ONCOLOGY CARE MODEL

OCM STAGING AND CLINICAL DATA OVERVIEW PP7

Version 2.1.1
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Note: This version of the OCM Staging and Clinical Data Overview is to be used for reporting Performance Period (PP) 7 data to the OCM Data Registry. For patients who were previously reported who continue to be in an active episode during this time period, practices should make any updates that are needed. Practices may utilize the OCMR Staging Abstraction Tool PP7 v2.1.1 and the OCMR Staging Upload Template PP7 v2.0 for reporting PP7 data. Practices will be notified when data from this version can be submitted to the OCM Data Registry. Practices should continue submitting data included in this version until notified that an updated version has been released and the data are able to be submitted to the OCM Data Registry.

COVID-19 PHE Notes:
In response to COVID-19, staging and clinical data reporting will be optional for PP6, PP7, PP8, and PP9. If a practice has elected to not report staging and clinical data for the affected performance periods (PP6, PP7, PP8, and PP9), one of the practice's Primary or Secondary POCs will need to notify CMMI of that decision by contacting OCMSupport@cms.hhs.gov prior to the submission deadline for the performance period.

If a practice elects to not report staging and clinical data in PP7, PP8, and PP9, the metastatic adjustment will not be included in the reconciliation calculation. That is, the practice's benchmark would not be adjusted for metastatic status of its beneficiaries. (The benchmarking methodology would be the same as in PP6.) In order to receive the metastatic adjustment starting in PP7, practices must report staging and clinical data on at least 75% of their attributed beneficiaries.

Introduction

The "OCM Staging and Clinical Data Overview" provides information to Oncology Care Model (OCM) Participants regarding required staging and clinical data collected on OCM Fee-For-Service (FFS) Beneficiaries through the OCM Data Registry.

The primary objectives of this document are to:

1. Outline which staging and clinical data are required, as applicable for each cancer bundle.
2. Provide information regarding results or values that may be required for reporting.
3. Provide additional information regarding how data may be submitted to support collection of staging and clinical data.

Practices may also reference the "OCM Staging and Clinical Data Specifications" document which contains the data elements and detailed code values (e.g., TNM, LOINC®, ICD-O-3, SNOMED CT®) acceptable for all clinical and staging data that are supported by electronic data transmission.

The "OCM Staging and Clinical Data Overview" document covers staging and clinical data only; additional quality measure data must also be reported in the OCM Data Registry. Information on the specific quality measure data to be reported may be found in the "OCM Quality Measures Guide," "OCM Measure Specifications" and the "OCM Tech Spec Value Set" document.

Note: All documents referenced within this guide are located on OCM Connect.

Section 1: Requirements for Reporting Staging and Clinical Data

COVID-19 PHE Notes:
In response to COVID-19, staging and clinical data reporting will be optional for PP6, PP7, PP8, and PP9. If a practice has elected to not report staging and clinical data for the affected performance periods (PP6, PP7, PP8, and PP9), one of the practice's Primary or Secondary POCs will need to notify CMMI of that decision by contacting OCMSupport@cms.hhs.gov prior to the submission deadline for the performance period.

If a practice elects to not report staging and clinical data in PP7, PP8, and PP9, the metastatic adjustment will not be included in the reconciliation calculation. That is, the practice's benchmark would not be adjusted for metastatic status of its beneficiaries. (The benchmarking methodology would be the same as in PP6.) In order to receive the metastatic adjustment starting in PP7, practices must report staging and clinical data on at least 75% of their attributed beneficiaries.

CMS requires OCM Participants to report demographics and staging and clinical data on all patients meeting the OCM FFS Beneficiary identification criteria. These criteria can be found in Section 1.1. Beginning with episodes active on January 1, 2017, OCM Participants are required to report staging and clinical data including biomarker and molecular mutation data and Current Clinical Status, as appropriate for the specified cancer at the OCM FFS Beneficiary patient level. OCM Participants should report these data upon initial entry for an OCM FFS Beneficiary into the OCM Data Registry for each performance period, as described in Section 1.2.

