

#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
	Chart ID	
Site		
Managing/Treating Physician (optional)		
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)	<ul> <li>Do not enter ICD-10 codes related to symptoms or toxicities.</li> <li>ICD-10 codes are only accepted if within the invasive malignancy range provided.</li> <li>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.</li> <li>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.</li> <li>For charts of patients diagnosed in the 16-month period, exclude patients with simultaneous bilateral breast cancer or 2 distinct cancers in one breast.</li> <li>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.</li> <li>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.</li> <li>Breast: C50.x (Female breast cancer).</li> <li>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</li> <li>NSCLC: Non-small cell only: C34.x.</li> <li>NHL: C82.x, C83, C84, C85, C86. Indolent NHL may be included.</li> <li>GYNONC: Primary peritoneal: C48.1, C48.2, C48.8, Ovarian: C56.x, Fallopian tube: C57, C57.01, C57.02</li> <li>Prostate: C61, C61.0, C61.00</li> <li>SCLC: Small cell only: C34.x</li> <li>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)</li> <li>Exclude C80.2,</li></ul>	□ ICD



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	C91.92, C92.02, C92.22, C92.32, C92.42, C92.52, C92.62, C92.72, C92.92, C93.02, C93.12, C93.32, C93.92, C93.72, 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 - D47.29), 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	
<ul> <li>Date of Diagnosis</li> <li>Date of collection of first specimen in which a pathologist confirms invasive cancer.</li> <li>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.</li> </ul>	<ul> <li>Refer to the pathology or cytology report and record the date the specimen was collected (not the date of the report).</li> <li>In the absence of a specimen date, record any documentation regarding date of initial diagnosis (e.g., a practitioner's notation).</li> <li>To be included in QOPI, the date of diagnosis must occur within the 16-month period (7/1/2017 - 10/31/2018).</li> <li>Exceptions: <ul> <li>Exceptions:</li> <li>Exceptions:</li> <li>Exceptions:</li> <li>Exceptions:</li> <li>Exceptions:</li> <li>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.</li> <li>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.</li> </ul> </li> <li>If the patient has had a recurrence, enter the date of the initial cancer diagnosis.</li> <li>For prostate cancer, diagnosis date or documentation of castration resistant prostate cancer status must occur in 16-month diagnosis window.</li> <li>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,</li> </ul>	□ Date:



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	<ul> <li>nor Symptom/Toxicity, nor any disease module) as initial treatment for the disease isn't current.</li> <li>Charts applicable for modules will be required even if target sample size has already been met for a particular module.</li> <li>For measure calculations, the earlier of either the cytology specimen date (cytology report) or tissue sample date (hematopathology report) will be used as the diagnosis date.</li> </ul>	
Gender		☐ Male ☐ Female
Date of Birth		□ Date:
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.	<ul> <li>Do not include visits during which a practitioner wasn't seen (e.g., laboratory testing).</li> <li>Do not include dates of inpatient consults/visits, phone or email consults.</li> <li>For prostate cancer, respond based on date of CRPC if diagnosis date outside of 16-month diagnosis window.</li> <li>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.</li> <li>Do not include visits to a surgeon or radiation oncologist for this element.</li> <li>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.</li> <li>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.</li> </ul>	□ Date:
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	<ul> <li>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.</li> <li>Do not include visits to a surgeon or radiation oncologist for this element.</li> <li>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).</li> <li>For charts that are applicable to the EOL module, the visit must have occurred in the 9 months preceding death.</li> </ul>	□ Date:



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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).		
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.	<ul> <li>Select 'Yes' only if a copy of the report is located in the medical record of the reporting practice.</li> <li>Enter the date of the earliest pathology and/or cytology specimen collection that confirms the malignancy.</li> <li>The earliest date entered will be considered the date of diagnosis.</li> </ul>	<ul> <li>Yes, both cytology and pathology / hematopathology report</li> <li>Yes, pathology/ hematopathology report</li> <li>Yes, cytology report</li> <li>No Report</li> </ul>
Documented reason no report (optional)		
Cytology specimen collection date		☐ Date:
Pathology/hemato-pathology specimen collection date		□ Date:
Confirm Colon/Rectum Location  If ICD-10 code C19 Indicate whether the treating physician considered the cancer to be located in the colon or rectum, for the purposes of clinically managing the patient.	ICD-10 code C19 represents 'Malignant neoplasm of rectosigmoid junction'	☐ Colon ☐ Rectum



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
DATA ELEMENT/HELF TEXT	Practice Encounter	REST ONSE OF HONS
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.	<ul> <li>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.</li> <li>For ovarian/fallopian tube/primary peritoneal cancer consider initial course of treatment to include cytoreduction surgery.</li> <li>For prostate cancer, if patient diagnosed outside of 16-month period, consider initial course of treatment to include CRPC treatment.</li> </ul>	<ul> <li>□ Reporting practice has/had primary responsibility for the initial course of the patient's medical oncology care</li> <li>□ Patient transferred to reporting practice during the initial course of medical oncology treatment</li> <li>□ Patient transferred to reporting practice following completion of initial course of medical oncology treatment</li> </ul>
<ul> <li>Chemotherapy Ever Received</li> <li>Indicate whether this patient ever received chemotherapy.</li> <li>Include oral chemotherapy agents and all forms of chemotherapy provided under the direction of the reporting practice (onsite and offsite administration).</li> <li>Hormonal therapy alone is not considered chemotherapy.</li> <li>Do not include hormonal therapies, such as tamoxifen, raloxifene (Evista), toremifene (Fareston), exemestane (Aromasin, anastrazole (Arimidex).</li> <li>Biologics such as rituximab and trastuzumab are considered chemotherapy agents.</li> </ul>	<ul> <li>Include all forms of chemotherapy received by the patient since the diagnosis that are included the chart.</li> <li>Do not include supportive care therapies (e.g., growth factors, bisphosphonates, nausea medications or fluids if these are not given in association with "chemotherapy.").</li> <li>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.</li> </ul>	<ul> <li>Yes, patient has received chemotherapy in or overseen by the reporting practice Intrathecal</li> <li>Yes, patient has received chemotherapy prior to or outside of the care of the reporting practice</li> <li>No, patient has never received chemotherapy for this diagnosis</li> </ul>



