Quality ID #506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

2026 COLLECTION TYPE:
MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS) CLINICAL QUALITY MEASURE (CQM)

MEASURE TYPE:
Process – High Priority

DESCRIPTION:
Percentage of patients aged 18 years and older with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.

INSTRUCTIONS:

Reporting Frequency:
This measure is to be submitted a minimum of once per performance period for denominator eligible cases as defined in the denominator criteria.

Intent and Clinician Applicability:
This measure is intended to reflect the quality of services provided for patients on first-line immune checkpoint inhibitor (ICI) 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 services provided and the measure-specific denominator coding.

Measure Strata and Performance Rates:
This measure contains one strata defined by a single submission criteria.
This measure produces a single performance rate.

Implementation Considerations:
For the purposes of MIPS implementation, this patient-process measure is submitted a minimum of once per patient during the performance period. The most advantageous quality data code will be used if the measure is submitted more than once.

Telehealth:
NOT TELEHEALTH ELIGIBLE: This measure is not appropriate for nor applicable to the telehealth setting. Patient encounters for this measure conducted via telehealth should be removed from the denominator eligible patient population. Therefore, if the patient meets all denominator criteria but the encounter is conducted via telehealth, it would be appropriate to remove them from the denominator eligible patient population. Telehealth eligibility is at the measure level for inclusion within the denominator eligible patient population and based on the measure specification definitions which are independent of changes to coding and/or billing practices.

Measure Submission:
The quality data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this collection type for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data. The coding provided to identify the measure criteria: Denominator or Numerator, may be an example of coding that could be used to identify patients that meet the intent of this clinical topic. When implementing this measure, please refer to the 'Reference Coding' section to determine if other codes or code languages that meet the intent of the criteria may also be used within the medical record to identify and/or assess patients. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

DENOMINATOR:
Patients aged 18 years and older with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) and on first-line immune checkpoint inhibitors without chemotherapy

Definitions:

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, and CTLA-4 inhibitor drugs.

- PD-1 inhibitors drugs include: Pembrolizumab, Nivolumab, Cemiplimab
- PD-L1 inhibitor drugs include: Atezolizumab
- CTLA-4 inhibitor drugs include: Ipilimumab

First-line treatment – Initial or first treatment recommended for cancer

- Various treatment regimens were considered, including immune checkpoint inhibitors
- PD-L1 testing required per FDA approval for the applicable histology

Denominator Instructions:

Additionally, immune checkpoint inhibitors FDA approved for specific histology must meet the following criteria to be considered denominator eligible:

- Pembrolizumab (PD-1 inhibitor drug) AND
  - first-line treatment in patients with metastatic NSCLC
  - OR first-line treatment in patients with metastatic HNSCC
- Cemiplimab (PD-1 inhibitor drug) AND
  - first-line treatment in patients with metastatic NSCLC
- Atezolizumab (PD-L1 inhibitor drug) AND
  - first-line treatment in patients with metastatic NSCLC
- Nivolumab (PD-1 inhibitor drug) and Ipilimumab (CTLA-4 inhibitor drug) combination AND
  - first-line treatment in patients with metastatic NSCLC

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 and older on the date of the encounter

AND

Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on the date of the encounter (ICD-10-CM): 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, 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, 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, C30.0, C31.0, C31.1, C31.2, C31.3, C31.8, C31.9, C32.0, C32.1, C32.2, C32.3, C32.8, C32.9, C76.0

AND

Patient encounters during the performance period (CPT): 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241*, 99242*, 99243*, 99244*, 99245*

WITHOUT

Encounters conducted via telehealth: M1426

AND

Currently on first-line immune checkpoint inhibitors without chemotherapy: M1411

AND NOT

DENOMINATOR EXCLUSION:

Patients with metastatic NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy, such as NSCLC with ROS1 rearrangement, BRAF V600E mutation, NTRK 1/2/3 gene fusion, MET ex14 skipping mutation, and RET rearrangement: M1412

NUMERATOR:

Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy.

Definitions:
PD-L1 biomarker expression test – FDA-approved test that measures the expression of PD-L1 on cancer and/or immune cells.
Positive PD-L1 biomarker expression test result – PD-L1 test is considered positive if the cancer and/or immune cells have an appropriate threshold of PD-L1 expression based on the approved companion diagnostic.

Numerator Instructions:
The denominator exception is applicable for the following situations:

- PD-L1 biomarker expression testing was unable to be performed prior to the initiation of first-line immune checkpoint inhibitor therapy due to an urgent or emergent situation where any treatment delay would jeopardize the patient's health and/or cancer care.
- Lack of available tissue for PD-L1 biomarker expression testing due to a documented medical and/or surgical contraindication which would not allow for the patient to undergo a tissue biopsy safely.

