EOM CLINICAL DATA ELEMENTS GUIDE

Version 2.4

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ENHANCING ONCOLOGY MODEL

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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 alternative payment model designed to promote high quality, person-centered care, 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 cancer therapy for included cancer types. The model is centered on 6-month episodes of care triggered by receipt of an Initiating Cancer Therapy for an included cancer type. Seven cancer types are included in the model:

- Breast Cancer[1]
- Chronic Leukemia
- Lung Cancer
- Lymphoma
- Multiple Myeloma
- Prostate Cancer[1]
- Small Intestine/Colorectal Cancer

This document provides guidance on the details, terminologies, and definitions necessary for the required collection and reporting of EOM clinical data elements (CDE) for the seven cancer types listed above. This document also describes the two reporting options available to participants: 1) a "low-tech" reporting approach which utilizes a standardized Excel template, referred to as the Health Data Reporting (HDR) submission template, and 2) a "high-tech" reporting approach that is based on Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)®.

Section 1: EOM CDE Overview - Episodes and Performance Periods

EOM participants are required to report CDEs for EOM-attributed beneficiaries semi-annually, within 30 days of attribution data being made available in the EOM HDR application for each performance period (PP).

The receipt of a qualifying Initiating Cancer Therapy by an eligible beneficiary for an included cancer type will trigger the start of an episode if the beneficiary receives a qualifying evaluation and management (E&M) service during the episode.

[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 androgen deprivation and/or anti-androgen therapy without any other chemotherapy.

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 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 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 are required to report clinical data on beneficiaries attributed to their PGP for each performance period. Specific due dates will be communicated to EOM participants in a timely manner. Each performance period includes episodes with the initiation and end dates shown in Table 1.

Note:

- **Cohort 1:** Reporting of clinical data is required to begin PP1, with initial reporting in Fall 2024 and True-up reporting in Fall 2025.
- **Cohort 2:** Reporting of clinical data is required to begin PP5, with initial reporting in Fall 2026 and True-up reporting in Fall 2027.

Table 1: Performance Periods and Episodes

Cohort 1 Performance Period	Cohort 2 Performance Period	Episode Initiation Dates	Episode End Dates	Reporting Timeline
1	N/A	7/1/2023–12/31/2023	12/31/2023–6/29/2024	Initial Reporting: Fall 2024* True-up Reporting: Fall 2025*
2	N/A	1/1/2024–6/30/2024	6/30/2024–12/29/2024	Initial Reporting: Spring 2025* True-up Reporting: Spring 2026*
3	N/A	7/1/2024–12/31/2024	12/31/2024–6/29/2025	Initial Reporting: Fall 2025* True-up Reporting: Fall 2026*
4	N/A	1/1/2025–6/30/2025	6/30/2025–12/29/2025	Initial Reporting: Spring 2026* True-up Reporting: Spring 2027*
5	5	7/1/2025–12/31/2025	12/31/2025–6/29/2026	Initial Reporting: Fall 2026 True-up Reporting: Fall 2027
6	6	1/1/2026–6/30/2026	6/30/2026–12/29/2026	Initial Reporting: Spring 2027 True-up Reporting: Spring 2028
7	7	7/1/2026–12/31/2026	12/31/2026–6/29/2027	Initial Reporting: Fall 2027 True-up Reporting: Fall 2028
8	8	1/1/2027–6/30/2027	6/30/2027–12/29/2027	Initial Reporting: Spring 2028 True-up Reporting: Spring 2029

Cohort 1 Performance Period	Cohort 2 Performance Period	Episode Initiation Dates	Episode End Dates	Reporting Timeline
9	9	7/1/2027–12/31/2027	12/31/2027–6/29/2028	Initial Reporting: Fall 2028 True-up Reporting: Fall 2029
10	10	1/1/2028–6/30/2028	6/30/2028–12/29/2028	Initial Reporting: Spring 2029 True-up Reporting: Spring 2030
11	11	7/1/2028–12/31/2028	12/31/2028–6/29/2029	Initial Reporting: Fall 2029 True-up Reporting: Fall 2030
12	12	1/1/2029–6/30/2029	6/30/2029–12/29/2029	Initial Reporting: Spring 2030 True-up Reporting: Spring 2031
13	13	7/1/2029–12/31/2029	12/31/2029–6/29/2030	Initial Reporting: Fall 2030 True-up Reporting: Fall 2031

*Note: Cohort 2 reporting of clinical data is not required for PP1, PP2, PP3, or PP4.

Section 2: CDE Reporting Requirements

EOM participants are required to report complete clinical data for at least 90%, or such other percentage as specified by CMS in writing, of their attributed beneficiaries for a given performance period. That is, the percentage designated by CMS is the minimum percentage of attributed beneficiaries that must have complete and valid clinical data reported by EOM participants to qualify for the clinical adjusters for episodes involving certain cancer types.

CMS or its designee(s) will provide the EOM participant with a list of EOM beneficiaries whose episodes were attributed to the EOM participant, including the cancer type assigned to each episode, for that performance period as part of the initial reconciliation and again as part of the subsequent true-up reconciliation for that performance period. EOM participants will therefore have two opportunities to report on attributed patients for each performance period.

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

To successfully complete CDE reporting, EOM participants must adhere to these 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 CMS.
- The reported records are "complete," meaning all CDEs required for the cancer type are reported via the EOM HDR application or via a FHIR Application Programming Interface (API).
- The relevant data are reported 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 CDEs on a semi-annual basis to CMS on at least 90%, or such other percentage as specified by CMS in writing, of attributed episodes for a given performance period for the 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 in the EOM HDR application or via a FHIR API for each performance period in which the beneficiary is attributed.

2.2 Identifying EOM-attributed Beneficiaries

EOM participants are required to report CDEs for EOM-attributed beneficiaries semi-annually, within 30 days of attribution data being made available in the EOM HDR application or via a FHIR API for each performance period. Since attribution is retrospective, CMS identifies the beneficiaries that require clinical data reporting after episodes are complete. It is recommended that participants collect clinical data during the course of care delivery to be prepared for later reporting. The criteria below can help practices identify potential EOM-attributed beneficiaries prior to attribution.

