



INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Genetic Testing

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*Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system.*

*For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect, Hoosier Healthwise or Indiana PathWays for Aging (PathWays) member services – providers must contact the member’s managed care entity (MCE) or refer to the MCE provider manual.*

MCE contact information is included in the [IHCP Quick Reference Guide](#) at in.gov/medicaid/providers.

For updates to the information in this module, see [IHCP Bulletins](#) at in.gov/medicaid/providers.

Introduction

According to the National Human Genome Research Institute, the term *genetic testing* covers an array of techniques, including analysis of human DNA, RNA or protein. In the clinical setting, genetic tests can be performed to do the following:

- Confirm a suspected diagnosis.
- Predict the possibility of future illness.
- Detect the presence of a carrier state in unaffected individuals whose children may be at risk.
- Predict response to therapy.

Genetic tests are also performed to screen for genetic defects in fetuses, newborns or embryos used in in-vitro fertilization.

For information about genetic counseling, see the [Genetic Counseling](#) section.

Coverage for Genetic Testing

The Indiana Health Coverage Programs (IHCP) covers a variety of genetic tests when provided in compliance with IHCP coverage and billing guidelines, including obtaining PA when required. IHCP coverage of these services is subject to limitations established for certain benefit plans and in accordance with the policies and procedures described in this module.

The IHCP covers designated testing when medically necessary for the purposes of diagnosis, testing, treatment, appropriate management or ongoing monitoring of a member’s disease or condition and when testing is supported by medical evidence, including:

- Labeled indications for a test approved or cleared by the U.S. Food and Drug Administration (FDA)
- Indicated tests for a drug approved by the FDA
- A warning or precaution on the label of a drug approved by the FDA (where a drug may not be suitable for patients with a specific genetic makeup)
- A national coverage determination (NCD) of the Centers for Medicare & Medicaid Services (CMS)
- A local coverage determination (LCD) of a Medicare administrative contractor
- Nationally recognized clinical practice guidelines or consensus statements

The testing services must be provided in a manner that limits disruptions in care, including the need for multiple biopsies of biospecimen samples.

The IHCP does not include coverage of testing for screening purposes, unless there is evidence of a high risk to the member and a screening may be appropriate to inform the plan of care. Tests that are not FDA approved or supported by nationally recognized clinical practice guidelines will not be considered a covered benefit. Tests that do not have a Medicare fee schedule will not be considered a covered benefit.

In accordance with *Senate Enrolled Act 273* (SEA 273), beginning July 1, 2024, the IHCP expanded coverage for biomarker testing to include additional procedures, when all criteria are met. Refer to the applicable Outpatient Fee Schedule or Professional Fee Schedule, accessible from the [IHCP Fee Schedules](#) webpage, to determine whether a particular testing procedure may be covered by the IHCP and, if so, whether prior authorization is required.

Definitions

For the purpose of this coverage policy, the following definitions apply:

- *Biomarker testing* means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker. All genetic tests are potentially applicable to this definition.
- *Nationally recognized clinical practice guidelines* means evidence-based clinical practice guidelines that:
 - Are developed by an independent organization or medical professional society that:
 - Uses a transparent methodology and reporting structure
 - Has a conflict-of-interest policy
 - Establish standards of care informed by:
 - A systematic review of evidence
 - An assessment of the benefits and risks of alternative care options
 - Recommendations intended to optimize patient care
- *Consensus statement* means a statement that is:
 - Issued by an independent, multidisciplinary panel of experts that:
 - Uses a transparent methodology and reporting structure
 - Has a conflict-of-interest policy
 - Aimed at specific clinical circumstances
 - Based on the best available evidence
 - Developed for the purpose of optimizing the outcomes of clinical care

General Coverage Criteria

All the following general criteria must be met for any genetic testing service to be covered:

- The genetic disorder must be associated with a potentially significant disability.
- The risk of the significant disability from the genetic disorder cannot be identified through biochemical or other testing (for example, ultrasound screening for aortic disease in Marfan's syndrome).
- A specific mutation, or set of mutations, has been established in scientific literature to be reliably associated with the disease.
- The results of the genetic test could impact the medical management of the member with improved net-health outcomes.
- No determinable diagnosis can be gathered from the history, physical examination, pedigree analysis, genetic counseling and completion of conventional diagnostic studies.
- Prior authorization (PA) is obtained, if required.