OCM Participants will have 30 days from attribution data being available in the OCM Data Registry for each respective performance period to report or update the OCM Data Registry to ensure complete patient demographic, staging and clinical data have been reported for all attributed beneficiaries, as appropriate for the specified cancer bundle.

1.1 Identification of OCM FFS Beneficiaries

OCM Participants are required to report staging and clinical data on a semiannual basis, within 30 days of attribution data being made available in the OCM Data Registry for each performance period. Since attribution is retrospective, CMS identification of which beneficiaries require staging and clinical data reporting will occur after episodes have finished. It is recommended that practices collect staging and clinical data during the course of care delivery to be prepared for reporting later. The criteria below can help practices identify potential OCM FFS Beneficiaries prior to attribution.

To identify potential OCM FFS Beneficiaries with an associated qualifying episode, OCM Participants must:

1. Identify patients that have a qualifying cancer diagnosis code.

   Note: A general list of qualifying ICD-10-CM diagnosis codes utilized within the OCM program for episode identification is located in the "OCM Cancer Type Mapping and Codes" document. Each document includes cancer types (bundles) that are both eligible and ineligible for performance-based payments. OCM Participants are required to report on all cancer types included in the table, regardless of payment eligibility. Detailed lists of all diagnosis codes are located in the "OCM

Staging and Clinical Data Specifications PP7 v2.1.1" document.

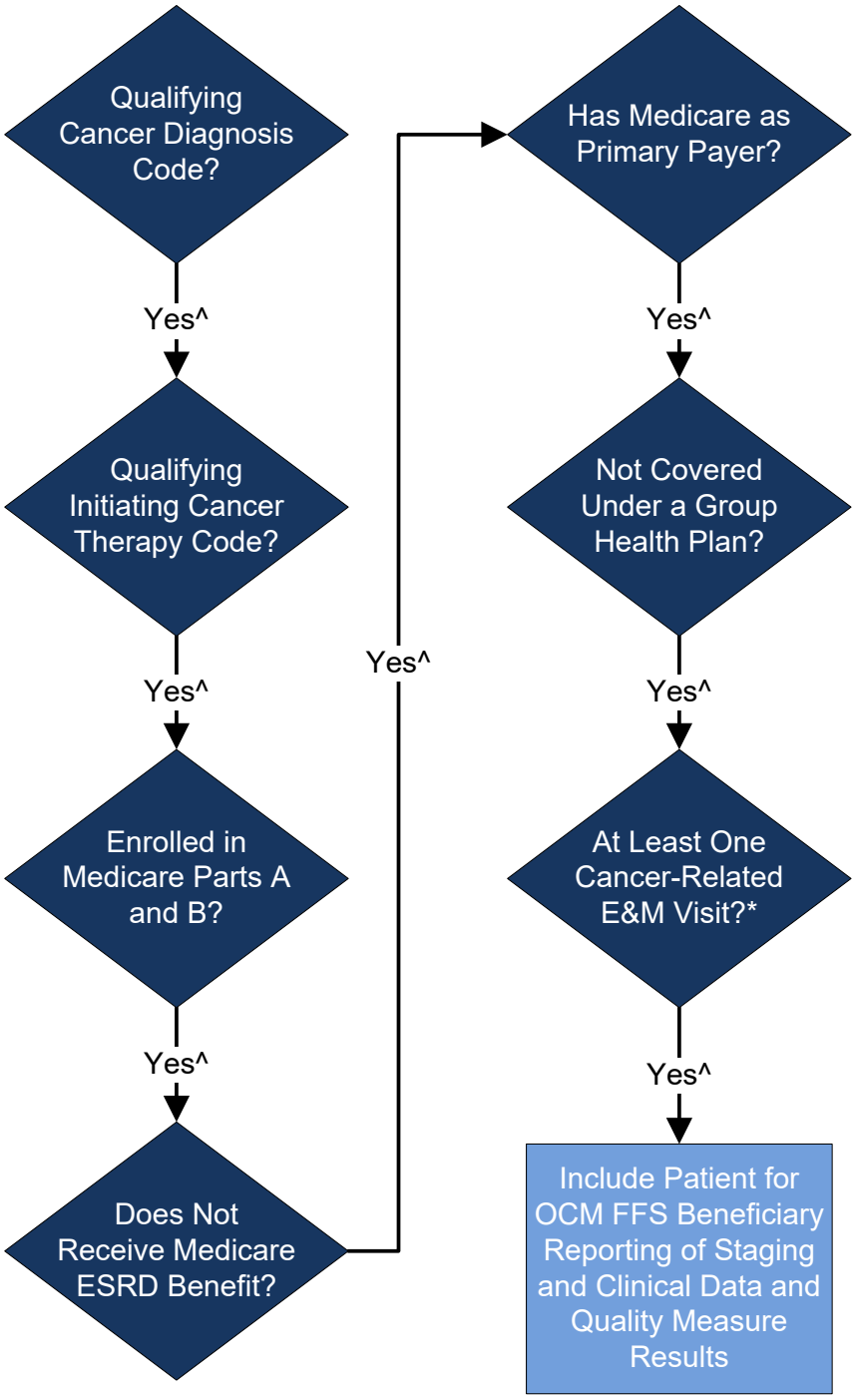
2. Of the patients identified above with a qualifying cancer diagnosis code, identify those that have a qualifying initiating cancer therapy code. Receipt of this qualifying initiating cancer therapy code triggers the beginning of an episode. Once an episode has begun, it will last for six calendar months. If a beneficiary enters hospice during the episode, the OCM Participant is only required to report staging and clinical data through the initiation of hospice. If the beneficiary leaves hospice before the six-month episode has ended, the OCM Participant is required to resume reporting.