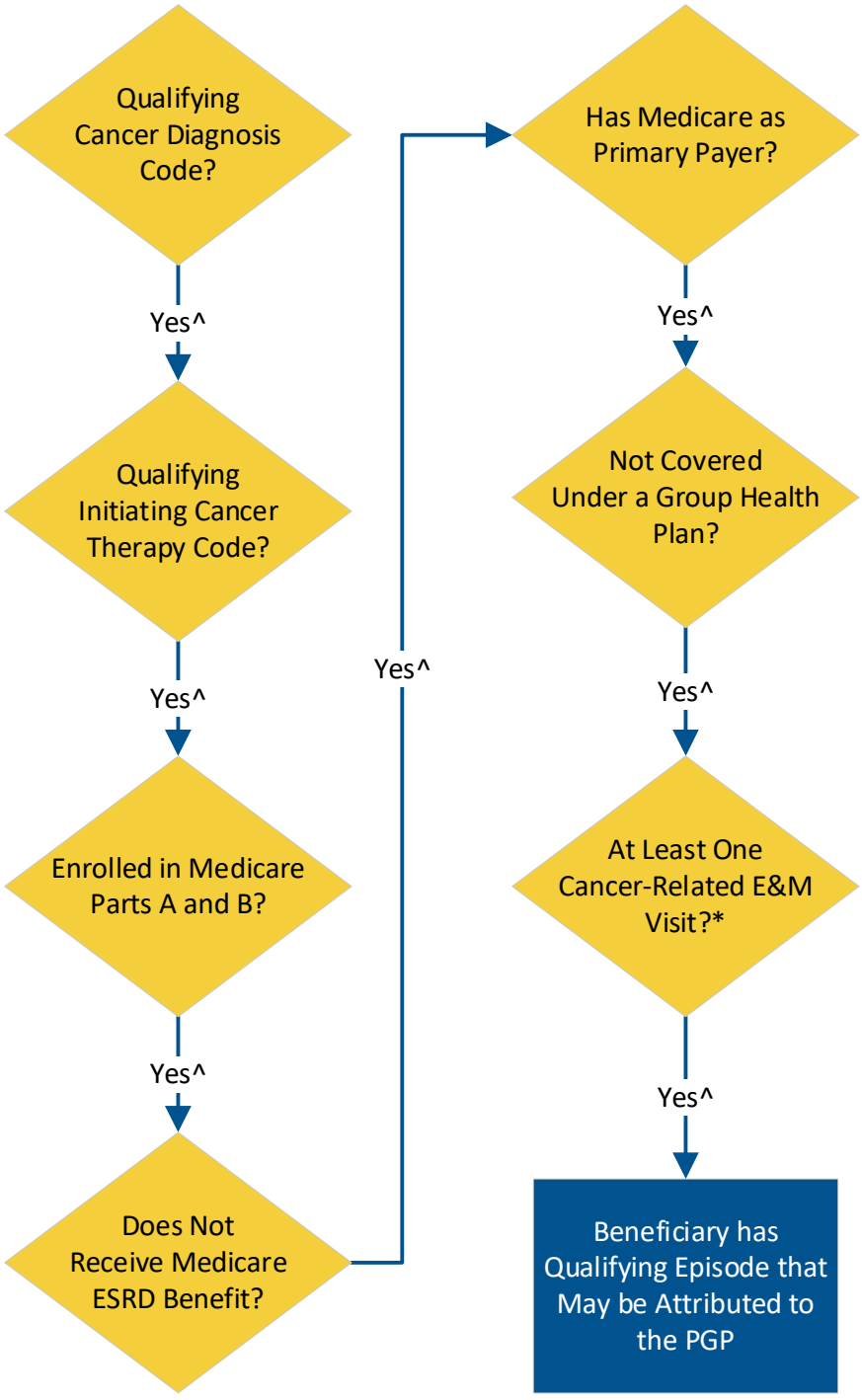
1. Identify patients that have a qualifying cancer diagnosis code.
   a. A list of qualifying ICD-10-CM diagnosis codes utilized within EOM for episode identification is located in the EOM Technical Payment Resources document on the "Cancer Type Mapping" tab.
   b. Of the patients identified with a qualifying cancer diagnosis code, identify those that have a qualifying initiating cancer therapy code, which may include Healthcare Common Procedure Coding System (HCPCS) codes or National Drug Codes (NDCs). A list of qualifying initiating cancer therapies and codes can be found in the "EOM Initiating Therapies List" document (available on the EOM website) for the performance period in the "HCPCS Codes" and "NDC Codes" tabs.[2]
2. Of the patients identified above with a qualifying cancer diagnosis code, a beneficiary must meet the following requirements for all 6 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 Taxpayer Identification Number (TIN) with at least one oncology provider during the performance period.[4]

[2] The EOM Initiating Cancer Therapies List is updated for each EOM performance period. Participants must use the performance period specific list when determining potential eligibility for an episode. 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.
[3] ESRD status is determined using information in the Medicare Enrollment Database.
[4] When determining attribution, each episode is attributed to the TIN that provided the first qualifying E&M service during the

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.

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.

Figure 1: Identification of Potential EOM-attributed Beneficiaries



^ If any of these criteria are answered "No," the patient does not qualify as a potential EOM-attributed beneficiary.

Section 3: Data Collection and Reporting Options

This section describes the data collection and reporting options for the CDEs to be reported by EOM participants for their attributed beneficiaries each performance period.

EOM participants are required to report all CDEs applicable to the ICD-10 diagnosis code for the attributed cancer type associated with each EOM-attributed beneficiary. Two reporting options are available for EOM participants to report their data: the low-tech option (HDR submission template) and the high-tech (FHIR API) option. Participants will have an opportunity to gain familiarity with both reporting options prior to the beginning of each reporting period.

Participants may use both the low-tech and high-tech options for reporting (e.g., SDE data may be submitted via the low-tech option and CDE data may be submitted via the high-tech option or vice versa). However, data cannot be combined across reporting methods for a single beneficiary and data type (SDE or CDE). When using either the low-tech or high-tech option, data is not combined across submissions for the same beneficiary (i.e., portions of data from one submission for a single beneficiary are not combined with portions of data from a different submission for the same beneficiary). The last successful submission for each beneficiary will be the data recorded in the HDR, for both SDE and CDE.

