

## Quality ID #176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

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

**MEASURE TYPE:**  
Process

**DESCRIPTION:**  
If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.

**INSTRUCTIONS:**  
This measure is to be submitted a minimum of **once per performance period** for patients who are being considered or prescribed a first course of a biologic and/or immune response modifier therapy 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.

***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. Please note that effective January 1, 2025, while a measure may be denoted as telehealth eligible, specific denominator codes within the encounter may no longer be eligible due to changes outlined in the CY 2024 PFS Final Rule List of Medicare Telehealth Services.*

### 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 aged 18 years and older who are receiving a first course of therapy using a biologic and/or immune response modifier (such as kinase inhibitors) that includes a warning for potential reactivation of a latent infection

**Denominator Instructions:**  
Patients are considered to be receiving a first course of therapy using a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection only if they have been prescribed such a biologic and/or immune response modifier during the performance period and also have not been prescribed any such biologic and/or immune response modifier in the 15 months preceding the encounter at which the biologic and/or immune response modifier was newly started. A biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection includes:

- Abatacept (Orencia)
- Adalimumab (HUMIRA)
- Adalimumab-aacf (Idacio)
- Adalimumab-aaty (Yuflyma)

- Adalimumab-adaz (Hyrimoz)
- Adalimumab-adbm (Cyltezo)
- Adalimumab-afzb (Abrilada)
- Adalimumab-aqvh (Yusimry)Adalimumab-atto (Amjevita)
- Adalimumab-bwwd (Hadlima)
- Adalimumab-fkjp (Hulio)
- Anakinra (Kineret)
- Baricitinib (Olmiant)
- Brodalumab (Siliq)
- Canakinumab (ILARIS)
- Certolizumab pegol and lyophilized certolizumab pegol (CIMZIA)
- Etanercept (Enbrel)
- Golimumab (Simponi)
- Guselkumab (Tremfya)
- Infliximab (REMICADE)
- Infliximab-abda (Renflexis)
- Infliximab-axxq (Avsola)
- Infliximab-dyyb (Inflectra)
- Ixekizumab (Taltz)
- Risankizumab-rzaa (Skyrizi)
- Sarilumab (KEVZARA)
- Secukinumab (Cosentyx)
- Tildrakizumab (Ilumya)
- Tocilizumab (ACTEMRA)
- Tofacitinib (XELJANZ)
- Upadacitinib (RINVOO)
- Ustekinumab (STELARA)

*The list of therapies is subject to change as new therapies are approved by the FDA.*

To be included in the denominator, patient must have an encounter and a prescription for a biologic and/or immune response modifier in the performance period (1/1/2025-12/31/2025) WITHOUT a prior prescription for a biologic and/or immune response modifier within the 15 months prior to the biologic and/or immune response modifier prescribed during the performance period.

***DENOMINATOR NOTE:*** \*Signifies that this HCPCS 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 the MIPS CQMs.

**Denominator Criteria (Eligible Cases):**

Patients aged ≥ 18 years on date of encounter

**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, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350, 99424, 99426, G0402, G0468\*

**AND**

**Patient receiving first-time biologic and/or immune response modifier therapy:** G2182

**NUMERATOR:**

Patients for whom any record of TB testing is documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic and/or immune response modifier prescription

**Numerator Options:**

***Performance Met:***

TB screening performed and results interpreted within twelve months prior to initiation of first-time biologic and/or immune response modifier therapy (M1003)

**OR**

***Denominator Exception:***

Documentation of medical reason for not screening for TB or interpreting results (i.e., patient positive for TB and documentation of past treatment; patient who has recently completed a course of anti-TB therapy) (M1004)

**OR**

***Performance Not Met:***

TB screening not performed or results not interpreted, reason not given (M1005)

**RATIONALE:**

Regardless of a patient's diagnosis, it is essential to screen the patient for tuberculosis before initiating therapy with a biologic and/or immune response modifier, as research has documented a higher incidence of TB after anti-TNF $\alpha$  therapy. All patients being considered for a biologic and/or immune response modifier should receive a tuberculin skin test, even if the patient has previously received the BCG vaccination. Test results, in addition to patient risk for TB and other tests, should be used to assess the patient's risk for latent TB infection; for documented latent TB infection, treatment with isoniazid or similar medication should be started prior to or concurrent with biologic initiation as clinically appropriate (<https://www.cdc.gov/tb/publications/ltpi/default.htm>).