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



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Treatment Type		☐ Chemotherapy
Respond based on chart		☐ Radiation
documentation specifying what was the treatment for curative intent.		☐ Surgery
		□ None
		☐ Unknown
Surgery for primary tumor/cancer	• 'Surgical resection' includes any attempted surgery, regardless	☐ None/unknown
If the patient underwent surgery:	<ul><li>of results.</li><li>If the patient had biopsy and resection, select 'Surgical</li></ul>	☐ Diagnostic biopsy only
<ul><li>Record the type of the procedure.</li><li>Do not include surgery for recurrence</li></ul>	resection;' if the patient had multiple procedures during initial	☐ Surgical resection
or disease progression (e.g., liver lesions).	treatment course, enter the date of the most recent procedure.	
	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.	☐ White
		☐ Black or African American
	• Asian A person having origins in any of the original peoples of	☐ Asian
	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.	☐ American Indian or Alaska Native
	<ul> <li>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."</li> </ul>	☐ Other
	• Native Hawaiian or Other Pacific Islander A person having origins in any of the original peoples of Hawaii, Guam, Samoa,	□ Not reported
	<ul> <li>or other Pacific Islands.</li> <li>White A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.</li> <li>Not Reported There isn't documentation in the chart regarding race of the patient.</li> <li>Unknown The chart documents that race is unknown</li> </ul>	□ Unknown



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Ethnicity		☐ Not Hispanic or Latino
<ul> <li>Not Hispanic or Latino Chart documents that the patient is NOT of Cuban, Mexican, Puerto Rica,</li> </ul>		☐ Hispanic or Latino
South or Central American, or other Spanish culture or origin regardless of race.		□ Not reported
<ul> <li>Not Reported There isn't documentation in the chart regarding ethnicity of the patient.</li> </ul>		□ Unknown
<ul> <li>Unknown The chart documents that ethnicity is unknown.</li> </ul>		☐ Skip
<ul> <li>Skip Select this option if your practice is not including race ethnicity for any charts.</li> </ul>		
Vital Status		☐ Alive
Status of the patient at the time of abstraction.		□ Dead
<ul> <li>Select 'Alive' if patient is not known to be deceased.</li> <li>Only patients deceased as consequence of cancer or cancer treatment are eligible for the EOL module.</li> </ul>		
Cause of Death	Patients who died from an un-related cause will not be included	☐ Patient is deceased as a
If deceased: Indicate if the patient	<ul> <li>in the EOL module.</li> <li>A death certificate is NOT required for confirmation that patient</li> </ul>	consequence of his/her
died as a consequence of cancer or cancer-related treatment.	died as a result of cancer or cancer-related treatment.	cancer or cancer treatment  Description:
	If clinicians in the practice conclude that the death was cancer-	consequence of another
	related, you may check 'Yes, patient is deceased as a consequence of his/her cancer or cancer treatment.'	disease or cause
	You may assume the patient died of cancer or cancer-related	☐ Patient is deceased and
	treatment, unless there is indication otherwise (e.g., MI in an early stage patient unrelated to treatment).	cause is unknown
Date of Death	carry crops parters am outcome to a contractive	□ Date:
		☐ Unknown



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS						
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.	<ul> <li>Notation by the Practitioner that the cancer has distant metastases at diagnosis is sufficient in the absence of more detailed staging information.</li> <li>'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.</li> <li>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.</li> <li>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.</li> <li>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 without interpretation by a practitioner in the practice, answer 'No' for this item.</li> <li>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.</li> <li>Staging should be accomplished using any standardized system, including, but not limited to:         <ul> <li>TNM (Tumor, Nodes, Metastasis) scoring, such as T2N1M0 (Cancer is considered staged if only T and N are documented and M is missing)</li> <li>AICC stage grouping score such as I, II, III, or IV</li> <li>Dukes' for colorectal cancer</li> <li>FIGO for gynecologic tumors</li> <li>Clark's or Breslow's levels for melanoma</li> <li>Hematologic diagnoses: Durie-Salmon Criteria, International Staging System for multiple myeloma, Ann Arbor Staging System, International Prognostic Index&lt;</li></ul></li></ul>	□ Documentation of cancer stage at diagnosis present in medical record □ Documentation of cancer stage at diagnosis NOT present in medical record						
Cancer Stage Documented date	Tumor Grade for brain cancers	□ Date:						
		□ Unknown						



