metastatic disease for EOM is accomplished in different ways for Performance Period 1 and is updated in Performance Period 2.

Reporting of the "Current or History of Metastatic Disease" (for PP1 via the CDE Data Submission Template) or reporting of "History of Metastatic Cancer" (using the CDE Data Submission Template beginning with PP2 or FHIR-based API beginning with PP1) is not required for cancer types of lymphoma, multiple myeloma and chronic leukemia. Reporting is required for breast, lung, small intestine/colorectal and prostate cancer types.

To qualify for the EOM Clinical Adjusters (see Section 4.1.3 of the [EOM Payment Methodology](#)), participants may report Current or History of Metastatic Disease (using the CDE Data Submission Template for PP1 only), or History of Metastatic Cancer (all performance periods for those reporting via the FHIR API or beginning with PP2 for those using the CDE Data Submission Template), or report the Metastasis (M) value not equal to M0 or MX for beneficiaries who were metastatic at diagnosis, or may report the Current Clinical Status Trend of "Distant Metastasis Present".

Performance Period 1 (Applicable to CDE Data Submission Template only)

For PP1, the Current or History of Metastatic Disease data element is collected in the CDE Data Submission Template. This data element indicates if the patient currently has metastatic disease or if the patient ever had metastatic disease. For PP2, this data element is replaced in the CDE Data Submission Template with the data element, "History of Metastatic Cancer".

In the CDE Data Submission Template for PP1, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): current_or_hx_mets_disease
- Response:
 - i. Yes - Current or History of Metastatic Disease.
 - ii. No – No Evidence of Current or History of Metastatic Disease

Performance Period 2 (CDE Data Submission Template)

In the CDE Data Submission Template for PP2 and forward, this CDE has been updated to 'History of Metastatic Cancer' in alignment with the mCODE standard.

In the CDE Data Submission Template for PP2, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B): history_mets_cancer
- Response:
 - i. Yes - History of Metastatic Cancer
 - ii. No – No History of Metastatic Cancer

Performance Period 1 FHIR-based API (mCODE)

The FHIR-based API (mCODE) will accept History of Metastatic Cancer in alignment with mCODE beginning with PP1. This data element maps to observation.value[boolean] in the mCODE History of Metastatic Cancer Profile. Each observation.value[boolean] must have a corresponding observation.code and observation.status. For the purposes of EOM reporting, the corresponding observation.status must be equal to “final.”

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE observation.value[boolean]
 - To represent the History of Metastatic Cancer as **Yes**, the value of the observation will be True indicating positive, yes history of metastatic cancer.
 - To represent the History of Metastatic Cancer as **No**, the value of the observation will be False indicating negative, no history of metastatic cancer.
 - ii. FHIR Data Element: mCODE observation.code (History of Metastatic Neoplasm Value Set – required if observation.value[boolean] is True)
 - 1288652008 - History of metastatic cancer
 - 88701000119109 - History of disseminated malignant neoplasm.
 - 1098931000119102 - History of cancer metastatic to lymph nodes (situation)
 - 1098941000119106 - History of cancer metastatic to skin (situation)
 - 1098951000119108 - History of cancer metastatic to liver (situation)
 - 1098961000119105 - History of cancer metastatic to lung
 - 1098971000119104 - History of cancer metastatic to brain (situation)
 - 1099291000119102 - History of cancer metastatic to bone
 - iii. FHIR Data Element: mCODE observation.status = **final** for all cases
 - iv. mCODE Profile: History of Metastatic Cancer

IMPORTANT NOTE: EOM participants utilizing the FHIR-based API reporting option are able to report “History of Metastatic Cancer” beginning with PP1 as this data element was recently added to the mCODE IG. EOM participants using the CDE Data Submission Template will report “Current or History of Metastatic Disease” for PP1. Beginning with PP2, the CDE Data Submission Template will replace the data element, “Current or History of Metastatic Disease” with “History of Metastatic Cancer” to align data elements across both reporting methods.