Patients without a PD-L1 biomarker expression test prior to the initiation of first-line immune checkpoint inhibitor therapy who do not fall into the denominator exception should be considered performance not met.

NUMERATOR NOTE:
Test performance is necessary prior to initiation of first-line immune checkpoint inhibitor therapy for each new diagnosis of NSCLC or HNSCC. This ensures that there is not retesting of a recurrent disease where PD-L1 status may have already been performed. Testing for PD-L1 performance has a look back period of 6 months prior to the current performance period.

Numerator Options:

Performance Met:	Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy (M1413)
OR	
Denominator Exception:	Documentation of medical reason(s) for not performing the PD-L1 biomarker expression test prior to initiation of first-line immune checkpoint inhibitor therapy (e.g., patient is in an urgent or emergent situation where delay of treatment would jeopardize the patient's health status; other medical reasons/contraindication) (M1414)
OR	
Performance Not Met:	Patients who did not have a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy (M1415)

RATIONALE:
The evidence-based NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer and NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancer address the measure's quality actions of a positive PD-L1 biomarker expression test prior to giving first-line immune checkpoint inhibitor therapy in the metastatic NSCLC or squamous cell carcinoma of head and neck populations (NCCN Guidelines: NSCLC, 2024; NCCN Guidelines HNSCC, 2024). The measure will enhance compliance with the clinical guidelines by ensuring the eligible provider addresses timely biomarker testing that makes a difference in treatment decisions and improves patient outcomes.

CLINICAL RECOMMENDATION STATEMENTS:
Biomarker testing that is not timely may make a difference in treatment decisions and/or patient outcomes. Appropriate treatment delivery could be delayed, or ineffective therapies could be prescribed, resulting in poor clinical outcomes and unnecessary healthcare costs (Pai et al., 20120 Lim et al., 2015).

REFERENCES:

The NCCN NSCLC Panel emphasizes that clinicians should obtain molecular testing results for actionable biomarkers before administering first-line ICI therapy, if feasible (NCCN Guidelines: NSCLC, 2024).

Despite the ambiguities of PD-L1 testing and definitions, PD-L1 expression may be associated with better outcomes from immunotherapy for recurrent or metastatic HNSCC (i.e., greater likelihood of response to pembrolizumab and greater survival benefit in response to nivolumab) (NCCN Guidelines: HNSCC, 2024).

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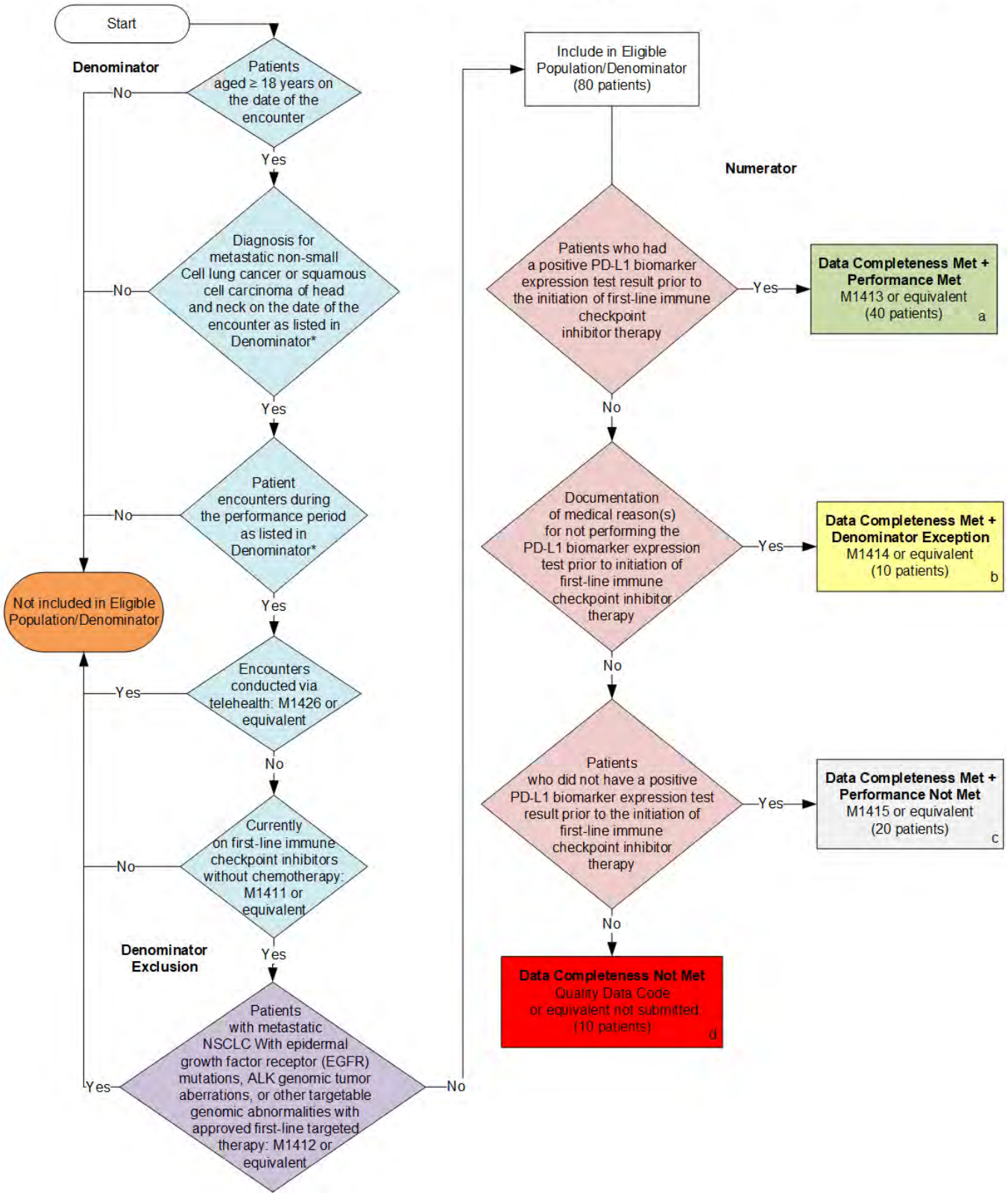
2026 Clinical Quality Measure Flow for Quality ID #506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

