Medical Policy

Genetic Testing for Hereditary Thrombophilia

Policy Number: OCA 3.728
Version Number: 5
Version Effective Date: 11/01/16

Product Applicability

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<td>☒ New Hampshire Medicaid</td>
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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers genetic testing for hereditary thrombophilia to be medically necessary to identify predisposition to thrombosis when Plan criteria are met. **Plan prior authorization is required for molecular and chromosomal genetic testing.**

The Plan supports the National Comprehensive Cancer Network (NCCN) guidelines for genetic counseling for all genetic tests conducted with Plan members; NCCN recommends that adequate pre-test and post-test genetic counseling be provided by a health care professional with expertise in genetics. Genetic counseling provided to a Plan member (and/or guardian if the member is under the age of 18) should be documented in the member’s medical record and conducted by an appropriately
trained practitioner with expertise and experience in genetics, including a provider acting within the scope of his/her license and practice, clinical geneticist, or genetic counselor.

It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested use. See the Plan’s policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. See the following Plan policies available at www.bmchp.org for BMC HealthNet Plan members (or at www.SeniorsGetMore.org for Senior Care Options members) and www.wellsense.org for Well Sense Health Plan members for additional prior authorization guidelines for genetic testing:

1. *Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies*, policy number OCA 3573

2. *Gene Expression Profiling of Tumor Tissue to Predict Cancer Recurrence and Risk Stratification (Including Oncotype DX™ and Other Tests)*, policy number OCA 3.572

3. *Genetic Testing for Familial Malignant Melanoma*, policy number OCA 3.78


5. *Genetic Testing Guidelines and Pharmacogenetics*, policy number OCA 3.727


7. *Genetic Testing for Hereditary Colorectal Cancer*, policy number OCA 3.64

8. *Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Pregenetic Screening)*, policy number OCA 3.726

**Description of Item or Service**

**Molecular Genetic Testing for Hereditary Thrombophilia:** Molecular genetic tests that identify genetic variant defects associated with a predisposition to thrombosis. A genetic susceptibility to thrombosis in combination with other risk factors increases the individual’s risk of venous thromboembolism (VTE). Genetic testing for gene variants associated with thrombophilias include testing of factor V Leiden, prothrombin gene G20210A, and the methylenetetrahydrofolate reductase (MTHFR) C677T gene. See the Medical Policy Statement section and the Limitations section of this policy for Plan criteria and prior authorization guidelines for these tests. (Guidelines for factor V Leiden and prothrombin gene G20210A testing to determine predisposition to thrombosis are outlined in the Medical Policy Statement section. Criteria for methylenetetrahydrofolate reductase (MTHFR) C677T genetic testing to diagnose hereditary thrombophilia are specified in the Limitations section of this Plan policy.)

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*
**Genetic Testing for Hereditary Thrombophilia**

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**Thrombophilia Panel:** In addition to the molecular genetic tests specified above, a thrombophilia panel may include the following biochemical genetic tests, coagulation tests, and antibody screening tests (that do NOT require Plan prior authorization).

1. Protein C activity level
2. Protein S activity level
3. Antithrombin III activity (recommended for recurrent VTE)
4. Antiphospholipid antibody screening (including Lupus anticoagulant, anticardiolipin antibodies, and beta 2 glycoprotein antibodies) to rule out acquired thrombophilia

In selected high risk obstetric or VTE patients or those with a striking family history of thrombosis, additional testing under the direction of a hematologist, perinatologist or clinical geneticist may be indicated.

**Medical Policy Statement**

Genetic testing for inherited thrombophilia is considered medically necessary when ALL of the following applicable Plan criteria are met and documented in the member’s medical record, as specified below in items 1 through 3:

1. The result of the testing will directly impact the treatment being delivered to the member; AND
2. Member has at least ONE (1) of the following medical conditions, as specified below in item a or item b:
   a. Member has at least ONE (1) of the following **obstetric complications**, as listed below in items (1) through (5):
      (1) Recurrent pregnancy loss (i.e., 2 or more lost pregnancies); OR
      (2) Early onset preeclampsia; OR
      (3) Placental abruption; OR
      (4) Severe intrauterine growth restriction (IUGR); OR
      (5) Placental abnormality related to vascular underperfusion; OR
b. Member has a **personal history** of single or multiple venous thromboembolism (VTE) of **unknown etiology** and at least ONE (1) of the following criteria is met, as specified below as item (1) or item (2):

1. **Member has had a VTE of unknown etiology before age 50** (with or without a family history of known thrombophilia or thrombosis, i.e., VTE or pulmonary embolism); OR

2. **Member has had a VTE of unknown etiology (at any age)** and meets at least ONE (1) of the following criteria, as specified below in item (a) or item (b):

   a. **Member has at least ONE (1) first-degree relative with a documented genetic thrombophilia diagnosis**; OR

   b. **Member has at least ONE (1) first-degree relative with a history of thrombosis (VTE or pulmonary embolism) of presumed unknown etiology before age 50**;

3. **ONE (1) or more of the following molecular genetic tests will be conducted** as part of a thrombophilia panel (and does require Plan prior authorization):

   a. **Factor V Leiden (FVL) gene variant DNA analysis** (p.Arg506Gln); AND/OR

   b. **Prothrombin gene G20210A DNA analysis**

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**Limitations**

1. Genetic testing for hereditary thrombophilia is considered experimental and investigational when Plan criteria are not met, (with criteria specified in the Medical Policy Statement section of this policy), including but not limited to ANY of the following conditions/indications, as specified below in items a through f:

   a. **Testing of a member when the indication is related to oral contraceptive use** (when Plan criteria are not met); OR

   b. **Testing for a member with his/her first venous thromboembolism (VTE) less than age 50 years of age with a known etiology unrelated to thrombophilia**;‡ OR

   ‡ **Note:** Examples of a VTE etiology unrelated to hereditary thrombophilia may include trauma or cancer only when the condition is the known cause of the member’s thrombophilia or thrombosis.
Genetic Testing for Hereditary Thrombophilia

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1. Genetic testing for hereditary thrombophilia is considered experimental and investigational.