In addition to these general criteria, test-specific guidelines established by the American College of Medical Genetics must also be met. See the [Additional Information for Specific Types of Genetic Testing](#) section for guidelines related to specific types of genetic tests.

Coverage Restrictions and Limitations

Genetic testing services are **not** covered under the following circumstances:

- For the sole convenience of information for the patient without impacting treatment
- For the medical management of other family members, unless otherwise specified in policy
- For the establishment of paternity
- All screening tests, except the screening tests listed under the state's required newborn screening policy (see *Indiana Administrative Code 410 IAC 3-3-3* and the [Inpatient Hospital Services](#) module)
- If history, physical examination, pedigree analysis, genetic counseling or completion of conventional diagnostic studies has given a definitive diagnosis
- If a genetic test has previously been performed to provide a conclusive diagnosis of the same genetic disorder

Reimbursement for genetic tests specific to a gene or a condition is limited to once per member per lifetime, unless otherwise specified in a test-specific coverage policy. For genetic tests *not* specific to a gene or a condition, providers must have medical documentation on file indicating that each testing procedure is for a separate and distinct diagnosis. The IHCP does not cover genetic testing panels unless otherwise stated.

Prior Authorization for Genetic Testing

PA is required for all genetic testing procedures, unless otherwise noted within the Outpatient Fee Schedule or Professional Fee Schedule (accessible from the [IHCP Fee Schedules](#) webpage at in.gov/medicaid/providers) or by a test-specific coverage policy.

PAs are test-specific, and providers must follow all available guidelines established by the American College of Medical Genetics. If no guidelines are available, providers should follow commonly accepted medical guidelines, such as Amsterdam II or revised Bethesda guidelines for hereditary nonpolyposis colorectal cancer (HNPCC) diagnoses. All IHCP policy guidelines must also be met for PA approval.

The following documentation is required for PA review:

- Documentation outlining medical necessity, specifically stating the impact on the patient's treatment
- Results from any commonly used conventional diagnostic testing showing inconclusive diagnosis
- Documentation that genetic counseling has been performed prior to testing
- All other general documentation required for PA

For more information about PA requests, see the [Prior Authorization](#) module. For PA policies specific to providers located outside of Indiana, see the [Out-of-State Providers](#) module.

Additional Information for Specific Types of Genetic Testing

The following sections include additional coverage guidelines for certain specific types of genetic testing.

Chromosomal Microarray Analysis

The IHCP covers chromosomal microarray analysis (CMA), also known as cytogenomic microarray analysis, when it is determined to be medically necessary for diagnosing a genetic abnormality in children with apparent nonsyndromic cognitive developmental delay/intellectual disability (DD/ID) or autism spectrum disorder (ASD), according to the latest accepted *Diagnostic and Statistical Manual of Mental Disorders* (DSM) guidelines. Prior authorization is required.

Prior authorization for CMA testing requires documentation of **all** the following:

- The child has been diagnosed with nonsyndromic DD/ID or ASD.
- The child has one or more of the following:
 - Two or more major malformations
 - A single major malformation or multiple minor malformations in an infant or child who is also small-for-dates
 - A single major malformation and multiple minor malformations
- Any indicated biochemical tests for metabolic disease have been performed, and results are nondiagnostic.
- FMR1 gene analysis (for Fragile X), when clinically indicated, is negative.
- The results for the genetic testing have the potential to impact the clinical management of the patient.
- Testing is requested after the parent(s) engaged in face-to-face genetic counseling with a healthcare professional licensed under *Indiana Code IC 25-17.3*.

