ASCO QOPI
Quality Oncology Practice Initiative

QOPI® 2018 Data Elements

CORE + Breast Modules

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Chart ID		
Site		
Managing/Treating Physician (optional)		
Primary Site Anatomic site of the cancer diagnosis • 4-digit or 5-digit ICD-10-CM code for the patient's most recent or primary diagnosis (principal neoplastic disease code)	• Do not enter ICD-10 codes related to symptoms or toxicities. • ICD-10 codes are only accepted if within the invasive malignancy range provided. • Use the most relevant code for the purpose of the abstraction. For example, use the code for the patient's specific type of cancer, even if the most recent recorded visit denotes some other condition. • The ICD-10 code selected will determine which pre-selected modules are applicable to the chart. For example, if your site selected the breast cancer module and C50.219 is entered, the chart will be tagged for the breast cancer module and all applicable questions will open for that chart. If the breast cancer module wasn't selected, the chart will be tagged as "Other" and will only be applicable to the core data elements and any domain modules selected. • For charts of patients diagnosed in the 16-month period, exclude patients with simultaneous bilateral breast cancer or 2 distinct cancers in one breast. • Exclude cases with ductal or lobular carcinoma in situ (DCIS) only. Cases with invasive malignancy and DCIS may be included and abstraction should focus on the invasive malignancy only. • Male breast cancer is C50.92x. Charts of male patients with invasive breast cancer may be abstracted for QOPI but will not apply to the breast cancer module. • Breast: C50.x (Female breast cancer). • Colorectal: invasive adenocarcinoma of the colon: C18.x (C18.1 cancer of the appendix will be excluded from several colorectal measures), C19 or rectum: C20.x, C21.x • NSCLC: Non-small cell only: C34.x. • NHL: C82.x, C83, C84, C85, C86. Indolent NHL may be included. • GYNONC: Primary peritoneal: C48.1, C48.2, C48.8, Ovarian: C56.x, Fallopian tube: C57, C57.01, C57.02 • Prostate: C61, C61.0, C61.00 • SCLC: Small cell only: C34.x	☐ ICD _____

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	• Other: Other invasive malignancy for chart selected for domain specific modules (C00.xx-C7A.1, D46.x, D46.22, D46.C, D46.9, R18.0) • Exclude C80.2, C88.8, C90.02, C90.12, C90.22, C90.32, C91.02, C91.12, C91.32, C91.42, C91.52, C91.62, C91.A2, C91.Z2, C91.92, C92.02, C92.22, C92.32, C92.42, C92.52, C92.62, C92.Z2, C92.92, C93.02, C93.12, C93.32, C93.92, C93.Z0, C93.Z2, C94.02, C94.21, C94.22, C94.32, C94.42, C94.82, C95.02, C95.12, C95.92, D45. These codes are for disease relapse and are not appropriate for the QOPI sample. • Solid Tumor (Top 5): C00.0 - C76.8, C80.0 - C83.38, C96.4, C96.9, C96.Z, C92.30,C92.31, C75 - C7B.8 (Excludes multiple myeloma (C90.0 - C90.01), leukemia (C90.10 - C95.92) lymphoma (C81.00 - C86.6), MDS (D47.3 - D47.Z9), and malignant ascites (R18.0)	
Chart ID	System generated	
Chart Creation Date	System generated	
Chart Last Saved Date	System generated	
Chart Abstraction Date	System generated	
Chart Last Saved By	System generated	
Chart Saved/Submitted	System generated	
Chart Profile		
Date of Diagnosis • Date of collection of first specimen in which a pathologist confirms invasive cancer. • To be included in QOPI, the date of diagnosis must occur within the 16-month period (**7/1/2017 - 10/31/2018**), except for EOL, prostate cancer, and cases that qualify for the palliative care module.	• Refer to the pathology or cytology report and record the date the specimen was collected (not the date of the report). • In the absence of a specimen date, record any documentation regarding date of initial diagnosis (e.g., a practitioner's notation). • To be included in QOPI, the date of diagnosis must occur within the 16-month period (**7/1/2017 - 10/31/2018**). - Exceptions: o EOL: For deceased patients, if Care at End of Life (EOL) module is selected, the diagnosis date may occur prior to 10/31/2018, once all eligible charts for patients diagnosed in the 16-month window have been identified. o Prostate Cancer (C61): patient can be diagnosed **before** 07/01/2017 if castration resistant prostate status documented within 16-month window (**7/1/2017 - 10/31/2018**); otherwise, diagnosis date must occur within 16-month window.	☐ Date: _____ ☐ Unknown

QOPI® 2018 Data Elements

CORE + Breast Modules

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
	• If the patient has had a recurrence, enter the date of the initial cancer diagnosis. • For prostate cancer, diagnosis date or documentation of castration resistant prostate cancer status must occur in 16-month diagnosis window. • Patients included with a diagnosis date more than 16 months ago will only be included in the EOL module. No other questions/data elements will apply to these charts (not Core, nor Symptom/Toxicity, nor any disease module) as initial treatment for the disease isn't current. • Charts applicable for modules will be required even if target sample size has already been met for a particular module. • For measure calculations, the earlier of either the cytology specimen date (cytology report) or tissue sample date (hemato-pathology report) will be used as the diagnosis date.	
Gender		☐ Male ☐ Female
Date of Birth		☐ Date: _____ ☐ Unknown
Age at Diagnosis		System Calculated
First Office Visit to this Practice Enter the date the patient was first seen in the office by a medical oncologist or hematology oncologist for the confirmed cancer diagnosis being abstracted.	• Do not include visits during which a practitioner wasn't seen (e.g., laboratory testing). • Do not include dates of inpatient consults/visits, phone or email consults. • For prostate cancer, respond based on date of CRPC if diagnosis date outside of 16-month diagnosis window. • Enter the date the patient was first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for the QOPI sample. • Do not include visits to a surgeon or radiation oncologist for this element. • The visit must have occurred within the diagnosis start period and visit window end date (**07/01/2017 - 12/01/2018)** (except for charts of patients who were diagnosed **before 07/01/2018** that were selected for EOL module. • Include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient.	☐ Date: _____ ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Most Recent Office Visit to this Practice Record the date of most recent practitioner visit (medonc/hemeonc) for this cancer diagnosis during the 8-month visit window (**5/1/2018 - 12/1/2018**). • Do not include visits during which a practitioner wasn't seen, inpatient consults/visits, phone, or email consults. • For prostate cancer, respond based on date of CRPC if diagnosis date outside of 16-month window. For Palliative Care module, enter the most recent visit that occurred during 6-month visit window (**05/1/2018 - 10/31/2018**).	• Include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. • Do not include visits to a surgeon or radiation oncologist for this element. • Enter the most recent visit that occurred during 8-month visit window. This visit must have occurred in the 8-month period (**5/1/2018 - 12/1/2018**). • For charts that are applicable to the EOL module, the visit must have occurred in the 9 months preceding death.	☐ Date: _____ ☐ Unknown
Report Confirming Invasive Malignancy Formal statement of diagnosis based on the microscopic examination of material by a pathologist or hematopathologist • If both cytology and pathology reports are available, enter information for both. • If multiple cytology or pathology reports available, enter earliest specimen collection date that confirms diagnosis for type of report.	• Select 'Yes' only if a copy of the report is located in the medical record of the reporting practice • Enter the date of the earliest pathology and/or cytology specimen collection that confirms the malignancy • The earliest date entered will be considered the date of diagnosis	☐ Yes, both cytology and pathology / hemato-pathology report ☐ Yes, pathology/ hemato-pathology report ☐ Yes, cytology report ☐ No Report
Documented reason no report (optional)		
Cytology specimen collection date		☐ Date: _____ ☐ Unknown
Pathology/hemato-pathology specimen collection date		☐ Date: _____ ☐ Unknown

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Confirm Breast Cancer Cell Type	ICD 10 codes C50x require confirmation of **histologic** type of the breast cancer diagnosis	☐ Breast Cancer - Other Types ☐ Breast Cancer - Cystosarcoma Phyllodes ☐ Breast Cancer - Adenoid Cystic Carcinoma ☐ Breast Cancer - Secretory Breast Carcinoma ☐ Breast Cancer - Tubular Carcinoma ☐ Breast Cancer - Mucinous Carcinoma ☐ Not documented/Unknown
Practice Encounter		
Practice Management of Initial Course of Therapy Select 'Reporting practice has/had primary responsibility …' if: • An oncologist in the practice is currently involved in planning the patient's treatment. • Care that was initiated by this site (or at another site within the practice) is underway/completed. • A treatment recommendation was provided at another site (e.g., via consultation/second opinion) but treatment was initiated at the reporting site.	• Select 'Patient transferred to practice…' if part of the med onc care (e.g., chemo) was provided elsewhere, with treatment continuing (e.g., hormonal therapy) in the reporting practice. • For ovarian/fallopian tube/primary peritoneal cancer consider initial course of treatment to include cytoreduction surgery. • For prostate cancer, if patient diagnosed outside of 16-month period, consider initial course of treatment to include CRPC treatment.	☐ Reporting practice has/had primary responsibility for the initial course of the patient's medical oncology care ☐ Patient transferred to reporting practice during the initial course of medical oncology treatment ☐ Patient transferred to reporting practice following completion of initial course of medical oncology treatment