The EOM Reporting Timelines and Frequently Asked Questions (FAQs) resource is available in EOM Connect. This document includes information on SDE, CDE, and quality measure reporting requirements, EOM data submission timeframes, and available tools and resources. More information on the reporting process can be found in the Health Data Reporting (HDR) User Guide, and the EOM FAQ located in EOM Connect.

3.1 EOM HDR Application

EOM participants use a centralized reporting platform called 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 use to submit data, including practice-level quality measures, beneficiary-specific CDEs, and beneficiary-specific SDEs. The HDR User Guide is available in EOM Connect.

Participants reporting via the low-tech (HDR submission template) option will submit their CDE data on the HDR application. Participants reporting via the high-tech (FHIR API) option are encouraged to access the HDR application to view the completion status of their FHIR submissions.

3.2 Low-Tech and High-Tech Reporting Options

Participants and their vendors must report all CDEs applicable to the ICD-10 diagnosis code for the cancer type using either the low-tech (HDR submission template) or high-tech (FHIR API) option.

3.2.1 HDR Submission Template (Low-Tech)

The low-tech reporting approach utilizes a standardized Excel template, the HDR submission template, which can be downloaded via the HDR application during the reporting period. The HDR submission template contains two tabs for reporting data: one for CDE and one for Sociodemographic Data Elements (SDE).

This reporting option allows EOM participants to leverage the CDE tab of the HDR submission template, which is pre-populated with the list of attributed beneficiaries for reporting cancer-specific CDEs. The HDR submission template is designed for EOM participants who may not have the ability to send CDE data conformant with the mCODE, and specifically the EOM Implementation Guide (IG), via a FHIR API. The pre-populated HDR submission template will be available via download from the HDR application and must be used to submit data. Participants who have used the sample HDR submission template to collect data will need to move the data into the HDR submission template downloaded from the HDR for the attributed beneficiaries. Please ensure you download the template for the correct performance period. Submission of data using the sample HDR submission template or any format other than the official pre-populated template will not be accepted by the EOM HDR application.

3.2.2 HL7 FHIR API (High-Tech)

The high-tech reporting approach is based on HL7 FHIR and leverages the EOM IG. This reporting option allows for the reporting of CDEs directly from the EOM participant's electronic health record (EHR) system via a FHIR API. Reporting via FHIR API enables the electronic sharing of healthcare data across systems. This approach enables different healthcare systems, such as hospitals and specialty clinics, to share patient data seamlessly and securely. By using FHIR API, EOM participants can use different healthcare applications to "talk" to each other more easily, which improves interoperability and coordination of oncology care.

The EOM IG was developed to provide guidance on the details, terminologies, and definitions necessary for collection and reporting CDEs. To improve interoperability and reduce administrative burden, the EOM IG and its reporting options are aligned with HL7 FHIR® minimal Common Oncology Data Elements (mCODE), which is a set of standardized data elements specifically designed for oncology. The EOM IG is limited to a subset of data elements which are supported by mCODE and are required for EOM CDE reporting.[5] It also provides further guidance and detail specific to data expected for EOM (e.g., patient identifier must include the Medicare Beneficiary Identifier (MBI)).

The EOM IG uses US Core Data for Interoperability (USCDI)+ Cancer standards, which are a set of cancer data classes and elements, to ensure that EOM data can be integrated across healthcare systems. Collaborating with the U.S. Department of Health and Human Services' Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC), CMS also identified EOM as an initial use case for the USCDI+ Cancer initiative. Engaging with the EOM IG ensures that participating EOM PGPs and their vendors can share and receive the core USCDI+ Cancer data elements. This allows a more robust exchange of cancer data on FHIR. Furthermore, it provides the ability to work with the critical core set of cancer data on FHIR that are foundational for future USCDI+ Cancer initiative use cases such as clinical trial matching, tracking adverse events, and facilitating better clinical data registry reporting.

[5] The EOM IG is derived from the Health Level 7 (HL7) FHIR® mCODE standard. mCODE is a "domain of knowledge" IG and does not define a specific set of information that must be collected for each cancer patient. mCODE was developed as a base on which specific use cases could build, leveraging its 40 profiles and controlled terminologies.

Section 3.4 includes a description of the data element applicable for the attributed cancer type, 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 mCODE standards, and ultimately the USCDI+ Cancer initiative.

3.3 Pre-populated Data Elements in the HDR Submission Template

EOM participants will have access to the HDR submission template within the EOM HDR application. The HDR submission template will be pre-populated with key information for each attributed beneficiary for the performance period. The CDE tab of the HDR submission template must be used for participants using the "low-tech" option to complete CDE reporting for attributed beneficiaries or may be used as a reference for those using the "high-tech" FHIR API[6] 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 are pre-populated in the HDR 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 SDE data. These data are collected via the HDR submission template within the SDE tab or via a FHIR API leveraging the US Core IG Patient Resource. If the Beneficiary Date of Birth or Sex pre-populated in the CDE tab of the HDR 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 tab of the HDR submission template, but please ensure accurate information is included when reporting the SDE data for that beneficiary within the SDE tab. The EOM Sociodemographic Data Elements Guide is located on the EOM website.

IMPORTANT: Do not include non-attributed beneficiaries in the HDR submission template for reporting to the EOM HDR application as the file will be rejected.[7]

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[6] EOM participants submitting CDEs via a FHIR API will be provided directions to query the CMS FHIR server to receive their attributed beneficiary list and the relevant information indicated in section 3.3 that will be pre-populated in the EOM HDR template. Additional information about accessing this information will be made available in the EOM IG.

[7] A sample HDR submission template is available for each submission period that does not include any prefilled data. These resources can support you as you prepare for your data submission and are for reference only. If you choose to submit data via HDR, you will have to submit the official HDR submission template, which contains both the CDE tab and the SDE tab. When downloaded from the HDR, the prefilled data has all the necessary metadata to ensure successful validation and submission. Please ensure you download the template for the correct performance period. Participants who have used the sample HDR submission template to collect data will need to move the data into the HDR submission template. The sample HDR submission template or any format other than the official HDR submission template will not be accepted by the HDR application.

3.4 Clinical Data Elements

The high-level CDEs listed in **Table 2** are required to be reported (as applicable for the attributed cancer type) by the participant for each attributed beneficiary. Note that **Table 3** and **Section 4** provide additional details regarding how reporting occurs for these data elements using the CDE tab of the HDR submission template or the HL7 FHIR API and the EOM IG based on mCODE.