4.7.6 Current Clinical Status Date

The current clinical status date is when the patient’s health status changed as determined by the provider during the episode. That is, **the Current Clinical Status Date is associated with the reported response in Current Clinical Status Trend data element AND must be within the attributed beneficiary episode dates.** The date format must be numeric YYYY-MM-DD. The Current Clinical Status Date is required to be reported for all attributed beneficiaries.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): current_clinical_status_date

- Format: Numeric YYYY-MM-DD

In the FHIR-based API (mCODE), this CDE is mapped to observation.effective[dateTime] in the mCODE Cancer Disease Status Profile.

- FHIR-based API (mCODE):
 - i. Format: Numeric YYYY-MM-DD
 - ii. FHIR Data Element: mCODE observation.effective[dateTime]
 - iii. mCODE Profile: Cancer Disease Status

4.8 Cancer Specific Data

EOM participants are required to collect cancer specific data for the attributed beneficiary. This includes the classification of TNM Stage (if applicable), breast cancer hormone receptor results, and histology for all cancer types at the time of initial diagnosis. The following subsections review these cancer specific data elements to be reported by the EOM participant.

4.8.1 Primary Tumor (T)

The Primary Tumor (T) describes the primary tumor at initial diagnosis and is based on AJCC staging guidelines. The Primary Tumor (T) data element is required to be reported by EOM participants for several attributed cancer types and diagnosis codes. If the Primary Tumor (T) is not applicable for an attributed cancer type, the EOM participant can select “Not Applicable” in the CDE Data Submission Template. The Primary Tumor (T) value may be represented by a prefix of clinical ‘c’ or pathologic ‘p’ for example, cT1 or pT1. In the CDE Data Submission Template, EOM participants will be able to select the Primary Tumor (T) value from the drop-down list of choices. This data element is related to the attributed cancer type and episode dates, and it is required to be reported for attributed beneficiaries. The most complete final status of the Primary Tumor (T) stage as noted in the medical record system should be reported by the EOM participant.

Note: Additional information on AJCC cancer staging can be found on the website: www.cancerstaging.org

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): primary_tumor_(T)
- Format: clinical prefix of ‘c’ or pathological prefix of ‘p’ of Primary Tumor (T) value

In the FHIR-based API (mCODE), this CDE is mapped to observation.status, observation.code, observation.value[CodeableConcept] and observation.method in the mCODE TNM Primary Tumor Category Profile. Of note, the term ‘prefix’ correlates with the term, ‘observation’ in mCODE.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE observation.status = **final**
 - ii. FHIR Data Element: mCODE observation.code
 - 78873005 T category
 - 399504009 cT category
 - 384625004 pT category

- iii. FHIR Data Element: mCODE observation.value[CodeableConcept]
 - o SNOMED-CT equivalents of the AJCC codes for the T category according to AJCC TNM staging rules as defined in the TNM Primary Tumor Category Value Set
- iv. FHIR Data Element: mCODE observation.method
 - o Codes representing the different editions of AJCC TNM staging systems as defined in the TNM Staging Method Value Set
- v. mCODE Profile: TNM Primary Tumor Category

4.8.2 Nodal Disease (N)

The Nodal Disease (N) describes the regional lymph node involvement at initial diagnosis and is based on AJCC staging guidelines. The Nodal Disease (N) data element is required to be reported by EOM participants for several cancer types and diagnosis codes. If Nodal Disease (N) staging is not applicable for a cancer type, the EOM participant can select “Not Applicable” in the CDE Data Submission Template. The Nodal Disease (N) value may be represented by a prefix of clinical ‘c’ or pathologic ‘p,’ for example, cN0 or pN1. In the CDE Data Submission Template, EOM participants will be able to select the Nodal Disease (N) value from the drop-down list of choices. This data element is related to the attributed cancer type and episode dates, and it is required to be reported for attributed beneficiaries. The most complete final status of the Nodal Disease (N) stage as noted in their medical record system should be reported by the EOM participant.

