

Special Circumstances Influencing Coverage Determinations

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Introduction

EviCore performs independent Healthcare Technology Assessments (HTA) to assess analytical validity, clinical validity, and clinical utility of laboratory testing. These HTAs are used as the foundation for EviCore's coverage determinations and medical necessity criteria. However, there may be special circumstances, including state and federal legislation, which may override or supplement EviCore criteria. This guideline outlines special circumstances that may impact coverage determinations for certain laboratory testing.

Note:

This benefit/harm statement only applies to those jurisdictions that do not have Medicare guidance. Based upon the clinical policy, following EviCore's Special Circumstances Influencing Coverage Determinations guideline will ensure adherence to state and federal regulations. However, it is possible that there will be a delay in care until the outlined procedures in the guideline are followed.

Special Circumstances

Federal Legislation

Preventive Services Addressed by the Affordable Care Act

EviCore's position is that the Affordable Care Act does not preclude EviCore's laboratory management program from determining the medical necessity of preventive services.

While private health plans must provide coverage for such preventive services without cost sharing, these tests may be subject to medical necessity requirements. A list of preventive services covered under the regulation can be found at <https://www.healthcare.gov/preventive-care-benefits>.

Section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, states that:¹

- "Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage."
- "[T]o the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service."

Therefore, EviCore's managed procedure codes for a Health Plan are subject to medical necessity requirements, even if the requested test is considered a preventive service.

State Mandates

Autism Screening

EviCore's position is that because autism is a diagnosis that is made clinically based on an individual's symptoms, genetic testing is not required by state mandate unless explicitly stated.

According to the National Conference of State Legislatures (NCSL), "[m]ost states require insurers to provide coverage for the treatment of autism."²

Such state mandates typically apply to the diagnosis, screening, and/or treatment of autism, for which genetic testing is not relevant, as autism is diagnosed through evaluation of an individual's development and behaviors by an appropriate specialist (such as neurodevelopmental pediatrician or developmental-behavioral pediatrician).³ While genetic testing may identify an underlying genetic cause for the individual's autism, it does not diagnose autism. In addition, there is not a specific genetic test to diagnose autism, as there are numerous genetic syndromes which may include autism as a component of the condition. For example, a child who has a clinical diagnosis of autism may have genetic testing to determine if there is an underlying genetic condition, such as Fragile X Syndrome, that may explain the child's autism. However, the genetic test is not required to make a diagnosis of autism or to treat the child's autism. For information on the medical necessity criteria that must be met for coverage of genetic testing for autism, please refer to the guideline *Autism, Intellectual Disability, and Developmental Delay Genetic Testing*.

Delaware State Mandate: House Bill 319

House Substitute No. 1 for HB 319 "An Act to Amend Title 18 of the Delaware Code Relating to Experimental Treatment Health Insurance Coverage" states that no individual or group policy or health insurance contract:⁴

- "...shall deny coverage, payment, or reimbursement for a National Coverage Determination Service on the basis that the treatment is experimental or

investigational. ... "National Coverage Determination Service" as used in this section shall mean a service, item, or test which receives reimbursement from the Centers for Medicare and Medicaid Services pursuant to the Social Security Act 1869 (f)."

A synopsis of the Delaware General Assembly House Bill 319 (HB319) states:⁴

- "This legislation creates a benchmark for determining when a treatment or service is no longer experimental or investigational. Essentially, when Medicare determines that a treatment is safe for its population, commercial insurers in Delaware may no longer deny coverage on that basis. This will remove inconsistencies for properly-evidenced treatments between payers."

Therefore the state of Delaware prohibits denial of a service as investigational/experimental if the service is coverable under CMS National Policy outlined in an National Coverage Determination (NCD) or National Coverage Analysis (NCA). If EviCore has an experimental, investigational, or unproven (E/I/U) coverage determination for the billed procedure code(s) and CMS has a current NCD or NCA with specific coverage of that procedure code, EviCore will apply the CMS national coverage policy for non-Medicare members identified as Delaware residents. This policy application may occur during pre-service review, through automated claim edits (such as enforcing ICD requirements), or through post-service medical necessity review.

