Pharmacogenomics Testing

THE HEALTH ALLIANCE

CMS Policy for Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas

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

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Genetic testing holds the potential to provide great value in improving health outcomes for all individuals. The scope of this LCD includes testing to determine how genes affect the body's response to certain medicines, known as pharmacogenetic, or pharmacogenomic testing. Clinicians face a daunting task to individualize therapies to maximize beneficial outcomes and minimize adverse events and lack of effect. Pharmacogenomic (PGx) testing holds the hope of improved choice of drug therapy for multiple conditions for which drug therapy is appropriate.

A person's genetic code can influence various steps in drug response. Examples of these steps where genetic variation may influence response include drug receptor type and number, increased or decreased drug uptake, and increased or decreased drug metabolism. Depending on the specific situation, these interactions can result in increased or decreased drug effectiveness as well as adverse drug reactions.

This LCD addresses single gene, multi-gene panels, and combinatorial tests aimed at determining an individual's drug response.

Definitions

Combinatorial PGx test – a type of multi-gene panel that requires a proprietary algorithm to evaluate pharmacokinetic or pharmacodynamic relationships resulting in drug recommendations or warnings.

Actionable use – A test is considered to have an actionable use when the genotype information may lead to selection of or avoidance of a specific therapy or modification of dosage of a therapy. The selection, avoidance, or dose change must be based on the U.S. Food and Drug Administration (FDA) label for the drug, an FDA warning or safety concern, or a Clinical Pharmacogenetics Implementation Consortium (CPIC) level A or B gene-drug interaction. An intended change in therapy based on the result of a genotyping test that is not supported by one of these sources is not considered an actionable use for the purposes of this LCD.

Covered Indications

Pharmacogenetics testing will be considered medically reasonable and necessary if:

1. The patient has a condition where clinical evaluation has determined the need for a medication that has a known gene-drug interaction(s) for which the test results would directly impact the drug management of the patient's condition; AND
2. The test meets evidence standards for genetic testing as evaluated by a scientific, transparent, peer-reviewed process and determined to demonstrate actionability in clinical decision making by CPIC guideline level A or B; or is listed in the FDA table of known gene-drug interactions where data support therapeutic recommendations or a potential impact on safety or response or the FDA label; https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling ; https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations

Some panel/combinatorial tests may include content that has demonstrated actionability and some that has not. In these circumstances, the components of the tests that have demonstrated actionability as noted in #2 will be considered medically reasonable and necessary. Refer to the related billing and coding article for coding information.

Please refer to National Coverage Determination (NCD) 90.1 for anticoagulation dosing with warfarin.

Limitations

The following is considered not medically reasonable and necessary:

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- Genetic testing where either analytical validity, clinical validity, or clinical utility has not been established.
- Germline testing may be performed once in a lifetime per beneficiary.
    - Any laboratory test that investigates the same germline genetic content, for the same genetic information, that has already been tested in the same Medicare beneficiary is not medically reasonable and necessary as it is duplicative. The germline sequence of an individual does not change over time, and therefore repeat testing of the same germline content for the same genetic information does not provide new clinical information.

Provider Qualifications

The ordering provider of a PGx test for a patient with a medical condition:

- Must be the treating clinician who is responsible for the pharmacologic management of the patient's condition. The ordering provider of a PGx test is restricted to providers who have the licensure, qualifications, and necessary experience/training to both diagnose the condition being treated and to prescribe medications (the provider must be able to do both) for the condition either independently or in an arrangement as required by all the applicable state laws; and
- is considering or has already prescribed a pharmacologic treatment with actionable gene-drug interactions; and
- understands the actionability of the ordered test.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Medicare Local Coverage Determination Policy

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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.**
Note—Bolded diagnoses below have the highest utilization

Code	Description

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58801

Visit MAKOMedical.com/coverageguidance 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

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39063 Last Updated: 3/18/25