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Medicare Policy for Genomic Test Orders:

Resources that Describe CMS Policy

Bruce Quinn Associates LLC, with support from LUNGevity Foundation and ACS CAN.

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To care for cancer patients, diverse stakeholders must coordinate efficiently to ensure optimal modern treatment. Modern healthcare institutions are complex and often siloed. Lack of smooth integration has been shown to delay or harm patient outcomes, like ensuring that all eligible patients receive targeted therapies (Agarwal et al, 2024; Sadik et al., 2022). The scale and scope of the challenge was recently described by Dagogo-Jack and colleagues (Dagogo-Jack et al., 2023).

Early Ordering of Genomic Testing

One critical link in the chain is **early ordering of genomic testing** for appropriate cancer patients. Several weeks may pass as a patient's biopsy and decisions are handing surgeon to pathologist to oncologist to genomics laboratory to tumor board to pharmacy. Are there **policy solutions** available today which could reduce the delay in obtaining genomic test results?

The short answer is yes, and a critical step forward is provided by a 2024 article from the MolDx program. MolDx is a policy system for genomic test coverage and reimbursement that provides a uniform set of rules for 28 states. In article A59744, MolDx maps out the authorities under which pathologists can order genomic tests for cancer patients, bringing together multiple parts of several existing CMS policies. These include authorities for pathologist test ordering, for reflex tests (if test A, then test B), and standing orders (which CMS states may include a "population," as long as the tests are reasonable and necessary.)

Where to Find the Key Medicare Policy Documents

Policy components are found in least four places – regulations at 42 CFR 410.32 (1996/1997), Medicare's Benefits Manual Chapter 15, a recent MedLearn article from CMS, document MLN909221, and finally, Article A59744.

In the following pages, we'll indicate where these authorities come from, and reprint what they say.

- One-Page Summary: Comprehensive Genomic Testing for Lung Cancer Patients
- Medicare regulation on ordering diagnostic tests. 42 CFR 410.32.
- Medicare Benefits Manual, Chapter 15, Section 80. Order Exceptions.
- MolDx Article A50744 (2024). Pathologists Orders for Diagnostic Tests.
- CMS MedLearn ICN 909221 (2020). Complying with Laboratory Services.

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

- The Medicare MolDx program, which applies in 28 states, has issued an important article describing when pathologists can order genomic tests. (See their article on page 6.)
- 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 MolDx program, a Medicare policy initiative that applies in 28 states, supports shortening the clinical care pathway. In 2024, the MolDx program helped health systems by clarifying that pathologists can order molecular diagnostic tests in certain situations. In their 2024 article, MolDx describes that exceptions exist for pathologist-initiated orders (MolDx, 2024). When the pathologist for a cancer case orders a genomic test, MolDx 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 MolDx article on pathologist-driven test orders is an important new resource for the 29 states that recognize MolDx 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.
MolDx (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.

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42 CFR 410.32 (1996/1997): The Back Story

Dating to 1996, with revisions in 1997, regulation 42 CFR 410.32 establishes ground rules for all diagnostic tests, including who may order them. The regulation is concise, but gains important context by going back to the original publication, its rationale, and its question-and-answer sections (CMS 1996, CMS 1997).

CMS wrote (1996) that "we have heard of instances in which a physician is employed for the sole purpose of ordering tests. This physician has no relationship with the beneficiary, and it is highly likely that tests by this physician would not be medically necessary." Therefore, CMS placed in regulation "a long-standing manual instruction" that "the physician ordering the test must be the physician treating the patient." This was incorporated into 42 CFR 410.32. In 1997, CMS added a remark that tests not ordered by the treating physician were unnecessary under statute 1861(a)(1)(A), in order to be sure that future enforcement was tied to a statutory denial.

However, CMS immediately recognized through public comment that many exceptions to the literal text could occur. For example, a treating cardiologist might order a test on Friday, leave on vacation, and his office partner would get the results and treat the patient on Monday. Taken literally, under the regulation, the ordering physician is not the one who is using the result to treat the patient, although it would be absurd to deny payment. Other exceptions might occur if a test order is obviously wrong (x-ray of the left foot, when the right foot is broken.) Not placed in the regulation, but provided in a guidance manual, there are also circumstances when pathologists order tests.