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 tab of the HDR submission template or HL7 FHIR API
	Initial Date of Diagnosis	All Cancer Types	CDE tab of the HDR submission template or HL7 FHIR API
Current Clinical Status	Date Patient Died	All Cancer Types	CDE tab of the HDR submission template or HL7 FHIR API
	Recurrence or Relapse Clinical Status	All Cancer Types	CDE tab of the HDR submission template or HL7 FHIR API
	Current Clinical Status Trend	All Cancer Types	CDE tab of the HDR submission template or HL7 FHIR API
	History of Metastatic Cancer	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE tab of the HDR submission template or HL7 FHIR API
	Current Clinical Status Date	All Cancer Types	CDE tab of the HDR submission template or HL7 FHIR API
Primary Tumor, Nodal Disease, Metastasis (TNM) Staging	Primary Tumor (T)	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE tab of the HDR submission template or HL7 FHIR API
	Nodal Disease (N)	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE tab of the HDR submission template or HL7 FHIR API
	Metastasis (M)	Breast, Lung, Prostate, Small Intestine/Colorectal Cancer	CDE tab of the HDR 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 tab of the HDR submission template or HL7 FHIR API

Data Element Concepts	Data Element Names*	Applicable Cancer Types	Reporting Options
Tumor Markers (continued)	Result of Progesterone Receptor (PR) Test Progesterone Receptor (PR) Test Specified Progesterone Receptor (PR) Test Quantity	Breast Cancer	CDE tab of the HDR submission template or HL7 FHIR API
	Result of HER2 Test HER2 Test Specified HER2 Test Quantity	Breast Cancer	CDE tab of the HDR submission template or HL7 FHIR API
Histology	Histology	All Cancer Types	CDE tab of the HDR 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).

Table 3 displays how the data element names in the HDR submission template are related to the corresponding data element names utilized in mCODE and the EOM IG. This is important as the data submitted via the HDR submission template will be stored in a FHIR server together with the data collected via HL7 FHIR 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.

Table 3: EOM CDE Names by Reporting Option

HDR Submission Template Data Element Name	HL7 FHIR API Data Element Name (mCODE/EOM IG)
ICD-10 Diagnosis Code	Primary (Initial) Cancer Condition Code
Initial Date of Diagnosis	Primary (Initial) Cancer Condition Extension: Asserted Date
Date Patient Died	Patient Deceased [Date Time]
Recurrence or Relapse Clinical Status	Condition Clinical Status
	Condition Verification Status
Current Clinical Status Trend Blank on Purpose	Current Clinical Status Trend Observation Value [Codeable Concept]
	Current Clinical Status Trend Observation Status
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

HDR Submission Template Data Element Name	HL7 FHIR API Data Element Name (mCODE/EOM IG)
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]
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

*__Note:__ Either qualitative or quantitative values are required for reporting the result of the ER test (see Section 4.8.4), PR test (see Section 4.8.5), and the results of specific HER2 tests (see Section 4.8.6). Quantitative results are optional to report for PP2 and beyond if Qualitative results are submitted.

**__Note__: Due to the nature of prostate cancer, histology may be unknown upon arrival to the oncologist for treatment. Therefore, if histology results are not available for prostate cancer, leave the Histology field blank. (See section 4.8.7).

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 and the EOM IG. All CDEs applicable to the ICD-10 diagnosis code for the cancer type are required to be reported via the HDR application or a FHIR API.

4.1 Model ID

The Model ID refers to the EOM-ID developed by CMS. The Model ID will be pre-populated in the HDR submission template for EOM participants. Model ID cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: model_id
- Pre-populated CDE tab of the HDR submission template: EOM

4.2 EOM-ID

The EOM identification number (EOM-ID) is a unique number assigned by CMS for each EOM participant and will be pre-populated in the HDR submission template for EOM participants. EOM-ID cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: entity_id
- Pre-populated CDE tab of the HDR submission template: EOM-ID (format = EOM-PGP-XXXX)

4.3 EOM Beneficiary-level Demographic Data

This subsection lists the EOM-attributed beneficiary-level demographic data that will be pre-populated in the HDR 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 MBI. The MBI for the EOM-attributed beneficiary will be pre-populated in the HDR submission template for the EOM participant. MBI cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: mbi
- Pre-populated CDE tab of the HDR submission template: 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 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/EOM IG: EOM Cancer Patient

4.3.2 Beneficiary First Name

The first name of the EOM-attributed beneficiary will be pre-populated in the HDR submission template for EOM participants. Beneficiary First Name cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: first_name
- Pre-populated CDE tab of the HDR submission template: First Name

In the FHIR 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 HDR submission template for EOM participants. Beneficiary Last Name cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: last_name
- Pre-populated CDE tab of the HDR submission template: Last Name

In the FHIR 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 HDR submission template for EOM participants based on Medicare claims data. If the beneficiary date of birth pre-populated in the CDE tab of the HDR submission template is not accurate (e.g., inaccurate information was in claims data), please ensure accurate information is included when reporting the SDE data for that beneficiary. Date of Birth cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: date_of_birth
- Pre-populated CDE tab of the HDR submission template format: YYYY-MM-DD

In the FHIR 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 will be pre-populated in the HDR submission template for EOM participants based on Medicare claims data. If the beneficiary sex pre-populated in the CDE tab of the HDR

submission template is not accurate (e.g., inaccurate information was in claims data), please ensure accurate information is included when reporting the SDE data for that beneficiary. Beneficiary Sex cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: sex
- Pre-populated CDE tab of the HDR submission template: Sex

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

- FHIR Data Element: patient.gender
- 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 and the EOM Payment Methodology document for additional details on identifying potential attributed beneficiaries. 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 HDR submission template for EOM participants. Attributed Cancer Type cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: attributed_cancer_type
- Pre-populated CDE tab of the HDR submission template: 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 6 calendar months. The episode start date will be pre-populated in the HDR submission template for EOM participants. Episode Start Date cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: episode_start_date
- Pre-populated CDE tab of the HDR submission template: Episode Start Date (YYYY-MM-DD)

4.4.3 Episode End Date

The episode end date occurs 6 months after the date on which an episode initiated. The episode end date will be pre-populated in the HDR submission template for EOM participants. Episode End Date cannot be modified in the CDE tab of the HDR submission template.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: episode_end_date
- Pre-populated CDE tab of the HDR submission template: Episode End Date (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 HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: ICD-10_diagnosis_code
    i. The ICD-10 diagnosis code and description are available in the CDE tab of the HDR submission template, allowing users to report a valid primary cancer diagnosis for the attributed cancer type.