Applicable Laws

States are increasingly addressing the coverage and management of certain laboratory tests. EviCore monitors evolving legislation to ensure compliance.

These bills can generally be grouped into 3 categories:

- Broad Biomarker Bills: these bills generally govern biomarker testing across medical diagnoses
- Cancer-Specific Biomarker Bills: these bills govern biomarker testing for individuals with a medical diagnosis of cancer
- Other State Bills: these bills are specific to a type of clinical test (e.g. BRCA testing), or address the requirement for prior authorization in specific circumstances

The EviCore process for assessing these types of bills differs, and is detailed below.

Broad Biomarker Bills

The following is a list of broad biomarker bills that are applicable to laboratory testing at the time of this guideline. These bills generally address tests performed specifically for diagnosis, treatment, management, or monitoring of a disease or condition. Note that this excludes screening tests or any test that is not focused on a specific diagnosis, management, or treatment decision.

State	Bill	Effective Date	Line(s) of Business*	Jurisdiction**
Arizona	HB 2144 ⁵	January 1, 2023	Commercial	Sitused
California	SB 496 ⁶	July 1, 2024	Commercial; Medicaid	Sitused; Residents
Colorado	SB 124 ⁷	January 1, 2025	Commercial	Sitused
Connecticut	SB 307 ⁸	July 1, 2024	Medicaid	Sitused
Florida	HB 885 ⁹	July 1, 2024	State Employee Plans; Medicaid	Sitused
Georgia	HB 85 ¹⁰	July 1, 2023	Commercial	Sitused
Illinois	HB 1779 ¹¹	January 1, 2022	Commercial	Sitused
Indiana	S 273 ¹²	July 1, 2024	Commercial	Sitused
Iowa	HF 2668 ¹³	January 1, 2025	Commercial; Medicaid	Sitused
Kentucky	HB 180 ¹⁴	January 1, 2024	Commercial; Medicaid	Sitused; Residents
Louisiana	SB 104 ¹⁵	January 1, 2024	Commercial	Sitused; Residents
Maryland	HB 1217 ¹⁶	January 1, 2024	Commercial	Sitused
Minnesota	SF 2995 ¹⁷	January 1, 2025	Commercial; Medicaid	Sitused; Residents
New Mexico	HB 73 ¹⁸	January 1, 2024	Commercial	Sitused; Residents
New York***	A 8502 ¹⁹	January 1, 2025	Commercial; Medicaid	Sitused
Oklahoma	SB 513 ²⁰	January 1, 2024	Commercial	Sitused
Rhode Island	HB 7587 ²¹	January 1, 2024	Commercial	Sitused
Texas	SB 989 ²²	January 1, 2024	Commercial; Medicaid	Sitused; Residents

Note:

*There are some insurance products within these broad categories subject to the biomarker bills, but certain products may be excluded (e.g. Federal Employee Health Plans or those serving military members).

**Sitused indicates the jurisdiction in which the health insurance is issued. Residents indicates the state in which the member lives.

Decision hierarchy criteria

When making medical necessity determinations subject to broad biomarker bill requirements, EviCore will employ the following strategy for both utilization management case reviews and automated claim edit application:

- Apply EviCore criteria and approve if possible.
- If not approvable under EviCore criteria, approve if consistent with coverable indications based on Medicare National Coverage Determinations (NCDs), Medicare Local Coverage Determinations (LCDs), U.S. Food and Drug Administration (FDA) approved tests, FDA cleared tests, indicated tests for a drug that is approved by the FDA, nationally recognized clinical practice guidelines, and/or consensus statements as defined by applicable legislation.

*** New York A 8502 adds a provision to consider peer-reviewed literature that "recognizes the efficacy and appropriateness" of biomarker testing. EviCore already considers all published clinical utility literature in its coverage guideline development. However, given the development rate and quantity of such literature, EviCore will consider clinical utility studies outside of this usual process when submitted by the laboratory for the purposes of biomarker coverage decisions only.

