

Quality ID #490: Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

2025 COLLECTION TYPE: **MIPS CLINICAL QUALITY MEASURES (CQMS)**

MEASURE TYPE: Process

DESCRIPTION:

Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.

INSTRUCTIONS:

This measure is to be submitted a minimum of **once per episode** for patients with a diagnosis of cancer and on immune checkpoint inhibitors and who have grade 2 or above diarrhea and/or grade 2 or above colitis seen during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Submission Type:

Measure data may be submitted by individual MIPS eligible clinicians, groups, or third-party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third-party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third-party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

NOTE: Patient encounters for this measure conducted via telehealth (including but not limited to encounters coded with GQ, GT, POS 02, POS 10) are allowable.

DENOMINATOR:

Patients 18 years and older, with a diagnosis of cancer and on immune checkpoint inhibitors and who have grade 2 or above diarrhea and/or grade 2 or above colitis

Definitions:

Episode – Onset of grade 2 or above diarrhea or grade 2 colitis or above until resolution.

Immune checkpoint inhibitors – Class of medications that prevent tumors from “hiding” or “evading” the body’s natural immune system. This is a form of cancer immunotherapy. Immune checkpoint inhibitor medications include PD-1 inhibitor drugs, PD-L1 inhibitor drugs, CTLA-4 inhibitor drugs, and LAG-3 inhibitor drug.

- PD-1 inhibitors drugs include: Pembrolizumab, Nivolumab, Cemiplimab
- PD-L1 inhibitors drugs include: Atezolizumab, Avelumab, Durvalumab
- CTLA-4 inhibitor drugs include: Ipilimumab, Tremelimumab
- LAG-3 inhibitor drug include: Relatlimab

Grade 2 Diarrhea – 4-6 bowel movements above baseline per day. Moderate increase in ostomy output compared to baseline; limiting instrumental ADL.

Grade 3 Diarrhea – Increase of ≥ 7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL.

Grade 4 Diarrhea – Life-threatening consequences; urgent intervention indicated.

Grade 2 Colitis – Abdominal pain, mucus or blood in stool.

Grade 3 Colitis – Severe abdominal pain; peritoneal signs.

Grade 4 Colitis – Life-threatening consequences; urgent intervention indicated.

*DENOMINATOR NOTE: *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for MIPS CQMs.*

Denominator Criteria (Eligible Cases):