In the FHIR 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 API (mCODE):
    i. Code System: ICD-10 Diagnosis Code or Systemized Nomenclature of Medicine - Clinical Terms (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 must be reported in the format YYYY-MM-DD. The initial date of diagnosis is to be reported for all attributed beneficiaries. To determine a patient's cancer diagnosis date, refer to the pathology/hemato-pathology or cytology report and record the date of the report (not the date of the specimen). If there are multiple reports, enter the first date. In the absence of a pathology or cytology report, record any clinical documentation regarding date of initial diagnosis (e.g., a practitioner's notation). If a cancer diagnosis was made by the practitioner based on clinical findings prior to a pathology/hemato-pathology or cytology report, the date that diagnosis is documented is the initial diagnosis date.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: initial_date_diagnosis
- Format in the CDE tab of the HDR submission template: YYYY-MM-DD

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

- FHIR API (mCODE):
    i. Format: 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: 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 Date

If the patient is deceased, the date the patient died is required to be reported. The patient deceased date is not required to be during the beneficiary episode dates. The Patient Deceased Date should remain blank if not applicable.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: patient_deceased_date
- Format in the CDE tab of the HDR submission template: YYYY-MM-DD (if applicable)

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

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

4.7.2 Recurrence or Relapse Clinical Status

Recurrence is the return of a solid tumor cancer after a clinically disease-free interval (even after a previous recurrence); 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 is required to be reported for all attributed beneficiaries. This should be reported as "Yes" if the episode is either the result of a relapse or recurrence, or the relapse or recurrence occurs during the episode. The relapse or recurrence does not need to occur within the episode dates.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: recurrence_relapse_clinical_status
- Response in the CDE tab of the HDR submission template:
    i. Yes (Active Recurrence or Active Relapse)
    ii. No (Inactive Recurrence or Inactive Relapse)

In the FHIR 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 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

4.7.3 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 HDR submission template by EOM participants. If more than one current clinical status trend value is documented during the episode, the participant should report the value most clinically relevant for the episode. For example, this could be the most severe clinical status documented during the episode, the status at the start of the episode, or the status at the end of the episode. This data element is left to the discretion of the participant. Please note that the status chosen can expand beyond episode dates as long as it is the most clinically appropriate for the patient within the episode. For example, if the patient is diagnosed with metastatic disease prior to the episode window but continues to have active metastatic disease during the episode, and the status remains the most clinically relevant status for the patient during the episode, "Distant metastasis present" would be an appropriate status trend.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: current_clinical_status_trend
- Response in the CDE tab of the HDR submission template:
    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 reported 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 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 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

4.7.4 History of Metastatic Cancer

Metastatic disease occurs when there is evidence of cancer in a different site other than the primary tumor site. Reporting of "History of Metastatic Cancer" 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. The metastatic status should be relevant to the attributed cancer type.

To qualify for the EOM metastatic status clinical adjusters, participants may report History of Metastatic Cancer, or report the Metastasis (M) value not equal to M0 for beneficiaries who were metastatic at diagnosis or may report the Current Clinical Status Trend of "Distant Metastasis Present." For additional information and criteria regarding metastatic status clinical adjusters for episodes involving certain cancer types, refer to Section 4.1.3 in the EOM Payment Methodology document.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: history_mets_cancer
- Response in the CDE tab of the HDR submission template:
    i. Yes – History of Metastatic Cancer
    ii. No – No History of Metastatic Cancer

The FHIR API (mCODE) will accept History of Metastatic Cancer in alignment with mCODE. 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 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)
    - 1287652008 - History of metastatic malignant neoplasm (situation)
    - 88701000119109 - History of disseminated malignant neoplasm (situation)
    - 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 (situation)
    - 1098971000119104 - History of cancer metastatic to brain (situation)
    - 1099291000119102 - History of cancer metastatic to bone (situation)
  iii. FHIR Data Element: mCODE observation.status = **final** for all cases
  iv. mCODE Profile: History of Metastatic Cancer

4.7.5 Current Clinical Status Date

The current clinical status date is when the patient's health status changed as determined by the EOM practitioner 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 must be reported in format YYYY-MM-DD. The Current Clinical Status Date is required to be reported for all attributed beneficiaries.

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: current_clinical_status_date
- Format in CDE tab of the HDR submission template: YYYY-MM-DD

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

- FHIR API (mCODE):
  i. Format: 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 Primary Tumor, Nodal Disease, Metastasis (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) data element describes the primary tumor **at initial diagnosis** and is based on American Joint Commission on Cancer (AJCC) staging guidelines. The Primary Tumor (T) data element is required, if applicable, 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, this field may remain blank. The Primary Tumor (T) value may be represented by a prefix of clinical 'c' or pathologic 'p' for example, cT1 or pT1. Participants are encouraged to use their clinical judgement and report the most complete and accurate data. However, in the absence of "c" or "p" prefix, please default to "c" status. In the HDR submission template, EOM participants will be able to report the Primary Tumor (T) value which is related to the attributed cancer type and episode dates, and it is required, if applicable, 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 HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: primary_tumor_T
- Format in the CDE tab of the HDR submission template: clinical prefix of 'c' or pathological prefix of 'p' of Primary Tumor (T) value

In the FHIR 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 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]
    - 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
    - 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) data element describes the regional lymph node involvement **at initial diagnosis** and is based on AJCC staging guidelines. The Nodal Disease (N) data element is required, if applicable, 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, this field may remain blank. The Nodal Disease (N) value may be represented by a prefix of clinical 'c' or pathologic 'p,' for example, cN0 or pN1. Participants are

encouraged to use their clinical judgement and report the most complete and accurate data. However, in the absence of "c" or "p" prefix, please default to "c" status. In the HDR submission template, EOM participants are able to report the Nodal Disease (N) value which is related to the attributed cancer type and episode dates, and it is required, if applicable, 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 HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: nodal_disease_N
- Format in the CDE tab of the HDR submission template: clinical prefix of 'c' or pathological prefix of 'p' of Nodal Disease (N) value