QOPI® 2018 Data Elements

CORE + Breast Modules

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Chemotherapy Ever Received Indicate whether this patient ever received chemotherapy. • Include oral chemotherapy agents and all forms of chemotherapy provided under the direction of the reporting practice (onsite and offsite administration). • Hormonal therapy alone is not considered chemotherapy. • Do not include hormonal therapies, such as tamoxifen, raloxifene (Evista), toremifene (Fareston), exemestane (Aromasin, anastrazole (Arimidex). • Biologics such as rituximab and trastuzumab are considered chemotherapy agents.	• Include all forms of chemotherapy received by the patient since the diagnosis that are included the chart. • Do not include supportive care therapies (e.g., growth factors, bisphosphonates, nausea medications or fluids if these are not given in association with "chemotherapy."). • If patient received chemotherapy in or overseen by the practice and prior to or outside of the care of the practice for the diagnosis for which the chart was selected – answer 'Yes', patient received chemotherapy in or overseen by the practice.	☐ Yes, patient has received chemotherapy in or overseen by the reporting practice Intrathecal ☐ Yes, patient has received chemotherapy prior to or outside of the care of the reporting practice ☐ No, patient has never received chemotherapy for this diagnosis

QOPI® 2018 Data Elements

CORE + Breast Modules

<table>
<tr><th>DATA ELEMENT/HELP TEXT</th><th>ADDITIONAL NOTES</th><th>RESPONSE OPTIONS</th></tr>
<tr><td>Route of Chemotherapy
(Check all that apply)
Route of all chemotherapy received in or overseen by practice during initial course of treatment</td><td>Common oral therapies:
<table>
<tr><th><u>Generic</u></th><th><u>Brand Name</u></th></tr>
<tr><td>Abiterone</td><td>Zytiga</td></tr>
<tr><td>Afatinib</td><td>Gilotrif</td></tr>
<tr><td>Capecitabine</td><td>Xeloda</td></tr>
<tr><td>Ceritinib</td><td>Zykadia</td></tr>
<tr><td>Chlorambucil</td><td>Leukeran</td></tr>
<tr><td>Crizotinib</td><td>Xalkori</td></tr>
<tr><td>Cyclophosphamide</td><td>Cytoxan</td></tr>
<tr><td>Dasatinib</td><td>Sprycel</td></tr>
<tr><td>Erlotinib</td><td>Tarceva</td></tr>
<tr><td>Enzalutamide</td><td>Xtandi</td></tr>
<tr><td>Etoposide</td><td>Toposar</td></tr>
<tr><td>Everolimus</td><td>Afinitor</td></tr>
<tr><td>Fludarabine phosphate</td><td>Oforta</td></tr>
<tr><td>Gefitinib</td><td>Iressa</td></tr>
<tr><td>Hydroxyurea</td><td>Droxia</td></tr>
<tr><td>Idarubicin</td><td>Idamycin</td></tr>
<tr><td>Idelalisib</td><td>Zydelig</td></tr>
<tr><td>Imatinib</td><td>Gleevec</td></tr>
<tr><td>Lapatinib</td><td>Tykerb</td></tr>
</table>
<table>
<tr><th><u>Generic</u></th><th><u>Brand Name</u></th></tr>
<tr><td>Lenalidomide</td><td>Revlimid</td></tr>
<tr><td>Lomustine</td><td>Ceenu</td></tr>
<tr><td>Melphalan</td><td>Alkeran</td></tr>
<tr><td>Mercaptopurine</td><td>Purinethol</td></tr>
<tr><td>Methotrexate</td><td>Rheumatrex, Trexall</td></tr>
<tr><td>Olaparib</td><td>Lynparza</td></tr>
<tr><td>Palbociclib</td><td>Ibrance</td></tr>
<tr><td>Panobinostat</td><td>Farydak</td></tr>
<tr><td>Procarbazine</td><td>Matulane</td></tr>
<tr><td>Regorafenib</td><td>Stivarga</td></tr>
<tr><td>Sonidegib</td><td>Odomzo</td></tr>
<tr><td>Sorafenib</td><td>Nexavar</td></tr>
<tr><td>Sunitinib malate</td><td>Sutent</td></tr>
<tr><td>Temozolomide</td><td>Temodar</td></tr>
<tr><td>Topotecan</td><td>Hycamtin</td></tr>
<tr><td>Thalidomide</td><td>Thalomid</td></tr>
<tr><td>Thioguanine</td><td>Tabloid</td></tr>
<tr><td>Vinorelbine</td><td>Navelbine</td></tr>
<tr><td>Vorinostat</td><td>Zolinza</td></tr>
</table></td><td>☐ IV
☐ Oral
☐ Intrathecal
☐ Intraperitoneal
☐ Other
☐ Unknown</td></tr>
<tr><td>Treatment with Curative Intent
Respond based on evidence in the chart of treatment that was provided with curative intent.
• Treatment may include adjuvant chemotherapy drug treatment, curative surgery, endocrine therapy, radiation, or other curative therapy.</td><td></td><td>☐ Yes
☐ No
☐ Unknown</td></tr>
</table>

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Treatment Type Respond based on chart documentation specifying what was the treatment for curative intent.		☐ Chemotherapy ☐ Radiation ☐ Surgery ☐ None ☐ Unknown
Patient Characteristics		
Race Choose all that apply and are documented in the chart.	• *American Indian or Alaska Native* A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. • *Asian* A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. • *Black or African American* A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." • *Native Hawaiian or Other Pacific Islander* A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. • *White* A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. • *Not Reported* There isn't documentation in the chart regarding race of the patient. • *Unknown* The chart documents that race is unknown	☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Other ☐ Not reported ☐ Unknown
Ethnicity • **Not Hispanic or Latino** Chart documents that the patient is NOT of Cuban, Mexican, Puerto Rica, South or Central American, or other Spanish culture or origin regardless of race. • **Not Reported** There isn't documentation in the chart regarding ethnicity of the patient. • **Unknown** The chart documents that ethnicity is unknown.		☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Not reported ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Vital Status Status of the patient at the time of abstraction. • Select 'Alive' if patient is not known to be deceased. • Only patients deceased as consequence of cancer or cancer treatment are eligible for the EOL module.		☐ Alive ☐ Dead
Cause of Death If deceased: Indicate if the patient died as a consequence of cancer or cancer-related treatment.	• Patients who died from an un-related cause will not be included in the EOL module. • A death certificate is NOT required for confirmation that patient died as a result of cancer or cancer-related treatment. • If clinicians in the practice conclude that the death was cancer-related, you may check 'Yes, patient is deceased as a consequence of his/her cancer or cancer treatment.' • You may assume the patient died of cancer or cancer-related treatment, unless there is indication otherwise (e.g., MI in an early stage patient unrelated to treatment).	☐ Patient is deceased as a consequence of his/her cancer or cancer treatment ☐ Patient is deceased as a consequence of another disease or cause ☐ Patient is deceased and cause is unknown
Date of Death		☐ Date: _____ ☐ Unknown
Tumor Staging		
Cancer Stage Documented by Practitioner Respond based on documentation/ acknowledgement by a practitioner in the practice. • Record the first date the stage (clinical or pathologic) was documented. • Staging only applies to the time of diagnosis if the patient's disease status has changed (e.g., disease has progressed to metastases) enter the date the cancer was staged by a practitioner in the practice at diagnosis.	• Notation by the Practitioner that the cancer has distant metastases at diagnosis is sufficient in the absence of more detailed staging information. • 'Practitioner' refers to licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law. • Cancer stage documented does not apply to patients with diagnosis code C90.00-C95.92, D46.0 - D46.Z. This item will not be available during web entry for those diagnoses. • If the patient is receiving/has received neoadjuvant therapy and only clinical stage (information obtained about the extent of cancer before initiation of definitive treatment) is available, enter date that clinical stage was noted by a practitioner in the practice. • Staging should be documented by a practitioner in the reporting practice. If staging information is only included in a pathology report, hospital admission/discharge report, or some other form generated outside of the reporting practice	☐ Documentation of cancer stage at diagnosis present in medical record ☐ Documentation of cancer stage at diagnosis NOT present in medical record