   Note: A list of Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Codes (NDCs) which have been identified as qualifying initiating cancer therapy codes is located in the "OCM Initiating Cancer Therapies" document.

3. Of the patients identified above with a qualifying cancer diagnosis code, identify those that meet the following criteria:

   a. Beneficiary is enrolled in Medicare Parts A and B;
   b. Beneficiary does not receive the Medicare End Stage Renal Disease (ESRD) benefit;
   c. Beneficiary has Medicare as his or her primary payer;
   d. Beneficiary is not covered under Medicare Advantage or any other group health program;
   e. Beneficiary has at least one cancer-related Evaluation & Management (E&M) visit during the six-month episode, defined as HCPCS codes in the ranges 99201-99205 and 99211-99215.
      Note: The goal is that the practice which primarily manages the oncology care of the OCM FFS Beneficiary is the practice that will report on the patient.

Figure 1: Identification of OCM FFS Beneficiaries



* The practice which primarily manages the oncology care of the patient is the practice that will report on the patient.

^ If any of these criteria is answered "No," the patient does not qualify as an OCM FFS Beneficiary.

1.2 OCM Data Registry Reporting for Staging and Clinical Data

OCM Participants are required to utilize a centralized data registry (OCM Data Registry) for staging and clinical data reporting. CMS has contracted with CORMAC, Premier, and Deloitte to provide the OCM Data Registry, which is a web-based data submission and collection tool. A separate user manual for the OCM Data Registry is available to guide OCM Participants through the detailed process of reporting data to the OCM Data Registry.

1.2.1 OCM Demographics

OCM Participants are required to report OCM FFS Beneficiary demographic data including:

- Patient Health Insurance Claim Number (HICN)/Medicare Beneficiary Identifier (MBI)
- Patient First Name
- Patient Last Name
- Patient Gender
- Patient Date of Birth

Demographic data may be reported using the following methods:

- Manual entry
- Upload the "OCMR Patient Upload File v1.1"

1.2.2 Staging and Clinical Data

All staging and clinical data, unless identified as optional for the cancer diagnosis, are required. All required staging and clinical data elements must be reported for the patient record to be marked complete in the OCM Data Registry. The staging and clinical data elements are listed in Section 2 and details can be found in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document. Staging and clinical data may be reported using the following methods:

- Manual entry
- Upload the "OCMR Staging Abstraction Tool PP7 v2.1.1"
- Upload the "OCMR Staging Upload Template PP7 v2.0"

Section 2: Detailed Staging and Clinical Data Requirements

COVID-19 PHE Notes:
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If a practice elects to not report staging and clinical data in PP7, PP8, and PP9, the metastatic adjustment will not be included in the reconciliation calculation. That is, the practice's benchmark would not be adjusted for metastatic status of its beneficiaries. (The benchmarking methodology would be the same as in PP6.) In order to receive the metastatic adjustment starting in PP7, practices must report staging and clinical data on at least 75% of their attributed beneficiaries.

This section provides the detailed requirements for collection and reporting of staging and clinical data by major cancer bundles for OCM FFS Beneficiaries required for reporting for each performance period. Each subsection provides an itemized listing of the data required for that cancer bundle, as well as vocabularies accepted for electronic submission of data. A general list of qualifying ICD-10-CM diagnosis codes utilized within the OCM program is in the "OCM Cancer Type Mapping and Codes" document. A detailed list of all diagnosis codes is in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document. All staging data relevant to the diagnosis is required in the OCM Data Registry unless identified as being optional. Cancer bundles that are not reconciliation eligible (Monthly Enhanced Oncology Services [MEOS] only) require the diagnosis code and initial diagnosis date to be reported. Other staging and clinical data elements will not be required.

All staging and clinical data may be electronically submitted using the "OCMR Staging Abstraction Tool PP7 v2.1.1" or the "OCMR Staging Upload Template PP7 v2.0".

2.1 All Cancer Bundles

Regardless of the cancer bundle, the following data are required to be reported to the OCM Data Registry for patients meeting the OCM FFS Beneficiary identification criteria:

- Cancer Bundle
  - Requires entry of valid ICD-10-CM diagnosis code
- Initial Diagnosis Date

2.2 Current Clinical Status

- Current Clinical Status values are required for all cancer bundles **except** the following:
  - MEOS-only diagnosis codes
- Current Clinical Status and date should be updated whenever there is a change in the patient's Current Clinical Status, or at minimum, should be reviewed and reported at least once for each episode even if the patient's Current Clinical Status didn't change from the prior episode. Practices should report the current clinical status history that documents the historical updates to the patient's disease, if they occur outside the episode dates as well. Current Clinical Status values of "Progressive Disease", "Metastasis", and "Local or Regional Recurrence/Relapse" capture the therapy the patient is receiving is not working, and are important to report if applicable for the patient's diagnosis. Practices are not limited in the number of statuses that can be reported, either within an episode or outside episode dates.
- Response options include the following:
  - Initial Diagnosis
  - No Evidence of Disease/Remission
  - Responding
  - Stable Disease
  - Progressive Disease
  - Metastasis
  - Local or Regional Recurrence/Relapse
  - Deceased

2.2.1 Current Clinical Status Definitions

All cancer bundles except MEOS-only diagnosis codes require the patient's Current Clinical Status and associated date to be reported. The Current Clinical Status options and definitions are listed below:

- **Initial Diagnosis:** Any patient whose treatment of the disease has started, and the disease has not been re-evaluated since treatment began. Once the disease has been re-assessed after diagnosis (e.g., diagnostic scans or bone marrow aspirate/biopsy), the patient should no longer be included in this category.

- **No Evidence of Disease/Remission:** When radiological examinations or complete surgical resection of tumor with negative margins show 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.

- **Responding:** Cancer that is decreasing in extent or severity in response to current treatment (including if there has been a previous recurrence/relapse).
- **Stable Disease:** Cancer that is neither decreasing nor increasing in extent or severity (including if there has been a previous recurrence/relapse).

- **Progressive Disease:** Cancer 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.

- **Metastasis:** Evidence of cancer in a site other than the primary tumor site that was not present at initial diagnosis or initial relapse (including if the patient becomes metastatic after the initial diagnosis).

