Quality ID #275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
– National Quality Strategy Domain: Effective Clinical Care
– Meaningful Measure Area: Management of Chronic Conditions

**2019 COLLECTION TYPE:**
MIPS CLINICAL QUALITY MEASURES (CQMS)

**MEASURE TYPE:**
Process

**DESCRIPTION:**
Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy

**INSTRUCTIONS:**
This measure is to be submitted a minimum of **once per performance period** for all patients with a diagnosis of inflammatory bowel disease 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.

**DENOMINATOR:**
All patients, regardless of age, with a diagnosis of inflammatory bowel disease who initiated an anti-TNF agent

**Definitions:**
**Patient receiving an anti-TNF agent** - May include but is not limited to the following HCPCS codes: C9249, J0717, J0718, J0135, J1602, J1745, Q5102, S9359 or CPT codes: G8869, 86317, 86704, 86706, 90636, 90723, 90744, 90745, 90746, 90747, 90748

**DENOMINATOR NOTE:** *Signifies that this CPT Category I code is a non-covered service under the PFS (Physician Fee Schedule). These non-covered services will not be counted in the denominator population for MIPS CQMs measures.*

**Denominator Criteria (Eligible Cases):**
All Patients, regardless of age

**AND**

AND

AND
Patient receiving an anti-TNF agent (HCPCS): G9914

NUMERATOR:
Patients who had HBV status assessed and results interpreted prior to initiating anti-TNF therapy

Numerator Instructions:
HBV status must be assessed by one of the following: HBsAG, HBsAG neutralization, HBcAb total, HBsAB.

Numerator Options:

Performance Met:
Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy (G9912)

OR

Performance Met:
Patient has documented immunity to hepatitis B and initiating anti-TNF therapy (G8869)

OR

Denominator Exception:
Documented reason for not assessing Hepatitis B Virus (HBV) status (e.g. patient not initiating anti-TNF therapy, patient declined) prior to initiating anti-TNF therapy (G9504)

OR

Performance Not Met:
Hepatitis B Virus (HBV) status not assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy, reason not otherwise specified (G9913)

OR

Performance Not Met:
No record of HBV results documented (G9915)

RATIONALE:
Before initiating biologic anti-TNF therapy for a patient with IBD, it is essential to screen the patient for HBV, as research has documented reactivation of HBV after anti-TNF therapy. This is a patient safety measure.

Opportunity for improvement: While there are a limited number of studies that investigate gaps in care for patients with IBD, the research that does exist identifies opportunities for improvement in care areas: 1) there is a lack of adherence to documentation of HBV screening, most noticeably in the use of disease-modifying anti-TNF drugs, and variations in care by practice setting, geographic region and physician specialty.

See FDA package labeling for anti-TNF biological agents — golimumab, certolizumab pegol, infliximab and adalimumab.

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF blocker medicines. (Kaiser T, Moessner J, McHutchison JG, Tillmann HG. Life threatening liver disease during treatment with monoclonal antibodies. BMJ. 2009;338:b508)

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2019 Clinical Quality Measure Flow for Quality ID #275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

**Denominator**
- Start
- All Patients, Regardless of Age
- Diagnosis of Inflammatory Bowel Disease as Listed in Denominator
  - Yes
    - Not Included in Eligible Population / Denominator
  - No
    - Encounter as Listed in Denominator (1/1/2019 thru 12/31/2019)
      - Yes
        - Hepatitis B Virus (HBV) Status Assessed and Results Interpreted Prior To Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
          - No
            - Data Completeness Met + Performance Met G9512 or equivalent (20 patients)
          - Yes
            - Patient Has Documented Immunity To Hepatitis B and Initiating Anti-TNF Therapy
              - No
                - Data Completeness Met + Performance Met G9516 or equivalent (20 patients)
              - Yes
                - Documented Reason For Not Assessing Hepatitis B Virus (HBV) Status Or Patient Not Initiating Anti-TNF Therapy
                  - No
                    - Data Completeness Met + Denominator Exception G9504 or equivalent (10 patients)
                  - Yes
                    - Hepatitis B Virus (HBV) Status Not Assessed and Results Interpreted Prior To Initiating Anti-TNF (Tumor Necrosis Factor) Therapy, Reason Not Otherwise Specified
                      - No
                        - Data Completeness Met + Performance Not Met G9913 or equivalent (10 patients)
                      - Yes
                        - No Record of HBV Results Documented
                          - No
                            - Data Completeness Met Failure: Data Code or equivalent not submitted (10 patients)
                          - Yes
                            - Include in Eligible Population / Denominator (80 patients)

**Numerator**
- Data Completeness Met + Performance Met G9512 or equivalent (20 patients)
- Data Completeness Met + Performance Met G9516 or equivalent (20 patients)
- Data Completeness Met + Denominator Exception G9504 or equivalent (10 patients)
- Data Completeness Met + Performance Not Met G9913 or equivalent (10 patients)
- No Record of HBV Results Documented
- Include in Eligible Population / Denominator (80 patients)

**Data Completeness Calculations**

Performance Rate: Performance Met (2 * 40 patients) / Eligible Population / Denominator (80 patients) = 66.67%
Data Completeness Numerator (70 patients) / Denominator Exception (20 patients) = 70 patients / 80 patients = 87.50%

*See the posted Measure Specification for specific coding and instructions to submit this measure.
NOTE: Submission Frequency: Patient process

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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 as a substitute for the measure specifications.
2019 Clinical Quality Measure Flow Narrative for Quality ID #275

Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in submitting this Individual Measure.