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CORE + Breast Modules

<table>
<tr><th>DATA ELEMENT/HELP TEXT</th><th>ADDITIONAL NOTES</th><th>RESPONSE OPTIONS</th></tr>
<tr><td></td><td>without interpretation by a practitioner in the practice, answer ‘No’ for this item.
• The date of the first practitioner visit and the cancer staged date will be used to calculate whether the cancer was staged within one month of the first office visit.
• Staging should be accomplished using any standardized system, including, but not limited to:
– TNM (Tumor, Nodes, Metastasis) scoring, such as T2N1M0 (Cancer is considered staged if only T and N are documented and M is missing)
– AJCC stage grouping score such as I, II, III, or IV
– Dukes’ for colorectal cancer
– FIGO for gynecologic tumors
– Clark’s or Breslow’s levels for melanoma
– Hematologic diagnoses: Durie-Salmon Criteria, International Staging System for multiple myeloma, Ann Arbor Staging System, International Prognostic Index
• Tumor Grade for brain cancers</td><td></td></tr>
<tr><td>Cancer Stage Documented date</td><td></td><td>☐ Date: _____
☐ Unknown</td></tr>
<tr><td>AJCC Stage Group – Breast
AJCC stage (0-IV) at diagnosis
• Select 'AJCC stage group NOT documented' if stage at diagnosis is documented using TNM only or an alternate staging system.
If AJCC group (I-IV) is documented as I, II, III, or IV, but the system will only accept a more specific code, such as IA, IB, use T,N, M to map to appropriate code level or enter AJCC not documented and enter actual T, N, M values instead.</td><td>
<table>
<tr><th>Breast Stage</th><th colspan="3">TNM Subset</th></tr>
<tr><td>0</td><td>Tis</td><td>N0</td><td>M0</td></tr>
<tr><td>IA</td><td>T1*</td><td>N0</td><td>M0</td></tr>
<tr><td>IB</td><td>T0</td><td>N1mi</td><td>M0</td></tr>
<tr><td></td><td>T1*</td><td>N1mi</td><td>M0</td></tr>
<tr><td>IIA</td><td>T0</td><td>N1</td><td>M0</td></tr>
<tr><td></td><td>T1*</td><td>N1</td><td>M0</td></tr>
<tr><td></td><td>T2</td><td>N0</td><td>M0</td></tr>
<tr><td>IIB</td><td>T2</td><td>N1</td><td>M0</td></tr>
<tr><td></td><td>T3</td><td>N0</td><td>M0</td></tr>
<tr><td>IIIA</td><td>T0</td><td>N2</td><td>M0</td></tr>
<tr><td></td><td>T1*</td><td>N2</td><td>M0</td></tr>
<tr><td></td><td>T2</td><td>N2</td><td>M0</td></tr>
<tr><td></td><td>T3</td><td>N1</td><td>M0</td></tr>
<tr><td></td><td>T3</td><td>N2</td><td>M0</td></tr>
<tr><td>IIIB</td><td>T4</td><td>N0</td><td>M0</td></tr>
<tr><td></td><td>T4</td><td>N1</td><td>M0</td></tr>
<tr><td></td><td>T4</td><td>N2</td><td>M0</td></tr>
</table>
</td><td>☐ 0
☐ IA
☐ IB
☐ IIA
☐ IIB
☐ IIIA
☐ IIIB
☐ IIIC
☐ IV
☐ AJCC stage group not documented; Patient noted to have distant metastatic breast cancer at diagnosis
☐ AJCC stage group NOT documented</td></tr>
</table>

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS

IIIC	Any T	N3	M0
IV	Any T	Any N	M1
	(*T1 includes T1mi)		

TX Primary tumor cannot be assessed

T0 No evidence of primary tumor

Tis Carcinoma in situ (DIS – Ductal; LCIS – Lobular; Paget's – Paget's disease of the nipple NOT associated with invasive carcinoma and/or carcinoma in situ in the underlying breast parenchyma.

T1 Tumor ≤20 mm in greatest dimension

T1mi Tumor ≤1 mm in greatest dimension

T1a Tumor >1 mm but ≤5 mm in greatest dimension

T1b Tumor >5 mm but ≤10 mm in greatest dimension

T1c Tumor >10 mm but ≤20 mm in greatest dimension

T2 Tumor> 20 mm but ≤50 mm in greatest dimension

T3 Tumor >50 mm in greatest dimension

T4 Tumor of any size with direct extension to chest wall and/or the skin (ulceration or skin nodules)

T4a Extension to chest wall, not including only pectoralis muscle adherence/invasion

T4b Ulceration and/or ipsilateral satellite nodules and/or edema (including peau d'orange) of the skin, which do not meet the criteria for inflammatory carcinoma

T4c Both T4a and T4b

T4d Inflammatory carcinoma

NX Regional lymph nodes cannot be assessed (e.g., previously removed)

N0 No regional lymph node metastases

N1 Metastases to movable ipsilateral level I, II axillary lymph node(s)

N1mi Micrometastastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm)

N1a Metastases 1-3 axillary lymph nodes, at least one metastasis greater than 2.0 mm

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
	N1b Metastases in internal mammary nodes with micrometastases or macrometastases detected by sentinel node biopsy but not clinically detected *N1c* Metastases 1-3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel node biopsy but not clinically detected *N2* Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in absence of clinically evident axillary lymph node metastases *N2a* Metastases in ipsilateral level I, II axillary lymph nodes fixed to one another (matted) or to other structures *N2b* Metastases only in clinically detected* ipsilateral internal mammary nodes and in the absence of clinically evident level I, II axillary lymph node metastases *N3* Metastases in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement; or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement *N3a* Metastases in ipsilateral infraclavicular lymph node(s) *N3b* Metastases in ipsilateral internal mammary lymph nodes and axillary lymph node (s) *N3c* Metastases in ipsilateral supraclavicular lymph node (s) *M0* No clinical or radiological evidence of distant metastases *cM0(i+)* No clinical or radiological evidence of distant metastases, but deposits of molecularly or microscopically detected tumor cells in circulating blood, bone marrow, or other nonregional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastases. *M1* Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2 mm. Used with the permission of the American Joint Committee on Cancer (AJCC), Chicago, Illinois. The original source for this material is the AJCC Cancer Staging Manual, Seventh Edition (2010) published by Springer Science and Business Media LLC, www.springer.com	

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
AJCC T – Breast Required for all Breast Cancer Cases	• AJCC TNM stage at diagnosis: The size of the primary tumor should be a measurement with dimensions. If more than one tumor or more than one dimension is documented in the chart, use the largest dimension documented • Use the most recent report prior to treatment (chemotherapy/hormonal/radiation) to identify the TNM stage • If no pathology report available, report clinical TNM if available • If the only actual dimensions of the tumor and node status are listed and TNM have not been noted by practitioner in the practice, you may translate the information to T and N stage.	☐ T0 ☐ T1mi ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T3 ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ TX ☐ Not Documented
AJCC N – Breast If AJCC Stage Group NOT documented: AJCC N-Stage at breast cancer diagnosis	• AJCC TNM stage at diagnosis: The size of the primary tumor should be a measurement with dimensions. If more than one tumor or more than one dimension is documented in the chart, use the largest dimension documented. • Use the most recent report prior to treatment (chemotherapy/hormonal/radiation) to identify the TNM stage. • If no pathology report available, report clinical TNM if available. • If the only actual dimensions of the tumor and node status are listed and TNM have not been noted by practitioner in the practice, you may translate the information to T and N stage.	☐ N0 ☐ N1mi ☐ N1 ☐ N1a ☐ N1b ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ NX ☐ Not Documented
AJCC M – Breast If AJCC Stage Group NOT documented: AJCC M-Stage at breast cancer diagnosis.	• The MX designation was removed from the 7th edition of the AJCC/UICC system. Subcategories are allowed, such as cM0 (i+), M1a. • Use M0 unless clinical or pathologic evidence of mets CS Mets at Dx code 99 (unknown) maps to M0.	☐ M0 ☐ cM0(i+) ☐ M1 ☐ Not Documented
AJCC Stage IV at Diagnosis or Developed Distant Metastases Indicate whether the patient was diagnosed with Stage IV disease or developed distant metastases anytime since diagnosis.		☐ Documentation of distant metastases ☐ NO documentation of distant metastases