CMA testing is **not** considered medically necessary and will **not** be covered under the following circumstances:

- To confirm the diagnosis of a disorder or syndrome that is routinely diagnosed based on clinical evaluation alone
- For prenatal genetic testing
- For the screening, diagnosis and management of hematologic or oncologic malignancies
- As a means to predict or evaluate pregnancy loss
- In cases of family history of chromosome rearrangement in a phenotypically normal individual
- In cases of suspected genetic abnormality in children with DD/ID or ASD that do not meet the criteria in the following section

Definitions

The following definitions are from the American College of Medical Genetics Guidelines, Evaluation of the Newborn with Single or Multiple Congenital Abnormalities:

- A *malformation* refers to abnormal structural development.
 - A *major malformation* is a structural defect that has a significant effect on function or social acceptability, such as ventricular septal defect or cleft lip.
 - A *minor malformation* is a structural abnormality that has a minimal effect on function or social acceptance, such as preauricular ear pit or partial syndactyly (fusion) of the second or third toes.
 - A *syndrome* is a recognizable pattern of multiple malformations. Syndrome diagnoses are often relatively straightforward and common enough to be clinically recognized without specialized testing. Examples include Down syndrome, neural tube defects and achondroplasia. However, in the very young, or in the case of symptoms with variable presentation, confident identification may be difficult without additional testing.

Genetic Testing for Cancer Susceptibility

Several genetic tests exist for a determination of risk (or risk score) associated with inheritable cancer susceptibility, such as for breast and ovarian cancer or hereditary nonpolyposis colorectal cancer (HNPCC). For coverage of specific tests, providers should check the appropriate fee schedule; both the Outpatient Fee Schedule or Professional Fee Schedule are accessible from the [IHCP Fee Schedules](http://in.gov/medicaid/providers) webpage at in.gov/medicaid/providers.

Cancer-susceptibility genetic testing is a covered service when the general criteria **and both** the following conditions are met:

- A specific mutation, or set of mutations, has been established in the scientific literature to be reliably associated with the risk of developing malignancy.
- The results of the genetic test potentially affect at least one of the management options considered by the physician, in accordance with accepted standards of medical care, including any one of the following:
 - Surgery, or the extent of surgery
 - A change in surveillance
 - Hormonal manipulation
 - A change in standard therapeutic or adjuvant chemotherapy

All criteria set forth in test-specific coverage policies must also be met.

Human Epidermal Growth Factor Receptor 2 (HER2/neu) Gene Detection Test and HER2 Protein Overexpression Test

The IHCP covers certain laboratory testing for HER2 protein overexpression and HER2/neu gene detection when medically necessary for members who have been diagnosed with a malignant neoplasm of the breast. Prior authorization is not required for HER2 testing. However, documentation of medical necessity is required. The ordering practitioner must have documentation in the member's medical records to support the medical necessity of the tests ordered.

BRCA1, BRCA2 and PALB2 Genetic Testing for Breast, Ovarian and Related Cancers

The IHCP covers BRCA1, BRCA2 and PALB2 (partner and localizer of BRCA2) testing when it is determined to be medically necessary based on personal history or family history, as described in this section. Prior authorization is required.

IHCP members referred to an oncologist or geneticist for BRCA1, BRCA2 or PALB2 testing must have a completed personal and family cancer history that should include three generations on both maternal and paternal sides of the family in the member's medical record to include the following:

- Relatives with breast, ovarian and other relevant cancers, such as prostate and colon cancer
- Age at diagnosis in affected family members
- Other significant factors, such as ethnic background

Providers must submit documentation with the PA request and must maintain the documentation in the member's medical record.

Definitions

For the purpose of the medical policy for this service, the following definitions apply:

- *Close blood relatives* are first, second and third-degree relatives as defined below:
 - First-degree relatives include parents, siblings and offspring
 - Second-degree relatives include half-brothers/-sisters, aunts/uncles, grandparents, grandchildren and nieces/nephews affected on the same side of the family
 - Third-degree relatives include first cousins, great-aunt/-uncles, great-grandchildren and great grandparents affected on the same side of the family
- A *breast cancer diagnosis* includes either invasive or noninvasive (ductal carcinoma in situ) types.
- *Ovarian cancer* also includes fallopian tube cancers and primary peritoneal carcinoma.
- Persons are not considered to have a *limited family history* unless they have fewer than two first-degree or second-degree female relatives or female relatives surviving beyond 45 years of age on either side of the family.
- *Two breast primary cancers* include cancers appearing at the same time (synchronous) and one is not a metastasis of the other, or primary cancers developing at intervals (metachronous). The tumors may be in one or two breasts.
- *Hereditary breast ovarian cancer (HBOC)-syndrome-associated malignancies* include prostate cancer, pancreatic cancer or melanoma. The presence of these malignancies does not necessarily justify BRCA testing. For example, a female with breast cancer over age 50 whose sister had melanoma at age 40 and whose father has prostate cancer would meet criteria. In another example a female with breast cancer over age 50 whose maternal aunt had pancreatic cancer and whose paternal uncle had prostate cancer would not meet criteria because the aunt and uncle are on different sides of the family.
- *Triple-negative breast cancer* refers to any breast cancer that does not express the genes for estrogen receptor (ER), progesterone receptor (PR) or HER2/neu. This subtype of breast cancer is clinically characterized as more aggressive and less responsive to standard treatment and is associated with poorer overall patient prognosis. It is diagnosed more frequently in younger women, women with BRCA1 mutations, and those belonging to African American and Hispanic ethnic groups.

Medical Necessity Based on Personal History

BRCA1, BRCA2 and PALB2 genetic testing are considered medically necessary for members **with a personal history** of at least one of the following:

- Breast cancer diagnosis at age 45 or younger
- Breast cancer diagnosis at age 50 or younger and one or more of the following:
 - Two breast primary cancers, with the first breast cancer diagnosis occurring at age 50 or younger
 - At least one close blood relative with breast cancer at age 50 or younger
 - At least one close blood relative with epithelial ovarian/fallopian tube/primary peritoneal cancer diagnosed at any age
 - A limited family history or adopted
- Triple-negative (ER–, PR– and HER2–) breast cancer diagnosis at age 60 or younger
- Breast cancer diagnosis at any age and one or more of the following:
 - Two breast primary cancers in a single individual with at least one close blood relative with breast cancer diagnosed at age 50 or younger
 - Two breast primary cancers in a single individual with at least one close blood relative with epithelial ovarian/fallopian tube/primary peritoneal cancer diagnosed at any age

- Two or more close blood relatives with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer diagnosed at any age
 - Two or more close blood relatives with pancreatic cancer diagnosed at any age
 - Two or more close blood relatives with prostate cancer (Gleason score of 7 or greater) diagnosed at any age
 - First-degree or second-degree relative with male breast cancer
 - A close relative with a known BRCA1, BRCA2 or PALB2 gene mutation
 - At least two close blood relatives on the same side of the family with other hereditary breast and ovarian cancer (HBOC)-syndrome-associated malignancies (prostate, pancreatic, melanoma)
 - Ethnicity associated with deleterious mutations, including Ashkenazi Jewish, Icelandic, Hungarian, Swedish and Dutch
- Pancreatic, prostate (Gleason score of 7 or greater), or epithelial ovarian/fallopian-tube/primary peritoneal cancer diagnosis and two or more close blood relatives with at least one of the following:
 - Breast cancer diagnosed at any age
 - Ovarian cancer diagnosed at any age
 - Pancreatic cancer diagnosed at any age
 - Prostate cancer (Gleason score of 7 or greater) diagnosed at any age
 - Male breast cancer diagnosis

Medical Necessity Based on Family History

BRCA1, BRCA2 and PALB2 genetic testing is considered medically necessary to assess the risk of female breast cancer for members **with a family history** of at least one of the following (no personal history required):

