DRAFT Medical Coverage Policy | Biomarker Testing Mandate

EFFECTIVE DATE: 01|01|2024
POLICY LAST UPDATED: 09|26|2023

OVERVIEW

This is an administrative policy to document the state-mandated coverage guidelines for biomarker testing (§ 27-19-81 and §27-20-77, full text below).

This policy is applicable to Commercial Products only.

MEDICAL CRITERIA

Medical criteria may vary based on the service being rendered. Please refer to the Related Policies section for services with recommended prior authorization.

PRIOR AUTHORIZATION

Prior authorization review may be recommended. Please refer to the Related Policies section.

POLICY STATEMENT

Commercial Products

Biomarker testing may be considered medically necessary for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a member's disease or condition to guide treatment decisions, when the test provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to:

- Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA-approved drug;
- Centers for Medicare Services (CMS) National Coverage Determinations (NCD) or Medicare Administrative Contractor (MAC) Local Coverage Determinations (LCD); or
- Nationally recognized clinical practice guidelines and consensus statements.

Some genetic testing services are not medically necessary when:

- there is insufficient clinical evidence or strength of recommendation,
- results would not reasonably be used in management of a patient,
- services are unlikely to impact therapeutic decision-making in the clinical management of the patient.

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 below. 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 and 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/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for laboratory tests and applicable coverage/benefits.

BACKGROUND

§27-19-81 Nonprofit Hospital Service Corporations, Coverage for biomarker testing.
§27-20-77 Nonprofit Medical Service Corporations, Coverage for biomarker testing.

(a) As used in this section:

(1) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. Biomarkers include, but are not limited to, gene mutations or protein expression.

(2) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multi-plex panel tests, and whole genome sequencing.

(3) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

(4) "Consensus statements" as used here are statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(5) "Nationally recognized clinical practice guidelines" as used here are evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

(b) Every individual or group health insurance contract, or every individual or group hospital or medical expense insurance policy, plan, or group policy delivered, issued for delivery, or renewed in this state on or after January 1, 2024, shall provide coverage for the services of biomarker testing in accordance with each health insurer's respective principles and mechanisms of reimbursement, credentialing, and contracting. Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions, when the test provides clinical utility as demonstrated by medical and scientific evidence, including, but not limited to:

(1) Labeled indications for an FDA-approved or -cleared test or indicated tests for an FDA- approved drug;

(2) Centers for Medicare Services ("CMS") national coverage determinations or Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

(3) Nationally recognized clinical practice guidelines and consensus statements.

(c) Coverage as defined in subsection (b) is provided in a manner that limits disruptions in care including the need for multiple biopsies or biospecimen samples.

(d) The patient and prescribing practitioner shall have access to clear, readily accessible and convenient processes to request an exception to a coverage policy of a health insurer, nonprofit health service plan, and health maintenance organization. The process shall be made readily accessible on the health insurers', nonprofit health service plans', or health maintenance organizations' website.

CODING

Please refer to the Related Policies for coding information.

RELATED POLICIES

Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer
Blood Product Molecular Antigen Typing
CA-125
Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy)
Comprehensive Genomic Profiling for Selecting Targeted Cancer Therapies
Envisia for Idiopathic Pulmonary Fibrosis
Evaluation of Biomarkers for Alzheimer's Disease
Fecal Calprotectin Testing
Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer
Gene Expression Profiling and Protein Biomarkers for Prostate Cancer Management
Gene Expression Profiling for Cutaneous Melanoma
Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
Genetic Testing for Diagnosis and Management of Mental Health Conditions
Genetic Testing for Duchenne and Becker Muscular Dystrophy
Genetic Testing for Epilepsy
Genetic Testing for Mitochondrial Disorders
Genetic Testing Services
Genomic Sequence Analysis in the Treatment of Hematolymphoid Diseases
Genomic Sequence Analysis in the Treatment of Solid Organ Neoplasms
Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Breast Cancer
Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease
Identification of Microorganisms Using Nucleic Acid Probes
Immune Cell Function Assay
In Vitro Chemoresistance and Chemosensitivity Assays
Invasive Prenatal (Fetal) Diagnostic Testing
Laboratory Testing Investigational Services
Laboratory Tests Post Transplant and for Heart Failure
Lyme Disease Mandate
Lung Liquid Biopsy
Mass Spectrometry (MS) Testing in Monoclonal Gammopathy
Measurement of Lipoprotein-Associated Phospholipase A2 in the Assessment of Cardiovascular Risk
Measurement of Serum Antibodies to Selected Biologic Agents
Medicare Advantage Plans National and Local Coverage Determinations
Minimal Residual Disease Testing for Cancer
Molecular Markers in Fine Needle Aspiration of the Thyroid
Molecular Testing for the Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreaticobiliary Lesions (Former Title: PathfinderTG Molecular Testing)
Molecular Testing in the Management of Pulmonary Nodules
Multicancer Early Detection Testing
Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis
Multimarker Serum Testing Related to Ovarian Cancer
Next Generation Sequencing for Solid Tumors
Noninvasive Techniques for the Evaluation and Monitoring of Patients with Chronic Liver Disease
Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease
Nutrient/Nutritional Panel Testing
Preimplantation Genetic Testing
Prognostic and Predictive Molecular Classifiers for Bladder Cancer

Proprietary Laboratory Analyses (PLA) and Multianalyte Assays with Algorithmic Analyses (MAAA)
Proteogenomic Testing for Patients with Cancer
Proteomic Testing for Targeted Therapy in Non-Small-Cell Lung Cancer
Salivary Estriol as Risk Predictor Factor Preterm Labor and Management of Menopause and/or Aging
Serologic Genetic and Molecular Screening for Colorectal Cancer
Serum Biomarker Human Epididymis Protein 4
Serum Tumor Markers for Breast and Gastrointestinal Malignancies
Urinary Biomarkers for Cancer Screening, Diagnosis and Surveillance
Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders

PUBLISHED

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REFERENCES

RIGL Mandate 27-20-77. Accessed on 12/28/2022. webserver.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-77.htm

RIGL Mandate 27-19-81. Accessed on 1/5/23. webserver.rilin.state.ri.us/Statutes/TITLE27/27-19/27-19-81.htm

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Molecular Pathology Procedures L35000

Centers for Medicare and Medicaid Services (CMS). Local Coverage Article Billing and Coding: Molecular Pathology Procedures A56199