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AJCC Stage Group – Colorectal	Select most specific stage group documented.					AJCC Stage 0		
AJCC stage (0-IV) at Colorectal diagnosis	Colon/							AJCC Stage I/Dukes A
ulagilosis	Rectal							AJCC Stage IIA/Dukes B
Select 'AJCC stage group NOT	Stage		M Subset		Dukes'	MAC	-	AJCC Stage IIB/Dukes B
documented' if stage at diagnosis is documented using TNM only or an	0	Tis	NO	M0			_	AJCC Stage IIC/Dukes B
alternate staging system		T1	NO NO	M0	A	A D1	-	_
	IIA	T2 T3	NO NO	M0 M0	A B	B1 B2	-	AJCC Stage IIIA/Dukes C
	IIB	T4a	NO NO	M0	В	B2	-	AJCC Stage IIIB/Dukes C
	IIC	T4b	NO NO	M0	В	B3	-	AJCC Stage IIIC/Dukes C
	IIIA	T1-T2	N1/N1c	M0	С	C1		AJCC Stage IVA
		T1	N2a	M0	С	C1	-	AJCC Stage IVB
	IIIB	T3 - T4a	N1/N1c	M0	С	C2		AJCC stage group NOT
	IIIC	T4a	N2a	M0	С	C2		documented; Patient noted
		T3 - T4a	N2b	M0	С	C2		to have distant metastatic disease at diagnosis
		T4b	N1-N2	M0	С	C3		Neither AJCC stage group
	IVA	AnyT	AnyN	M1a			-	nor Dukes stage documented
		AnyT	AnyN	M1b			]	documented
		imary tumo			ssessed;			
		vidence of p noma in situ	•		invasion of	Flaminar	aronria	
		or invades s	· ·		iiivasioii oi	i aiiiii a <sub>l</sub>	лорна	
		or invades r						
	T3 Tumor invades through the muscularis propria into the							
	subserosa, or into non-peritonealized pericolic or perirectal tissues							
	<i>T4a</i> Tumor penetrates to the surface of the visceral primary peritoneal							
	•	nor directly	invades o	r is adh	nerent to o	other org	gans or	
		onal lymph	nodes can	not be a	ssessed			
	_	egional lym						
		astasis in 1-	•					
	N1a Met	astasis in oi	ne regional	lymph	node			
	N1b Metastasis in 2-3 regional lymph nodes							
	N1c Tur nonperito nodal met	nealized pe	sit (s) i ricolic, or p			nesenter vithout re	• •	



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	<ul> <li>N2 Metastasis in four or more regional lymph nodes</li> <li>N2a Metastasis in 4-6 regional lymph nodes</li> <li>N2b Metastasis in seven or more regional lymph nodes</li> <li>M0 No distant metastasis</li> <li>M1 Distant metastasis</li> <li>M1a Metastasis confined to one organ or site (e.g., liver, lung, ovary, nonregional node)</li> <li>M1b Metastases in more than one organ/site or the primary peritoneal</li> <li>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.</li> </ul>	
AJCC T – Colorectal  If AJCC Stage Group NOT documented:  AJCC T-Stage at diagnosis	<ul> <li>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</li> <li>Use the most recent report prior to treatment (chemotherapy/hormonal/radiation) to identify the TNM stage</li> <li>If no pathology report available, report clinical TNM if available</li> </ul>	☐ T0 ☐ Tis ☐ T1 ☐ T2 ☐ T3 ☐ T4a ☐ T4b ☐ TX ☐ Not Documented
AJCC N – Colorectal  If AJCC Stage Group NOT documented:  AJCC N-Stage at colorectal cancer  diagnosis	<ul> <li>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</li> <li>Use the most recent report prior to treatment (chemotherapy/hormonal/radiation) to identify the TNM stage</li> <li>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</li> </ul>	<ul> <li>N0</li> <li>N1</li> <li>N1a</li> <li>N1b</li> <li>N1c</li> <li>N2</li> <li>N2a</li> <li>N2b</li> <li>NX</li> <li>Not Documented</li> </ul>
AJCC M – Colorectal  If AJCC Stage Group NOT documented:  AJCC M-Stage at Colorectal diagnosis	<ul> <li>The MX designation was removed from the 7th edition of the AJCC/UICC system. Subcategories are allowed, such as cM0 (i+), M1a</li> <li>Use M0 unless clinical or pathologic evidence of mets CS Mets at Dx code 99 (unknown) maps to M0</li> </ul>	<ul><li>M0</li><li>M1</li><li>M1a</li><li>M1b</li><li>Not Documented</li></ul>



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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.		<ul><li>□ Documentation of distant metastases</li><li>□ NO documentation of distant metastases</li></ul>
PET or PET-CT ordered Indicate if a PET or PET-CT scan was ordered after completion of treatment with curative intent.		☐ Yes ☐ No ☐ Unknown
Date of PET or PET-CT		☐ Date:
Indicate who ordered the test Was the PET or PET-CT ordered by the practice or ordered outside the practice.		☐ Ordered by the Practice ☐ Ordered outside the Practice
PET 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 the PET or PET-CT.		☐ Yes ☐ No ☐ Unknown
Transrectal Ultrasound performed for staging Indicate whether a Transrectal Ultrasound was performed prior to initial chemotherapy or surgery.		☐ Yes ☐ No ☐ Unknown
Date of Transrectal Ultrasound		☐ Date:
Pelvic MRI performed for staging Indicate whether a Pelvic MRI was performed prior to initial chemotherapy or surgery.		☐ Yes ☐ No ☐ Unknown
Pelvic MRI Date		□ Date:



