

JM Palmetto — MoIDX: BDX-XL2

CPT: 0080U [Oncology (Lung) Mass Spectrometric Analysis of Galectin-3-Binding Protein...]

CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

This Medicare contractor will provide limited coverage for the (BDX-XL2) test (Biodesix, Boulder, CO and Seattle, WA) for the management of a lung nodule, between 8 and 30mm in diameter, in patients 40 years or older and with a pre-test cancer risk (as assessed by the Mayo Clinic Model for Solitary Pulmonary Nodules) of 50% or less. The intended use of the test is to assist physicians in the management of lung nodules by identifying those lung nodules with a high probability of being benign. These lung nodules would then be candidates for non-invasive computed tomography (CT) surveillance instead of invasive procedures.

Coverage Summary

The BDX-XL2 assay is reasonable and necessary to assist physicians in the management of lung nodules by identifying those lung nodules with a high probability of being benign. This assay is only covered when the following conditions are met:

- · Patient is at least 40 years of age and has a lung nodule of diameter 8 to 30mm, and
- The pre-test risk of cancer as determined by the Mayo risk prediction algorithm (10) is 50% or less, and

Note: The BDX-XL2 test should not be ordered if a physician does not intend to act upon the test result. It is expected that physicians will advise nodule surveillance for at least 80% of patients with a post-test probability of 98% or higher.



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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

Code	Description
Group 1 Codes: R91.1	Solitary pulmonary nodule
Group 2 Paragraph:	
	The code R91.8 may be used when a patient has multiple lung nodules with a single nodule of concern. To indicate that R91.8 is being used for this purpose, use the KX modifier following the CPT code. The use of this modifier indicates an attestation that the patient has multiple lung nodules with a single nodule of concern for malignancy.
	If the code R91.8 is being used to describe another (non-covered) diagnosis, use the appropriate modifier to indicate that the service is non-covered as not reasonable and necessary.
Group 2 Codes:	
R91.8	Other nonspecific abnormal finding of lung field

Visit QuestDiagnostics.com/MLCP to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov 🕨

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