Cancer-Specific Biomarker Bills

The following is a list of biomarker bills specific to cancer tests that are applicable to laboratory testing at the time of this guideline. Note that this excludes screening tests or any test that is not focused on a specific diagnosis, management, or treatment decision.

State	Bill	Effective Date	Line(s) of Business*	Jurisdiction**
Arkansas	HB 1121 ²³	July 31, 2023	Commercial	Sitused; Residents
Louisiana	SB 84 ²⁴	January 1, 2022	Commercial	Sitused; Residents
Nevada	AB 155 ²⁵	October 1, 2023	Commercial	Sitused; Residents

Note:

Special Circumstances

*There are some insurance products within these broad categories subject to the biomarker bills, but certain products may be excluded (e.g. Federal Employee Health Plans or those serving military members).

**Sited indicates the jurisdiction in which the health insurance is issued. Residents indicates the state in which the member lives.

Decision hierarchy criteria

When making medical necessity determinations subject to cancer specific biomarker bill requirements, EviCore will employ the following strategy for both utilization management case reviews and automated claim edit application:

- Purpose of the requested test is for one or more of the following:
 - early detection of cancer
 - diagnosis of cancer
 - treatment of cancer
 - appropriate management of cancer
 - ongoing monitoring of cancer
- Apply EviCore criteria and approve if possible.
- If not approvable under EviCore criteria, approve if consistent with coverable indications based on Medicare NCDs, Medicare LCDs, FDA approved tests, FDA cleared tests, indicated tests for a drug that is approved by the FDA, national guidelines, and/or consensus statements

Other Applicable Bills

The following is a list of bills applicable to laboratory testing at the time of this guideline.

- Arkansas (AR)
 - AR HB 1042 requires that commercial health insurance issued in AR and health insurance covering AR residents on or after January 1, 2023 provide prostate cancer screening coverage for "at least one (1) screening per year for any man forty (40) years of age or older according to the National Comprehensive Cancer Network guidelines."²⁶
 - In order to comply with this legislation, EviCore will use the screening requirements published in HB 1042 when evaluating the medical necessity of prostate cancer screening tests for members who live in AR or have health insurance under AR jurisdiction.
- California (CA)
 - CA SB 535 prohibits commercial insurers that contract in CA on or after July 1, 2022 from requiring prior authorization for biomarker testing for enrollees with advanced or metastatic stage 3 or 4 cancer. Biomarker testing is defined as "a diagnostic test, such as single or multigene, of the cancer patient's biospecimen,

such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide patient treatment." The prior authorization exemption only applies to biomarker testing necessary for an FDA-approved therapy.²⁷

- In order to comply with this legislation, a minimum amount of information must be registered with EviCore to document that the member is exempt from the prior authorization process.
- Connecticut (CT)
 - CT SB 358 requires that commercial and Medicaid health insurance issued in CT on or after January 1, 2023 provide coverage for "Genetic testing of the breast cancer gene one, breast cancer gene two, any other gene variant that materially increases the insured's risk for breast and ovarian cancer or any other gynecological cancer to detect an increased risk for breast and ovarian cancer when recommended by a health care provider in accordance with the United States Preventive Services Task Force recommendations for testing." USPSTF recommendations state "[t]esting for BRCA1/2 mutations should be done when an individual has personal or family history that suggests an inherited cancer susceptibility, when an individual is willing to see a health professional who is suitably trained to provide genetic counseling and interpret test results, and when test results will aid in decision -making."^{28,29}
 - EviCore's guidelines are consistent with the USPSTF requirements and can be used as published to determine coverage.
- Illinois (IL)
 - IL HB 2109 requires that commercial health insurance issued in IL on or after January 1, 2022 provide "coverage for medically necessary comprehensive cancer testing and testing of blood or constitutional tissue for cancer predisposition testing." According to the bill, "Comprehensive cancer testing" includes, but is not limited to, the following forms of testing: (1) Targeted cancer gene panels. (2) Whole-exome genome testing. (3) Whole-genome sequencing. (4) RNA sequencing. (5) Tumor mutation burden." Also, "Testing of blood or constitutional tissue for cancer predisposition testing includes, but is not limited to, the following forms of testing: (1) Targeted cancer gene panels. (2) Whole-exome genome testing. (3) Whole-genome sequencing."³⁰
 - As EviCore's guidelines are evidence-based, they are consistent with these requirements, and can be used as published to determine coverage.
 - IL HB 5334 requires that commercial health insurance issued in IL on or after January 1, 2024 provide coverage for the cost of BRCA1 and BRCA2 genetic testing when recommended by a health care provider in accordance with the United States Preventive Services Task Force's (USPSTF) recommendations for testing. USPSTF recommendations state "[t]esting for BRCA1/2 mutations should be done when an individual has personal or family history that suggests an inherited cancer susceptibility, when an individual is willing to see a health

