

## Comprehensive Genomic Testing for Lung Cancer Patients: Pathologist-Driven Solutions

- The Medicare MoDx program, which applies in 28 states, has issued an important article describing when pathologists can order genomic tests. (See their article on page 2.)
- Health systems should consider whether this approach will speed up access to cancer tests for their patients.

Nationally recognized guidelines recommend genomic testing for therapy selection in lung cancer patients, but timely access is still a major challenge. 64% of lung cancer patients experienced delays in care due to avoidable gaps in the care pathway (Sadik et al., 2022). Patients may be started on less-effective therapies simply because genomic results are still pending.

Integrated care models for cancer care have been shown to improve patient outcomes and to increase referrals to clinical trials (Agarwal et al., 2024; Dagogo-Jack et al., 2023). The MoDx program, a Medicare policy initiative that applies in 28 states, supports shortening the clinical care pathway. In 2024, the MoDx program helped health systems by clarifying that pathologists can order molecular diagnostic tests in certain situations. In their 2024 article, MoDx describes that exceptions exist for pathologist-initiated orders (MoDx, 2024). When the pathologist for a cancer case orders a genomic test, MoDx will apply the following criteria (CMS, 2024):

- 1.) The services are medically necessary for a complete and accurate diagnosis.
- 2.) The results are communicated to the treating physician for use in patient care.
- 3.) The pathologist documents the reasons for ordering the additional tests.

Medicare policy also allows for reflex and standing orders when tests are medically necessary (CMS, 2024).

The MoDx article on pathologist-driven test orders is an important new resource for the 28 states that recognize MoDx policy. Health systems may find that cancer care can be improved by this approach. If so, institutional guidance should provide protocols for surgeons, pathologists, and oncologists on whether pathologists are authorized to order genomic tests for lung cancer patients, and, if so, define which specific tests are appropriate in different clinical scenarios. For patients in Medicare Advantage plans, also consider the impact on prior authorization rules and requirements.

Agarwal A et al. (2024) Improvements in clinical cancer care associated with integration of personalized medicine. *J Pers Med* 14, 997.

CMS (2024) Benefit Policy Manual, Chapter 15, Section 80.6.5. For conditional or reflex orders from the treating physician, see 80.6.1. For standing orders from the treating physician, see MedLearn document MLN909221 (2020).

Dagogo-Jack I et al. (2023) Integrated radiology, pathology, and pharmacy program to accelerate access to Osimertinib. *JCO Oncol Pract* 19:786-92.

MoDx (2024) Clarification of ordering requirements [for pathologists]. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59744>.

Sadik H et al. (2022) Impact of clinical practice gaps on the implementation of personalized medicine in advanced NSCLC. *JCO Precis Oncol* 6:e2200246.

# MoldX Article: Clarification of Order Requirements for Laboratory and Molecular Diagnostic Services

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<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59744>

Documentation requirements for laboratory services require that services be ordered by a treating physician as defined in IOM 100-02 Chapter 15 §80.6.1 and meet other criteria set in 42CFR §410.32(b). Further clarifications were made in ICN MLN909221, December 2020.

In view of these requirements, this contractor provides the following supplemental clarifying information:

- **Pathologists may order molecular diagnostic services** when they fall under exemptions to the “treating physician” requirements as defined in the Medicare Benefits Manual 100-02 Chapter 15 sections 80.6.3, 80.6.4, or 80.6.5.
  - Most commonly, **pathologists may order molecular diagnostic tests** when performing diagnostic services from a sample submitted to them without a specific test order. In such instances, the pathologist must meet all the criteria listed in section 80.6.5. This includes ensuring the service is reasonable and necessary, the results are communicated, and that the pathologist documents why the service was performed in their report.
  - **A pathologist may also order additional testing** as defined in the above exemptions after the completion of an ordered service (molecular pathology or other pathology service) when that service is medically necessary and a delay in the performance of the test would have an adverse effect on the care of the beneficiary.
- **Test requisition forms** are part of the medical record. When requisition forms include complete information validating medical necessity, such as qualifying clinical information that demonstrate test coverage criteria are met, the requisition form may be sufficient to determine if the service is reasonable and necessary without other medical information from the ordering provider.
  - If the requisition form does NOT contain sufficient and relevant clinical information to determine if the service is reasonable and necessary for the intended patient, the requisition form is NOT considered sufficient to meet reasonable and necessary requirements, and additional documentation may be required to fulfil this criteria.
- **A “wet signature”** is NOT required for clinical diagnostic tests and electronic signatures are acceptable if they confer an attestation that the physician is placing the order.
  - A signature is also not required on orders for clinical diagnostic tests paid on the basis of the clinical lab fee schedule, the physician fee schedule, or for physician pathology services (IOM 100-02 Chapter 15 §80.6.1), provided that there is other evidence in the medical record that there is intent to place an order.
  - However, it should be understood by providers that the most common reason for improper payment upon review is insufficient documentation, and it is best practice to ensure there is a signed order in place.