Coverage of any medical intervention discussed in a WellFirst Health medical policy is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

Genetic Testing

Covered Service: Yes

Prior Authorization Required: Prior authorization is required for any genetic test not listed in this medical policy or in the medical policies referenced in 3.0.

Additional Information: Genetic counseling provided by in-plan genetic counselors is a covered benefit and prior authorization is not required. A Medical Geneticist consultation requires prior authorization.

WellFirst Health Medical Policy:

General Information and Medical Necessity Guidelines for Genetic Testing:

1.0 Genetic testing is covered for a WellFirst Health member if the test results provide a direct medical benefit or guides reproductive decision-making for the WellFirst Health member.

2.0 The member must meet ALL of the following criteria:

2.1 The member displays clinical features, or is at direct risk of inheriting the mutation in question (pre-symptomatic); AND

2.2 The result of the test will directly impact the treatment being delivered to the member; AND

2.3 After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies a definitive diagnosis remains uncertain or identification of a genetic mutation will guide reproductive decision making.

3.0 Please reference the following links for specific criteria for testing, genetic counseling, and prior authorization requirements:

3.1 Genetic Testing for Hereditary Cardiac Disease and Arrhythmias MP9472
3.2 Genetic Testing for Thrombophilia MP9473
3.3 Genetic Testing for Reproductive Carrier Screening and Prenatal Care MP9477
3.4 Genetic Testing for Breast and/or Epithelial Ovarian Cancer Susceptibility MP9478
3.5 Genetic Testing for Pharmacogenetics MP9479
3.6 Genetic Testing for Polyposis MP9482
3.7 Genetic Testing for Multiple Endocrine Neoplasia, Type 1 and 2 (MMEN1, RET) MP9483
Coverage of any medical intervention discussed in a WellFirst Health medical policy is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

3.8 Genetic Testing for Diffuse Gastric Cancer CDH1 Gene MP9484
3.9 Genetic Testing for Somatic Tumor Markers MP9486
3.10 Genetic Testing for Lynch Syndrome MP9487
3.11 Genetic Testing for Cowden Syndrome – PTEN Gene MP9488
3.12 Genetic Testing for Chromosomal Microarray Analysis (CMA) MP9491
3.13 Genetic Testing for Neurologic Disorders MP9497
3.14 Genetic Testing for Marfan Syndrome MP9506
3.15 Genetic Testing for Ehlers-Danlos Syndrome MP9505
3.16 Genetic Testing for Cancer Susceptibility MP9521
3.17 Maturity Onset Diabetes of the Young (MODY) Sequencing Panel MP9507
3.18 Genetic Testing for Stickler Syndrome MP9504
3.19 Genetic Testing for Hereditary Hemorrhagic Telangiectasia (HHT) MP9524
3.20 Genetic Testing for Familial Hypercholesterolemia MP9525
3.21 Genetic Testing for Birt-Hogg-Dubé Syndrome MP9527
3.22 Genetic Testing for Focal Segmental Glomerular Sclerosis MP9543

4.0 The following tests do NOT require prior authorization.

4.1 Alpha-1 antitrypsin deficiency (SERPINA1);
4.2 Fragile X syndrome (FMR1);
4.3 Hereditary hemochromatosis (HFE gene mutations) – HFE gene testing is covered when ordered by a Hematologist or Hepatologist.
4.4 Inflammatory Bowel Disease – TPMT Gene is covered when ordered by Gastroenterology and Rheumatology clinicians only.

5.0 Multigene hereditary cancer panels that may or may not accompany BRCA testing are considered experimental and investigational, and therefore not medically necessary.

6.0 Multigene panels used to predict risk for the development of many hereditary cancers are considered not medically necessary. See MP9521 Genetic Testing for Hereditary Cancer Susceptibility for more information.

7.0 All proposed tests must be FDA-approved and/or performed in a CLIA-accredited laboratory and clinical utility must be established.

8.0 Direct to consumer (DTC) genetic testing is not covered.

9.0 Genetic testing for heritable disorders of a WellFirst Health member’s non-WellFirst Health relative requires prior authorization through the Health Services Division and is considered medically necessary when ALL of the following conditions are met:
Coverage of any medical intervention discussed in a WellFirst Health medical policy is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

9.1 The information is needed to adequately assess risk in the WellFirst Health member; **AND**

9.2 The information will be used in the immediate care plan of the WellFirst Health member; **AND**

9.3 The non-plan relative’s benefit plan will not cover the test (a copy of the denial letter from the non-plan relative’s benefit plan must be provided); **AND**

9.4 Testing of the non-plan relative has been recommended by a genetics counselor and approved by a WellFirst Health Medical Director.