- **Local or Regional Recurrence/Relapse:** 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.

- **Deceased:** Patient is deceased. Record the date of death of the patient.

2.3 TNM Staging Data

Reporting of TNM staging data is required for a number of cancer bundles. The most precise, detailed documentation of staging should be used to reflect the most accurate staging information available for the patient. When a pathology or cytology report is available, that should be the source of the initial staging and clinical data that is reported. If there is no pathology or cytology report, any clinical documentation that is available should be used. For some cancer bundles, the TNM values for certain diagnoses are reported differently or are not required. These variations are reflected in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document and consists of both the AJCC Cancer Staging 7th edition and 8th edition TNM values as determined by the date of initial diagnosis.

Additional resources for TNM staging can be found on the AJCC Website.

Entry or submission of TNM values are required as follows:

- Primary Tumor

- "T" values are required for specific diagnosis codes where applicable **except** the following reconciliation-eligible cancer bundles:
  - Acute Leukemia Group
  - Anal Carcinoma Group (C21.2)
  - Bladder Cancer Group (specific diagnosis codes)
  - Chronic Leukemia Group
  - CNS Tumor Group
  - Endocrine Tumor Group (specific diagnosis codes)
  - Head and Neck Cancer Group (specific diagnosis codes)
  - Liver Cancer Group (specific diagnosis codes)
  - Lung Cancer Group (specific diagnosis codes)
  - Lymphoma Group (specific diagnosis codes)
  - MDS Group
  - Multiple Myeloma Group
  - Small Intestine/Colorectal Cancer Group (C17.3)
- Valid AJCC "T" values may be transmitted through data upload
- Examples of valid AJCC "T" values include:
  - TX, T0, T1, T2, T3, T4
- "T" values are specific to the cancer bundle based on AJCC staging guidelines.
- Detailed "T" values for each reconciliation-eligible cancer bundle are available in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document.

- Nodal Disease
  - "N" values are required for specific diagnosis codes where applicable **except** the following reconciliation-eligible cancer bundles:
    - Acute Leukemia Group
    - Anal Carcinoma Group (C21.2)
    - Bladder Cancer Group (specific diagnosis codes)
    - Chronic Leukemia Group
    - CNS Tumor Group
    - Endocrine Tumor Group (specific diagnosis codes)
    - Head and Neck Cancer Group (specific diagnosis codes)
    - Liver Cancer Group (specific diagnosis codes)
    - Lung Cancer Group (specific diagnosis codes)
    - Lymphoma Group (specific diagnosis codes)
    - MDS Group
    - Multiple Myeloma Group
    - Small Intestine/Colorectal Cancer Group (C17.3)
  - Valid AJCC "N" values may be transmitted through data upload
  - Examples of valid "N" values include:
    - NX, N0, N1, N2, N3
  - "N" values are specific to the cancer bundle based on AJCC staging guidelines
  - Detailed "N" values for each cancer bundle are available in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document.

- Metastasis
  - "M" values are required for specific diagnosis codes where applicable **except** the following reconciliation-eligible cancer bundles:
    - Acute Leukemia Group
    - Anal Carcinoma Group (C21.2)
    - Bladder Cancer Group (specific diagnosis codes)
    - Chronic Leukemia Group
    - CNS Tumor Group
    - Endocrine Tumor Group (specific diagnosis codes)
    - Head and Neck Cancer Group (specific diagnosis codes)
    - Liver Cancer Group (specific diagnosis codes)
    - Lung Cancer Group (specific diagnosis codes)
    - Lymphoma Group (specific diagnosis codes)
    - MDS Group
    - Multiple Myeloma Group
    - Small Intestine/Colorectal Cancer Group (C17.3)
  - For all cancer bundles, valid AJCC "M" values may be transmitted through data upload
  - Examples of valid "M" values include:
    - M0, M1
  - "M" values are specific to the cancer bundle based on AJCC staging guidelines
  - Detailed "M" values for each cancer bundle are available in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document.

