

Molecular Pathology: Quick Reference Medicare Requirements

Medicare covers Molecular Pathology testing only when ALL of the following criteria have been met. If you believe the coverage guidelines will not be met please have the patient sign an Advance Beneficiary Notice of Noncoverage (ABN) before ordering•

Alternative laboratory or clinical tests to definitively diagnose the disorder/identify the condition are unavailable or results are clearly equivocal; AND

- Availability of a clinically valid test, based on published peer reviewed medical literature; AND
- Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) of analytical validity and clinical utility; AND
- Results of the testing must directly impact treatment or management of the Medicare beneficiary; AND
- For testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making; AND
- Individual has not previously received genetic testing for the disease/condition. (In general, diagnostic genetic testing for a disease should be performed once in a lifetime.)