Note: Additional information on AJCC cancer staging can be found on the website: www.cancerstaging.org

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): nodal_disease_(N)
- Format: clinical prefix of ‘c’ or pathological prefix of ‘p’ of Nodal Disease (N) value

In the FHIR-based API (mCODE), this CDE is mapped to observation.status, observation.code, observation.value[CodeableConcept] and observation.method in the mCODE TNM Regional Nodes Category Profile. Of note, the term ‘prefix’ correlates with the term, ‘observation’ in mCODE.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE observation.status = **final**
 - ii. FHIR Data Element: mCODE observation.code
 - o 277206009 N category
 - o 399534004 cN category
 - o 371494008 pN category
 - iii. FHIR Data Element: mCODE observation.value[CodeableConcept]
 - o SNOMED-CT equivalents of the AJCC codes for the N category according to AJCC TNM staging rules as defined in the TNM Regional Nodes Category Value Set
 - iv. FHIR Data Element: mCODE observation.method
 - o Codes representing the different editions of AJCC TNM staging systems as defined in the TNM Staging Method Value Set
 - v. mCODE Profile: TNM Regional Nodes Category

4.8.3 Metastasis (M)

The Metastasis (M) value describes the presence of distant metastatic spread at initial diagnosis and is based on AJCC staging guidelines. The Metastasis (M) data element is required to be reported by EOM participants for several cancer types and diagnosis codes. If Metastasis (M) staging is not applicable for a cancer type, the EOM participant can select “Not Applicable” in the CDE Data Submission Template. The Metastasis (M) value may be represented by a prefix of clinical ‘c’ or pathologic ‘p,’ for example, cM0 or pM1. In the CDE Data Submission Template, EOM participants will be able to select the Metastasis (M) value from the drop-down list of choices. This data element is related to the attributed cancer type and episode dates, and it is required to be reported for attributed beneficiaries. The most complete final status of the Metastasis (M) stage as noted in their medical record system should be reported by the EOM participant.

Note: Additional information on AJCC cancer staging can be found on the website: www.cancerstaging.org

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): metastasis_(M)
- Format: clinical prefix of ‘c’ or pathological prefix of ‘p’ of Metastasis (M) value

Note: Reporting attributed beneficiaries with a value indicating the AJCC Metastatic (M) not equal to M0 or MX, will be considered in the clinical adjusters for episodes involving certain cancer types. For additional information and criteria regarding clinical adjusters for episodes involving certain cancer types, refer to Section 4.1.3, “Clinical Adjusters”, in the EOM Payment Methodology document on the [EOM website](#).

In the FHIR-based API (mCODE), this CDE is mapped to observation.status, observation.code, observation.value[CodeableConcept] and observation.method in the mCODE TNM Distant Metastases Category Profile. Of note, the term ‘prefix’ correlates with the term, ‘observation’ in mCODE.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE observation.status = **final**
 - ii. FHIR Data Element: mCODE observation.code
 - 277208005 M category
 - 399387003 cM category
 - 371497001 pM category
 - iii. FHIR Data Element: mCODE observation.value[CodeableConcept]
 - SNOMED-CT equivalents of the AJCC codes for the M category according to AJCC TNM staging rules as defined in the TNM Distant Metastases Category Value Set
 - iv. FHIR Data Element: mCODE observation.method
 - Codes representing the different editions of AJCC TNM staging systems as defined in the TNM Staging Method Value Set
 - v. mCODE Profile: TNM Distant Metastases Category

4.8.4 Result of Estrogen Receptor (ER) Test

A significant component of deciding treatment options for breast cancer patients is knowing the hormone receptor status. The test result for Estrogen Receptor (ER) is collected at initial diagnosis for attributed beneficiaries with breast cancer. This data element is required to be populated by the EOM participant for all attributed beneficiaries with the attributed cancer type of breast cancer. The most complete final status of the Estrogen Receptor (ER) Test result as noted in the EOM participant medical record system should be reported by the EOM participant. The subsections below outline the options for reporting ER status and results.

4.8.4.1 Result of Estrogen Receptor (ER) Test (Qualitative)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the ER test represents a complete final status in the medical record.
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_estrogen_rec_status
 - Qualitative result of ER test response options:
 - a. Positive (1% - 100%)
 - b. Negative (0% or less than 1%)
 - c. Indeterminate (result cannot be determined; inconclusive)
 - d. Not Tested

In the FHIR-based API (mCODE), this data element maps to observation.value[CodeableConcept] in the mCODE Tumor Marker Test Profile.