Here is the regulation regarding test orders, but see the following pages for exceptions.

42 CFR 410.32. Ordering diagnostic tests. Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

Link:
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.32

Medicare Benefits Manual, Chapter 15, Section 80: Order Exceptions

CMS recognized in 1996/1997 that there would be exceptions to regulation 410.32, and even commented, they were creating the regulation largely to help against fraud and abuse situations, not everyday care.

Medicare's exceptions to 410.32 are now found in its online Benefits Manual, Chapter 15, Section 80 (CMS 2024). Section 80.6 gives rules on diagnostic orders, and was last revised in 2008.

Section 80.6.1 defines "diagnostic test" to include all diagnostic tests, from x-rays to laboratory medicine. A "treating physician" furnishes a consultation or treats a beneficiary for a specific medical problem, using the results of the diagnostic test in management. An interventional radiologist may be a treating physician. An order may include reflex testing ("if X is negative, then perform test Y.")

Section 80.6.2 states that when the interpreting physician determines a different diagnostic test should be performed (e.g. MRI instead of CT), a new order from the treating physician must be received.

Section 80.6.3 is for additional tests. It states that the facility may change and order or institute a new order, if a initial, ordered, diagnostic test has been performed, and as a result, an additional test is medically necessary. A delay in the second test would have an adverse effect on the beneficiary.

Section 80.6.4 states that an interpreting physician may determine unspecified parameters, such a type of radiographic views. He may also modify "errors obvious to a lay person" like an X-ray order on the normal foot instead of the broken foot. If testing with several parts is truncated during testing, initial completed tests are payable.

Section 80.6.5 is a special section called, "Surgical/Cytopathology Exception." (Note that tumor biopsies are surgical or cytological cases). The pathologist may perform additional tests even though not specifically requested by the treating physician. Three rules must be met:

1.) The services are medically necessary for a complete and accurate diagnosis.
2.) The results are communicated to the treating physician.
3.) The pathologist documents why the testing was done.

Link:
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

MolDx Article A50744 (2024) Pathologist Orders for Genomic Tests

This article cites both regulation 410.32 and the Benefits Manual above. The article specifically states that the pathologist rules (Benefits Manual 80.6) can apply to molecular diagnostic services.

MolDx writes,

> 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.

The article goes on to state that Test Requisition Forms are "part of the medical record" and "may be sufficient to determine a service is reasonable and necessary." They add that a specific signed order is not necessary to justify a medical test, if other information is evident in the rest of the medical record. (However, best practice is to record and convey a signed order).

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

The above article applies in Medicare Jurisdiction E (HI, CA, NV), Jurisdiction F (AK, WA, OR, ID, MT, WY, ND, SD, UT, AZ), Jurisdiction 5 (NE, IA, KS, MO), Jurisdiction 8 (MI, IN), Jurisdiction 15 (OH, KY), Jurisdiction JJ (TN, AL, GA), and Jurisdiction JM (WV, VA, NC, SC), totaling 28 states.

CMS MedLearn ICN 909221 (2020) Complying with Laboratory Services

CMS publishes an extensive series of guidelines under the header, "MedLean." This 2020 5-page guide is called, "Complying with Laboratory Services Requirements." (CMS 2020).

The guide states that CMS does recognize standing orders – provided they are medically necessary – and that these may mean "recurring orders specific to a patient" as well as "orders for services delivered to a population of patients." Recurring orders might be, "Perform a glucose test daily x 5 days" and standing orders might be, "Perform an A1c test quarterly on diabetic patients in this practice".

Link:
https://www.cms.gov/sites/default/files/2020-12/ProviderComplianceLabServices_Fact_Sheet_ICN909221.pdf

Citations

CMS (1996) Medicare Program; Revisions to Payment Policies. 61 Fed Reg 59490, see 59497-59498.
CMS (1997) Medicare Program; Revisions to Payment Policies. 62 Fed Feg 33158, see 33179.
CMS (2020) Complying with Laboratory Services Requirements. https://www.cms.gov/sites/default/files/2020-12/ProviderComplianceLabServices_Fact_Sheet_ICN909221.pdf
CMS (2024) Medicare Benefits Manual, Chapter 15 (see section 80). https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
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