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Bone Metastases Indicate whether there is documentation of bone metastases anytime since diagnosis.		☐ Documentation of bone metastases ☐ NO documentation of bone metastases
Imaging within two months *(Check all that apply)* Indicate which of the following imaging tests the patient received within 2 months following diagnosis that were ordered by the practice or ordered outside the practice for staging.	• Do not include imaging prior to confirmed diagnosis. • Include scans ordered by any practitioner (medical oncologist, surgeon, radiation oncologist, etc.)	☐ PET for staging ☐ CT for staging ☐ Radionuclide bone scan for staging ☐ None of the Above ☐ No imaging for staging
Indicate who ordered the test Were the imaging tests ordered by the practice or ordered outside the practice for staging?		☐ Ordered by the Practice ☐ Ordered outside the Practice
Breast Imaging between two and twelve months ***(Check all that apply)*** Indicate which of the following imaging tests was ordered between day 61 and day 365 of diagnosis by the practice for monitoring.	• Do not include imaging prior to confirmed diagnosis. • Include scans ordered by any practitioner (medical oncologist, surgeon, radiation oncologist, etc.).	☐ PET for Monitoring/ Surveillance ☐ CT for Monitoring/ Surveillance ☐ Radionuclide bone scan for Monitoring/Surveillance ☐ No imaging for Monitoring/ Surveillance (None of the above)
Indicate who ordered the test Were the imaging tests ordered by the practice or ordered outside the practice?		☐ Ordered by the Practice ☐ Ordered outside the Practice
Imaging by as part of IRB approved protocol Indicate whether the patient was enrolled on any clinical trial or treatment protocol approved by an IRB which warranted imaging during the timing checked above.		☐ Yes ☐ No ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Tumor Markers		
ER Status Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test for ER status was ordered. • In the absence of any documentation regarding ER status, select 'Test not ordered/no documentation.' • Enter information from the most recent test report If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results'. • Estrogen receptor status is typically referenced in a pathology report from the first or second surgical or biopsy procedure that led to the diagnosis. • This report will commonly address the issue of hormone receptors and if positive will state that the tumor was "positive" for estrogen receptors. • Alternatively, a practitioner's note that references the tumor as ER positive is acceptable.	Positive: • >=1% of tumor nuclei are immunoreactive Negative: • < 1% of tumor cell nuclei are immunoreactive in the presence of evidence that the sample can express ER or PgR. Uninterpretable: No tumor nuclei are immunoreactive and internal epithelial elements present in the sample or separately submitted from the same sample lack any nuclear staining.	☐ ER positive ☐ ER negative ☐ ER uninterpretable ☐ Test ordered, results not yet documented ☐ Test ordered, insufficient sample for results ☐ Test NOT ordered/no documentation
PR Status Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test for PR status was ordered. • In the absence of any documentation regarding PR status, select 'Test not ordered/no documentation'. • Enter information from the most recent test report. • If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results'		☐ PR positive ☐ PR negative ☐ PR uninterpretable ☐ Test ordered, results not yet documented ☐ Test ordered, insufficient sample for results ☐ Test NOT ordered/no documentation

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
HER-2neu Status • Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test that included HER2 analyses was ordered. • In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation'. • Enter information from the most recent test report. • If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results'. • If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy Otherwise, report the status from the HER-2/neu report.	Use the following definitions to determine HER-2/neu status: • Positive: IHC 3+ based on circumferential membrane staining that is complete, intense - ISH positive based on: - Single-probe average HER2 copy number ≥60 signals/cell - Dual-probe HER2/CEP17 ratio ≥20 with an average HER2 copy number ≥40 signals/cell - Dual-probe HER2/CEP17 ratio ≥20 with an average HER2 copy number <40 signals/cell - Dual-probe HER2/CEP17 ratio < 20 with an average HER2 copy number ≥60 signals/cell • Equivocal: - IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells or complete and circumferential membrane staining that is intense and within ≤ 10% of the invasive tumor cells ISH equivocal based on: - Single-probe ISH average HER2 copy number ≥ 40 and < 60 signals/cell - Dual-probe HER2/CEP17 ratio < 20 with an average HER2 copy number ≥ 40 and < 60 signals/cell • Negative: IHC 1+ as defined by incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells or IHC 0 as defined by no staining observed or membrane staining that is incomplete and is faint/barely perceptible and within ≤ 10% of the invasive tumor cells ISH negative based on: - Single-probe average HER2 copy number < 40 signals/cell - Dual-probe HER2/CEP17 ratio < 20 with an average HER2 copy number < 40 signals/cell • Indeterminate: Indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal Conditions may include:	☐ HER2 positive ☐ HER2 negative ☐ HER2 equivocal ☐ Test ordered, results not yet documented ☐ Test ordered, insufficient sample for results ☐ Test NOT ordered/no documentation

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
	- Inadequate specimen handling, - Artifacts (crush or edge artifacts) that make interpretation difficult , Analytic testing failure	
Documented reason no HER-2neu test ordered (optional) For internal quality improvement efforts, indicate the documented reason why HER-2neu test was not ordered.		
Her-2neu Order Date Record the date on which the patient's Her-2neu test was ordered. • Enter information from the most recent test report.		☐ Date: _____ ☐ Unknown
Her-2 Test Reordered If test ordered, insufficient sample or equivocal results: New HER-2 test ordered within 10 days of report of insufficient sample or equivocal results.	• Respond 'Yes' if a new test was ordered within 10 days of oncologist review of the report with inconclusive results or there is documentation that a re-test isn't possible due lack of available tissue. • Choose 'N/A' if the patient died or transferred out of the practice within 10 days of review of the report with inconclusive results or fewer than 10 days have passed. • If the chart documents that the pathologist has ordered a new test, respond 'Yes.'	☐ Test not ordered ☐ New test ordered ☐ N/A - patient died/transferred out of practice
Serum Tumor Marker Test If patient received treatment with curative intent: Was a serum tumor marker test (CEA, CA 15-3, or CA 2729) ordered in the time period between 30 days and 365 days after diagnosis.		☐ Yes ☐ No ☐ Unknown
Indicate who ordered the test If Yes: Was the serum marker test ordered by your practice or outside of your practice.		☐ Ordered by the Practice ☐ Ordered outside the Practice
Indicate who outside your practice ordered the test If serum marker test ordered outside your practice, indicate who placed the order.		☐ Medical oncologist ☐ Radiation oncologist ☐ Surgeon ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Serum Tumor Marker Test by IRB Approved Protocol If Yes: Indicate whether the patient was enrolled on any clinical trial or treatment protocol approved by an IRB which warranted serum tumor marker testing in the time period between 30 days and 365 days after diagnosis.		☐ Yes ☐ No ☐ Unknown
Drug Therapy		
Chemotherapy Recommended Indicate whether chemotherapy treatment was recommended to the patient as part of initial course of therapy. • A physician is considered to recommend a treatment if the patient received the medication OR if the chart reflects that the physician discussed the medication with the patient as a recommended therapy. • Include oral chemotherapy or chemotherapy treatment provided offsite but under the direction of the reporting practice. • If recommendations include neoadjuvant and adjuvant chemotherapy treatment, respond based on adjuvant treatment.	• If both neoadjuvant and adjuvant chemotherapy agents were recommended, but the patient only received neoadjuvant, respond based on neoadjuvant chemotherapy. • Responses should be based on recommendations by a physician in the practice. • Include all forms of chemotherapy; biologics such as rituximab and trastuzumab are considered chemotherapy agents. • Hormonal therapy alone is not considered chemotherapy. • Do not include supportive care therapies (e.g., growth factors, bisphosphonates, nausea medications or fluids if these are not given in association with chemotherapy treatment). Exclusions are captured under 'Chemotherapy Administered.'	☐ Chemotherapy NOT recommended ☐ Chemotherapy recommended

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Chemotherapy Administered Indicate whether a chemotherapy agent was administered during initial treatment course. • 'Administered' applies to treatment underway or complete. • Include oral chemotherapy treatment and chemotherapy treatment provided offsite but under the direction of the reporting practice. • If administration includes neoadjuvant and adjuvant chemotherapy treatment, respond based on adjuvant treatment.		☐ Chemotherapy administered ☐ Chemotherapy NOT administered
Topical and/or Intravesical chemotherapy received		☐ Yes ☐ No ☐ Unknown
Multi-Agent Chemotherapy Recommended Indicate whether multi-agent chemotherapy treatment was recommended to the patient as part of initial course of therapy. • A physician is considered to recommend a treatment if the patient received the medication OR if the chart reflects that the physician discussed the medication with the patient as a recommended therapy. • Include oral chemotherapy or chemotherapy treatment provided offsite but under the direction of the reporting practice. • If recommendations include neoadjuvant and adjuvant chemotherapy treatment, respond based on adjuvant treatment.		☐ Multi-agent chemotherapy NOT recommended ☐ Multi-agent chemotherapy recommended

