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

<u>2018 OPTIONS FOR INDIVIDUAL MEASURES:</u>
REGISTRY ONLY

<u>MEASURE TYPE:</u>
Process

<u>DESCRIPTION:</u>
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

<u>INSTRUCTIONS:</u>
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 eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Submission:
The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry submissions; however, these codes may be submitted for those registries that utilize claims data.

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

> <u>Definitions:</u>
> **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
>
> <u>Denominator Criteria (Eligible Cases):</u>
> All Patients, regardless of age
> **AND**
> **Diagnosis for inflammatory bowel disease (ICD-10-CM)**: K50.00, K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, K50.919, K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.419, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.913, K51.914, K51.918, K51.919
> **AND**
> **Patient encounter during the performance period (CPT)**: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99406, 99407
> **AND**
> **Patient receiving an anti-TNF agent (HCPCS)**: G9914

<u>NUMERATOR:</u>
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)

CLINICAL RECOMMENDATION STATEMENTS:

Infliximab can reactivate latent HBV. (Esteve M, Saro C, González-Huix F, Suarez F, Forné M, Viver JM. Chronic hepatitis B reactivation following infliximab therapy in Crohn's disease patients: need for primary prophylaxis. Gut. 2004 Sep; 53(9):1363-5.)

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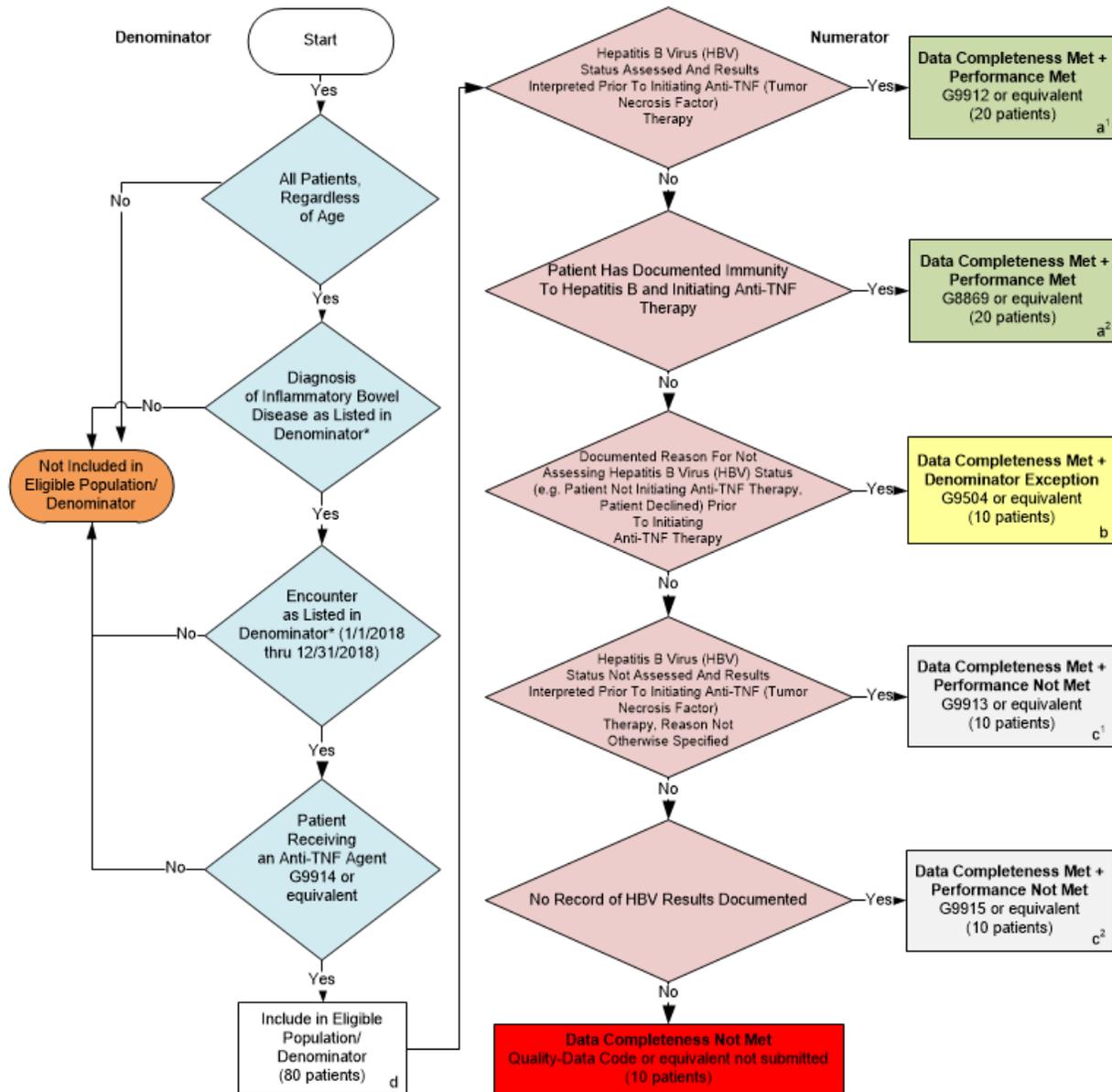
2018 Registry Flow for Quality ID #275:
Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Denominator — Start

