

LCD L31161 - OVA-1 Assay

Contractor Information

Contractor Name:	Contractor Number(s):	Contractor Type:
Novitas Solutions, Inc.	12501, 12502, 12101, 12102, 12201, 12202, 12301, 12302, 12401, 12402, 12901	MAC Part A & B

[Go to Top](#)

LCD Information

Document Information

LCD ID Number	Primary Geographic Jurisdiction
L31161	Pennsylvania, Maryland, Delaware, District of Columbia, New Jersey
LCD Title	Oversight Region
OVA-1 Assay	Central Office
Contractor's Determination Number	Original Determination Effective Date
L31161	For services performed on or after 11/05/2010
AMA CPT/ADA CDT Copyright Statement	Original Determination Ending Date
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	Revision Effective Date
	For services performed on or after 01/01/2013
	Revision Ending Date
	N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Indications and Limitations of Coverage and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

The OVA-1 test is specifically indicated for the pre-surgical evaluation of women with an ovarian mass, and suspicion of an ovarian neoplasm. It uses the results of 5 known biomarkers (B-2 microglobulin, apolipoprotein A1, CA 125, transferrin, and transthyretin (prealbumin) to generate a numerical score that correlates with the likelihood of malignancy. It is not a screening study, and should not be used in women with a diagnosis of malignancy in the past five years. It should also not be used in women under age 18, or with a rheumatoid factor concentration of greater than or equal to 250 IU/ml. It is expected that the use of this test will be followed in a timely fashion by an appropriate diagnostic study to confirm a pathologic diagnosis.

[Go to Top](#)

Coding Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x	Hospital Inpatient (Including Medicare Part A)
012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999	Not Applicable
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CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

81503	ONCOLOGY (OVARIAN), BIOCHEMICAL ASSAYS OF FIVE PROTEINS (CA-125, APOLIPROTEIN A1, BETA-2 MICROGLOBULIN, TRANSFERRIN, AND PRE-ALBUMIN), UTILIZING SERUM, ALGORITHM REPORTED AS A RISK SCORE
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ICD-9 Codes that Support Medical Necessity

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

789.33 - 789.34	ABDOMINAL OR PELVIC SWELLING MASS OR LUMP RIGHT LOWER QUADRANT - ABDOMINAL OR PELVIC SWELLING MASS OR LUMP LEFT LOWER QUADRANT
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Diagnoses that Support Medical Necessity

Conditions that are listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity

All those not listed under the "ICD-9 Codes that Support Medical Necessity" section of this policy.
All codes other than 789.33-789.34.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Conditions that are not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

[Go to Top](#)

Other Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must

include the physician or non-physician practitioner responsible for and providing the care of the patient.

3. The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
4. The ordering physician is expected to maintain in the patient's medical record the subsequent pathologic determination regarding the ovarian mass.

Appendices

N/A

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

It is expected that this study will be ordered once prior to the appropriate diagnostic study with appropriate pathologic diagnosis recorded as above.