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Tumor Markers			
KRAS Gene Mutation Testing If stage IV or metastatic colorectal cancer: Indicate the results of KRAS gene mutation testing.  In the absence of any documentation regarding testing for the KRAS gene mutation, select 'Test not ordered/no documentation.		<ul> <li>□ No KRAS mutation detected (wildtype)</li> <li>□ KRAS mutation detected</li> <li>□ Test ordered, results not yet documented</li> <li>□ Test NOT ordered/no documentation</li> <li>□ Patient transferred in from outside country; no analysis completed</li> </ul>	
Enter documented reason no KRAS test (optional) For internal quality improvement efforts, indicate the reason NRAS test was not ordered.			
<ul> <li>NRAS Gene Mutation Testing</li> <li>If stage IV or metastatic colorectal</li> <li>cancer: Indicate the results of NRAS</li> <li>gene mutation testing.</li> <li>In the absence of any documentation regarding testing for the NRAS gene mutation, select 'Test not ordered/no documentation.</li> </ul>		<ul> <li>No NRAS mutation detected (wildtype)</li> <li>NRAS mutation detected</li> <li>Test ordered, results not yet documented</li> <li>Test NOT ordered/no documentation</li> <li>Patient transferred in from outside country; no analysis completed</li> </ul>	
	Surgery		
Date of Surgical Resection		☐ Date:	
<ul> <li>Margin Status</li> <li>If patient had a surgical resection:</li> <li>record the surgical resection results.</li> <li>Select 'Tumor not resectable and/or known metastatic disease' if the tumor could not be removed; if</li> </ul>		<ul><li>☐ Tumor resected, clear margins</li><li>☐ Tumor resected, surgical margins noted as positive</li></ul>	



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
surgery occurred in presence of known metastatic disease (e.g., for palliation); or if distant metastases were discovered during surgery, even if the primary tumor was removed or partially removed.		(R1, microscopically or macroscopically positive)  □ Tumor NOT resectable and/or KNOWN  METASTATIC DISEASE  □ Awaiting results  □ Surgery NOT performed  □ Not documented
Number of Regional Lymph Nodes Pathologically Examined  If NOT stage IV or distant metastatic colorectal cancer: If patient had surgical resection, enter the total number of regional nodes examined (not just positive nodes).		
CEA following curative resection  If NOT stage IV or distant metastatic colorectal cancer: If tumor resected, clear margins, respond 'Yes' if CEA was measured within 4 months following the curative resection.  • If the patient had multiple surgical resections during initial treatment course, respond based on the most recent procedure.		☐ Yes ☐ No
Reason No CEA within 4 months (optional)  For internal quality improvement efforts, indicate the documented reason no CEA was measured within 4 months following the curative resection.		



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
If NOT stage IV or distant metastatic colorectal cancer: If patient had surgical resection, indicate if a colonoscopy was completed preoperatively, intraoperatively, at the time of diagnosis, within 6 months of surgical resection or completion of primary adjuvant chemotherapy treatment.  • Respond 'Yes', only if there is documentation of a colonoscopy that included complete visualization of the bowel to the cecum.  • If the patient had multiple surgical resections during initial treatment course, respond based on the most recent procedure.		☐ Yes, complete colon examination via colonoscopy  ☐ No complete colon examination via colonoscopy
Reason for No Colonoscopy		<ul> <li>□ No reason documented</li> <li>□ Patient died (before 6 months past end of adjuvant chemo)</li> <li>□ Patient transferred out of practice (before 6 months past end of adjuvant chemo)</li> <li>□ Patient still receiving adjuvant chemotherapy</li> <li>□ Obstruction</li> <li>□ Other reason documented</li> </ul>
Other reason for No Colonoscopy (optional)  For internal quality improvement efforts, indicate the other documented reason no colonoscopy was performed.		



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS	
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.	<ul> <li>If both neoadjuvant and adjuvant chemotherapy agents were recommended, but the patient only received neoadjuvant, respond based on neoadjuvant chemotherapy.</li> <li>Responses should be based on recommendations by a physician in the practice.</li> <li>Include all forms of chemotherapy; biologics such as rituximab and trastuzumab are considered chemotherapy agents.</li> <li>Hormonal therapy alone is not considered chemotherapy.</li> <li>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)</li> <li>Exclusions are captured under 'Chemotherapy Administered.'</li> </ul>	☐ Chemotherapy NOT recommended ☐ Chemotherapy recommended	
Date Chemotherapy First Recommended Enter the date on which chemotherapy treatment was first documented as being recommended via discussion with the patient.		□ Date:	
<ul> <li>Chemotherapy Administered</li> <li>Indicate whether a chemotherapy agent was administered during initial treatment course.</li> <li>'Administered' applies to treatment underway or complete.</li> <li>Include oral chemotherapy treatment and chemotherapy treatment provided offsite but under the direction of the reporting practice.</li> <li>If administration includes neoadjuvant and adjuvant chemotherapy treatment, respond based on adjuvant treatment.</li> </ul>		<ul> <li>□ Chemotherapy administered</li> <li>□ Chemotherapy NOT administered</li> </ul>	



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Topical and/or Intravesical chemotherapy received		☐ Yes ☐ No ☐ Unknown
Date Chemotherapy Started		□ Date:
Enter the date the <b>initial</b> chemotherapy started.		☐ Unknown
Reason Chemotherapy NOT Administered Indicate the documented reason chemotherapy agent was not administered to the patient as part of the initial course of treatment		<ul> <li>□ No reason documented</li> <li>□ Awaiting test/staging results</li> <li>□ Patient declined (patient reason)</li> <li>□ Patient died or transferred</li> <li>□ Contraindication or other clinical exclusion documented</li> <li>□ Alternative treatment according to clinical trial protocol</li> <li>□ Other reason documented</li> </ul>
Chemotherapy for Stage IV or Distant Metastatic Disease		☐ Yes
Respond 'Yes' if the patient received		□ No
chemotherapy treatment ordered by		☐ Not Documented
your practice for stage IV or distant metastatic disease.		□ Unknown
Chemotherapy for Stage IV Disease by IRB Protocol	<ul> <li>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</li> </ul>	☐ Yes
If patient received chemotherapy		□ No
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.	status of 3, 4, or not documented.	□ Unknown