In the FHIR 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 API (mCODE):
  i. FHIR Data Element: mCODE observation.status = **final**
  ii. FHIR Data Element: mCODE observation.code
    - 277206009 N category
    - 399534004 cN category
    - 371494008 pN category
  iii. FHIR Data Element: mCODE observation.value[CodeableConcept]
    - 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
    - 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) data element describes the presence of distant metastatic spread **at initial diagnosis** and is based on AJCC staging guidelines. The Metastasis (M) data element is required, if applicable, to be reported by EOM participants for several cancer types and diagnosis codes. Unless there is clinical or pathological evidence of distant metastases, the patient should be classified as clinical M0 and denoted as cM0[8]. If Metastasis (M) staging is not applicable for a cancer type, this field may remain blank. The Metastasis (M) value may be represented by a prefix of clinical 'c' or pathologic 'p,' for example, cM0 or pM1. Participants are encouraged to use their clinical judgement and report the most complete and accurate data. However, in the absence of "c" or "p" prefix, please default to "c" status. In the HDR submission template, EOM participants will be able to report the Metastasis (M) value which is related to

[8] To align with AJCC Cancer Staging Manual, 8th Edition, no unknown or MX option can be reported. "Unless there is clinical or pathological evidence of distant metastasis, the patient is classified as clinical M0 and denoted as cM0. It is not necessary to perform any imaging or invasive studies to categorize a patient as cM0. A history and physical examination are all that is needed to assign cM0. The M category must always be known and reported to assign a stage group."

the attributed cancer type and episode dates, and it is required, if applicable, 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 HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: metastasis_M
- Format in the CDE tab of the HDR submission template: 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 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 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 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 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 ER Test result as noted in the EOM participant medical record system should be reported by the EOM participant. If more than one ER test result exists with a final status for a beneficiary associated with breast cancer, the earliest value during the episode should be reported. If no ER test result exists during the episode, report the ER test result closest to the start of the episode. The subsections below outline the options for reporting ER status and results.

Note: Results of ER testing should only be reported for a diagnosis of breast cancer. The ER data elements should remain blank if the cancer type reported is anything other than breast cancer.

4.8.4.1 Result of ER Test (Qualitative)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_estrogen_rec_status
- Status in the CDE tab of the HDR submission template: The reported result of the ER test represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template:
  i. Positive (1% - 100%)
  ii. Negative (0% or less than 1%)
  iii. Indeterminate (result cannot be determined; inconclusive)
  iv. Not Tested

In the FHIR 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 Logical Observation Identifiers Names and Codes (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 must be reported. The ER specified test performed must be reported 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 ER Test Specified (Required if Qualitative Result of ER Test is not provided)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_estrogen_rec_code
  - In the absence of a qualitative result of ER test, report the type of ER test performed.
- Status in the CDE tab of the HDR submission template: The reported result of the ER test specified represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template: The list below includes the LOINC values accepted for EOM clinical data submission.
  i. 14130-9 Estrogen receptor [Moles/mass] in Tissue
  ii. 14228-1 Cells.estrogen receptor/cells in Tissue by Immune stain
  iii. 85329-1 Cells.estrogen receptor/cells in Breast cancer specimen by Immune stain

In the FHIR 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 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/cells in Tissue by Immune stain
- 85329-1 Cells.estrogen receptor/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 ER Test Quantity (Required if Qualitative Result of ER Test is not provided)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_estrogen_rec_quantity
- Status in the CDE tab of the HDR submission template: The reported result of the ER test quantity represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template:
  i. Report as a valid numeric value up to two decimal places (for example, if the documented quantitative result of ER test is 95.242%, it should be reported as 95.24).
  ii. Quantitative results will be interpreted as follows:
  - Estrogen Receptor Positive (1% - 100%)
  - Estrogen Receptor Negative (0% or <1%)

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

- FHIR 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 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 PR Test result as noted in the EOM participant medical record system should be reported by the EOM participant. If more than one PR test result exists with a final status for a beneficiary associated with breast cancer, the earliest value during the episode should be reported. If no PR test result exists during the episode, report the PR test result closest to the start of the episode. The subsections below outline the options for reporting PR status and results.

Note: Results of PR testing should only be reported for a diagnosis of breast cancer. The PR data elements should remain blank if the cancer type reported is anything other than breast cancer.

4.8.5.1 Result of PR Test (Qualitative)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_progest_rec_status
- Status in the CDE tab of the HDR submission template: The reported result of the PR test represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template:
    i. Positive (1% - 100%)
    ii. Negative (0% or less than 1%)
    iii. Indeterminate (result cannot be determined; inconclusive)
    iv. Not Tested

In the FHIR 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 must be reported. The PR specified test performed must be reported 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 PR Test Specified (Required if Qualitative Result of PR Test is not provided)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_progest_rec_code
    - In the absence of a qualitative result of PR test, report the type of PR test performed.
- Status in the CDE tab of the HDR submission template: The reported result of the PR test specified represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template: The list below includes the LOINC values accepted for EOM clinical data submission.
    i. 10861-3 Progesterone receptor [Mass/mass] in Tissue
    ii. 31207-4 Progesterone receptor [Moles/mass] in Tissue
    iii. 14230-7 Cells.progesterone receptor/cells in Tissue by Immune stain
    iv. 85325-9 Cells.progesterone receptor/cells in Breast cancer specimen by Immune stain

In the FHIR 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 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/cells in Tissue by Immune stain
- 85325-9 Cells.progesterone receptor/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 PR Test Quantity (Required if Qualitative Result of PR Test is not provided)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: Tumor_marker_progest_rec_quantity
- Status in the CDE tab of the HDR submission template: The reported result of the PR test specified represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template:
  i. Report as a valid numeric value up to two decimal places (for example, if the documented quantitative result of PR test is 95.242%, it should be reported as 95.24).
  ii. Quantitative results will be interpreted as follows:
  - Progesterone Receptor Positive (1% – 100%)
  - Progesterone Receptor Negative (0% or <1%)

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

- FHIR 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 Human Epidermal Growth Factor Receptor 2 (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. If more than one HER2 status test result exists with a final status for a beneficiary associated

with breast cancer, the earliest value during the episode should be reported. If no HER2 test result exists during the episode, report the HER2 test result closest to the start of the episode. The subsections below outline the options for reporting HER2 status and results.