professional who is suitably trained to provide genetic counseling and interpret test results, and when test results will aid in decision -making."^{29,31}

- EviCore's guidelines are consistent with the USPSTF requirements and can be used as published to determine coverage.
- IL HB 3817 requires that beginning January 1, 2024, the State Employee Group Insurance Program "shall provide coverage for diagnosis and treatment of infertility, including, but not limited to, in vitro fertilization, uterine embryo lavage, embryo transfer, artificial insemination, gamete intrafallopian tube transfer, zygote intrafallopian tube transfer, and low tubal ovum transfer. The coverage required shall include procedures necessary to screen or diagnose a fertilized egg before implantation, including, but not limited to, preimplantation genetic diagnosis, preimplantation genetic screening, and prenatal genetic diagnosis."³²
 - EviCore will determine the medical necessity of laboratory infertility services for this membership group in the following manner:
 - Preimplantation Genetic Diagnosis: The EviCore Preimplantation Genetic Screening and Diagnosis guideline addresses the medically necessary indications for preimplantation genetic diagnosis. It is compliant with the legislation and will used to determine coverage for these services.
 - Preimplantation Genetic Screening: Coverable for those seeking diagnosis and treatment of infertility as defined in the legislation.
 - Prenatal Diagnosis: Coverable when related to preimplantation genetic screening or diagnosis (i.e., to confirm such results) for those seeking diagnosis and treatment of infertility as defined in the legislation.
- IL HB 3202 requires that commercial health insurance issued in IL beginning January 1, 2025 provides coverage for "medically necessary home saliva cancer screening every 24 months if the patient is asymptomatic and at high risk for the disease being tested for or demonstrates symptoms of the disease being tested for at a physical exam." For members subject to this law, home saliva cancer screening testing will be considered medically necessary when one of the following criteria are met:³³
 - Member is asymptomatic and at high risk for oral cancer by one of the following:
 - tobacco and/or alcohol use
 - male
 - older age
 - use of betel quid
 - ultraviolet light exposure
 - infection with Candida or bacterial flora
 - compromised immune system, OR
 - Member demonstrates symptoms of oral cancer as described by their provider.
- IL HB 2350 requires that commercial health insurance issued in IL beginning January 1, 2025 provide coverage for "an annual prostate cancer screening for

insureds upon the recommendation of a physician licensed to practice medicine in all its branches for: (A) asymptomatic individuals age 50 and over; (B) African-American individuals age 40 and over; and (C) individuals age 40 and over with a family history of or genetic predisposition to prostate cancer." Further, "prostate cancer screening" includes medically necessary subsequent follow-up testing as directed by a health care provider, including, but not limited to: (1) urinary analysis; (2) serum biomarkers; and (3) medical imaging, including, but not limited to magnetic resonance imaging."³⁴