- Member has a relative with known BRCA1, BRCA2 or PALB2 mutation
- Member of Ashkenazi Jewish, Icelandic, Hungarian, Swedish or Dutch ancestry has one or more of the following:
 - One or more close blood relatives with male breast cancer
 - One or more first-degree relative with breast cancer or epithelial ovarian cancer
 - Two or more second-degree relative on same side of family with breast cancer
 - Two or more second-degree relative on same side of family with epithelial ovarian cancer
- Member not of Ashkenazi Jewish, Icelandic, Hungarian, Swedish or Dutch ancestry has one or more of the following:
 - First-degree or second-degree relative with breast cancer and one or more of the following:
 - Diagnosed at age 45 or younger
 - Diagnosed at age 50 or younger with unknown or limited family history
 - Diagnosed at age 50 or younger with one or more close blood relatives with breast cancer diagnosed at any age
 - Diagnosed at age 60 or younger with triple-negative breast cancer
 - First-degree or second-degree relative with two breast primary cancers with the first primary diagnosed at age 50 or younger
 - First-degree or second-degree relative with breast cancer diagnosed at any age, who in turn has one or more of the following:
 - One or more close blood relatives with breast cancer diagnosed at age 50 or younger
 - One or more close male blood relatives with breast cancer diagnosed at any age
 - One or more close blood relatives with epithelial ovarian cancer diagnosed at any age
 - Two or more close blood relatives with breast cancer diagnosed at any age

- Two or more close blood relative with pancreatic cancer diagnosed at any age
- Two or more close blood relative with prostate cancer (Gleason score of 7 or greater) diagnosed at any age
- First-degree or second-degree relative with male breast cancer diagnosed at any age
- First-degree or second-degree relative with breast cancer who is of ethnicity associated with deleterious mutations, including Ashkenazi Jewish, Icelandic, Hungarian, Swedish or Dutch
- First degree or second-degree relative with epithelial ovarian cancer diagnosed at any age
- First-degree or second-degree relative with pancreatic cancer diagnosed at any age who in turn has two or more close blood relative with one or more of the following:
 - Breast cancer diagnosed at any age
 - Ovarian cancer diagnosed at any age
 - Pancreatic cancer diagnosed at any age
 - Prostate cancer (Gleason score of 7 or greater) diagnosed at any age
- First-degree or second-degree relative with prostate cancer (Gleason score of 7 or greater) diagnosed at any age, who in turn has two or more close blood relatives with one or more of the following:
 - Breast cancer diagnosed at any age
 - Ovarian cancer diagnosed at any age
 - Pancreatic cancer diagnosed at any age
 - Prostate cancer (Gleason score of 7 or greater) diagnosed at any age
- Third-degree relative with breast or epithelial ovarian cancer, who in turn has one or more of the following:
 - One close blood relative with epithelial ovarian cancer and another close blood relative with breast cancer diagnosed at age 50 or younger
 - Two or more close blood relatives with breast cancer with at least one diagnosed at age 50 or younger
 - Two or more close blood relatives with epithelial ovarian cancer diagnosed at any age

*Note: The IHCP considers BRCA1, BRCA2 and PALB2 testing to assess the risk of **male** breast cancer or prostate cancer in members **without breast cancer** to be **not** medically necessary.*

Billing and Reimbursement

BRCA1, BRCA2 and PALB2 genetic testing is billed using the appropriate Current Procedural Terminology (CPT^{®1}) codes.

Consistent with IHCP billing guidelines, IHCP reimbursement for BRCA1, BRCA2 and PALB2 genetic testing is limited to once per member per lifetime.

To maintain consistency with other bundled laboratory codes, the IHCP considers BRCA1 and BRCA2 testing to be components of certain other, more comprehensive tests. The IHCP does not reimburse for certain additional tests if a claim for BRCA1 and BRCA2 testing has previously paid. For applicable codes, see the *Reimbursement Guidelines for BRCA1 and BRCA2 Genetic Testing Procedure Codes* table in *Genetic Testing Codes*, accessible from the [Code Sets](https://www.in.gov/medicaid/providers) webpage at [in.gov/medicaid/providers](https://www.in.gov/medicaid/providers). Claims for these additional genetic testing procedure codes will be denied with an explanation of benefits (EOB) 6276 – *Breast cancer analysis (BRCA1 & BRCA2) is not payable when a breast cancer analysis code has already been paid.*

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Gene Expression Profiling for the Management of Breast Cancer

Gene expression profiling is covered when it is considered medically necessary for managing the treatment of breast cancer. The IHCP covers two tests:

- **Oncotype DX Breast Recurrence Score** – The Oncotype DX Breast Recurrence Score is a 21-gene RT-PCR assay that should be ordered only after surgery and subsequent pathological examination of the tumor have been completed. Oncotype DX Breast Recurrence Score testing is billed using procedure code 81519 – *Test for detecting genes associated with breast cancer*.
- **EndoPredict Breast Cancer Assay** – The IHCP covers the EndoPredict Breast Cancer Assay for breast cancer recurrence. This gene assay looks specifically at patients who have been diagnosed with estrogen receptor positive and HER2 negative breast cancer. The test is used to determine the likelihood of distant recurrence and the probability of response to chemotherapy in patients. The EndoPredict Breast Cancer Assay is billed with procedure code 81522 – *Oncology (breast), mRNA gene expression analysis of 12 genes in breast tumor tissue*. This test is limited to once in a lifetime per member.

These tests should be ordered in the context of a provider-patient discussion regarding risk preferences when the test result will aid in making decisions regarding chemotherapy. Prior authorization is required.

Prior Authorization Requirements for Gene Expression Profiling

To obtain PA for these tests, *all* the following criteria must be met:

- Individual has had surgery, and a full pathological evaluation of the specimen has been completed.
- Histology is ductal, lobular, mixed or metaplastic.
- Histology is not tubular or colloid.
- Estrogen receptor is positive (ER+), or progesterone receptor is positive (PR+), or both.
- HER2 receptor is negative.
- Pathological regional lymph node stage is one of the following:
 - pN0 (node negative or isolated tumor cells [cluster less than or equal to 0.2 mm])
 - pN1mi (micrometastases greater than 0.2 mm but less than or equal to 2 mm)
 - pN1a (metastases in one to three axillary lymph nodes, and at least one is larger than 2 mm)
 - pN1b (metastases in the internal mammary sentinel lymph nodes, and at least one is larger than 2 mm)
 - pN1c (pN1a and pN1b combined)
- Individual has one of the following:
 - Tumor size 0.6–1.0 cm moderate/poorly differentiated
 - Tumor size 0.6–1.0 cm well-differentiated with any of the following unfavorable features: angiolymphatic invasion, high nuclear grade or high histologic grade
 - Tumor size greater than 1.0 cm and less than or equal to 4.0 cm
- Individual does not have a pT4 lesion.
- Chemotherapy is a therapeutic option being considered and will be supervised by the practitioner ordering the gene expression profile.

Gene expression profiling with the EndoPredict Breast Cancer Assay or Oncotype DX Breast Recurrence Score as a technique of managing the treatment of breast cancer is considered not medically necessary when the criteria listed have not been met.

Noncovered Services

Gene expression profiling as a technique of managing the treatment of breast cancer is considered **investigational and not medically necessary** when a gene profiling test *other than* the EndoPredict Breast Cancer Assay or Oncotype DX Breast Recurrence Score is being used.

Gene expression profiling as a technique of managing the treatment of ductal carcinoma in situ (DCIS) is considered **investigational and not medically necessary** under all circumstances.

Repeat gene expression profiling with the Oncotype DX Breast Recurrence Score for the same tumor, such as a metastatic focus, or from more than one site when the primary tumor is multifocal, is considered **investigational and not medically necessary**. The IHCP does not cover more than one EndoPredict Breast Cancer Assay per member per lifetime.

Genetic Testing for Managing the Treatment of Chronic Myelogenous Leukemia

The IHCP covers genetic testing for managing the treatment of chronic myelogenous leukemia (CML). To determine whether a specific code is covered, see the Outpatient Fee Schedule or Professional Fee Schedule, accessible from the [IHCP Fee Schedules](http://in.gov/medicaid/providers) webpage at in.gov/medicaid/providers.

Prior authorization for these laboratory pathology tests is granted only when the test is medically necessary for managing the treatment of CML, and the test is being used by the patient's practitioners to develop a treatment plan specific to the needs of the patient.

Molecular Pathology Procedures

The IHCP covers the molecular pathology procedure codes in Table 1 for laboratory services when medically necessary for the conditions indicated.