**CLINICAL RECOMMENDATION STATEMENTS:**

The American College of Rheumatology recommends screening to identify latent TB infection (LTBI) in all RA patients being considered for therapy with biologic agents, regardless of the presence of risk factors for LTBI. (Level of Evidence: C) (ACR, 2012) The Centers for Disease Control and Prevention (CDC) also recommends screening for tuberculosis prior to starting therapy with any TNF- $\alpha$  blocker (Centers for Disease Control and Prevention. MMWR Morb Mortal Wkly Rep. 2004;5:683–686). Multiple studies have found similarly increased risks of latent TB reactivation with biologics in other auto-inflammatory syndromes other than RA, such as inflammatory bowel disease, ankylosing spondylitis and psoriasis. This has led to many consensus statements supporting screening of latent TB prior to initiation of a range of biologic and/or immune response modifiers in a range of autoimmune/auto-inflammatory diseases (Hasan et al. BMJ Open 2018;8:e022445. doi:10.1136/bmjopen-2018-022445; Doherty et al. J Am Acad Derm 2008 59(2): 209–217), supporting that this measure applies to a broad population of patients being considered for biologic and/or immune response modifier therapy.

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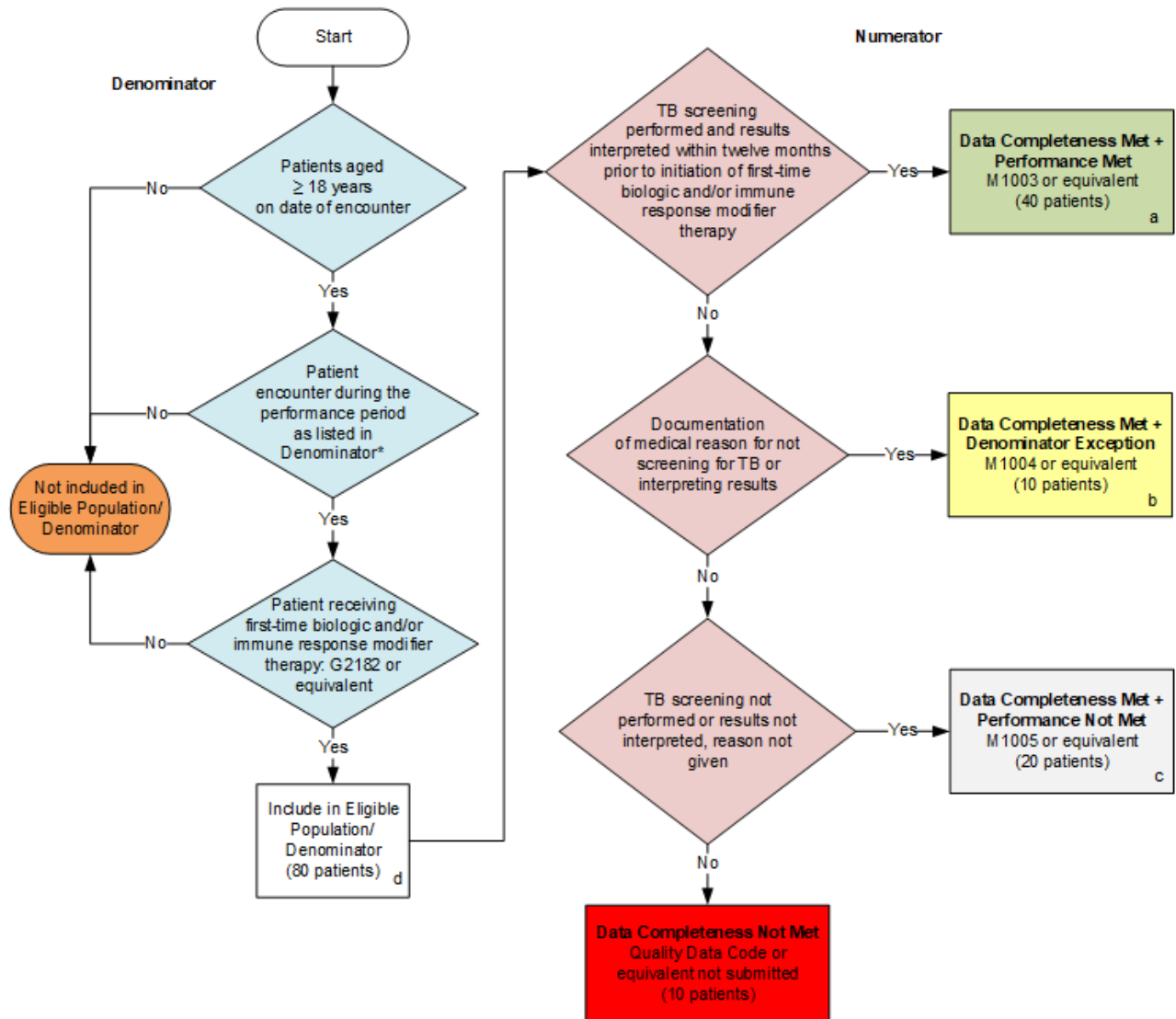
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## 2025 Clinical Quality Measure Flow for Quality ID #176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