- FHIR Data Element: mCODE observation.value[CodeableConcept]
 - i. Response: Any LOINC code qualifier value shown here
 - Positive - LA6576-8
 - Negative - LA6577-6
 - Indeterminate - LA11884-6
 - Not Tested - LA13538-6

Note: If the qualitative result of the ER test is not provided, the quantitative result of the ER test may be reported. However, the ER specified test performed must be selected along with the corresponding quantitative result of the ER specified test. If the qualitative result of the ER test status is provided, reporting the specified ER test and the quantitative result of the specified ER test is not required.

4.8.4.2 Estrogen Receptor (ER) Test Specified (Optional)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the ER test specified represents a final status in the medical record.
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_estrogen_rec_code
 - In the absence of a qualitative result of ER test, select the type of ER test performed.

- Quantitative response options: The list below includes the LOINC values accepted for EOM clinical data submission.
 - a. 14130-9 Estrogen receptor [Moles/mass] in Tissue
 - b. 14228-1 Cells.estrogen receptor/100 cells in Tissue by Immune stain
 - c. 85329-1 Cells.estrogen receptor/100 cells in Breast cancer specimen by Immune stain

In the FHIR-based API (mCODE), this data element maps to `observation.status`, `observation.code` and `observation.dataAbsentReason` (if applicable) in the mCODE Tumor Marker Test Profile. The list below includes the LOINC values accepted for EOM clinical data submission.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE `observation.status` = **final**
 - ii. FHIR Data Element: mCODE `observation.code` (LOINC)
 - 16112-5 Estrogen receptor [Interpretation] in Tissue
 - 14130-9 Estrogen receptor [Moles/mass] in Tissue
 - 40556-3 Estrogen receptor Ag [Presence] in Tissue by Immune stain
 - 85337-4 Estrogen receptor Ag[presence] in Breast cancer specimen by Immune stain
 - 85310-1 Estrogen receptor fluorescence intensity [Type] in Breast cancer specimen by Immune stain
 - 14228-1 Cells.estrogen receptor/100 cells in Tissue by Immune stain
 - 85329-1 Cells.estrogen receptor/100 cells in Breast cancer specimen by Immune stain
 - iii. FHIR Data Element: mCODE `observation.dataAbsentReason`
 - Data Absent Reason (if value not reported)
 - a. Unknown (value not known)
 - b. Not Applicable
 - iv. mCODE Profile: Tumor Marker Test

4.8.4.3 Estrogen Receptor (ER) Test Quantity (Optional)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the ER test quantity represents a final status in the medical record.
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. `tumor_marker_estrogen_rec_quantity`
 - Quantitative result of ER test code response options:
 - a. Report as a valid numeric value up to two decimal places
 - b. Quantitative results will be interpreted as follows:
 - Estrogen Receptor Positive (1% - 100%)
 - Estrogen Receptor Negative (0% or <1%)

In the FHIR-based API (mCODE), this data element maps to `observation.value[Quantity]` in the mCODE Tumor Marker Test Profile.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: Observation.value[Quantity]
 - If there is an associated quantity or numeric value of the test result for the specific tumor marker test conducted, a response entered as a numeric value with up to two decimal places can be included.
 - ii. mCODE Profile: Tumor Marker Test

4.8.5 Result of Progesterone Receptor (PR) Test

A significant component of deciding treatment options for breast cancer patients is knowing the hormone receptor status. The result of Progesterone Receptor (PR) test is collected at initial diagnosis for attributed beneficiaries with breast cancer. This data element is required to be populated by the EOM participant for all attributed beneficiaries with the attributed cancer type of breast cancer. The most complete final status of the Progesterone Receptor (PR) Test result as noted in the EOM participant medical record system should be reported by the EOM participant. The subsections below outline the options for reporting PR status and results.

4.8.5.1 Result of Progesterone Receptor (PR) Test (Qualitative)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the PR test represents a complete final status in the medical record
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_progest_rec_status
 - Qualitative result of PR test response options:
 - a. Positive (1% - 100%)
 - b. Negative (0% or less than 1%)
 - c. Indeterminate (result cannot be determined; inconclusive)
 - d. Not Tested

In the FHIR-based API (mCODE), this data element maps to observation.value[CodeableConcept] in the mCODE Tumor Marker Test Profile.

