Medica Coverage Policy

<table>
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<tr>
<th>Policy Name:</th>
<th>VeriStrat® Proteomic Testing</th>
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<td>Effective Date:</td>
<td>2/17/2020</td>
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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

VeriStrat® proteomic testing is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Description**

VeriStrat® (Biodesix, Inc., Boulder, CO) is a proteomic blood test that analyzes the proteins in an individual’s serum. Proteomic testing is a laboratory test that uses human tissue or body fluids to analyze an individual’s unique pattern of protein expression. Proteins serve vital functions in the body as they are the main components of the physiological pathways of the cells. However, unlike an individual’s genome, which remains relatively constant, the proteome differs from cell to cell and constantly changes in response to the internal and external environment.

VeriStrat uses matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) to analyze protein patterns in the blood and predict how individuals are likely to respond to erlotinib (Tarceva) or other pharmaceutical agents. Erlotinib is an oral drug that is classified as an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI). EGFR TKIs play a role in the regulation of cell growth, proliferation, differentiation and survival and may be used in patients with advanced non-small cell lung cancer (NSCLC) who have failed at least one prior chemotherapy regimen. Based on the protein pattern identified, VeriStrat assigns a rating of “good” or “poor.” A rating of VeriStrat “good” indicates that the individual may respond to treatment with EGFR TKIs, while VeriStrat “poor” indicates that the individual is unlikely to benefit from the drugs. VeriStrat is also under investigation for use in advanced breast, head, and neck cancer. However, proteomic testing, including VeriStrat, is limited by several technical challenges including but not limited to possible protein breakdown during specimen handling and storage and limited sensitivity of mass spectrometers leading to issues with reproducibility.

**FDA Approval**

Laboratory developed tests that are performed only by certain labs and not commercially marketed as test kits are regulated by the Clinical Laboratory Improvement Act (CLIA) of 1988. Biodesix performs VeriStrat testing on patient blood samples in its own CLIA-certified lab. Therefore, FDA approval is not required.
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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

Original Effective Date: 4/1/2014
Re-Review Date(s): 1/18/2017
1/16/2020
3/16/2020 – administrative update; format

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