



Policy Attachment

Attachment to Policy #

MA06.017v

Attachment:

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Policy #:

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Description:

Services that are Considered Medically Necessary with Criteria

Title:

Molecular Diagnostics

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

Please refer to the NewsFLASH:

GeneSight Psychotropic panel (by Assurex Health, Mason, OH)

Attachment B lists codes and services that may represent medically necessary molecular diagnostic testing and may be covered when all of the general molecular diagnostic testing criteria listed in the main policy are met and the test-specific criteria outlined below are met.

Fetal Fibronectin

The fetal fibronectin (fFN) immunoassay is considered medically necessary and, therefore, covered for women who meet all of the following indications:

- Their symptoms are suggestive of current preterm labor severe enough to potentially warrant hospital admission for tocolysis.
- Lab results can be provided in order to make timely treatment determinations (i.e., rapid test results should be provided in less than an hour).
- Singleton or twin gestation between 24 weeks and less than 35 weeks.
- · Intact amniotic membranes.
- · Cervical dilation less than 3 cm.

The fFN immunoassay is considered experimental/investigational for all other indications including, but not limited to:

- As part of routine clinical monitoring in asymptomatic pregnant women with singleton gestation and no risk factors for PTL.
- As part of routine clinical monitoring in asymptomatic pregnant women at risk for PTL, including those with a
 history of multiple gestations, preterm birth, uterine malformation, cervical incompetence, or a history of two or
 more spontaneous second-trimester abortions.
- As part of routine clinical monitoring in women with triplet or higher-order gestations, intact membranes, cervical dilation less than 3 cm, and who are experiencing symptoms suggestive of PTL.
- As a test to identify women at term being considered for induction who are likely to deliver within 24 to 48 hours and, therefore, do not require induction.

Code	
82731	

CellSearch™

For more information and medical necessity criteria, see the current version of the policy entitled Circulating Tumor Cell (CTC) Assay, MA06.030.

Code

86152

86153

OVA1 and ROMA

OVA1[™] and ROMA1[™] proteomic testing as an adjunctive test for the evaluation of ovarian (adnexal) masses is considered medically necessary and, therefore, covered when all of the following criteria are met:

- The individual is over 18 years of age.
- Ovarian adnexal mass is present, for which surgery is planned.
- The individual has not yet been referred to an oncologist.
- For OVA1™ Test: other clinical and radiological evaluation for ovarian cancer does not indicate malignancy.

Code	Narrative
81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score

<u>Miscellaneous</u>
Code
81490

1528	
1538	
1539	
7806	
8363	

Version Effective Date: 03/03/2021 Version Issued Date: 03/01/2021 Version Reissued Date: N/A