Table 1 – Coverage Parameters for Molecular Pathology Laboratory Procedure Codes

Coverage Parameters	Procedure Code	Description
Covered when medically necessary for managing the treatment of metastatic colon cancer	81403	Molecular pathology procedure level 4
	81404	Molecular pathology procedure level 5
Covered when medically necessary for detecting the presence of hemophilia in pregnant women	81403	Molecular pathology procedure level 4
	81405	Molecular pathology procedure level 6
	81407	Molecular pathology procedure level 8
	81479	Unlisted molecular pathology procedure
	G0452*	Molecular pathology procedure; physician interpretation and report
* Note: G0452 is not reimbursable in the outpatient facility setting.		

All general PA criteria must be met for any lab pathology code to be covered. See the [Prior Authorization for Genetic Testing](#) section.

Plasma-Based Genomic Testing for Individuals With Advanced Solid Cancers

Effective July 24, 2023, the IHCP covers the following plasma-based genomic tests, billed with the procedure codes indicated, for individuals with advanced solid cancers:

- **Guardant360 CDx**, billed with CPT code 0242U – *Gene analysis of 55-74 genes associated with solid organ cancer in cell-free circulating DNA, targeted genomic sequence analysis panel*
- **Guardant360 LDT**, billed with CPT code 0326U – *Targeted genomic sequence analysis of 83 or more genes in cell free circulating DNA for detection of abnormalities associated with solid organ cancers)*

Prior authorization is required.

Prenatal Genetic Testing and Screening

The IHCP covers certain prenatal genetic testing and screening services, including those described in the following sections, without prior authorization when performed by IHCP-enrolled providers located in-state (or that have been designated as in-state for PA purposes, as described in the [Out-of-State Providers](#) module).

Screenings for Aneuploidy

The following cell-free DNA prenatal screenings for aneuploidy (noninvasive prenatal testing [NIPT] and noninvasive prenatal screening [NIPS]) are covered for all pregnant members:

- 81420 – *Test for detecting genes associated with fetal disease, aneuploidy genomic sequence analysis panel*
- 81507 – *DNA analysis using maternal plasma*

Only one fetal chromosomal aneuploidy screening will be permitted per pregnancy per member.

Screenings for Cystic Fibrosis Screenings

The IHCP covers the following carrier screening for cystic fibrosis, subject to a limit of one screening per lifetime per member:

- 81220 – *Gene analysis (cystic fibrosis transmembrane conductance regular) common variants*

Screenings for Spinal Muscular Atrophy and Hemoglobinopathies

The IHCP covers the following routine carrier screenings for spinal muscular atrophy (SMA) and hemoglobinopathies. Each procedure code is subject to a limitation of one unit per lifetime per member:

- 81329 – *Gene analysis (survival of motor neuron 1, telomeric) for dosage/deletion*
- 81361 – *Gene analysis (hemoglobin, subunit beta) for common variant*

These screenings are available without prior authorization to all IHCP members of reproductive age who have the capacity for pregnancy. The screenings may also be available to an affiliated sperm-producing IHCP member, if the member who can become pregnant tests positive for a given carrier screen.

Genetic Counseling

Although licensed physicians and nurses are not required to be licensed as a genetic counselor to provide genetic counseling within their scope of practice, *IC 25-17.3-4-4* stipulates that providers cannot use the title “genetic counselor” unless licensed as such.

Professionally licensed genetic counselors can enroll in the IHCP as provider type 36 – *Genetic Counselor*, as described in the [Provider Enrollment](#) module. Genetic counselors are limited to providing only genetic counseling services and to billing only the following procedure codes:

- 96041 – *Counseling for genetic testing provided by a genetic counselor, each 30 minutes of total time on the date of encounter*
- S9981 SE – *Medical records copying fee, administrative*

Note: Procedure code 96041 is allowable as a telehealth service, when provided and billed as indicated in the [Telehealth and Virtual Services](#) module.

For dates of service prior to Jan. 1, 2025, this service was billed using procedure code 96040 – Medical genetic patient or family counseling services each 30 minutes was used.

This restriction applies to all billing, group and rendering providers enrolled under the genetic counselor provider type.

Other provider types enrolled with the IHCP that have genetic counseling within their scope of practice should bill for these services following standard billing guidance.