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
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	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
Patient Received Folfoxiri or Folfirinox Indicate whether Folfoxiri or Folfirinox were administered to the patient at any time during his/her therapy.		□ No □ Yes □ Unknown
Anti-EGFR Therapy Indicate whether anti-EGFR monoclonal antibody therapy (cetuximab (Erbitux) or panitumumab (Vectibix) was administered to the patient by your practice for metastatic colon or rectal cancer.	The monoclonal antibody may have been provided alone or in combination with chemotherapy.	☐ Anti-EGFR monoclonal antibody therapy received ☐ No anti-EGFR monoclonal antibody therapy received



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Consent Documentation Indicate documented consent obtained prior to first administration of chemotherapy treatment (including oral).	<ul> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>	□ 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.	<ul> <li>Performance status documented within two weeks prior to or on the day of chemotherapy treatment administration.</li> <li>Respond based on first administration of the initial chemotherapy treatment regimen.</li> </ul>	<ul> <li>□ 0 / 100% / Normal activity</li> <li>□ 2 / 60-70% / Bed time,</li> <li>&lt;50% daytime)</li> <li>□ 3 / 40-50% / Bed time,</li> <li>&gt;50%</li> <li>□ 4 / 10-30% / Unable to get out of bed</li> <li>□ Not Documented</li> </ul>



#### **CORE + Colorectal Modules**

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.		<ul> <li>□ Curative/adjuvant/ neoadjuvant</li> <li>□ Non-curative (Palliative, life extending, symptom control)</li> <li>□ No, 14 days has not passed after chemotherapy administration</li> <li>□ Not documented</li> </ul>
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.	<ul> <li>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.</li> <li>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.</li> <li>If the patient received neoadjuvant and adjuvant chemotherapy, respond regarding the adjuvant treatment.</li> <li>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.</li> <li>Documentation of prognosis does not qualify for documentation of intent of treatment.</li> </ul>	☐ Yes, discussion documented☐ No, discussion NOT documented
Indicate the sequence with which chemotherapy treatment and surgery were provided during the initial treatment course.  Respond based on documentation/acknowledgement of intent for the initial treatment course, by a practitioner in the practice.  Select 'Curative chemotherapy without curative surgery' if curative surgery not planned/ and/or not received by patient.		<ul> <li>□ Neoadjuvant</li> <li>□ Adjuvant</li> <li>□ Curative chemotherapy without curative surgery</li> <li>□ Intraoperative</li> </ul>



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
<ul> <li>Initial Chemotherapy Ended</li> <li>Indicate whether chemotherapy</li> <li>stopped for any reason (end of planned therapy, patient died, toxicities, etc.).</li> <li>Do not include treatment breaks or 'holidays' if the treatment regimen is expected to continue under the care of the practice.</li> <li>If patient stopped one drug and started on different agent due to toxicity or disease progression consider chemotherapy regimen discontinued".</li> </ul>		<ul> <li>□ Chemotherapy regimen discontinued or completed</li> <li>□ Chemotherapy regimen is ongoing</li> </ul>
Date Initial Course of Chemotherapy Ended		□ Date:
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.		<ul> <li>□ Completion</li> <li>□ Toxicity</li> <li>□ Progression of disease</li> <li>□ Death</li> <li>□ Patient request to stop</li> <li>□ Patient transfer to another practice/care facility</li> <li>□ Financial</li> <li>□ Other</li> <li>□ Not documented</li> </ul>
Initial Oral Chemotherapy prescription completed, discontinued, or changed Indicate if the initial oral chemotherapy prescription completed, discontinued, or changed.		□ No □ Yes



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Reason initial Oral Chemotherapy prescription completed, discontinued, or changed  If patient completed, discontinued, or changed initial planned oral chemotherapy prescription, indicate the reason.		<ul> <li>□ Completion</li> <li>□ Toxicity</li> <li>□ Progression of disease</li> <li>□ Death</li> <li>□ Patient request to stop</li> <li>□ Patient transfer to another practice/care facility</li> <li>□ Financial</li> <li>□ Other</li> <li>□ Not documented</li> </ul>
	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.	<ul> <li>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.</li> <li>If none of the key elements are documented, select 'No elements documented.'</li> <li>If the patient received neoadjuvant and adjuvant chemotherapy, respond regarding the adjuvant treatment.</li> <li>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:         <ol> <li>there is standard documentation that is physically available at the practice or in the practice EHR/electronic system for the regimen or protocol AND</li> <li>the standard documentation includes details of the medications, and the element(s) selected.</li> </ol> </li> <li>Refer to the initial prescription for oral chemotherapy.</li> </ul>	□ Chemotherapy regimen/drugs □ Doses □ Route □ Time Intervals □ Cycles □ Schedule/Start Dates □ Indications □ Patient Height □ Patient Weight □ Body Surface Area □ No elements documented