- **All Patients, Regardless of Age** — No → Not Included in Eligible Population/Denominator; Yes ↓
- **Diagnosis of Inflammatory Bowel Disease as Listed in Denominator*** — No → Not Included in Eligible Population/Denominator; Yes ↓
- **Encounter as Listed in Denominator* (1/1/2018 thru 12/31/2018)** — No → Not Included in Eligible Population/Denominator; Yes ↓
- **Patient Receiving an Anti-TNF Agent G9914 or equivalent** — No → Not Included in Eligible Population/Denominator; Yes ↓
- **Include in Eligible Population/Denominator (80 patients)** d

Numerator

- **Hepatitis B Virus (HBV) Status Assessed And Results Interpreted Prior To Initiating Anti-TNF (Tumor Necrosis Factor) Therapy** — Yes → Data Completeness Met + Performance Met G9912 or equivalent (20 patients) a^1; No ↓
- **Patient Has Documented Immunity To Hepatitis B and Initiating Anti-TNF Therapy** — Yes → Data Completeness Met + Performance Met G8869 or equivalent (20 patients) a^2; No ↓
- **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** — Yes → Data Completeness Met + Denominator Exception G9504 or equivalent (10 patients) b; No ↓
- **Hepatitis B Virus (HBV) Status Not Assessed And Results Interpreted Prior To Initiating Anti-TNF (Tumor Necrosis Factor) Therapy, Reason Not Otherwise Specified** — Yes → Data Completeness Met + Performance Not Met G9913 or equivalent (10 patients) c^1; No ↓
- **No Record of HBV Results Documented** — Yes → Data Completeness Met + Performance Not Met G9915 or equivalent (10 patients) c^2; No ↓
- **Data Completeness Not Met** Quality-Data Code or equivalent not submitted (10 patients)

SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met } (a^1 + a^2 = 40 \text{ patients}) + \text{Denominator Exception } (b = 10 \text{ patients}) + \text{Performance Not Met } (c^1 + c^2 = 20 \text{ patients})}{\text{Eligible Population / Denominator } (d = 80 \text{ patients})} = \frac{70 \text{ patients}}{80 \text{ patients}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met } (a^1 + a^2 = 40 \text{ patients})}{\text{Data Completeness Numerator (70 patients)} - \text{Denominator Exception } (b = 10 \text{ patients})} = \frac{40 \text{ patients}}{60 \text{ patients}} = 66.67\%$$

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

2018 Registry Flow 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. This flow is for registry-data submission.

1. Start with Denominator

2. Check Patient Age:

    a. All Patients Regardless of Age, proceed to check Patient Diagnosis.

3. Check Patient Diagnosis:

    a. If Diagnosis of Inflammatory Bowel Disease as Listed in the Denominator equals No, do not include in Eligible Patient 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 Patient 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 Patient Population.

    b. If Patient Receiving an Anti-TNF Agent Therapy Agent equals Yes, proceed to Check Denominator 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[1] 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 and Performance Rate in the Sample Calculation listed at the end of this document. Letter c1 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 and Performance Rate in the Sample Calculation listed at the end of this document. Letter c2 equals 10 patients in the Sample Calculation.

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

13. Check Data Completeness Not Met:

a. 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:

Data Completeness=

$$\frac{\text{Performance Met } (a^1+a^2=40 \text{ patients}) + \text{Denominator Exception } (b=10 \text{ patients}) + \text{Performance Not Met } (c^1+c^2=20 \text{ patients})}{\text{Eligible Population / Denominator } (d=80 \text{ patients})} = \frac{70 \text{ patients}}{80 \text{ patients}} = \mathbf{87.50\%}$$

Performance Rate=

$$\frac{\text{Performance Met } (a^1+a^2=40 \text{ patients})}{\text{Data Completeness Numerator } (70 \text{ patients}) - \text{Denominator Exception } (b=10 \text{ patients})} = \frac{40 \text{ patients}}{60 \text{ patients}} = \mathbf{66.67\%}$$