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



### SAMPLE CALCULATIONS

**Data Completeness=**  

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

**Performance Rate=**  

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

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

NOTE : Submission Frequency: Patient-Process

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**2025 Clinical Quality Measure Flow Narrative for Quality ID #176:  
Tuberculosis Screening Prior to First Course of Biologic and/or  
Immune Response Modifier Therapy**

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1. Start with Denominator
2. Check *Patients aged greater than or equal to 18 years on date of encounter*:
  - a. If *Patients aged greater than or equal to 18 years on date of encounter* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Patients aged greater than or equal to 18 years on date of encounter* equals Yes, proceed to check *Patient encounter during the performance period as listed in Denominator\**.
3. 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 check *Patient receiving first-time biologic and/or immune response modifier therapy*.
4. Check *Patient receiving first-time biologic and/or immune response modifier therapy*:
  - a. If *Patient receiving first-time biologic and/or immune response modifier therapy* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Patient receiving first-time biologic and/or immune response modifier therapy* equals Yes, include in *Eligible Population/Denominator*.
5. 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 patients in the Sample Calculation.
6. Start Numerator
7. Check *TB screening performed and results interpreted within twelve months prior to initiation of first-time biologic and/or immune response modifier therapy*:
  - a. If *TB screening performed and results interpreted within twelve months prior to initiation of first-time biologic and/or immune response modifier therapy* equals Yes, include in *Data Completeness Met and Performance Met*.
    - *Data Completeness Met and Performance Met* letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 patients in the Sample Calculation.
  - b. If *TB screening performed and results interpreted within twelve months prior to initiation of first-time biologic and/or immune response modifier therapy* equals No, proceed to check *Documentation of medical reason for not screening for TB or interpreting results*.
8. Check *Documentation of medical reason for not screening for TB or interpreting results*:

- a. If *Documentation of medical reason for not screening for TB or interpreting results* equals Yes, include in *Data Completeness Met and Denominator Exception*.
    - *Data Completeness Met and Denominator Exception* letter 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.
  - b. If *Documentation of medical reason for not screening for TB or interpreting results* equals No, proceed to check *TB screening not performed or results not interpreted, reason not given*.
9. Check *TB screening not performed or results not interpreted, reason not given*:
- a. If *TB screening not performed or results not interpreted, reason not given* equals Yes, include in *Data Completeness Met and Performance Not Met*.
    - *Data Completeness Met and Performance Not Met* letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 patients in the Sample Calculation.
  - b. If *TB screening not performed or results not interpreted, reason not given* equals No, proceed to check *Data Completeness Not Met*.
10. Check *Data Completeness Not Met*:
- 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

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

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

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

NOTE: Submission Frequency: Patient-Process

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.