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.	<ul> <li>Check for evidence in the chart that the patient was educated about the following prior to start of oral chemotherapy:</li> <li>Indications: Use of the oral agent for treating the malignancy.</li> <li>Schedule and start date: Date of first ingestion, not prescription date, pick-up date, or planned start date.</li> <li>Management of missed doses: Actions patient should take if a dose is skipped or extra dose is taken.</li> <li>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)</li> <li>When and how to contact the office: Situations that would trigger contact with the office, who to contact, and how to reach them.</li> </ul>	<ul> <li>□ Management of Missed         Doses</li> <li>□ Potential Side         Effects/Toxicities</li> <li>□ When and how to contact         the clinic</li> </ul>
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.		<ul><li>☐ Yes</li><li>☐ No</li><li>☐ No visit/contact following prescription</li></ul>
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.	<ul> <li>□ Medication adherence         NOT documented</li> <li>□ Notation, patient did NOT         adhere to oral         chemotherapy regimen</li> <li>□ Notation, patient adhered         to oral Chemotherapy         regimen</li> <li>□ No visit/contact following         prescription</li> </ul>



#### **CORE + Colorectal Modules**

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
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.	<ul> <li>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.</li> <li>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.</li> <li>The treatment summary may include elements in addition to the required elements.</li> <li>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.</li> </ul>	Treatment summary completed Treatment summary NOT completed
<b>Date Treatment Summary Completed</b> Provide the actual date of completion		Date:



#### **CORE + Colorectal Modules**

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.	<ul> <li>□ Chemotherapy delivered, (# of cycles, duration, and extent of dose reduction)</li> <li>□ Reason treatment was stopped</li> <li>□ Major toxicities and/or hospitalizations</li> <li>□ Treatment response</li> <li>□ Follow up care and relevant providers</li> <li>□ None of the above</li> </ul>
Provided to Patient		☐ Yes
Provide the actual date the treatment summary provided to the patient.		□ No
Date Provided to Patient		□ Date:
		☐ Unknown
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.'    Application	<ul> <li>Yes</li> <li>No</li> <li>N/A - no other practitioner(s) providing continuing care</li> </ul>
Date Provided to Practitioner(s) Record the actual date the treatment summary was provided or communicated to practitioner(s)		□ Date:



#### **CORE + Colorectal Modules**

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.	<ul> <li>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.</li> <li>Half siblings are not considered first degree relatives</li> <li>Step-parents are not biologically related and should not be included.</li> <li>History may be unobtainable for a variety of reasons (e.g., the patient is adopted; history is unknown on one side of the family).</li> </ul>	☐ 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).	<ul> <li>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'.</li> <li>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.</li> <li>Half siblings of the patient are second degree relatives.</li> <li>Half siblings of the patient's parents are not considered second degree relatives.</li> <li>Step-children of a patient's sibling are not biologically related and should not be included.</li> <li>Step-grandparents are not biologically related and should not be included.</li> <li>History may be unobtainable for a variety of reasons (e.g., the patient is adopted; history is unknown on one side of the family).</li> <li>If cancer is noted in one or more second-degree relatives, respond 'Yes'.</li> </ul>	☐ Yes ☐ No ☐ Documentation that family history is unobtainable



#### **CORE + Colorectal Modules**

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.  Genetic Risk Assessment (Check all that apply)  Respond based on information	<ul> <li>'Requested but unknown by family' if patient or family may be selected if patient is adopted.</li> <li>History of another cancer consistent with HNPCC syndrome (colorectal, endometrial, gastric, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain, small bowel cancers, sebaceous</li> </ul>	<ul> <li>☐ Yes</li> <li>☐ No</li> <li>☐ No blood relatives noted with cancer</li> <li>☐ Requested but unknown by family</li> <li>☐ Two or more related firstor second-degree blood relatives with colorectal,</li> </ul>
Respond based on information documented in the chart for each of the criteria listed for the risk evaluation *Blood relative (first-, second-, or third-degree relation by birth, not marriage or adoption).  • First-degree: parents, offspring, and siblings (shares about one half of genes with the person).  • Second-degree: aunts, uncles, grandparents, grandchildren, nieces, nephews, and half-sibling (shares about one quarter of genes with the person).  • Third-degree: first cousin, great-grandparent or great-grandchild (shares about one eighth of genes with the person).	gland adenomas, and keratoacanthomas) either concurrently or over multiple episodes: Select if the chart documents that the patient had a previous diagnosis of one of the HNPCC-related cancers listed.  • High results on microsatellite instability (MSI) testing (MSI-H): Cancers arising in cells with defective mismatch repair gene function exhibit an inconsistent number of microsatellite nucleotide repeats when compared to normal tissue, "microsatellite instability (MSI)." A panel of at least five markers is used to assess MSI in tumor and normal tissue.  • MSI-high - more than 30% of the markers show instability • MSI-low - fewer than 30% of the markers show instability • MSI-stable - 0% of the markers show instability.  • Blood relative diagnosed with colorectal cancer: Include first-, second-, and third-degree relatives.  • First-degree blood relative with colorectal cancer, ovarian cancer or endometrial cancer diagnosed under the age of 50 years: Select if the patient's parents, offspring, or siblings have been diagnosed with colorectal cancer, ovarian cancer or endometrial cancer diagnosed under the age of 50 years  • Half siblings are not considered first degree relatives.  • Step parents are not biologically relatives and should not be included.  • Two or more first- or second-degree blood relatives with colorectal cancer, ovarian cancer or endometrial cancer in any of the following combination of relatives:  • Two or more first degree relatives (parents, offspring, or siblings).  • Two or more second degree relatives (aunts, uncles, grandparents, grandchildren, nieces, nephews, or half-siblings) or at least one first degree relative AND at least one second degree relative.	relatives with colorectal, ovarian, or endometrial cancer  Blood relative diagnosed with colorectal cancer  First-degree blood relative with colorectal, ovarian, or endometrial cancer diagnosed under the age of 50 years  High results on microsatellite instability (MSI) testing (MSI-H)  History of another cancer consistent with HNPCC syndrome: Blood relative diagnosed with colorectal cancer,  None of the above