1. Start with Denominator
2. All Patients Regardless of Age
3. Check Patient Diagnosis:
   a. If Diagnosis of Inflammatory Bowel Disease as Listed in the Denominator equals No, do not include in Eligible Population. Stop Processing.
   b. If Diagnosis of Inflammatory Bowel Disease as Listed in the Denominator equals Yes, proceed to check Encounter Performed.
4. Check Encounter Performed:
   a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Population. Stop Processing.
   b. If Encounter as Listed in the Denominator equals Yes, proceed to check Patient Receiving and Anti-TNF Agent.
5. Check Patient Receiving an Anti-TNF Agent.
   a. If Patient Receiving an Anti-TNF Agent Therapy Agent equals No, do not include in Eligible Population.
   b. If Patient Receiving an Anti-TNF Agent Therapy Agent equals Yes, include in Eligible Population.
6. Denominator Population:
   a. 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 patients in the Sample Calculation.
7. Start Numerator
8. Check (HBV) Status Assessed and Results Interpreted Prior to Initiating Anti-TNF Therapy:
   a. If (HBV) Status Assessed and Results Interpreted Prior to Initiating Anti-TNF Therapy equals Yes, include in Data Completeness Met and Performance Met.
   b. Data Completeness Met and Performance Met is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a’ equals 20 patients in Sample Calculation.
   c. If (HBV) Status Assessed and Results Interpreted Prior Initiating Anti-TNF Therapy equals No, proceed to check Patient has Documented Immunity to Hepatitis B and Initiating Anti-TNF Therapy.
9. Check Patient has Documented Immunity to Hepatitis B and Initiating Anti-TNF Therapy:
   a. If Patient has Documented Immunity to Hepatitis B and Initiating Anti-TNF Therapy equals Yes, include in Data Completeness Met and Performance Met.
b. Data Completeness Met and Performance Met is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter $a^2$ equals 20 patients in the Sample Calculation.

c. If Patient has Documented Immunity to Hepatitis B and Initiating Anti-TNF Therapy equals No, proceed to check Documented Reason for Not Assessing Hepatitis B Virus (HBV) Status Prior to Initiating Anti-TNF Therapy.

10. Check Documented Reason for Not Assessing Hepatitis B Virus (HBV) Status Prior to Initiating Anti-TNF Therapy:

   a. If Documented Reason for Not Assessing Hepatitis B Virus (HBV) Prior Initiating Anti-TNF Therapy equals Yes, include in Data Completeness Met and Denominator Exception.

   b. Data Completeness Met and Denominator Exception is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter $b$ equals 10 patients in the Sample Calculation.

   c. If Documented Reason for Not Assessing Hepatitis B Virus (HBV) Status Prior to Initiating Anti-TNF Therapy equals No, proceed to check HBV Status Not Assessed and Results Interpreted Prior to Initiating Anti-TNF Therapy, Reason Not Otherwise Specified.

11. Check HBV Status Not Assessed and Results Interpreted Prior to Initiating Anti-TNF Therapy, Reason Not Otherwise Specified:

   a. If HBV Status Not Assessed and Results Interpreted Prior to Initiating Anti-TNF Therapy, Reason Not Otherwise Specified equals Yes, include in Data Completeness Met and Performance Not Met.

   b. Data Completeness Met and Performance Not Met is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter $c^1$ equals 10 patients in the Sample Calculation.

   c. If HBV Status Not Assessed and Results Interpreted Prior to Initiating Anti-TNF Therapy, Reason Not Otherwise Specified equals No, proceed to check No Record Of HBV Results Documented.

12. Check No Record Of HBV Results Documented:

   a. If No Record Of HBV Results Documented equals Yes, include in Data Completeness Met and Performance Not Met.

   b. Data Completeness Met and Performance Not Met is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter $c^2$ equals 10 patients in the Sample Calculation.

   c. If No Record Of HBV Results Documented equals No, proceed to check Data Completeness Not Met.

13. Check Data Completeness Not Met:

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

**SAMPLE CALCULATIONS:**

<table>
<thead>
<tr>
<th>Data Completeness</th>
<th>Performance Met ($a^2 + a^2 = 40$ patients) + Denominator Exception ($b = 10$ patients) + Performance Not Met ($c^1 + c^2 = 20$ patients) = 70 patients</th>
<th>87.50%</th>
<th>Eligible Population / Denominator (d=80 patients)</th>
</tr>
</thead>
</table>

| Performance Rate  | Performance Met ($a^1 + a^2 = 40$ patients) = 40 patients | 66.67% | Denominator Exception ($b = 10$ patients) = 60 patients |

| Data Completeness Numerator (70 patients) - Denominator Exception (10 patients) = 60 patients | 80 patients |

| Data Completeness Met = 40 patients | 66.67% | Denominator Exception = 60 patients | 80 patients |