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Reason Mutli-Agent Chemotherapy NOT recommended (optional) For internal quality improvement efforts, indicate the documented reason multi-agent chemotherapy was not recommended.		
Date Multi-Agent Chemotherapy First Recommended Enter the date on which multi-agent chemotherapy treatment was first documented as being recommended to the patient.	• If neoadjuvant and adjuvant chemotherapy were administered, refer to documentation regarding the neoadjuvant treatment when you enter the date of administration.	☐ Date: _____ ☐ Unknown
Multi-Agent Chemotherapy Administered Multi-agent chemotherapy treatment administered during initial treatment course (Breast cancer). • Do not include immunotherapy agents.	• 'Administered' applies to treatment underway or complete. Include oral chemotherapy and chemotherapy provided offsite but under the direction of the reporting practice. Include monoclonal antibodies such as trastuzumab, pertuzumab, or bevacizumab as one of the chemotherapy agents when determining whether multi-agent chemotherapy was administered.	☐ Multi-agent chemotherapy NOT administered ☐ Multi-agent chemotherapy administered
Date Multi-Agent Chemotherapy Started Enter the date the first agent was started.		☐ Date: _____ ☐ Unknown
Reason Multi-Agent Chemotherapy NOT Administered		☐ No reason documented ☐ Awaiting test/staging results ☐ Patient declined ☐ Patient died or transferred ☐ Contraindication or other clinical exclusion documented ☐ Alternative treatment according to clinical trial protocol ☐ Other reason documented
Other Reason Multi-Agent Chemotherapy NOT Administered (optional) For internal quality improvement efforts, indicate the other documented reason multi-agent chemotherapy was not administered.		

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Trastuzumab Recommended Indicate whether trastuzumab (Herceptin) was recommended to the patient as part of initial course of therapy.	• A physician is considered to recommend a treatment if the patient received the medication OR if the chart reflects that the physician discussed the medication with the patient as a recommended therapy. In the absence of any documentation regarding trastuzumab, select 'NOT recommended.' • Exclusions are captured under 'Trastuzumab Administered.'	☐ Trastuzumab recommended ☐ Trastuzumab NOT recommended
Trastuzumab NOT Recommended (optional) For internal quality improvement efforts, indicate the documented reason Trastuzumab was not recommended.		
Trastuzumab Administered Trastuzumab (Herceptin) administered during initial treatment course.	Trastuzumab (Herceptin) administered during initial treatment course	☐ Trastuzumab administered ☐ Trastuzumab NOT administered
Trastuzumab Administered by IRB Protocol (optional) If trastuzumab administered and tumor NOT documented as Her-2/neu positive: Trastuzumab administered according to clinical trial protocol.	Respond 'Yes', if the patient received trastuzumab according to a clinical trial protocol without documentation of Her-2/neu positive tumor.	☐ Trastuzumab administered per IRB protocol ☐ Trastuzumab administered NOT per IRB protocol
Reason Trastuzumab Not Administered In the absence of any documentation regarding trastuzumab, select 'NOT administered'. • Select 'Contraindication or other clinical exclusion documented' only if there is documentation of a medical reason why a patient who would otherwise be recommended trastuzumab is not given that recommendation.		☐ No reason documented ☐ Awaiting test/staging results ☐ Patient declined ☐ Patient died or transferred ☐ Contraindication or other clinical exclusion documented ☐ Alternative treatment according to clinical trial protocol ☐ Chemotherapy or radiation are not complete ☐ Her2-neu negative ☐ Other reason documented
Other Reason Trastuzumab Not Administered (optional) For internal quality improvement efforts, indicate the other documented reason Trastuzumab was not administered.		

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Chemotherapy for Stage IV or Distant Metastatic Disease Respond 'Yes' if the patient received chemotherapy treatment ordered by your practice for stage IV or distant metastatic disease.		☐ Yes ☐ No ☐ Not Documented ☐ Unknown
Chemotherapy for Stage IV Disease by IRB Protocol If patient received chemotherapy treatment for stage IV or distant metastases and PS 3, PS4, or Not Documented: Received chemotherapy treatment for metastatic disease as part of IRB approved protocol.	• Note whether the patient was enrolled on any clinical trial or treatment protocol approved by an IRB which warranted chemotherapy for metastatic disease despite performance status of 3, 4, or not documented.	☐ Yes ☐ No ☐ Unknown
GCSF Administered During First Course of Chemotherapy for Stage IV Disease Indicate whether GCSF was administered with chemotherapy treatment to patients with Stage IV disease or distant metastases during course of chemotherapy treatment for Breast cancer.	• Check medication records or chemotherapy flow sheet to determine if the patient received GCSF (Neulasta/Neupogen) while receiving chemotherapy for metastatic disease. • Respond 'Yes' if the GCSF was ordered by the practice.	☐ No ☐ Yes ☐ Unknown
Bone Modifying Agents Administered Indicate whether bone modifying agents (zoledronic acid (Zometa), pamidronate (Aredia) or denosumab (Xgeva) after diagnosis of bone metastases, while under the care of the practice.		☐ Recommended and planned, not yet started ☐ Administered ☐ Recommended, patient declined ☐ Not recommended/ administered, contraindication or other clinical exclusion documented ☐ Not recommended due to alternative treatment according to clinical trial protocol ☐ Not recommended/ administered, other reason/reason not documented

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Creatinine Assessed Indicate whether creatinine levels were assessed prior to the administration of the bone modifying agent. • Respond 'Yes' if the creatinine was assessed within 31 days prior to the first administration of the bone modifying Agent (zoledronic acid (Zometa), pamidronate (Aredia), or denosumab (Xgeva)).		☐ Yes ☐ No
Hormone Therapy Recommended Indicate whether hormone OR aromatase inhibitor (AI) therapy was recommended to the patient as part of initial course of therapy.	• A physician is considered to recommend a treatment if the patient received the medication OR if the chart reflects that the physician discussed the medication with the patient as a recommended therapy. In the absence of any documentation regarding hormonal or AI therapy (including for patients who are hormone receptor negative), select 'NOT recommended. • Do not include Zoladex (goserelin acetate) or Faslodex (fulvestrant) administered as sole agents.	☐ Hormone or AI therapy recommended ☐ Neither Hormone nor AI therapy recommended
Date Hormone Therapy First Recommended Enter the date on which hormone or AI therapy was first documented as being recommended to the patient.		☐ Date: _____ ☐ Unknown
Hormone Therapy Administered Respond based on hormone or AI therapy administered as part of the initial course of treatment.		☐ Hormone therapy administered ☐ AI therapy administered ☐ Neither hormone nor AI therapy administered
Hormone Therapy Administered by IRB Protocol (optional) If hormonal or AI therapy administered and tumor not documented as ER or PR positive: Respond 'Yes', if the patient received hormonal or AI therapy according to a clinical trial protocol without documentation of ER or PR positive tumor.		☐ Yes ☐ No

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Reason Hormone Therapy Not Administered		☐ No reason documented ☐ Awaiting test/staging results ☐ Patient declined (patient reason) ☐ Patient died or transferred (patient reason) ☐ Contraindication or other clinical exclusion documented (medical reason) ☐ Alternative treatment according to clinical trial protocol (system reason) ☐ Chemotherapy or radiation not complete (medical reason) ☐ ER/PR negative or unknown ☐ Other reason documented
Date Hormone or AI Therapy Started Enter prescription date for oral agents if actual start date for oral agent is not known.		☐ Date: _____ ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Consent Documentation Indicate documented consent obtained prior to first administration of chemotherapy treatment (including oral).	• QOPI assesses whether informed consent for chemotherapy is given by the patient prior to administration of chemotherapy. The informed consent may be documented in a signed consent form or in a practitioner notation that indicates the patient consented to the treatment. • Documentation must occur prior to first administration of all forms of chemotherapy (including oral). Practitioner notation may include discussion of diagnosis, the proposed treatment, intended benefits, associated risks and side effects, medically reasonable alternatives (and their corresponding risks and side effects), and, at a minimum, indication that the treatment was discussed with the patient and the patient voluntarily agreed to the treatment. • Signed consent: signed by the patient prior to treatment and is specifically for chemotherapy agents, or equivalent intravenous agent to treat cancer. Generic consents for treatment that do not reference chemotherapy should not be considered a signed consent form for chemotherapy. • Patient consent documented in practitioner note: may be found in a practitioner's note on the day treatment is started, or the last visit before that time. The note should document that the patient consented to chemotherapy, or equivalent intravenous agent(s) to treat cancer. • This item is addressing patient consent during treatment discussions with a practitioner. If a signed patient consent form is the only available consent documentation, do not select this option.	☐ Consent NOT documented ☐ Patient consent documented in PRACTITIONER note ☐ Signed consent form in chart ☐ Signed consent form in chart: Patient consent documented in PRACTITIONER note
Performance Status Performance status documented within two weeks prior to or on the day of chemotherapy treatment administration. • Respond based on first administration of the initial chemotherapy treatment regimen.	• Performance status documented within two weeks prior to or on the day of chemotherapy treatment administration. • Respond based on first administration of the initial chemotherapy treatment regimen.	☐ 0 / 100% / Normal activity ☐ 2 / 60-70% / Bed time, <50% daytime) ☐ 3 / 40-50% / Bed time, >50% ☐ 4 / 10-30% / Unable to get out of bed ☐ Not Documented