- In order to comply with this legislation, EviCore will use its own medical necessity criteria in conjunction with the criteria published in HB 2350 when making medical necessity determinations for individuals seeking prostate cancer screening (as defined in the regulations) who have health insurance under IL jurisdiction.
- Louisiana (LA)
 - LA SB 154 requires that commercial and Medicaid health insurance issued in LA on or after January 1, 2023 provide coverage for "traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening that includes individual sequencing, trio sequencing for a parent or parents of the infant, and ultra-rapid sequencing for an infant who is one year of age or younger, is receiving inpatient hospital services in an intensive care unit or in a pediatric care unit, and has a complex illness of unknown etiology."³⁵
 - In order to comply with this legislation, EviCore will use the medical necessity criteria published in SB 154 when making medical necessity determinations for critically ill infants (as defined in the regulations) who have health insurance under LA jurisdiction.
- Minnesota
 - MN HF 5247 requires that commercial health insurance issued in MN and health insurance covering MN residents on or after January 1, 2025 provide coverage for rapid whole genome sequencing "if the enrollee: (1) is 21 years of age or younger; (2) has a complex or acute illness of unknown etiology that is not confirmed to have been caused by an environmental exposure, toxic ingestion, an infection with a normal response to therapy, or trauma; and (3) is receiving inpatient hospital services in an intensive care unit or a neonatal or high acuity pediatric care unit."³⁶
 - In order to comply with this legislation, EviCore will use the clinical criteria published in HF 5247 when evaluating the medical necessity of rapid whole genome sequencing requests for members who live in MN or have health insurance under MN jurisdiction.
- New Jersey
 - NJ A5235 requires that commercial health insurance issued in NJ on or after August 1, 2024 provide coverage "for any services related to infertility in accordance with American Society for Reproductive Medicine guidelines and as

determined by a physician, which includes, but is not limited to: diagnosis and diagnostic tests; ... genetic testing."³⁷

- As EviCore's guidelines are evidence-based, they are consistent with these requirements, and can be used as published to determine coverage.
- Pennsylvania (PA)
 - PA SB 8 requires that commercial health insurance issued in PA on or after January 1, 2024 provide "coverage for BRCA-related genetic counseling and genetic testing...The minimum coverage required shall include all costs associated with...a genetic laboratory test of the BRCA1 and BRCA2 genes for individuals assessed to be at an increased risk, based on a clinical risk assessment tool, of potentially harmful mutations in the BRCA1 or BRCA2 genes due to a personal or family history of breast or ovarian cancer."³⁸
 - In order to comply with this legislation, when reviewing cases related to BRCA1/2 testing for members with PA jurisdiction, EviCore will consider the results of clinical risk assessment tools and approve if these results indicate a lifetime risk of breast cancer greater than 20%.
- Washington (WA)
 - WSR 21-16-076, effective July 1, 2022, applies to commercial and Medicaid health insurers that contract in WA as well as residents living in the state of Washington. "The purpose of WSR 21-16-076 "is to update the state board of health's (board) existing rules outlining prenatal screenings and diagnostic tests required to be covered by certain payers to align with current clinical standards and best practices."³⁹
 - In order to comply with this regulation, EviCore will use the medical necessity criteria published in WSR 21-16-076 when making medical necessity determinations for the specific prenatal screening and diagnostic testing described within the regulation.
 - WA HB 1689 prohibits commercial insurers that contract in WA on or after January 1, 2023 from requiring prior authorization for biomarker testing for enrollees with stage 3 or 4 cancer; or recurrent, relapsed, refractory, or metastatic cancer. 163 Biomarker testing must "be recommended in the latest version of nationally recognized guidelines or biomarker compendia." The biomarker test must also be a covered service and prescribed by an in-network provider.⁴⁰
 - In order to comply with this legislation, a minimum amount of information must be registered with EviCore to document that the member is exempt from the prior authorization process.

Health Plan Exclusions

Benefit Exclusions

EviCore performs medical necessity determination for any laboratory test that is within the delegated scope of management for the Health Plan (see each Plan's managed procedure code list). However, health plans set varying limitations and exclusions; EviCore's medical necessity review does not take such member-specific benefits into account. Therefore, a medical necessity approval is not a guarantee of payment. Please see the Certificate of Coverage for detail regarding benefit limitations or exclusions (e.g. screening, fertility benefits).

References

Introduction

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