Patients aged ≥ 18 years on the date of the encounter

AND

Diagnosis of Cancer (ICD-10-CM): C00.0, C00.1, C00.2, C00.3, C00.4, C00.5, C00.6, C00.8, C00.9, C01, C02.0, C02.1, C02.2, C02.3, C02.4, C02.8, C02.9, C03.0, C03.1, C03.9, C04.0, C04.1, C04.8, C04.9, C05.0, C05.1, C05.2, C05.8, C05.9, C06.0, C06.1, C06.2, C06.80, C06.89, C06.9, C07, C08.0, C08.1, C08.9, C09.0, C09.1, C09.8, C09.9, C10.0, C10.1, C10.2, C10.3, C10.4, C10.8, C10.9, C11.0, C11.1, C11.2, C11.3, C11.8, C11.9, C12, C13.0, C13.1, C13.2, C13.8, C13.9, C14.0, C14.2, C14.8, C15.3, C15.4, C15.5, C15.8, C15.9, C16.0, C16.1, C16.2, C16.3, C16.4, C16.5, C16.6, C16.8, C16.9, C17.0, C17.1, C17.2, C17.3, C17.8, C17.9, C18.0, C18.1, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20, C21.0, C21.1, C21.2, C21.8, C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8, C22.9, C23, C24.0, C24.1, C24.8, C24.9, C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9, C26.0, C26.1, C26.9, C30.0, C30.1, C31.0, C31.1, C31.2, C31.3, C31.8, C31.9, C32.0, C32.1, C32.2, C32.3, C32.8, C32.9, C33, C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91, C34.92, C37, C38.0, C38.1, C38.2, C38.3, C38.4, C38.8, C39.0, C39.9, C40.00, C40.01, C40.02, C40.10, C40.11, C40.12, C40.20, C40.21, C40.22, C40.30, C40.31, C40.32, C40.80, C40.81, C40.82, C40.90, C40.91, C40.92, C41.0, C41.1, C41.2, C41.3, C41.4, C41.9, C43.0, C43.10, C43.111, C43.112, C43.121, C43.122, C43.20, C43.21, C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59, C43.60, C43.61, C43.62, C43.70, C43.71, C43.72, C43.8, C43.9, C44.00, C44.01, C44.02, C44.09, C44.101, C44.1021, C44.1022, C44.1091, C44.1092, C44.111, C44.1121, C44.1122, C44.1191, C44.1192, C44.121, C44.1221, C44.1222, C44.1291, C44.1292, C44.131, C44.1321, C44.1322, C44.1391, C44.1392, C44.191, C44.1921, C44.1922, C44.1991, C44.1992, C44.201, C44.202, C44.209, C44.211, C44.212, C44.219, C44.221, C44.222, C44.229, C44.291, C44.292, C44.299, C44.300, C44.301, C44.309, C44.310, C44.311, C44.319, C44.320, C44.321, C44.329, C44.390, C44.391, C44.399, C44.40, C44.41, C44.42, C44.49, C44.500, C44.501, C44.509, C44.510, C44.511, C44.519, C44.520, C44.521, C44.529, C44.590, C44.591, C44.599, C44.601, C44.602, C44.609, C44.611, C44.612, C44.619, C44.621, C44.622, C44.629, C44.691, C44.692, C44.699, C44.701, C44.702, C44.709, C44.711, C44.712, C44.719, C44.721, C44.722, C44.729, C44.791, C44.792, C44.799, C44.80, C44.81, C44.82, C44.89, C44.90, C44.91, C44.92, C44.99, C45.0, C45.1, C45.2, C45.7, C45.9, C46.0, C46.1, C46.2, C46.3, C46.4, C46.50, C46.51, C46.52, C46.7, C46.9, C47.0, C47.10, C47.11, C47.12, C47.20, C47.21, C47.22, C47.3, C47.4, C47.5, C47.6, C47.8, C47.9, C48.0, C48.1, C48.2, C48.8, C49.0, C49.10, C49.11, C49.12, C49.20, C49.21, C49.22, C49.3, C49.4, C49.5, C49.6, C49.8, C49.9, C49.A0, C49.A1, C49.A2, C49.A3, C49.A4, C49.A5, C49.A9, C4A.0, C4A.10, C4A.111, C4A.112, C4A.121, C4A.122, C4A.20, C4A.21, C4A.22, C4A.30, C4A.31, C4A.39, C4A.4, C4A.51, C4A.52, C4A.59, C4A.60, C4A.61, C4A.62, C4A.70, C4A.71, C4A.72, C4A.8, C4A.9, C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C60.0, C60.1, C60.2, C60.8, C60.9, C61, C62.00, C62.01, C62.02, C62.10, C62.11, C62.12, C62.90, C62.91, C62.92, C63.00, C63.01, C63.02, C63.10, C63.11, C63.12, C63.2, C63.7, C63.8, C63.9, C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0, C67.1, C67.2, C67.3, C67.4, C67.5, C67.6, C67.7, C67.8, C67.9, C68.0, C68.1, C68.8, C68.9, C69.00, C69.01, C69.02, C69.10, C69.11, C69.12, C69.20, C69.21, C69.22, C69.30, C69.31, C69.32, C69.40, C69.41, C69.42, C69.50, C69.51, C69.52, C69.60, C69.61, C69.62,

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D37.031, D37.032, D37.039, D37.04, D37.05, D37.09, D37.1, D37.2, D37.3, D37.4, D37.5, D37.6, D37.8, D37.9, D38.0, D38.1, D38.2, D38.3, D38.4, D38.5, D38.6, D39.0, D39.10, D39.11, D39.12, D39.2, D39.8, D39.9, D40.0, D40.10, D40.11, D40.12, D40.8, D40.9, D41.00, D41.01, D41.02, D41.10, D41.11, D41.12, D41.20, D41.21, D41.22, D41.3, D41.4, D41.8, D41.9, D42.0, D42.1, D42.9, D43.0, D43.1, D43.2, D43.3, D43.4, D43.8, D43.9, D44.0, D44.10, D44.11, D44.12, D44.2, D44.3, D44.4, D44.5, D44.6, D44.7, D44.9, D45, D46.0,

D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z, D47.1, D47.2, D47.3, D47.4, D47.9, D47.01, D47.02, D47.09, D47.Z1, D47.Z2, D47.Z9, D48.0, D48.2, D48.3, D48.4, D48.5, D48.60, D48.61, D48.62, D48.7, D48.9, D49.0, D49.1, D49.2, D49.3, D49.4, D49.511, D49.512, D49.519, D49.59, D49.6, D49.7, D49.81, D49.89, D49.9

AND

Patient encounter during the performance period (CPT or HCPCS): 98000, 98001, 98002, 98003, 98004, 98005, 98006, 98007, 98008, 98009, 98010, 98011, 98012, 98013, 98014, 98015, 98016, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99242*, 99243*, 99244*, 99245*

AND

Patients on immune checkpoint inhibitor therapy: M1180

AND

Grade 2 or above diarrhea and/or grade 2 or above colitis: M1181

AND NOT

DENOMINATOR EXCLUSION:

Patients not eligible due to pre-existing inflammatory bowel disease (IBD) (e.g., ulcerative colitis, Crohn's disease): M1182

NUMERATOR:

Patients with immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered

Definitions:

Corticosteroids – Examples include but are not limited to methylprednisolone, prednisone, or dexamethasone.

