

Medical Policy



Veristrat Testing

Policy Number: PG0111

Last Reviewed Date: 01/01/2025

Last Revised: 01/01/2025

HMO AND PPO

ELITE (MEDICARE ADVANTAGE)

MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

☒ Professional

☐ Facility

DESCRIPTION:

VeriStrat is a clinically validated serum test for advanced non-small cell lung cancer (NSCLC) patients. VeriStrat is a blood-based test for patients with cancer that provides fast, clear results on the patient's proteomic profile. It is a serum proteomic test that is primarily for use in identifying NSCLC patients who are good candidates for treatment with epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs).

The VeriStrat test uses mass spectrometry and proprietary algorithms to analyze the proteomic profile of pretreatment serum (or plasma) from patients with NSCLC. The VeriStrat test assigns a rating of "good," or "poor" based on the mass spectral intensity of eight specific peaks or "features," each of which represents a specific (but currently unidentified) protein. A result of VeriStrat "good" indicates that the patient may respond to treatment with EGFR TKIs, while VeriStrat "poor" indicates the patient is unlikely to benefit from this type of therapy. The test is also being studied for use in breast cancer as well as head and neck cancer.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **VeriStrat (81538) requires prior authorization**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

VeriStrat proteomic testing is considered medically when ALL the following criteria are met:

- Diagnosis of NSCLC (see appropriate ICD-10 codes below); AND
- EGFR wild type (i.e., no mutation detected) or unknown; AND
- First line systemic chemotherapy has failed; AND
- Treatment decision for Tarceva (erlotinib) will be based on the test result

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival
84999	Unlisted chemistry procedure
ICD-10 CODES	
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus, or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus, or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus, or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus, or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus, or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C38.4	Malignant neoplasm of pleura
C45.0	Mesothelioma of pleura

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 10/01/2021

Date	Explanation & Changes
03/14/2014	<ul style="list-style-type: none"> Removed CPT code 83789 Policy reviewed and updated to reflect most current clinical evidence Policy approved per the Technology Assessment Working Group (TAWG) as revised
03/15/2015	<ul style="list-style-type: none"> Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/17/2015	<ul style="list-style-type: none"> Added effective 1/1/16 new code 81538 Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
03/25/2016	<ul style="list-style-type: none"> Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
05/26/2017	<ul style="list-style-type: none"> VeriStrat (81538) is now covered with prior authorization for HMO, PPO, Individual Marketplace, & Elite per CMS guidelines Added appropriate ICD-10 codes for VeriStrat (81538) coverage per CMS guidelines Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
05/24/2018	<ul style="list-style-type: none"> Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/14/2020	<ul style="list-style-type: none"> Medical policy placed on the new Paramount Medical Policy Format
02/07/2023	<ul style="list-style-type: none"> Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
02/01/2024	<ul style="list-style-type: none"> Medical Policy reviewed and updated to reflect the most current clinical evidence
01/01/2025	<ul style="list-style-type: none"> Medical Policy reviewed and updated to reflect the most current clinical evidence

- No changes in coverage criteria

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies
<https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting
<https://www.cms.gov/medicare/coding/icd10>

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf>

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services <https://www.cms.gov/medicare-medicare-coordination/national-correct-coding-initiative-ncci/ncci-medicare>

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs)
<https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits>
 U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>

Centers for Medicare and Medicaid Services, Medicare Coverage Database, LCD Reference Article, Billing and Coding Article, Billing and Coding: Biomarkers for Oncology, <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52986&ver=224&keyword=VERISTRAT&keywordType=starts&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP&contractOption=all&sortBy=relevance&bc=1>

Centers for Medicare and Medicaid Services, Medicare Coverage Database, Local Coverage Determination, Biomarkers for Oncology L35396, <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=35396&ver=208>

Hayes, Inc., <https://www.hayesinc.com/> <https://evidence.hayesinc.com/report/qte.veristrat2309>