- FHIR Data Element: mCODE observation.value[CodeableConcept]
 - i. Response: Any LOINC code qualifier value shown here
 - Positive - LA6576-8
 - Negative - LA6577-6
 - Indeterminate - LA11884-6
 - Not Tested - LA13538-6

Note: If the qualitative result of the PR test status is not provided, the quantitative result of the PR test may be reported. However, the PR specified test performed must be selected along with the corresponding quantitative result of the PR specified test. If the qualitative result of the PR test status is provided, reporting the specified PR test and the quantitative result of the specified PR test is not required.

4.8.5.2 Progesterone Receptor (PR) Test Specified (Optional)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the PR test specified represents a complete final status in the medical record
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_progest_rec_code
 - In the absence of a qualitative result of PR test, select the type of PR test performed.
 - Quantitative response options: The list below includes the LOINC values accepted for EOM clinical data submission.
 - a. 10861-3 Progesterone receptor [Mass/mass] in Tissue
 - b. 31207-4 Progesterone receptor Ag [Moles/mass] in Tissue
 - c. 14230-7 Cells.progesterone receptor/100 cells in Tissue by Immune stain
 - d. 85325-9 Cells.progesterone receptor/100 cells in Breast cancer specimen by Immune stain

In the FHIR-based API (mCODE), this data element maps to observation.status, observation.code and observation.dataAbsentReason in the mCODE Tumor Marker Test Profile. The list below includes the LOINC values accepted for EOM clinical data submission.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE observation.status = **final**
 - ii. FHIR Data Element: mCODE observation.code (LOINC)
 - 16113-3 Progesterone receptor [Interpretation] in Tissue
 - 10861-3 Progesterone receptor [Mass/mass] in Tissue
 - 31207-4 Progesterone receptor [Moles/mass] in Tissue
 - 40557-1 Progesterone receptor Ag [Presence] in Tissue by Immune stain
 - 85339-0 Progesterone receptor Ag[presence] in Breast cancer specimen by Immune stain
 - 85331-7 Progesterone receptor fluorescence intensity [Type] in Breast cancer specimen by Immune stain
 - 14230-7 Cells.progesterone receptor/100 cells in Tissue by Immune stain
 - 85325-9 Cells.progesterone receptor/100 cells in Breast cancer specimen by Immune stain
 - iii. FHIR Data Element: mCODE observation.dataAbsentReason
 - Data Absent Reason (if value not reported)
 - a. Unknown (value not known)
 - b. Not Applicable
 - iv. mCODE Profile: Tumor Marker Test

4.8.5.3 Progesterone Receptor (PR) Test Quantity (Optional)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the PR test specified represents a complete final status in the medical record
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. Tumor_marker_progest_rec_quantity
 - Quantitative result of PR test code response options:
 - a. Report as a valid numeric value up to two decimal places.
 - Quantitative results will be interpreted as follows:
 - a. Progesterone Receptor Positive (1 – 100%)
 - b. Progesterone Receptor Negative (0% or <1%)

In the FHIR-based API (mCODE), this data element maps to observation.value[Quantity] in the mCODE Tumor Marker Test Profile.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: observation.value[Quantity]
 - If there is an associated quantity or numeric value of the test result for the specific tumor marker test conducted, a response entered as a numeric value with up to two decimal places can be included.
 - ii. mCODE Profile: Tumor Marker Test

4.8.6 Result of HER2 Test

A significant component of deciding treatment options for breast cancer patients is knowing the hormone receptor status. The test result for HER2 is collected at initial diagnosis for attributed beneficiaries with breast cancer. This data element is required to be populated by the EOM participant for all attributed beneficiaries with the attributed cancer type of breast cancer. The most complete final status of the HER2 test result as noted in the EOM participant medical record system should be reported by the EOM participant. The subsections below outline the options for reporting HER2 status and results.

