2018

MEDICARE LOCAL COVERAGE DETERMINATION (LCD) - L35160 PROCEDURE CODES: 81161-81599, 84999, 86849, 87999, 88199, 88399, 89398

MOLDX: Molecular Diagnostic Tests

For services performed on or after 10-1-2015

DLS TEST CODE AND NAME	
41269	FRAGILE X TEST (SYMPTOMATIC/FAMILY) (Proc Code: 81243, 81244)
41279	FRAGILE X CARRIER SCREEN - PCR (Proc Code: 81243)
41289	FRAGILE X CARRIER-SOUTHERN BLOT (Proc Code: 81244)
45679	FACTOR V (Proc Code: 81241) - non covered, see CMS policy L36155
50478	JAK2 V617F MUTATION ANALYSIS (Proc Code: 81270) - see CMS policy L36180
51499	CYSTIC FIBROSIS, CARRIER SCREEN (Proc Code: 81220)
52749	CYTOCHROME P450 2C19 (Proc Code: 81225) - see CMS policy L36310
52999	BCR-ABL GENE REARRANGE, QNT. REFLEX (Proc Code: 81206) - see CMS policy L36180
54289	PROTHROMBIN G20210A MUTATION (FACTOR II) (Proc Code: 81240) - non covered, see
	CMS policy L36155
54329	P210 BCR-ABL1 (Proc Code: 81206) - see CMS policy L36180
54419	P190 BCR-ABL1 (Proc Code: 81207) - see CMS policy L36180
55069	THALASSEMIA, ALPHA GLOBIN DNA (Proc Code: 81257)
56169	PCA3 - PROSTATE CANCER BIOMARKER (Proc Code: 81313) - see CMS policy A54489
56599	HEMOCHROMATOSIS DNA ANALYSIS (Proc Code: 81256)
58089	HLA-B*5701 TYPING (Proc Code: 81381) - see CMS policy L36145
61859	MTHFR MUTATION (Proc Code: 81291) - non covered, see CMS policy L36155
62069	IGVH MUTATION (Proc Code: 81263)
64429	HGB ELECTROPHORESIS, BLOOD (Proc Code: 81257, 81401, 81403) - see CMS policy L36145
66139	JAK2, V617F MUTATION, QUAL W/ REFLEX EXON 12 (Proc Code: 81270) - see CMS
	policy L36180
66149	JAK2 EXON 12 MUTATION ANALYSIS (Proc Code: 81403) - see CMS policy L36180
71350	HLA-DQ, RENAL (Proc Code: 81376)
71360	HLA-A,B,C,DR,DQ, RENAL (Proc Code: 81370)
71409	HLA A,B,C,DR,DQ TYPING (TRALI) (Proc Code: 81370)

Source: www.cms.hhs.gov/mcd MOLDX MDT Effective Date: 10-01-2015, last updated 4-1-2018 1 of 2

Coverage Indications, Limitations, and/or Medical Necessity

This coverage policy provides the following information:

- defines tests required to register for a unique identifier
- defines tests required to submit a complete technical assessment (TA) for coverage determination
- defines the payment rules applied to covered tests that are not reported with specific procedure codes
- lists some examples of specific covered tests that have completed the registration and TA process and meet
 Medicare's reasonable and necessary criteria for coverage. This listing is not inclusive.

Payment Rules

MoIDX will reimburse:

• approved tests covered for dates of service consistent with the effective date of the coverage determination.

Covered Tests

Please refer to the Noridian website for covered tests' specific coding and billing information.

Other tests/assays may be covered by a separate Noridian policy. In addition the procedure codes listed under Group 1 are covered. If a test is not listed, it may be covered under a separate Noridian policy or it has not been approved for coverage as it has either not been vetted by the MolDx contractor or has been found to be considered statutorily excluded. A list of approved tests may be found on the Noridian website.

For additional MoIDX Program information, go to the Noridian Medicare home page at noridianmedicare.com and select MoIDX under the Policies Tab.

MoIDX expects laboratory providers to follow test indications published by the developer.

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MOLDX MDT