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

2025 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

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:
This measure is to be submitted a minimum of once per performance period for patients with a diagnosis of NSCLC or HNSCC on first-line ICI therapy seen during the performance period. This measure is intended to reflect the quality of services provided for patients aged 18 years and older with a diagnosis of metastatic NSCLC or HNSCC on first-line ICI therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy during the measurement 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 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:
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 (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
Telehealth modifier (including but not limited to): GQ, GT, POS 02, POS 10
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).

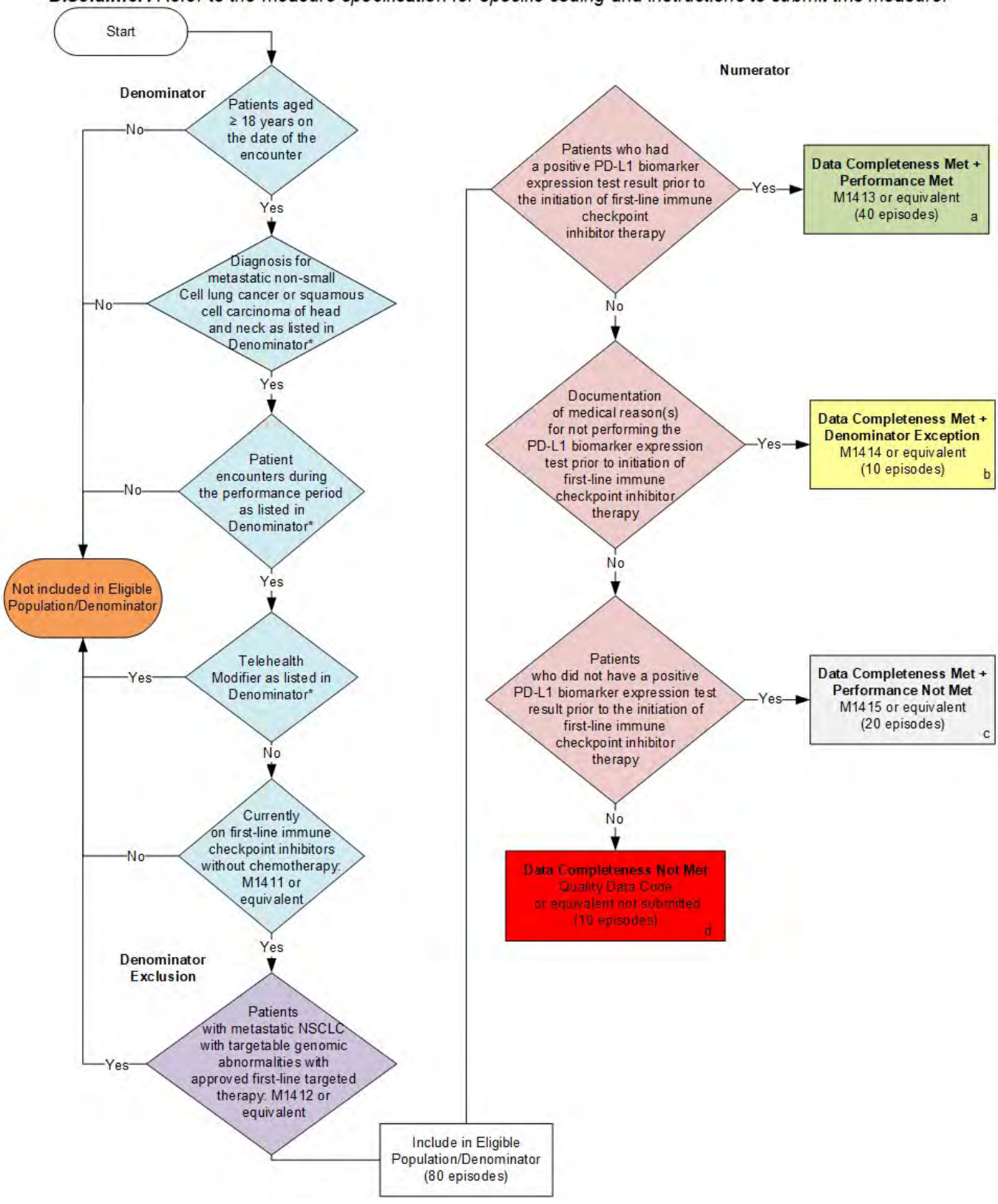
The NCCN NSCLC Panel emphasizes that clinicians should obtain molecular testing results for actionable biomarkers before administering first-line ICI therapy, if feasible (NCCN Guidelines: NSCLC, 2024).

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).

should obtain all necessary licenses from the owners of the code sets. SITC disclaims all liability for use or accuracy of any third party codes contained in the specifications.

2025 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 episodes) + Denominator Exception (b=10 episodes) + Performance Not Met (c=20 episodes) = 70 episodes = **87.50%**

Eligible Population / Denominator (d=80 episodes) = 80 episodes

Performance Rate=

Performance Met (a=40 episodes) = 40 episodes = **66.67%**

Data Completeness Numerator (70 episodes) - Denominator Exception (b=10 episodes) = 60 episodes

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

NOTE: Submission Frequency: Episode

2025 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 as listed in Denominator*.*
3. Check *Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck as listed in Denominator**:
    a. If *Diagnosis for metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck 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 as listed in Denominator** equals Yes, proceed to *Patient encounter 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 *Telehealth Modifier as listed in Denominator*.*
5. Check *Telehealth Modifier as listed in Denominator**:
    a. If *Telehealth Modifier as listed in Denominator** equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Telehealth Modifier as listed in Denominator** 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 episodes 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 episodes 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 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 *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 episodes 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 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

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.