4.8.6.1 Result of HER2 Test (Qualitative)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the HER2 test represents a complete final status in the medical record.
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_HER2_rec_status
 - Qualitative response options for HER2 testing validated by IHC (immunohistochemistry) assay:
 - a. Positive
 - If IHC assay score of 3+, result is HER2 positive
 - b. Negative

- If IHC assay result 1+, result is HER2 negative
- If IHC assay result 0, result is HER2 negative
- c. Equivocal
 - If IHC assay result 2+, result is HER2 equivocal

Note: If the test result for HER2 by IHC is 2+ equivocal and additional HER2 testing validated by FISH is performed, report the qualitative value of the HER2 by FISH test result (amplified/positive; non-amplified/negative).

- d. Indeterminate (HER2 result cannot be determined; inconclusive)
- e. Not Tested

Note: If the qualitative result of the HER2 test by IHC is not provided, the quantitative result of the HER2 test by IHC may be reported. However, the specified HER2 by IHC test performed must be selected along with the corresponding result of the specified HER2 by IHC test. If the qualitative result of the HER2 test status is provided, reporting the specified HER2 test and the HER2 test quantity is not required.

- Qualitative response options for HER2 testing validated by **FISH (fluorescence in situ hybridization)**:
 - i. Positive (amplified)
 - ii. Negative (non-amplified)
 - iii. Indeterminate (HER2 result cannot be determined; inconclusive)
 - iv. Not Tested

Note: If HER2 testing is validated by FISH, interpretation of the qualitative results based on clinician assessment is required. The qualitative response must be provided for HER2 testing by FISH to ensure appropriate clinical interpretation by the clinician providing the care. As HER2 testing by FISH results vary by HER2/CEP17 ratio and average HER2 copy number, please refer to established clinical guidelines for interpreting HER2 testing results.

In the FHIR-based API (mCODE), this data element maps to `observation.value[codeableConcept]` in the mCODE Tumor Marker Test Profile.

- FHIR Data Element: `mCODE observation.value[CodeableConcept]`
 - i. Response: LOINC code qualifier values
 - Positive - LA6576-8
 - Negative - LA6577-6
 - Equivocal - LA11885-3
 - Indeterminate - LA118884-6
 - Not Tested - LA13538-6

4.8.6.2 HER2 Test Specified (Optional)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- **Status:** The reported result of the HER2 test specified represents a complete final status in the medical record.

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_HER2_rec_code
 - In the absence of qualitative test results for HER2 validated by IHC, select the type of HER2 by IHC quantitative test performed.
 - ii. Quantitative response options for HER2 testing by IHC: The list below includes the LOINC values accepted for EOM clinical data submission.
 - 32996-1 HER2 [Mass/volume] in Serum
 - 72382-5 HER2 [Units/volume] in Tissue by Immunoassay
 - 42914-2 HER2 [Mass/volume] in Serum by Immunoassay

In the FHIR-based API (mCODE), this data element maps to observation.status, observation.code and observation.dataAbsentReason in the mCODE Tumor Marker Test Profile. The list below includes the LOINC values accepted for EOM clinical data submission.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: mCODE observation.status = **final**
 - ii. FHIR Data Element: mCODE observation.code (LOINC)
 - 32996-1 HER2 [Mass/volume] in Serum
 - 48676-1 HER2 [Interpretation] in Tissue
 - 72382-5 HER2 [Units/volume] in Tissue by Immunoassay
 - 51981-9 HER2 [Presence] in Serum by Immunoassay
 - 72383-3 HER2 [Presence] in Tissue by Immunoassay
 - 42914-2 HER2 [Mass/volume] in Serum by Immunoassay
 - 18474-7 HER2 Ag [Presence] in Tissue by Immune stain
 - 85319-2 HER2 [Presence] in Breast cancer specimen by Immune stain
 - 85328-3 Cells.HER2 uniform intense membrane staining/100 cells in Breast cancer specimen by Immune stain
 - 74885-5 ERBB2 gene (HER2) duplication associated observations panel - Tissue by FISH
 - 74860-8 ERBB2 gene copy number/nucleus in Tissue by FISH
 - 49683-6 ERBB2 gene copy number/Chromosome 17 copy number in Tissue by FISH
 - 96893-3 ERBB2 gene duplication in Tumor by FISH
 - 31150-6 ERBB2 gene duplication [Presence] in Tissue by FISH
 - 85318-4 ERBB2 gene duplication [Presence] in Breast cancer specimen by FISH
 - 42783-1 ERBB2 gene mutations found [Identifier] in Blood or Tissue by Molecular genetics method Nominal
 - iii. FHIR Data Element: mCODE observation.dataAbsentReason
 - Data Absent Reason (if value not reported)
 - a. Unknown (value not known)
 - b. Not Applicable
 - iv. mCODE Profile: Tumor Marker Test