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



SAMPLE CALCULATIONS

Data Completeness=

Performance Met (a=40 patients) + Denominator Exception (b=10 patients) + Performance Not Met (c=20patients) = 70 patients = **87.50%**
Eligible Population / Denominator (d=80 patients) = 80 patients

Performance Rate=

Performance Met (a=40 patients) = 40 patients = **66.67%**
Data Completeness Numerator (70 patients) - Denominator Exception (b=10 patients) = 60 patients

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

2026 Clinical Quality Measure Flow Narrative for Quality ID #506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

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 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 18 years on the date of the encounter* equals Yes, proceed to *Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on the date of the encounter as listed in Denominator*.*
3. Check *Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on the date of the encounter as listed in Denominator**:
    a. If *Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on the date of the encounter as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on the date of the encounter as listed in Denominator** equals Yes, proceed to *Patient encounters during the performance period as listed in Denominator*.*
4. Check *Patient encounters during the performance period as listed in Denominator**:
    a. If *Patient encounters during the performance period as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Patient encounters during the performance period as listed in Denominator** equals Yes, proceed to check *Encounters conducted via telehealth.*
5. Check *Encounters conducted via telehealth.*
    a. If *Encounters conducted via telehealth* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Encounters conducted via telehealth* equals No, proceed to check *Currently on first-line immune checkpoint inhibitors without chemotherapy*.
6. Check *Currently on first-line immune checkpoint inhibitors without chemotherapy*:
    a. If *Currently on first-line immune checkpoint inhibitors without chemotherapy* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Currently on first-line immune checkpoint inhibitors without chemotherapy* equals Yes, proceed to *Patients with metastatic NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy*.
7. Check *Patients with metastatic NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy*:
    a. If *Patients with metastatic NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy*

equals Yes, do not include in *Eligible Population/ Denominator*. Stop processing.

b. If *Patients with metastatic NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy* 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 patients in the Sample Calculation.

9. Start Numerator

10. Check *Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy*:

    a. If *Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy* 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 patients in the Sample Calculation.

    b. If *Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy* equals No, proceed to *Documentation of medical reason(s) for not performing the PD-L1 biomarker expression test prior to initiation of first-line immune checkpoint inhibitor therapy*.

11. Check *Documentation of medical reason(s) for not performing the PD-L1 biomarker expression test prior to initiation of first-line immune checkpoint inhibitor therapy*:

    a. If *Documentation of medical reason(s) for not performing the PD-L1 biomarker expression test prior to initiation of first-line immune checkpoint inhibitor therapy* 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 patients in the Sample Calculation.

    b. If *Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment* equals No, proceed to *Patients who did not have a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy.*

12. Check *Patients who did not have a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy*:

    a. *If Patients who did not have a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy* 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 patients in the Sample Calculation.

    b. *If Patients who did not have a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy* 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 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 Dominator 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.