- **Route of administration** – May be oral or intravenous dependent on agent.

Immunosuppressants – Include but are not limited to vedolizumab or anti-TNF agent such as infliximab.

- **Route of administration** – May vary dependent on agent.

Numerator Instructions:

Denominator Exception(s) are determined at the time of the denominator eligible encounter.

Diarrhea is not attributed to immune checkpoint inhibitor mucosal inflammation.

Immune checkpoint inhibitors should be held for patients who have grade 2 or above diarrhea and/or grade 2 or above colitis.

NUMERATOR NOTE: *Performance is not met in the instance where either one or both of these actions occur: Inhibitor therapy is not held and corticosteroids or immunosuppressants are not prescribed.*

Numerator Options:

Performance Met:

Documentation of immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered **(M1183)**

OR

Denominator Exception:

Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment (e.g., allergy, intolerance, infectious etiology, pancreatic insufficiency, hyperthyroidism, prior bowel surgical interventions, celiac disease, receiving other medication, awaiting diagnostic workup results for alternative etiologies, other medical reasons/contraindication) **(M1184)**

OR

Performance Not Met:

Documentation of immune checkpoint inhibitor therapy not held and/or corticosteroids or immunosuppressants

prescribed or administered was not performed, reason not given (M1185)

RATIONALE:

This measure is designed to promote appropriate intervention of managing immune-related diarrhea and colitis, as recommended by numerous clinical guidelines on the topic of toxicities in immunotherapy. The occurrence of diarrhea and colitis can be a normal and treatable toxicity (and is many times not immune-related), but if it is immune-related, it can become life-threatening if not addressed in a timely manner (Acharya et al., 2013). Diarrhea and colitis are the second-most commonly reported AEs (adverse events) with ICIs (immune checkpoint inhibitors), and symptoms typically develop within 6 to 8 weeks of starting treatment (NCCN Guidelines 2020).

Preventing diarrhea includes early recognition of symptoms. Proper grading of diarrhea is essential for proper management. Regardless of immunotherapy agent used, effective colitis and diarrhea management is accomplished by early intervention. Colitis related mortality with immunotherapy agents has been associated with delayed reporting, nonadherence with antidiarrheal regimen, and failure to hold the immunotherapy agent. With early intervention, colitis is reversible (ONS 2019).

Incidence of diarrhea is higher among patients taking combination anti-CTLA-4/anti-PD-1 therapy (44%) than those receiving anti-CTLA4 (23–33 percent) or anti-PD-1 (≤ 19 percent) monotherapy. The combinatorial approach is also associated with increased risk of grade 3-4 symptoms compared with monotherapy, and the proportion of patients experiencing high-grade symptoms is greater with ipilimumab than anti-PD-1 or anti-PD-L1 agents. Diarrhea and/or colitis may recur months after discontinuation of immunotherapy and can mimic chronic inflammatory bowel disease (IBD) (Puzanov et al 2017). The hallmark symptom of ipilimumab-associated colitis is 3-20 loose bowel movements per day with possible associated hematochezia (ONS 2019). For patients on pembrolizumab, 16 percent of patients have diarrhea of any grade, while 1 percent of patients will have grade 3-4 diarrhea. (ONS 2019).

This quality measure will support and possibly incentivize efforts to implement these necessary improvements to practice quality in the field of immunotherapy. This quality measure includes all FDA approved Immune Checkpoint Inhibitors and is updated annually to reflect the most up-to-date list of approved therapies.

CLINICAL RECOMMENDATION STATEMENTS:

All the five clinical guidelines below address the measure's quality actions of holding immunotherapy and administering corticosteroids or immunosuppressant for grade 2 or above diarrhea and/or grade 2 or above colitis. The measure will enhance compliance with the clinical guidelines by ensuring the eligible provider is addressing the adverse event of diarrhea or colitis by immediately providing an intervention to prevent the adverse event from worsening.

NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.2020.- (Evidence Based)

AGA Clinical Practice Update on Diagnosis and Management of Immune Checkpoint Inhibitor (ICI) Colitis and Hepatitis: Expert Review. 2020.- (Evidence-based and Consensus-based)

Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice. ONS. 2019.