4.8.6.3 HER2 Test Quantity (Optional)

In the CDE Data Submission Template, this CDE is consistent with the following components:

- Status: The reported result of the HER2 test quantity represents a complete final status in the medical record.
- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab):
 - i. tumor_marker_HER2_rec_quantity
 - Quantitative result of HER2 test code response options:
 - a. Report as a valid numeric value up to two decimal places.
 - Quantitative results will be interpreted as follows:
 - a. 3 = Positive (3+)
 - b. 2 = Equivocal (2+)
 - c. 1 = Negative (1+)
 - d. 0 = Negative (0)

In the FHIR-based API (mCODE), this data element maps to observation.value[Quantity] in the mCODE Tumor Marker Test Profile.

- FHIR-based API (mCODE):
 - i. FHIR Data Element: Observation.value[Quantity]
 - If there is an associated quantity or numeric value of the test result for the specific tumor marker test conducted, a response entered as a numeric value with up to two decimal places can be included.
 - ii. mCODE Profile: Tumor Marker Test

4.8.7 Histology

Histology describes the morphologic and behavioral characteristics of the cancer type. Information about histology helps clinicians determine what treatment(s) are recommended using established guidelines. The reported histology for the attributed cancer type is based on pathology or cytology findings from biopsy or surgical resection at the time of initial diagnosis. This data element is required to be populated for all attributed beneficiaries. The reported histology represents a complete final status in the medical record.

In the CDE Data Submission Template, this CDE is consistent with the following components:

- CDE Data Submission Template Data Element Label (column B on the Data Element Description tab): histology
- Response options: textual (ICD-O-3)
 - i. Select the specific histology for the attributed cancer type
 - ii. If the specific histology is not listed for the Cancer Type, select 'Other Histology'

Refer to the [EOM CDE Histology Cancer Type document](#) in EOM Connect for a list of histology descriptions and codes which will be available for selection in the CDE Data Submission Template.

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In the FHIR-based API (mCODE), this data element maps to `condition.extension:histologyMorphologyBehavior` in the mCODE Primary Cancer Condition Profile.

- FHIR-based API (mCODE):
 - i. Response:
 - SNOMED-CT Codes
Note: The corresponding SNOMED-CT code will be accepted via FHIR-based API; additional details will be provided in the future.
 - ii. FHIR Data Element: `mCODE condition.extension:histologyMorphologyBehavior`
 - iii. mCODE Profile: Primary Cancer Condition

Note: If the histology submitted via FHIR is not aligned with one of the histology codes in the EOM CDE Histology Cancer Type reference document, the histology will be considered in the “Other Histology” category for the EOM clinical data submission.

Appendix A: Acronyms and Abbreviations

Table A-1: Acronyms and Abbreviations

Acronym	Literal Translation
AJCC	American Joint Commission on Cancer
API	Application Programming Interface
CDE	Clinical Data Element
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
EOM	Enhancing Oncology Model
E&M	Evaluation and Management
ER	Estrogen Receptor
ESRD	End Stage Renal Disease
FHIR	Fast Healthcare Interoperability Resources
HCPCS	Healthcare Common Procedure Coding System
HDR	Health Data Reporting
HER2	Human Epidermal Growth Factor Receptor 2
HL7	Health Level Seven
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
IG	Implementation Guide
ISP	Innovation Support Platform
LOINC	Logical Observation Identifiers Names and Codes
mCODE	Minimal Common Oncology Data Elements
MEOS	Monthly Enhanced Oncology Services
NOS	Not Otherwise Specified
PGP	Physician Group Practice
PR	Progesterone Receptor
SDE	Sociodemographic Data Elements
SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
TIN	Taxpayer Identification Number
TNM	Primary Tumor, Nodal Disease, Metastasis
USCDI	United States Core Data for Interoperability