Note: Results of HER2 testing should only be reported for a diagnosis of breast cancer. The HER2 data elements should remain blank if the cancer type reported is anything other than breast cancer.

4.8.6.1 Result of HER2 Test (Qualitative)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_HER2_rec_status
- Status in the CDE tab of the HDR submission template: The reported result of the HER2 test represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template for HER2 testing validated by **immunohistochemistry (IHC) assay**:
  i. Positive
     - If IHC assay score of 3+, result is HER2 positive

  ii. Negative
     - If IHC assay result 1+, result is HER2 negative
     - If IHC assay result 0, result is HER2 negative

  iii. 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 fluorescence in situ hybridization (FISH) is performed, report the qualitative value of the HER2 by FISH test result (amplified/positive; non-amplified/negative).

  iv. Indeterminate (HER2 result cannot be determined; inconclusive)

  v. 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 must be reported. The specified HER2 by IHC test performed must be reported 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.

- Response in the CDE tab of the HDR submission template for HER2 testing validated by FISH:
  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. A 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 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 – LA11884-6
        - Not Tested – LA13538-6

4.8.6.2 HER2 Test Specified (Required if Qualitative Result of HER2 Test is not provided)

In the HDR submission template this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_HER2_rec_code
    - In the absence of qualitative test results for HER2 validated by IHC, report the type of HER2 by IHC quantitative test performed.
- Status in the CDE tab of the HDR submission template: The reported result of the HER2 test specified represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template: The list below includes the LOINC values accepted for EOM clinical data submission.
    i. 32996-1 HER2 [Mass/volume] in Serum
    ii. 72382-5 HER2 [Units/volume] in Tissue by Immunoassay
    iii. 42914-2 HER2 [Mass/volume] in Serum by Immunoassay

In the FHIR 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 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
        - 85319-2 HER2 [Presence] 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
        - 104279-5 ERBB2 gene mutations tested for 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 (Required if Qualitative Result of HER2 Test is not provided)

In the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: tumor_marker_HER2_rec_quantity
- Status in the CDE tab of the HDR submission template: The reported result of the HER2 test quantity represents a complete final status in the medical record.
- Response in the CDE tab of the HDR submission template:
  i. Report as a valid numeric value up to two decimal places (for example, if the documented quantitative result of HER2 test is 95.242%, it should be reported as 95.24).
  ii. Quantitative results will be interpreted as follows:
    - 3 = Positive (3+)
    - 2 = Equivocal (2+)
    - 1 = Negative (1+)
    - 0 = Negative (0)

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

- FHIR 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 attributed beneficiaries. The reported histology represents a complete final status in the medical record. If more than one histological examination is documented for a beneficiary associated with the attributed cancer type, the earliest value during the episode should be reported. If no histology exists during the episode, report the histology closest to the start of the episode.

Note: Due to the nature of prostate cancer, histology may be unknown upon arrival to the oncologist for treatment. Therefore, if histology results are not available for prostate cancer, leave the Histology field blank.

In the CDE tab of the HDR submission template, this CDE is consistent with the following components:

- CDE Data Element Label: histology
- Response options in CDE tab of the HDR submission template: textual (ICD-O-3)
  i. Report the specific histology for the attributed cancer type
  ii. If the specific histology does not correspond to the options available for the cancer type, report “Other Histology”

- **Important note for prostate cancer**: Leave the Histology data element blank if the specific histology is not documented.

Refer to the **EOM Clinical Data Elements Specifications** document (available on EOM Connect) for the calendar year in which your data will be submitted for a list of histology descriptions and codes which will be available in the HDR submission template.

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

- FHIR API (mCODE):
  i. Response:
     - ICD-O-3 codes in addition to a subset of SNOMED CT Codes as defined in the Primary Cancer Condition Profile.
  ii. **Important note for prostate cancer**:
     - Leave the Histology data element blank if the specific histology is not documented.
  iii. FHIR Data Element: mCODE condition.extension:histologyMorphologyBehavior
  iv. 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

Acronym	Literal Translation
AJCC	American Joint Commission on Cancer
API	Application Programming Interface
ASTP/ONC	Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology
CDE	Clinical Data Element
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
EOM	Enhancing Oncology Model
E&M	Evaluation and Management
ER	Estrogen Receptor
ESRD	End Stage Renal Disease
FFS	Fee-For-Service
FHIR	Fast Healthcare Interoperability Resources
FISH	Fluorescence in situ Hybridization
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
ICD-O-3	International Classification of Diseases for Oncology, Third Edition
IG	Implementation Guide
IHC	Immunohistochemistry
ISP	Innovation Support Platform
LOINC	Logical Observation Identifiers Names and Codes
MBI	Medicare Beneficiary Identifier
mCODE	Minimal Common Oncology Data Elements
NDC	National Drug Codes
OCM	Oncology Care Model
PGP	Physician Group Practice
PP	Performance Period
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

Revision History

Revision #	Revision Date	Description of Change
1.0	June 1, 2023	Initial Version
1.1	July 20, 2023	Section 4.2: Updated the section title from "EOM-PGP-ID" to "EOM-ID." Section 4.3.4: Updated the section title and data element name from "Beneficiary Date of Birth" to "Date of Birth." 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." Section 4.8.3 Metastasis (M): updated the example noted within the data element description. Section 4.8.4 Result of Estrogen Receptor (ER) Test: removed response option, "Not Performed (Not Tested)." Section 4.8.5 Result of Progesterone Receptor (PR) Test: removed response option, "Not Performed (Not Tested." Section 4.8.6 Result of HER2 Test: removed the response option, "Not Performed (Not Tested)".
2.0	January 8, 2024	Introduction: Updated content to align with EOM Payment Methodology verbiage and EOM guides. Section 1 EOM CDE Overview - Episodes and Performance Periods: Updated verbiage to include reporting of PP2 in Spring 2025 in current reporting cycle. Section 2.2 Identifying EOM-Attributed Beneficiaries: Updated name of section; updated location of new list of EOM initiating therapies. Section 3: Renamed Excel template to CDE Data Submission Template. Table 2: Updated Current or History of Metastatic Disease and added new CDE, History of Metastatic Cancer. Section 3.3 EOM Health Data Reporting (HDR) Application: Updated description of the EOM HDR Application. Table 3: Updated content to reflect naming of CDEs to be consistent with naming in CDE Data Submission Template. Section 4.7.3 Recurrence or Relapse Clinical Status: Updated responses for both reporting options. 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.

