



State of New Jersey
DEPARTMENT OF BANKING AND INSURANCE
OFFICE OF THE COMMISSIONER
PO Box 325
TRENTON, NJ 08625-0325
TEL (609) 633-7667

MIKIE SHERRILL
Governor

SUSAN OCHS
Acting Commissioner

BULLETIN NO. 26-08

TO: ALL HEALTH INSURANCE COMPANIES, HEALTH SERVICE CORPORATIONS, HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE CORPORATIONS, AND HEALTH MAINTENANCE ORGANIZATIONS AUTHORIZED TO ISSUE HEALTH BENEFITS IN THIS STATE

FROM: SUSAN OCHS, ACTING COMMISSIONER

RE: COVERAGE FOR BIOMARKER PRECISION MEDICAL TESTING

The purpose of this bulletin is to provide guidance regarding compliance with P.L. 2025, c. 49 (“Act”), which requires all health insurance companies, health maintenance organizations, health service corporations, hospital service corporations, medical service corporations issuing health benefits plans in this State (collectively “carriers”) to provide coverage for biomarker precision medical testing¹ for the diagnosis, treatment, management, or monitoring of diseases or conditions. The Act applies to policies and contracts delivered, issued, executed, renewed, or approved for issuance or renewal in New Jersey on or after July 22, 2025.

First, Carriers must cover a biomarker precision medical test if the test is for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition, excluding asymptomatic screening, to guide the treatment decisions of the insured, when the appropriateness and efficacy of the test is demonstrated by any of the following five criteria:

1. A labeled indication for a test approved or cleared by the United States Food and Drug Administration (“FDA”);
2. A test indicated for an FDA-approved drug or included in the warnings/precautions of an FDA-approved drug label;
3. Warnings and precautions on FDA-approved drug labels;
4. A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare administrative contractor; or

¹ “Biomarker precision medical testing” means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker precision medical testing includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

5. Nationally recognized clinical practice guidelines.

Carriers do not have discretion to apply additional or different coverage criteria. For example, where a biomarker test is covered under Local Coverage Determinations of Medicare Administrative Contractors (“LCD”), a carrier may not require additional or different coverage criteria than those included in the LCD to determine clinical utility. Furthermore, carriers must provide coverage in a manner that limits disruption in care, including the need for multiple biopsies or biospecimens samples.

Second, because any one of the above five criteria is sufficient to demonstrate appropriateness and efficacy under the Act, carriers may not require multiple categories of evidence to provide coverage, and carriers must apply the least restrictive coverage criteria if more than one of the five criteria are satisfied by the biomarker precision medical test. For example, if a biomarker precision medical test has a labeled indication approved by the FDA and an LCD that imposes coverage criteria that is more restrictive than the labeled indication, carriers must cover the biomarker precision medical test in accordance with the less restrictive coverage criteria, which would be its labeled indication.

Third, in the absence of any of the five criteria identified in the Act, carriers may make determinations as to the appropriateness and efficacy of a biomarker precision medical test in accordance with their judgment, applicable medical policies, and available evidence.

Fourth, in formulating any medical policy used to make coverage decisions for biomarker precision medical tests, carriers should explicitly state the requirements of the Act and follow those requirements. If a carrier utilizes a medical policy that is intended to be generally applicable in multiple jurisdictions, such policy must explicitly provide that the Act governs insurance policies to which it applies, and that the coverage requirements of the Act supersede any other more general or different requirements. The Department emphasizes that clear medical policy provisions that faithfully reflect the requirements of the Act are critical to effectuating access to biomarker precision medical testing.

If utilization review is required, a decision shall be made pursuant to the guidelines and timeframes under N.J.S.A. 17B:30-55.1. If an insurer denies a biomarker precision medical test, the insurer must provide clear, readily accessible, and conspicuous information on the process to submit an appeal to the subscriber, and the treating health care provider or treating health care entity that prescribed biomarker precision medical testing. The benefits shall be provided to the same extent as for any other medical condition.

Failure to comply with the statute may result in enforcement action as authorized under New Jersey law. If you have any questions, please contact lifehealth@dobi.nj.gov.

10/5/2026
Date

Jd biomarker testing cov bul/Bulletins



Susan Ochs
Acting Commissioner