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Intent of Chemotherapy Documented within 60 Days prior or 14 Days after Chemo Admin Indicate whether there is documentation/acknowledgement of intent for the initial treatment course, by a practitioner in the practice . • Palliation may be to prolong life (without goal of cure) or to control symptoms.		☐ Curative/adjuvant/ neoadjuvant ☐ Non-curative (Palliative, life extending, symptom control) ☐ No, 14 days has not passed after chemotherapy administration ☐ Not documented
Intent of Chemotherapy Discussed with Patient Indicate whether there is documentation of a discussion regarding intent, by a practitioner in the practice. • Only include discussion documented prior to the first administration of chemotherapy agent for the initial course of treatment.	• Respond based on documentation of a discussion regarding intent, by a practitioner in the practice. Only include discussion documented prior to the first administration of chemotherapy for the initial course of treatment. • Documentation should include the planned treatment approach for the entire chemotherapy regimen (including oral). Select all elements that were documented in the chart prior to the first administration of the chemotherapy. • If the patient received neoadjuvant and adjuvant chemotherapy, respond regarding the adjuvant treatment. • Documentation of discussion regarding intent may include descriptions such as curative, palliative, adjuvant, neoadjuvant or a basic discussion of the purpose, benefits, or rationale for the therapy. • Documentation of prognosis does not qualify for documentation of intent of treatment.	☐ Yes, discussion documented ☐ No, discussion NOT documented
Initial Chemotherapy Ended Indicate whether chemotherapy stopped for any reason (end of planned therapy, patient died, toxicities, etc.) • Do not include treatment breaks or 'holidays' if the treatment regimen is expected to continue under the care of the practice. • If patient stopped one drug and started on different agent due to toxicity or disease progression consider chemotherapy regimen discontinued".		☐ Chemotherapy regimen discontinued or completed ☐ Chemotherapy regimen is ongoing

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Date Initial Course of Chemotherapy Ended		☐ Date: _____ ☐ Unknown
Reason for Ending Treatment If patient stopped original planned regimen and started new regimen due to toxicity or disease progression, indicate the reason the regimen was changed. • If enrolled in hospice, respond patient transferred to another practice/care facility.		☐ Completion ☐ Toxicity ☐ Progression of disease ☐ Death ☐ Patient request to stop ☐ Patient transfer to another practice/care facility ☐ Financial ☐ Other ☐ Not documented
Initial Oral Chemotherapy prescription completed, discontinued, or changed Indicate if the initial oral chemotherapy prescription completed, discontinued, or changed.		☐ No ☐ Yes
Reason initial Oral Chemotherapy prescription completed, discontinued, or changed If patient completed, discontinued, or changed initial planned oral chemotherapy prescription, indicate the reason.		☐ Completion ☐ Toxicity ☐ Progression of disease ☐ Death ☐ Patient request to stop ☐ Patient transfer to another practice/care facility ☐ Financial ☐ Other ☐ Not documented

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Chemotherapy Treatment Plans and Summaries		
Chemotherapy Treatment Plan Select each all element documented in the chart prior to the first administration of the chemotherapy regimen • Documentation should include the planned treatment approach for the entire chemotherapy regimen (including oral) • Only select the elements that are documented for the entire planned regimen prior to treatment initiation, not solely for individual cycles	• Order sheets completed prior to each cycle are sufficient documentation of the key elements, if there is physician notation or other documentation that describes the entire course of treatment the patient should receive. For example, if the physician notes 'Standard TC' (Taxotere and Cyclophosphamide) for 4 cycles and 'standard TC' is documented in the practice and dose, route, drug names, and time intervals are included in the order sheets, chemotherapy consent form, or the 'standard TC' documentation before the patient receives treatment; all key elements are considered documented prior to administration of chemotherapy. • If none of the key elements are documented, select 'No elements documented.' • If the patient received neoadjuvant and adjuvant chemotherapy, respond regarding the adjuvant treatment. • If the chart documents a standard regimen name, an abbreviation for a standard regimen, or a protocol name, you may indicate elements listed that are included in the regimen or protocol if: 1. there is standard documentation that is physically available at the practice or in the practice EHR/electronic system for the regimen or protocol AND 2. the standard documentation includes details of the medications, and the element(s) selected. • Refer to the initial prescription for oral chemotherapy. • If there is evidence in the chart that the patient had follow-up lab and clinic visit/contact regarding the oral chemotherapy, then that is sufficient for these elements of the plan.	☐ Chemotherapy regimen/drugs ☐ Doses ☐ Route ☐ Time Intervals ☐ Cycles ☐ Schedule/Start Dates ☐ Indications ☐ Patient Height ☐ Patient Weight ☐ Body Surface Area ☐ No elements documented

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Oral Chemotherapy Treatment Patient Education (Check all that apply) Indicate each element included in patient education prior to first dose of oral chemotherapy treatment. • Respond based on the initial oral chemotherapy treatment prescription, not renewal.	• Check for evidence in the chart that the patient was educated about the following prior to start of oral chemotherapy: • Indications: Use of the oral agent for treating the malignancy. • Schedule and start date: Date of first ingestion, not prescription date, pick-up date, or planned start date. • Management of missed doses: Actions patient should take if a dose is skipped or extra dose is taken. • Potential side effects/toxicities: Possible signs and symptoms the patient should be cognoscente of when taking the oral chemotherapy agent (such as risk of infertility, nausea, fatigue) • When and how to contact the office: Situations that would trigger contact with the office, who to contact, and how to reach them.	☐ Management of Missed Doses ☐ Potential Side Effects/Toxicities ☐ When and how to contact the clinic
Oral Chemotherapy Treatment Start Date Documented Indicate whether the oral chemotherapy treatment start date is documented in chart at first visit/contact with patient. • This is not the prescription date or scheduled start date.		☐ Yes ☐ No ☐ No visit/contact following prescription
Oral Chemotherapy Treatment Adherence Assessed Indicate whether medication adherence was assessed at first visit/contact with patient after prescription. • Adherence assessment may be noted through reference to remaining pill count, pattern of consumption, or refill pattern.	• Examples for assessment may include: confirmation that the patient filled the prescription as written, inquiries regarding concerns about treatment costs, verification that the patient understands how to take the prescription, verification that the patient understands what to do in the case of a missed dose.	☐ Medication adherence NOT documented ☐ Notation, patient did NOT adhere to oral chemotherapy regimen ☐ Notation, patient adhered to oral Chemotherapy regimen ☐ No visit/contact following prescription