10.0 Genetic testing for variants of unknown significance (VUS) (also known as unclassified variant) is not medically necessary for an at-risk (unaffected) individual or affected individual when a family member has been tested for mutations.

11.0 Genetic Testing is medically necessary when the individual meets specific testing criteria outlined in the National Comprehensive Cancer Network (NCCN) guidelines with a category 1, 2A, or 2B level of evidence.

12.0 The following tests are considered experimental and investigational and therefore not medically necessary

12.1 Genome Wide Association Studies all indications;

12.2 Macular Degeneration Risk Genetic Testing (e.g. Vita Risk, Macular Risk PGx) Genetic testing to determine risk of macular degeneration;

12.3 Pancreatic Cancer Genetic Testing Panels all indications;

12.4 Comprehensive, pan-cancer multigene next generation sequencing of tumor tissue or cell-free tumor DNA (e.g. FoundationOne);

12.5 Susceptibility testing for multifactorial conditions using single gene testing or a multigene panel for example: wellness, diet-matching, fitness, cardiovascular health and general cancer risk.

12.6 Whole Genome Sequencing

12.7 Multigene panel testing for retinal disorders

12.8 AR (androgen receptor) gene analysis; full gene sequence and known familial variant

12.9 Growth stimulation expressed gene ST2 Assay
Coverage of any medical intervention discussed in a WellFirst Health medical policy is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

CPT/HCPCS Codes Related to MP9012

*The list of codes (and their descriptors, if any) is provided for informational purposes only and may not be all inclusive or current. Listing of a code in this medical policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member’s policy of health coverage with WellFirst Health. Inclusion of a code above does not imply any right to reimbursement or guarantee of claim payment. Other medical policies may also apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81173</td>
<td>AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence</td>
</tr>
<tr>
<td>81174</td>
<td>AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant</td>
</tr>
<tr>
<td>81243</td>
<td>FMR1 (fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles</td>
</tr>
<tr>
<td>81244</td>
<td>FMR1 (fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; characterization of alleles (e.g., expanded size and methylation status)</td>
</tr>
<tr>
<td>81256</td>
<td>HFE (hemochromatosis) (e.g., hereditary hemochromatosis) gene analysis, common variants (e.g., C282Y, H63D)</td>
</tr>
<tr>
<td>81332</td>
<td>SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (e.g., alpha-1-antitrypsin deficiency), gene analysis, common variants (e.g., *S and *Z)</td>
</tr>
<tr>
<td>81401</td>
<td>Molecular Pathology Procedure Level 2</td>
</tr>
<tr>
<td>81407</td>
<td>Molecular Pathology Procedure Level 8</td>
</tr>
<tr>
<td>81415</td>
<td>Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis</td>
</tr>
<tr>
<td>81416</td>
<td>Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (e.g., parents, siblings) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>81417</td>
<td>Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (e.g, updated knowledge or unrelated condition/syndrome)</td>
</tr>
<tr>
<td>81425</td>
<td>Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis</td>
</tr>
</tbody>
</table>
Coverage of any medical intervention discussed in a WellFirst Health medical policy is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81426</td>
<td>Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>81427</td>
<td>Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome)</td>
</tr>
<tr>
<td>81432</td>
<td>Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53</td>
</tr>
<tr>
<td>81433</td>
<td>Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11</td>
</tr>
<tr>
<td>81445</td>
<td>Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
<tr>
<td>82103</td>
<td>Alpha-1-antitrypsin; total</td>
</tr>
<tr>
<td>82104</td>
<td>Alpha-1-antitrypsin; phenotype</td>
</tr>
<tr>
<td>S3800</td>
<td>Genetic testing for amyotrophic lateral sclerosis (ALS)</td>
</tr>
<tr>
<td>83006</td>
<td>Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)</td>
</tr>
</tbody>
</table>

**Committee/Source**

**Document Created:** Medical Policy Committee/Health Services Division  
**Date(s):** June 19, 2019

**Revised:** Medical Policy Committee/Health Services Division  
**Date(s):** July 17, 2019  
**Reviewed:** Medical Policy Committee/Health Services Division  
**Date(s):** November 20, 2019  
**Published/Effective:** 01/01/2020