EFFECTIVE DATE: 12|01|2026
POLICY LAST REVIEWED: 08|05|2026

OVERVIEW

There are numerous commercially available genetic and molecular diagnostic, prognostic, and therapeutic tests for individuals with certain diseases or asymptomatic individuals with future risk. A polygenic risk score is used to estimate a person's risk for developing certain diseases based on their genetics.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

There is no specific CPT coding for the service referenced in this policy. Therefore, an Unlisted CPT code should be used (see Coding Section for details). All Unlisted genetic testing CPT codes require prior authorization to determine what service is being rendered and if the service is covered or not medically necessary. See the Related Policies section.

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Polygenic risk score testing performed to provide diagnostic, prognostic, therapeutic, or future risk assessment results is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products, as the evidence is insufficient to determine that the technology results in an improvement in net health outcome.

Commercial Products

Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L. **§27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable laboratory benefits/coverage.

BACKGROUND

This policy addresses polygenic risk score testing, which is available on a clinical basis before the required and necessary evidence base to support clinical validity and utility is established. Because this testing is often proprietary, there is no independent test evaluation data available in the early stages to support the laboratory's claims regarding test performance and utility. While studies using this testing may generate information that may help elucidate the biologic mechanisms of disease and eventually help design treatments, polygenic risk scoring is currently in a developmental phase, with limited evidence of clinical utility for diagnosis, prognosis, or risk assessment.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

National Human Genome Research Institute et al

In 2021, the National Human Genome Research Institute's ClinGen Complex Disease Working Group updated the Genetic Risk Prediction (GRIPS) Reporting Statement in collaboration with the Polygenic Score (PGS) Catalog. The 22-item reporting framework developed to define the minimal information needed to interpret and evaluate polygenic risk scores is summarized in the table below.

Polygenic Risk Score Reporting Statement

Reporting Standard	
Background	Study Type
	Risk Model Purpose & Predicted Outcome
Study Population and Data	Study Design & Recruitment
	Participant Demographic and Clinical Characteristics
	Ancestry
	Genetic Data
	Non-Genetic Variables
	Outcome of Interest
	Missing Data
Risk Model Development & Application	Polygenic Risk Score Construction & Estimation
	Risk Model Type
	Integrated Risk Model(s) Description & Fitting
Risk Model Evaluation	PRS Distribution
	Risk Model Predictive Ability
	Risk Model Discrimination
	Risk Model Calibration
	Subgroup Analyses

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Limitations & Clinical Implications	Risk Model Interpretation
	Limitations
	Generalizability
	Risk Model Intended Uses
Data Transparency & Availability	

PRS: polygenic risk score.

For individuals with various indications for diagnostic, prognostic, therapeutic, or future risk assessment testing who receive polygenic risk score testing, the evidence on clinical utility is insufficient or non-evaluable. The lack of demonstrated clinical utility of this testing is based on the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) it is unclear where in the clinical pathway the test fits (replacement, triage, add-on); and/or (3) it is unclear how the test leads to changes in management that would improve health outcomes and/or avoiding existing burdensome and invasive testing; and/or (4) thresholds for decision making have not been established; (5) and/or the outcome from the test result does not result in a clinically meaningful improvement relative to the outcomes(s) obtained without the test. As this testing does not have clinical utility, the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

CPT codes have not been assigned to Polygenic Risk Score testing, which is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products. Therefore, an Unlisted CPT code (81479, 81599, 84999) should be used:

81479 Unlisted molecular pathology procedure
81599 Unlisted multianalyte assay with algorithmic analysis
84999 Unlisted chemistry procedure

RELATED POLICIES

Biomarker Testing Mandate
Unlisted Procedures

PUBLISHED

Provider Update, March/October 2026
Provider Update, June/October 2025
Provider Update, December 2024
Provider Update, November 2023

REFERENCES

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7. Wand H, Lambert SA, Tamburro C, et al. Improving reporting standards for polygenic scores in risk prediction studies. Nature. Mar 2021; 591(7849): 211-219. PMID 33692554

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