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Patient Received Counseling or		☐ Yes
Referral for Counseling for Genetic		□ No
Testing		
• Select 'Yes' if the patient was		
referred to a risk clinic, geneticist,		
genetic counselor, specialist with		
expertise in genetics evaluation		
and/or testing, or if the patient		
received counseling in your office to		
discuss genetic testing for specific		
genes associated with cancer.		
<ul> <li>Select 'Yes' if the patient was</li> </ul>		
referred or counseled by another		
provider is outside of your practice.		
Pre-test counseling allows for		
advance consideration of medical		
options and the impact test results		
may have on family members. It		
includes informed consent for the		
testing and should address reasons		
for the test, possible impact on		
medical treatment options, and		
confidentiality of the results.		
Genetic counseling is the process by  Which patients or relatives, at risk of		
which patients or relatives, at risk of an inherited disorder, are advised of		
the consequences and nature of the		
disorder, the probability of		
developing or transmitting it, and the		
options open to them in		
management and family planning. It		
includes:		
Interpretation of family and medical		
histories to assess the chance of		
disease occurrence or recurrence.		
Education about inheritance, testing,		
management, prevention, resources		
and research .		
Counseling to promote informed		
choices and adaptation to the risk or		
condition.		
As providers of genetic risk		
assessment to patients and families		
affected by cancer, it is the role of		
ancologists and other health care		



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
providers to offer genetic tests in a manner that is safe and clinically appropriate.  • ASCO recommends that evaluation by a health care professional experienced in cancer genetics should be relied on in making interpretations of pedigree information and determinations of the appropriateness of genetic testing, including determinations of appropriateness for reimbursement		
Reason why no Counseling or Referral		☐ No reason documented
for Counseling  If the patient received pre-genetic test screening and results did not warrant further genetic counseling or testing, respond 'Pre-screening test negative for genetic testing.		<ul> <li>□ Patient declined</li> <li>□ Patient transferred out of practice</li> <li>□ Patient died</li> <li>□ Pre-screening test negative for genetic testing</li> <li>□ Other reason documented</li> </ul>
Enter other documented reason for NO counseling or referral (optional)		
For internal quality improvement efforts, indicate the other documented reason for no counseling or referral.		
Patient Completed Genetic Testing	Common genetic tests for cancer include:	□ No
Indicate whether the patient completed genetic testing related to his/her invasive malignancy.	<ul> <li>BRCA1 and/or BRCA2</li> <li>TP53</li> <li>CHEK2</li> <li>CDH1</li> <li>P53</li> <li>APC</li> <li>PTEN</li> <li>MLH1, MSH2, MSH6, IHC</li> <li>MSI panel if used for germline DNA testing rather than prescreening.</li> <li>* KRAS and NRAS are NOT considered genetic tests for the purpose of the QOPI genetic testing questions</li> </ul>	<ul> <li>Yes, ordered by practice</li> <li>Yes, not ordered by practice</li> <li>No, test is scheduled or patient referred for testing</li> </ul>



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
Patient Consent Obtained for Genetic Testing Ordered By Practice Indicate whether patient consent was obtained and documented before genetic testing occurred.	<ul> <li>Respond 'Yes' if there was a signed patient consent form or chart notation that indicates that the patient consented to the test prior to actual testing.</li> <li>Respond based on tests ordered by your practice.</li> </ul>	☐ Yes ☐ No
Discussion of Genetic Test Results Indicate whether the results of the genetic tests were discussed with the patient.	<ul> <li>Respond 'Yes' if there is a note in the chart or patient letter documenting post-test counseling with the patient.</li> <li>The discussion should include at a minimum, the results, significance of the results, impact on medical treatment, possible inherited cancer risk to relatives, and how/where the patient will be followed.</li> </ul>	☐ Yes ☐ No
Other reason Why No Discussion (optional)		
Microsatellite instability (MSI) status Testing Microsatellite instability (MSI) status determined by MS instability analysis.		☐ Yes ☐ No ☐ Unknown
Immunohistochemistry by mismatched repair proteins (MMR) Testing Microsatellite instability (MSI) status determined by Immunohistochemistry by mismatched repair proteins (MMR) MMR Testing.		☐ Yes ☐ No ☐ Unknown



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
	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.	<ul> <li>Refer only to the first two visits with a practitioner in the office.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>Answer 'Pain assessment not documented' if there is no documentation in the chart regarding pain or absence of pain.</li> </ul>	<ul> <li>□ Pain assessment NOT documented</li> <li>□ Notation, patient had NO pain</li> <li>□ Notation, patient had pain</li> </ul>
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'.	<ul> <li>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.'</li> <li>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.'</li> </ul>	☐ Pain intensity quantified ☐ Pain intensity NOT quantified
Pain Intensity, First Two Office Visits  If pain intensity quantified: Enter the	• If pain is reported using a numeric scale, map the numeric value to the categories provided. If pain is reported using non-	□ None (0)
highest level of pain documented on	numeric scale, refer to standard definitions for mild, moderate,	☐ Mild (1-3)
either of the first two visits.	and severe pain.	☐ Moderate (4-6)
		☐ Severe (7-10)



DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
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.	<ul> <li>This item is applicable only if intensity was quantified as moderate or severe.</li> <li>This item is not addressing whether pain improved.</li> <li>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.'</li> </ul>	☐ Yes ☐ No
Documented reason no plan for pain (optional)	<ul> <li>For internal quality improvement efforts, indicate the other documented reason there is no plan for pain.</li> </ul>	
<ul> <li>Emotional Well-Being Assessed, First Two Office Visits</li> <li>Indicate whether an emotional wellbeing assessment was performed on either of the first two office visits.</li> <li>Emotional well-being assessments may include evaluation of distress, depression, anxiety, coping, or adjustment.</li> <li>Respond 'NOT present', if the chart simply notes 'no complaints, 'good mood', 'alert', 'no acute distress', or similar vague descriptions.</li> <li>Mood and affect does suffice for evidence of assessment of emotional well-being.</li> </ul>	<ul> <li>The documentation may include any of the following:</li> <li>The presence of a formal screening tool used to evaluate distress, depression, or anxiety completed by the patient and present in the chart.</li> <li>A record of the patient's self-report of distress, depression, or anxiety on a general symptom review for or new patient intake form.</li> <li>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).</li> <li>Examples - the patient has increased anxiety since diagnosis; patient is feeling overwhelmed and having trouble coping with their cancer; patient is depressed.</li> </ul>	<ul> <li>□ Documented, patient had problems with emotional well-being</li> <li>□ Documented, patient had NO problems with emotional well-being</li> <li>□ Documentation NOT present in chart</li> </ul>



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
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.	<ul> <li>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.</li> <li>Action to address emotional well-being can include any of the following:         <ul> <li>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.</li> <li>Documentation describing referral to another professional for care of problem with coping, adjustment, depression, anxiety, or distress.</li> <li>Documentation of referral to mental health professional (e.g., psychiatrist, psychologist, social worker, pastoral care professional, mental health counselor, or psychotherapist).</li> <li>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.).</li> <li>Evidence that the patient was offered support services and/or resources to address the problem.</li> </ul> </li> </ul>	☐ 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.	<ul> <li>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.</li> <li>If the chart documents physician orders that express the patient's preferences, indicate that advance directives are available.</li> </ul>	☐ Yes ☐ No ☐ No third office visit
<b>Date of Last Smoking/Tobacco Assessment</b> The date smoking status and tobacco use was most recently assessed.	<ul> <li>Tobacco Use – Includes use of any type of tobacco. Do not abstract for non-tobacco products, such as e-cigarettes or marijuana.</li> </ul>	□ Date: □ Unknown □ Smoking/Tobacco Assessment NOT done



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
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.	<ul> <li>□ Smoker or tobacco use, while under the care of the practice</li> <li>□ Smoker or tobacco use, while under the care of the practice: Former smoker or tobacco use</li> <li>□ Former smoker or tobacco use</li> <li>□ Never smoked or used tobacco</li> </ul>
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.	<ul> <li>Respond 'No' if the patient wasn't prescribed an opioid OR was only prescribed an opioid while receiving care in an inpatient setting.</li> <li>Opioids include morphine, hydromorphone, fentanyl, methadone, oxycodone, hydrocodone, oxymorphone, codeine, tramadol, and tapentadol.</li> </ul>	☐ 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).	<ul> <li>Answer 'Yes' to this question if the chart documents any of the following at the time of the opioid prescription:</li> <li>Recommendation for prophylactic stimulant laxative or stool softener at the visit when the opioid was prescribed.</li> <li>Recommendation for increased fluids, and/or exercise, if feasible.</li> <li>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.</li> </ul>	☐ Yes ☐ No



#### **CORE + Colorectal Modules**

DATA ELEMENT/HELP TEXT	ADDITIONAL NOTES	RESPONSE OPTIONS
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).	<ul> <li>Notations regarding effectiveness may include documented dose adjustment, documentation of pain assessment, or documentation of pain relief.</li> <li>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.</li> </ul>	<ul><li>☐ Yes</li><li>☐ No</li><li>☐ N/A - No second visit or opioid NOT taken</li></ul>
Opioid induced constipation assessed Opioid induced constipation assessed on office visit following prescription	<ul> <li>Constipation may be documented as opioid induced bowel dysfunction (OBD), or other symptoms that characterize constipation, such as:         <ul> <li>infrequent, difficult or incomplete defecation, nausea, abdominal cramping, gastro-esophageal reflux OR bloating</li> </ul> </li> <li>You may respond 'Yes' if the chart documents any of the following at the visit following the opioid prescription:         <ul> <li>Recommendation for prophylactic stimulant laxative or stool softener</li> <li>Recommendation for increased fluids, and/or exercise, if feasible</li> <li>Constipation isn't a problem for this patient</li> </ul> </li> <li>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.</li> </ul>	☐ 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.	<ul> <li>Refer only to the two most recent office visits with a practitioner in the office.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>	<ul> <li>□ Notation, patient had pain</li> <li>□ Notation, patient had NO pain</li> <li>□ Pain assessment NOT documented</li> </ul>



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.	<ul> <li>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.</li> <li>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'.</li> </ul>	☐ 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'.	<ul> <li>Respond based on documentation/acknowledgement by a practitioner in the practice.</li> <li>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.</li> <li>This item is applicable only if intensity was quantified as moderate or severe.</li> <li>This item is not addressing whether pain improved.</li> </ul>	☐ 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'.	<ul> <li>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.</li> <li>Responses for "Performance status" questions should reference a standard scale used by the practitioner.</li> <li>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.</li> </ul>	<ul> <li>□ 0 / 100% / Normal activity</li> <li>□ 1 / 80-90% / Symptoms but nearly ambulatory</li> <li>□ 2 / 60-70% / Bed time, &lt; 50% daytime</li> <li>□ 3 / 40-50% / Bed time, &gt; 50%</li> <li>□ 4 / 10-30% / Unable to get out of bed</li> <li>□ Not documented</li> </ul>