American Society of Clinical Oncology Clinical Practice Guideline. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy. Journal of Clinical Oncology. 2018.- (Consensus-based)

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ASCO's significant efforts and contributions to the development of the Measure are acknowledged. SITC is solely responsible for the review and enhancement ("Maintenance") of the Measure as of June 2021.

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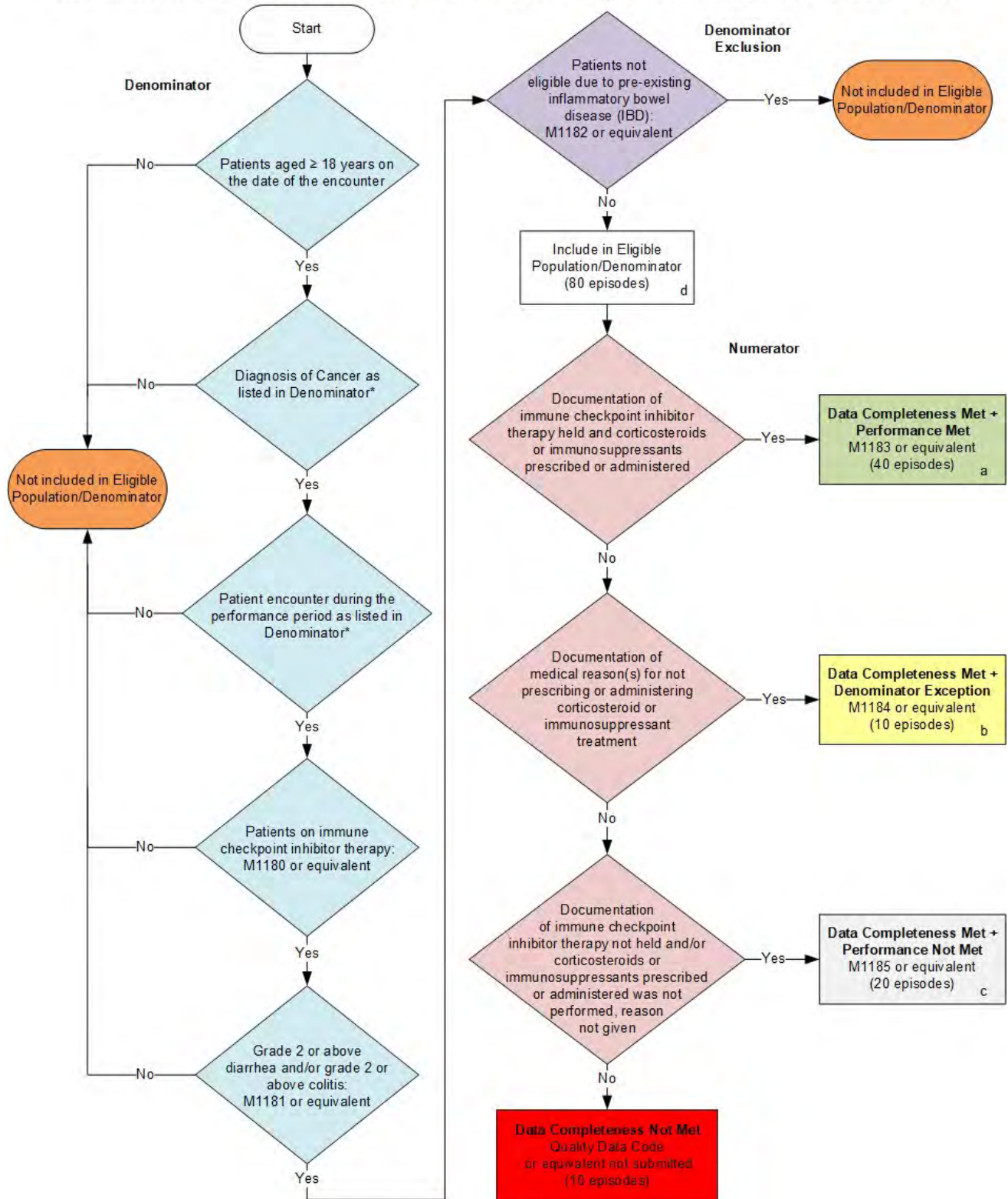
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2025 Clinical Quality Measure Flow for Quality ID #490: Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.