2.4 Revised ISS Stage

Revised ISS (R-ISS) staging data are required for the Multiple Myeloma Group only. Additional information regarding R-ISS staging can be found on the Cancer Network Website.

- R-ISS data collection is limited to the following options:
  - Stage I
  - Stage II
  - Stage III
  - None Selected

2.5 Tumor Type and Tumor Grade

- Tumor Type is collected for the following cancer bundles with the selection options noted below:
  - CNS Tumor Group
    - Astrocytoma
    - Ependymoma
    - Oligodendroglioma
    - Embryonal tumors
    - CNS lymphoma
    - Germ cell tumors
    - Other
    - None Selected
  - Lymphoma Group

        - CNS Lymphoma (Primary central nervous system lymphoma)
        - None Selected
    - Select SNOMED CT® Tumor Type values may be transmitted through data upload
- Tumor Grade is collected for the following cancer bundle with the selection options noted below:
    - CNS Tumor Group
        - I
        - II
        - III
        - IV
        - None Selected

2.6 Resection

- Resection is collected for the following cancer bundles with the selection options noted below:
    - CNS Tumor Group and Lymphoma Group
        - Biopsy
        - Partial Resection
        - Gross Total Resection
        - None Selected
    - Note: For Lymphoma Group, Resection is required when Tumor Type is CNS lymphoma.

2.7 Clinical Stage

- Clinical Stage is collected for the following cancer bundles with the selection options noted below:
    - CNS Tumor Group
        - Local extension
        - Distant CNS spread
        - Extra-neural spread
        - None Selected
    - Lymphoma Group (specific diagnosis codes involving Hodgkin Lymphoma (C81.00-C81.99)
        - None Selected
        - IA
        - IB
        - IEA
        - IEB
        - IIA
        - IIB
        - IIEA
        - IIEB
        - IIIA
        - IIIB
        - IVA
        - IVB
    - Lymphoma Group (specific diagnosis codes involving Non-Hodgkin Lymphoma)
        - None Selected
        - I

        - IE
        - II
        - IIE
        - III
        - IV
    - Note: Diagnosis codes within the Lymphoma Group which have a Tumor Type of CNS lymphoma do not require reporting of Clinical Stage.
    - Information on staging lymphoma is available on the following websites:

Lymphoma - Hodgkin: Stages | Cancer.Net
Lymphoma - Non-Hodgkin: Stages | Cancer.Net

2.8 Molecular Mutations

Molecular mutations are collected for the following cancer bundles with the selected options noted below:

1. EGFR Activating Mutation, ALK Gene Mutation, ROS1 Gene Mutation
    - Lung Cancer Group (specific diagnosis codes)
    - EGFR Activating Mutation, ALK Gene Mutation, ROS1 Gene Mutation options:
        - None Selected
        - Positive /POS
        - Negative /NEG
        - Not Tested
    - Valid LOINC® code may be transmitted through data upload
2. KRAS Mutation and NRAS Mutation
    - Small Intestine/Colorectal Cancer Group (specific diagnosis codes)
    - KRAS Mutation and NRAS Mutation options:
        - None Selected
        - Positive /POS
        - Negative /NEG
        - Not Tested
    - Valid LOINC® code may be transmitted through data upload.
3. BRAF Mutation
    - Malignant Melanoma Group
        - BRAF Mutation options:
            - None Selected
            - Positive (mutation present) /POS
            - Negative (wild type) /NEG
            - Not Tested
        - Valid LOINC® code may be transmitted through data upload
    - Small Intestine/Colorectal Cancer Group (specific diagnosis codes)
        - BRAF Mutation options:
            - None Selected
            - Positive /POS
            - Negative /NEG