Revision #	Revision Date	Description of Change
		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. Section 4.8.3 Metastasis (M): Added information regarding clinical adjusters. 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. Added Subsection 4.8.4.1 Estrogen Receptor (ER) Test Specified. Added Subsection 4.8.4.2 Estrogen Receptor (ER) Test Quantity. 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. Added Subsection 4.8.5.1 Progesterone Receptor (PR) Test Specified Added Subsection 4.8.5.2 Progesterone Receptor (PR) Test Quantity Section 4.8.6 Result of HER2 Test: Updated to include guidance of qualitative and quantitative test codes and values for both reporting options. Added Subsection 4.8.6.1 HER2 Test Specified Added Subsection 4.8.6.2 HER2 Test Quantity 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.
2.1	June 5, 2024	Introduction: Updated verbiage to clarify content in option 2. Added information about the EOM IG and the use of mCode. Table 1: Performance Periods and Episodes Added PP10, PP11, PP12 and PP13. Section 3.3: Updated information regarding the EOM Implementation Guide. Section 4.3.5 Beneficiary Sex: Updated the FHIR data element to patient.gender. Section 4.7.5 Current or History of Metastatic Disease (PP1 CDE Data Submission Template Only) and History of Metastatic Cancer (all Performance Periods): Updated content to include a reference to the EOM Payment Methodology document.

Revision #	Revision Date	Description of Change
		Section 4.8.1 Primary Tumor (T): Updated to clarify this is only required if applicable, and that it may remain blank if not applicable. Section 4.8.2 Nodal Disease (N): Updated to clarify this is only required if applicable, and that it may remain blank if not applicable. Section 4.8.3 Metastasis (M): Updated to clarify this is only required if applicable, and that it may remain blank if not applicable. Section 4.8.4.3 Estrogen Receptor (ER) Test Quantity (Optional): Updated guidance for reporting percentage values. Section 4.8.5.3 Progesterone Receptor (PR) Test Quantity (Optional): Updated guidance for reporting percentage values. Section 4.8.6.3 HER2 Test Quantity (Optional): Updated guidance for reporting percentage values.
2.2	November 22, 2024	Updated "Data submission template" to "HDR submission template" throughout. Introduction: Updated to reflect the HDR data submission template includes a tab for reporting SDE data and a tab for reporting CDE data. Section 2 CDE Reporting Requirements: Added information about reporting during the true-up reconciliation. Section 2.1 EOM Participant Reporting Criteria: Updated to specify the reporting requirement is "90% or such other percentage as specified by CMS in writing" and added a footnote regarding the PP1 CDE reporting requirement flexibility. Section 3.3 EOM HDR Application: Updated Table 3 to align with the removal of "Patient Deceased" and removed guidance indicating participants must report all CDE data using either the HDR submission template OR the FHIR API. Information about HDR testing period added. Sections 4.3.4, 4.4.2, 4.4.3, 4.6, 4.7.1, 4.7.5: Updated to remove "Numeric." Section 4.7.1 Patient Deceased: and Patient Deceased Date sections were combined, with the Patient Deceased element removed. Section 4.7.2 Recurrence or Relapse: Updated to provide guidance for reporting. Section 4.8 Cancer-specific Data: Updated to include further TMN reporting guidance. Section 4.8.1, 4.8.2 and 4.8.3: Updated the Primary Tumor (T), Nodal Disease (N), and Metastasis (M)

Revision #	Revision Date	Description of Change
		sections to provide guidance on what to report in the absence of the "c" or "p" prefix. Section 4.8.3 Metastasis (M): Removed reference to MX and updated to include further reporting guidance. Section 4.8.4, 4.8.5, and 4.8.6: Updated to add a note with reporting guidance for all cancer types that are not breast cancer. Section 4.8.6.2 HER 2 Specified: Updated to remove three codes from the FHIR value set. Section 4.8.7 Histology: Updated to include optional reporting of histology for prostate cancer.
2.3	June 6, 2025	Table 1: Performance Periods and Episodes updated to differentiate the Cohort 1 and Cohort 2 reporting requirements and add True-up reporting timelines. Section 3.1: Footnote updated for clarification on reporting of histology for prostate cancer. Section 3.2 Clinical Data Elements and Section 3.3 EOM HDR Application: Updated to replace references to a sample template and Intelligent Tool with sample HDR submission template. Section 4.7.4 History of Metastatic Cancer: FHIR value updated. Section 4.8.7: Updated for clarification on reporting of histology for prostate cancer.
2.4	November 25. 2025	Revision History: Moved to the end of the document. Section 2.2 Figure 1 Identification of Potential EOM-attributed Beneficiaries: The terminal box was updated to remove "Reporting Clinical Data Elements" for better clarity. Sections 4.7.4 History of Metastatic Cancer, 4.8.4.2 ER Test Specified, and 4.8.5.2 PR Test Specified: Updated code descriptions. Section 4.8.1 Primary Tumor (T), 4.8.2 Nodal Disease (N), and 4.8.3 Metastasis (M): Removed "the EOM participant can report "Not Applicable" in the HDR submission template" as "Not Applicable" is not a valid option. Sections 4.8.4.2, 4.8.4.3, 4.8.5.2, 4.8.5.3, 4.8.6.2, and 4.8.6.3: Updated the section titles for ER, PR and HER2 Test Specified and Test Quantity from including "Optional" to indicate the data element is required if the qualitative result is not provided. Section 4.8.6.1 Result of HER2 Test (Qualitative): Updated LOINC code from Indeterminate – LA118884-6 to Indeterminate – LA11884-6.

Revision #	Revision Date	Description of Change
		Section 4.8.6.2 HER2 Test Specified: Added LOINC code 104279-5 to the FHIR API values. Section 4.8.7 Histology: Reference to the EOM Clinical Data Elements Specifications document was updated from Performance Period Specific to Calendar Year Specific.