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Plan to Address Adherence Documented Indicate whether a plan to address medication adherence was documented at first visit/contact with patient after prescription. • Check for documentation that the patient was provided recommendations or means to improve adherence, such as, call reminder schedule, resources for financial assistance, or scheduled follow-up.		☐ Yes ☐ No
If Initial Chemotherapy was completed for any reason other than patient death: Treatment Summary Completed Indicate whether a treatment summary was completed at the conclusion of initial chemotherapy treatment • A complete treatment summary must include, at minimum: 1. Chemotherapy treatment delivered, including number of cycles administered, duration, and extent of dose reduction 2. Reason treatment was stopped 3. Major toxicities and/or hospitalizations 4. Treatment response 5. Follow up care and relevant providers • The treatment summary may be completed on paper or captured in the practice's EHR. • If the patient received neoadjuvant and adjuvant chemotherapy treatment respond regarding the adjuvant treatment.	• The chemotherapy treatment summary should be prepared at the completion of a course of treatment. However, QOPI gives a practice credit if the Treatment Summary is completed before chemotherapy ends, which is why the question will open up even though the response 'Chemotherapy is ongoing' was selected • The chemotherapy treatment summary may occur at the end of a course of adjuvant therapy or before a planned surgical resection (neoadjuvant, 'pre-operative' therapy), or after disease progression. Treatment breaks, holidays, and minor modifications do not require preparation of a treatment summary • The treatment summary may include elements in addition to the required elements • Answer 'Treatment summary NOT completed' if a treatment summary is not in the chart/available in the EHR or if the summary is missing any of the required elements • If the patient completed primary treatment and a treatment summary was completed at that time, you have the option to indicate that treatment summary was completed even though chemotherapy is ongoing.	☐ Treatment summary completed ☐ Treatment summary NOT completed
Date Treatment Summary Completed Provide the actual date of completion		☐ Date: _____ ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Treatment Summary NOT Completed Indicate which elements of a treatment summary are present in the chart.	Treatment Response refers to chemotherapy effectiveness, not how the patient tolerated the treatment.	☐ Chemotherapy delivered, (# of cycles, duration, and extent of dose reduction) ☐ Reason treatment was stopped ☐ Major toxicities and/or hospitalizations ☐ Treatment response ☐ Follow up care and relevant providers ☐ None of the above
Provided to Patient Provide the actual date the treatment summary provided to the patient.		☐ Yes ☐ No
Date Provided to Patient		☐ Date: _____ ☐ Unknown
Provided to Practitioner(s) Indicate whether the treatment summary was provided or communicated to practitioner(s) providing continuing care to the patient following their cancer care. • If practitioner(s) continuing care team has access to EMR with treatment summary, indicate 'Yes'. Answer 'N/A' – no other practitioner(s) providing continuing care' to 'Treatment summary provided or communicated to practitioner(s) providing continuing care' if the practice is still providing full care for the patient.	• If the treatment summary is captured in an EHR that is available to others on a multispecialty team providing continuing care, select 'Yes' for 'Treatment summary provided or communicated to practitioner(s) providing continuing care.'	☐ Yes ☐ No ☐ N/A - no other practitioner(s) providing continuing care
Date Provided to Practitioner(s) Record the actual date the treatment summary was provided or communicated to practitioner(s).		☐ Date: _____ ☐ Unknown

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Genetic Risk Assessment		
CA Diagnosis in 1st Degree Relative Documented Presence or absence of cancer diagnosis in first-degree relatives (parents, offspring, siblings). • If cancer is noted in one or more first-degree relatives, respond 'Yes'. • Select "Yes" if there is a note, a pedigree, or a completed family history questionnaire that documents the presence or absence of a cancer diagnosis in all first degree relatives of the patient. • Select 'Yes' if there is an explicit statement or notation indicating there are or are not any first-degree relatives with a diagnosis of cancer.	• If the chart documents 'No family history of cancer' or something similar, you may select 'Yes'. Select 'history is unobtainable' if there is no way for the patient to know his/her family history. • Half siblings are not considered first degree relatives. • Step parents are not biologically related and should not be included. • History may be unobtainable for a variety of reasons (e.g., the patient is adopted; history is unknown on one side of the family).	☐ Yes ☐ No ☐ Documentation that family history is unobtainable
CA Diagnosis in 2nd Degree Relative Documented Presence or absence of cancer diagnosis in second-degree relatives (aunts, uncles, grandparents, grandchildren, nieces, nephews, and half-siblings).	• Select 'Yes' if there is an explicit statement or notation indicating there are or are not any second-degree relatives with a diagnosis of cancer. If the chart documents 'No family history of cancer' or something similar, you may select 'Yes'. • Select "Yes" if there is a note, a pedigree, or a completed family history questionnaire that documents the presence or absence of a cancer diagnosis in all second degree relatives of the patient. • Half siblings of the patient are second degree relatives. • Half siblings of the patient's parents are not considered second degree relatives. • Step children of a patient's sibling are not biologically related and should not be included. • Step grandparents are not biologically related and should not be included. • History may be unobtainable for a variety of reasons (e.g., the patient is adopted; history is unknown on one side of the family). • If cancer is noted in one or more second-degree relatives, respond 'Yes'.	☐ Yes ☐ No ☐ Documentation that family history is unobtainable

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Age of Diagnosis Documented Age of diagnosis documented for each blood-relatives noted with cancer • Indicate 'Yes' if the chart lists the age of cancer diagnosis for each blood relative listed with cancer.	• 'Requested but unknown by family' if patient or family may be selected if patient is adopted.	☐ Yes ☐ No ☐ No blood relatives noted with cancer ☐ Requested but unknown by family
Patient Assessments		
Pain Assessed, First Two Office Visits If pain assessments were documented on either both visit, select 'patient had pain' if the patient was noted to have pain at either visit.	• Refer only to the first two visits with a practitioner in the office. • Notation may include patient self-assessment forms, physician consult/progress note, vital signs sheet, or other chart documentation prepared by a care team member of the practice. • The goal of these measures is to determine whether pain assessments are occurring; therefore, pain is broadly defined as an unpleasant sensory experience localized to a particular portion of the body. Documentation of pain unrelated to cancer applies to these questions, as this documentation indicates that the provider assessed the patient's pain. • Check the flow sheet, progress note, review of systems, examination and other practitioner's documentation for remarks/scores or ratings concerning the patient's pain. Look for both qualitative notations (e.g., pain is "mild" or "severe") and quantitative scores (e.g., 1-10 pain rating) when responding to pain assessment. • Answer 'Pain assessment not documented' if there is no documentation in the chart regarding pain or absence of pain.	☐ Pain assessment NOT documented ☐ Notation, patient had NO pain ☐ Notation, patient had pain
Pain Intensity Quantified, First Two Office Visits If patient had pain: Indicate whether pain intensity was quantified during the first two office visits. • If the pain is addressed in only qualitative terms and intensity is not documented (e.g., discomfort, soreness, or aches) – select 'Pain intensity not quantified'.	• If the chart documents the patient's pain using a standard instrument, such as, 0-10 numerical rating scale, a categorical scale (none, mild, moderate, severe), a visual analog scale (a line with no pain and worst pain on opposite ends), or other pictorial scale indicate the highest level of pain noted select 'Pain intensity quantified.' • If the pain is addressed in only qualitative terms and intensity is not documented (e.g., discomfort, soreness, or aches) – select 'Pain intensity not quantified.'	☐ Pain intensity quantified ☐ Pain intensity NOT quantified

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Pain Intensity, First Two Office Visits If pain intensity quantified: Enter the highest level of pain documented on either of the first two visits**.**	• If pain is reported using a numeric scale, map the numeric value to the categories provided. If pain is reported using non-numeric scale, refer to standard definitions for mild, moderate, and severe pain.	☐ None (0) ☐ Mild (1-3) ☐ Moderate (4-6) ☐ Severe (7-10)
Plan for Pain, First Two Office Visits If patient had moderate or severe pain: Indicate whether plan for pain management was documented during either of the first two office visits by a practitioner. • Plans for pain include use of opioids, non-opioid analgesics, psychosocial support, patient and/or family education on pain relief, referral to a pain clinic, or reassessment of pain at an appropriate time interval.	• This item is applicable only if intensity was quantified as moderate or severe. • This item is not addressing whether pain improved. • If the patient is continuing pain relief therapy prescribed by another facility or non-cancer pain is being managed by practitioner outside of practice and it is noted in the chart, answer 'Yes.'	☐ Yes ☐ No
Documented reason no plan for pain (optional)	• For internal quality improvement efforts, indicate the other documented reason there is no plan for pain	
Emotional Well-Being Assessed, First Two Office Visits Indicate whether an emotional well-being assessment was performed on either of the first two office visits. • Emotional well-being assessments may include evaluation of distress, depression, anxiety, coping, or adjustment. • Respond 'NOT present', if the chart simply notes 'no complaints, 'good mood', 'alert', 'no acute distress', or similar vague descriptions. • Mood and affect does suffice for evidence of assessment of emotional well-being.	• The documentation may include any of the following: • The presence of a formal screening tool used to evaluate distress, depression, or anxiety completed by the patient and present in the chart. • A record of the patient's self-report of distress, depression, or anxiety on a general symptom review for or new patient intake form. • Any note in chart regarding the status of the patient's coping, adjustment, distress, emotional, depression, or anxiety (e.g. patient reports feeling depressed in the past week; patient appears to be coping poorly with the news of disease recurrence). • Examples - the patient has increased anxiety since diagnosis; patient is feeling overwhelmed and having trouble coping with their cancer; patient is depressed.	☐ Documented, patient had problems with emotional well-being ☐ Documented, patient had NO problems with emotional well-being ☐ Documentation NOT present in chart