        - Not Tested
    - Valid LOINC® code may be transmitted through data upload

4. BRCA1 Result and BRCA2 Result
    - Breast Cancer Group
    - Ovarian Cancer Group
    - BRCA1 Result and BRCA2 Result options:
        - None Selected
        - Positive /POS
        - Negative /NEG
        - Not Tested
    - Valid LOINC® code may be transmitted through data upload
5. IDH2 Result
    - Acute Leukemia Group (specific diagnosis codes)
    - IDH2 Result options:
        - None Selected
        - Positive /POS
        - Negative /NEG
        - Not Tested
6. FLT3 Result
    - Acute Leukemia Group (specific diagnosis codes)
    - FLT3 Result options:
        - None Selected
        - Low Risk
        - High Risk
        - Not Tested
    - Valid LOINC® code may be transmitted through data upload
7. dMMR Result
    - Required for the following cancer bundles:
        - Female GU Cancer other than Ovary Group
        - Small Intestine/Colorectal Cancer Group (specific diagnosis codes)
    - Optional for the following cancer bundles:
        - Anal Carcinoma Group
        - Bladder Cancer Group
        - Breast Cancer Group
        - CNS Tumor Group
        - Endocrine Tumor Group
        - Gastro/Esophageal Cancer Group
        - Head and Neck Cancer Group
        - Kidney Cancer Group
        - Liver Cancer Group
        - Lung Cancer Group
        - Malignant Melanoma Group
        - Ovarian Cancer Group
        - Pancreatic Cancer Group
        - Prostate Cancer Group

  - Small Intestine/Colorectal Cancer Group (specific diagnosis codes)
- dMMR Result options:
  - None Selected
  - Positive (Expressed) /POS
  - Negative (Absent) /NEG
  - Not Tested
- Valid LOINC® code may be transmitted through data upload

2.9 Hormone Receptor Status

Hormone receptor statuses are collected for the following cancer bundles with the selection options noted below:

- Gastro/Esophageal Cancer Group
  - HER2 Amplification
- Breast Cancer Group
  - Estrogen Receptor
  - Progesterone Receptor
  - HER2 Amplification
- The OCM Data Registry is collecting the following results, as appropriate for each test type:
  - None Selected
  - Positive /POS
  - Negative /NEG
  - Equivocal /EQU (for HER2 Amplification only)
  - Not Tested
- Valid LOINC® codes and corresponding results, SNOMED CT®, ICD-9-CM, and ICD-10-CM may be transmitted through data upload.
- Detailed codes used within OCM for each cancer bundle are available in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document.

2.10 Histology

Histology is collected for the following cancer bundles with the selection options noted below:

- Gastro/Esophageal Cancer Group (specific diagnosis codes)
  - None Selected
  - Adenocarcinoma
  - Squamous cell carcinoma
  - Other
- Lung Cancer Group (specific diagnosis codes)
  - None Selected
  - Small Cell Lung Cancer
  - Other
  - NSCLC – Squamous Cell
  - NSCLC – Adenocarcinoma
  - NSCLC – Large Cell
- Breast Cancer Group
  - None Selected

  - Inflammatory
  - Other
- Select ICD-O-3 codes accepted for the histology specified:
  - Detailed codes used within OCM for each cancer bundle is available in the "OCM Staging and Clinical Data Specifications PP7 v2.1.1" document.

2.11 Prognostic Multi-Gene Assay Tests and Results

The practice must indicate if Prognostic Multi-Gene Assay testing was performed and the result(s) of the test(s). When reporting clinical and staging data for breast cancer patients who may have had prognostic multi-gene assay tests performed, if the results of the gene assay test are not available, or the results are not available in the numeric format required by the Registry, please report "Yes" to the prognostic multi-gene assay question, and leave the specific gene assay result field blank. Staging and clinical data reporting for breast cancer patients will be considered complete even if the specific gene assay results are not provided. This functionality in the OCM Data Registry will be updated in a future release.

- Prognostic Multi-Gene Assay testing is collected for the following cancer bundle:
  - Breast Cancer Group
- Prognostic Multi-Gene Assay performed options:
  - Yes
  - No
- Prognostic Multi-Gene Assay test(s) and result(s) options:
  - MammaPrint ® Result
    - Enter valid value: -1.000 to 1.000
  - Oncotype Dx ® Result
    - Enter valid value: 0 to 100
  - Prosigna ® Result
    - Enter valid value: 0 to 100