SAMPLE CALCULATIONS

Data Completeness=

$$\frac{\text{Performance Met (a=40 episodes)} + \text{Denominator Exception (b=10 episodes)} + \text{Performance Not Met (c=20 episodes)}}{\text{Eligible Population / Denominator (d=80 episodes)}} = \frac{70 \text{ episodes}}{80 \text{ episodes}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a=40 episodes)}}{\text{Data Completeness Numerator (70 episodes) - Denominator Exception (b=10 episodes)}} = \frac{40 \text{ episodes}}{60 \text{ episodes}} = 66.67\%$$

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Episode

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The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification. v9

2025 Clinical Quality Measure Flow Narrative for Quality ID #490:
Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.

1. Start with Denominator
2. Check *Patients aged greater than or equal to 18 years on the date of the encounter*:
 - a. If *Patients aged greater than or equal to 18 years on the date of the encounter* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Patients aged greater than or equal to 18 years on the date of the encounter* equals Yes, proceed to *Diagnosis of Cancer as listed in Denominator**.
3. Check *Diagnosis of Cancer as listed in Denominator**:
 - a. If *Diagnosis of Cancer as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Diagnosis of Cancer as listed in Denominator** equals Yes, proceed to *Patient encounter during the performance period as listed in Denominator**.
4. Check *Patient encounter during the performance period as listed in Denominator**:
 - a. If *Patient encounter during the performance period as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Patient encounter during the performance period as listed in Denominator** equals Yes, proceed to *Patients on immune checkpoint inhibitor therapy*.
5. Check *Patients on immune checkpoint inhibitor therapy*:
 - a. If *Patients on immune checkpoint inhibitor therapy* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Patients on immune checkpoint inhibitor therapy* equals Yes, proceed to *Grade 2 or above diarrhea and/or grade 2 or above colitis*.
6. Check *Grade 2 or above diarrhea and/or grade 2 or above colitis*:
 - a. If *Grade 2 or above diarrhea and/or grade 2 or above colitis* equals No, do not include in *Eligible Population/ Denominator*. Stop processing.
 - b. If *Grade 2 or above diarrhea and/or grade 2 or above colitis* equals Yes, check *Patients not eligible due to pre-existing inflammatory bowel disease (IBD)*.
7. Check *Patients not eligible due to pre-existing inflammatory bowel disease (IBD)*:
 - a. If *Patients not eligible due to pre-existing inflammatory bowel disease (IBD)* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Patients not eligible due to pre-existing inflammatory bowel disease (IBD)* equals No, include in *Eligible Population/Denominator*.

8. Denominator Population:
 - Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 episodes in the Sample Calculation.
9. Start Numerator
10. Check *Documentation of immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered*:
 - a. If *Documentation of immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered* equals Yes, include in *Data Completeness Met and Performance Met*.
 - *Data Completeness Met and Performance Met* letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 episodes in the Sample Calculation.
 - b. If *Documentation of immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered* equals No, proceed to *Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment*.
11. Check *Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment*:
 - a. If *Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment* equals Yes, include in the *Data Completeness Met and Denominator Exception*.
 - *Data Completeness Met and Denominator Exception* letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b equals 10 episodes in the Sample Calculation.
 - b. If *Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment* equals No, proceed to *Documentation of immune checkpoint inhibitor therapy not held and/or corticosteroids or immunosuppressants prescribed or administered was not performed, reason not given*.
12. Check *Documentation of immune checkpoint inhibitor therapy not held and/or corticosteroids or immunosuppressants prescribed or administered was not performed, reason not given*:
 - a. If *Documentation of immune checkpoint inhibitor therapy not held and/or corticosteroids or immunosuppressants prescribed or administered was not performed, reason not given* equals Yes, include in the *Data Completeness Not Met and Performance Not Met*.
 - *Data Completeness Met and Performance Not Met* letter is represented as Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 episodes in the Sample Calculation.
 - b. If *Documentation of immune checkpoint inhibitor therapy not held and/or corticosteroids or immunosuppressants prescribed or administered was not performed, reason not given* equals No, proceed to *Data Completeness Not Met*.
13. Check *Data Completeness Not Met*:

- If *Data Completeness Not Met*, the Quality Data Code or equivalent was not submitted. 10 episodes have been subtracted from the Data Completeness Numerator in the Sample Calculation.

Sample Calculations

Data Completeness equals Performance Met (a equals 40 episodes) plus Denominator Exception (b equals 10 episodes) plus Performance Not Met (c equals 20 episodes) divided by Eligible Population / Denominator (d equals 80 episodes). All equals 70 episodes divided by 80 episodes. All equals 87.50 percent.

Performance Rate equals Performance Met (a equals 40 episodes) divided by Data Completeness Numerator (70 episodes) minus Dominator Exception (b equals 10 episodes). All equals 40 episodes divided by 60 episodes. All equals 66.67 percent.

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Episode

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