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Emotional Well-Being Addressed, First Two Office Visits Indicate whether emotional well-being problems were addressed during either of the first two office visits. • Action may include care provided by the practice, referral to another professional, or documentation of ongoing activities to address emotional well-being.	• If action was taken by a care team member in the practice to address the patient's emotional well-being issue, you may indicate the patient had documented problem related to emotional well-being and that problem was addressed. • Action to address emotional well-being can include any of the following: o Documentation that practice staff has instituted care for a problem with coping, adjustment, depression, anxiety, or distress, such as counseling, support group, or informal/non-consultative referral. o Documentation describing referral to another professional for care of problem with coping, adjustment, depression, anxiety, or distress. o Documentation of referral to mental health professional (e.g., psychiatrist, psychologist, social worker, pastoral care professional, mental health counselor, or psychotherapist) . o Documentation describing that though a problem is identified, no action was taken by a member of the care team in the practice which would address the problem with coping, adjustment, depression, anxiety, or distress (such as patient is already under the care of another professional, patient is currently taking medication to address problem, patient is working on individual psychotherapy techniques, or the level of issue did not warrant action at this time, etc.). o Evidence that the patient was offered support services and/or resources to address the problem.	☐ Yes ☐ No
Advance Directives, Third Office Visit Indicate whether there is documentation in the medical record that provides the patient's advance directives for treatment or there is notation that the patient does not have any advance directives by the third office visit.	• Advance directives may include a living will, durable power of attorney, do-not-resuscitate (DNR), right-to-die or similar documents that describe the patient's preferences for treatment should he/she be incapable of decision making. • If the chart documents physician orders that express the patient's preferences, indicate that advance directives are available.	☐ Yes ☐ No ☐ No third office visit
Date of Last Smoking/Tobacco Assessment The date smoking status and tobacco use was most recently assessed.	• Tobacco Use – Includes use of any type of tobacco. Do not abstract for non-tobacco products, such as e-cigarettes or marijuana.	☐ Date: _____ ☐ Unknown ☐ Smoking/Tobacco Assessment NOT done

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Smoking/Tobacco Status IF smoking tobacco use assessed: Indicate if the patient smoked or used tobacco while under the care of the practice. • Smoking status must be documented by a practitioner in the reporting practice, not by a healthcare practitioner outside the reporting practice. • Chewing tobacco is abstracted for "Tobacco Status"	• Do not abstract for non-tobacco products, such as e-cigarettes or marijuana.	☐ Smoker or tobacco use, while under the care of the practice ☐ Smoker or tobacco use, while under the care of the practice: Former smoker or tobacco use ☐ Former smoker or tobacco use ☐ Never smoked or used tobacco
Date Cessation Advice Most Recently Given The date tobacco cessation assistance was most recently provided by the practice.		☐ Date: _____ ☐ Unknown ☐ No cessation advice recently given
Date Cessation Assistance Most Recently Given The date tobacco cessation assistance was most recently provided by the practice.	• Cessation Counseling Intervention – Includes brief counseling (3 minutes or less), and/or pharmacotherapy.	☐ Date: _____ ☐ Unknown ☐ No cessation assistance recently given
Opioid Prescription, Past Six Months Indicate whether the chart documents the patient was given a prescription (new or dose change for existing prescription; do not consider refill prescription) for an opioid by any clinician (medical oncologist, surgeon, radiation oncologist) in the practice at an office visit within past six months of the most recent office visit.	• Respond 'No' if the patient wasn't prescribed an opioid OR was only prescribed an opioid while receiving care in an inpatient setting. • Opioids include morphine, hydromorphone, fentanyl, methadone, oxycodone, hydrocodone, oxymorphone, codeine, tramadol, and tapentadol.	☐ Yes ☐ No
Constipation Discussed If opioid prescription written: Indicate whether constipation was discussed with the patient at the office visit when opioid prescription was written. • Respond based on the most recent opioid prescription (new prescription or refill).	• Answer 'Yes' to this question if the chart documents any of the following at the time of the opioid prescription: • Recommendation for prophylactic stimulant laxative or stool softener at the visit when the opioid was prescribed. • Recommendation for increased fluids, and/or exercise, if feasible . • Documentation of bowel habits at the time of the prescription as an indicator that the possibility of opioid induced constipation was considered for the patient.	☐ Yes ☐ No

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Effectiveness of Opioid Assessed Effectiveness of opioid assessed on office visit following prescription. • Respond based on the most recent opioid prescription (new prescription or refill).	• Notations regarding effectiveness may include documented dose adjustment, documentation of pain assessment, or documentation of pain relief. • Choose N/A if there is no notation AND the patient did not have a visit to the office following the visit when opioid was prescribed OR the patient didn't take the medication prescribed.	☐ Yes ☐ No ☐ N/A - No second visit or opioid NOT taken
Opioid induced constipation assessed Opioid induced constipation assessed on office visit following prescription.	• Constipation may be documented as opioid induced bowel dysfunction (OBD), or other symptoms that characterize constipation, such as: o infrequent, difficult or incomplete defecation, nausea, abdominal cramping, gastro-esophageal reflux OR bloating • You may respond 'Yes' if the chart documents any of the following at the visit following the opioid prescription: o Recommendation for prophylactic stimulant laxative or stool softener o Recommendation for increased fluids, and/or exercise, if feasible o Constipation isn't a problem for this patient • Choose N/A if there is no notation AND the patient did not have a visit to the office following the visit when the opioid was prescribed OR the patient did not take the medication prescribed.	☐ Yes ☐ No ☐ N/A - No second visit or opioid NOT taken
Pain Assessed, Two Most Recent Office Visits If pain assessments were documented on both visits, select 'Patient had pain' if the patient was noted to have pain at either visit. • Respond 'Pain assessment not documented' if there is no documentation in the chart regarding pain or absence of pain.	• Refer only to the two most recent office visits with a practitioner in the office. • Notation may include patient self-assessment forms, physician consult/progress note, vital signs sheet, or other chart documentation prepared by a care team member of the practice. • The goal of these measures is to determine whether pain assessments are occurring; therefore, pain is broadly defined as an unpleasant sensory experience localized to a particular portion of the body. Documentation of pain unrelated to cancer applies to these questions, as this documentation indicates that the provider assessed the patient's pain. • Check the flow sheet, progress note, review of systems, examination and other practitioner's documentation for remarks/scores or ratings concerning the patient's pain. Look for both qualitative notations (e.g., pain is "mild" or "severe") and quantitative scores (e.g., 1-10 pain rating) when responding to pain assessment.	☐ Notation, patient had pain ☐ Notation, patient had NO pain ☐ Pain assessment NOT documented

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DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Pain Intensity Quantified, Two Most Recent Office Visits If patient had pain: Specify whether pain intensity was quantified during either of the two most recent office visits.	• If 'Notation, patient had pain', respond regarding intensity. If the chart documents the patient's pain using a standard instrument, such as, 0-10 numerical rating scale, a categorical scale (none, mild, moderate, severe), a visual analog scale (a line with no pain and worst pain on opposite ends), or other pictorial scale. • If the pain is addressed in only qualitative terms and intensity is not documented (e.g., discomfort, soreness, or aches) – select 'Pain intensity not quantified'.	☐ Pain intensity quantified ☐ Pain intensity NOT quantified
Documented Plan for Pain, Two Most Recent Office Visits If patient had moderate or severe pain: Plan for pain was documented at either of the two most recent office visits. • If the patient is continuing pain relief therapy prescribed by another facility or non-cancer pain is being managed by practitioner outside of practice and it is noted in the chart, answer 'Yes'.	• Respond based on documentation/acknowledgement by a practitioner in the practice. • A documented plan for pain may include use of opioids, nonopioid analgesics, psychosocial support, patient and/or family education on pain relief, referral to a pain clinic, or reassessment of pain at an appropriate time interval. • This item is applicable only if intensity was quantified as moderate or severe. • This item is not addressing whether pain improved.	☐ Yes ☐ No
Performance Status within Two Weeks of Most Recent Chemotherapy administration for Metastatic Disease Performance status (PS) documented within two weeks of most recent chemotherapy administration for metastatic disease. • If the visit documenting PS occurs more than 2 weeks prior to administration, respond PS 'Not documented'.	• Look for performance status (PS) documented by a care team member within the 2 weeks/14 days prior to the most recent chemotherapy administration for metastatic disease. • Responses for "Performance status" questions should reference a standard scale used by the practitioner. • Correlation of the practitioner's statements or performance status (ambulatory…) may equate to the standard scale as long as the notes are not interpreted in order to match the scale.	☐ 0 / 100% / Normal activity ☐ 1 / 80-90% / Symptoms but nearly ambulatory ☐ 2 / 60-70% / Bed time, < 50% daytime ☐ 3 / 40-50% / Bed time, > 50% ☐ 4 / 10-30% / Unable to get out of bed ☐ Not documented