2. Genetic testing of methylenetetrahydrofolate reductase (MTHFR) to diagnose hereditary thrombophilia is considered experimental and investigational.

3. Factor V HR2 haplotype (F5 HR2) variant testing is considered experimental and investigational to determine thrombophilia, including reflex testing of F5 HR2 following identification of a member with the F5 p.Arg506Gln (FVL) variant.

4. Genetic testing that is marketed directly to consumers (direct-to-consumer or DTC) that are ordered by a member without the order of a treating health care provider is not covered.

5. Genetic testing for hereditary thrombophilia requires Plan Medical Director review when a member has had recurrent VTEs or had a VTE in unusual sites, the treating provider recommends testing, and Plan criteria are not met.

6. Factor 5 Leiden testing is considered not medically necessary for ANY of the following indications, as specified below in items a through d:
   a. Routine testing during pregnancy; OR
   b. Prenatal and newborn screening; OR
   c. Testing of individuals with arterial thrombosis; OR
   d. Testing of neonates and children with catheter-related thrombosis.

‡ Note: Examples of a VTE etiology unrelated to hereditary thrombophilia may include trauma or cancer only when the condition is the known cause of the member’s thrombophilia or thrombosis.

f. General population screening.
7. Multigene Panel Testing:

The use of a multigene testing panel is generally considered to be NOT medically necessary as an alternative to or in addition to factor V Leiden and prothrombin gene G20210A testing due to insufficient data on clinical validity and clinical utility of multigene testing. If the treating provider is recommending multigene panel testing rather than or in addition to the condition-targeted testing specified in the Medical Policy Statement section, Plan Medical Director review is required. ALL of the following written documentation must be submitted to the Plan with the prior authorization request to determine the medical necessity of multigene panel testing, as specified below in items a through c:

a. A recommendation for multigene panel testing for the member by an independent Board-Certified or Board-Eligible Medical Geneticist, an American Board of Medical Genetics or American Board of Genetic Counseling-certified Genetic Counselor not employed by a commercial genetic testing laboratory, or a genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APGN) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory; this provider has a documented evaluation of the member which includes a completed 3-generation pedigree and intends to engage in post-test follow-up counseling; AND

b. Member meets criteria for genetic testing outlined in the Medical Policy Statement section of this policy; AND

c. All genes included in the multigene panel are relevant to the personal history, family history, or treatment plan for the member being tested and there are professional society management guidelines or National Comprehensive Cancer Network (NCCN) guidelines (with applicable references provided) documenting the clinical utility of testing for the members who test positive for any and all genes in the panel.

If ALL of the above criteria are not met (as specified in items a through c), the Plan considers the multigene panel testing to NOT be medically necessary; disease-targeted genetic testing is considered medically necessary as an alternative when Plan criteria are met in the Medical Policy Statement and Limitations sections specified in this policy. See the limitations section of Genetic Testing Guidelines and Pharmacogenetics policy, policy number OCA 3.727, for guidelines related to multigene panel testing to determine response to drug metabolism and adjuvant therapy.

See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. Review Plan policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. Review Plan policy, Genetic Testing Guidelines and Pharmacogenetics, policy
number OCA 3.727, for Plan guidelines for genetic testing indications that may not be included in this Plan policy, including whole exome sequencing and whole genome sequencing.

Definitions

**Antiphospholipid Antibody Screening:** Testing for antiphospholipid antibody syndrome, a condition in which the plasma levels of antibodies (including lupus anticoagulant, cardiolipin antibodies, or other antibodies against phospholipids) are elevated, adversely affecting coagulation processes in the bloodstream. Antiphospholipid antibody syndrome is a cause of acquired thrombophilia.

**Antiprothrombin III Deficiency:** Antiprothrombin III is a nonvitamin K-dependent protease that inhibits coagulation by lysing thrombin and factor Xa. Congenital antithrombin III deficiency is an autosomal dominant disorder in which an individual inherits at least one copy of a defective gene, leading to increased risk of venous and arterial thrombosis.

**Factor V Leiden (FVL) Gene Mutation (p.Arg506Gln):** Factor V Leiden results from a point mutation that causes an amino acid change at position 506 in factor V and is a common genetic defect related to hereditary (inherited) thrombophilia.

**First-Degree Relative:** A blood relative of an individual who shares approximately 50% of their genes defined as a parent, full sibling, and children.

**Genetic Testing:** According to U.S. Library of Medicine, genetic testing is defined as a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person’s chance of developing or passing on a genetic disorder. More than 1,000 genetic tests are currently in use, and more are being developed. Several methods can be used for genetic testing:

1. Molecular genetic tests (or gene tests) study single genes or short lengths of DNA to identify variations or mutations that lead to a genetic disorder.

2. Chromosomal genetic tests analyze whole chromosomes or long lengths of DNA to see if there are large genetic changes, such as an extra copy of a chromosome, that cause a genetic condition.

3. Biochemical genetic tests study the amount or activity level of proteins; abnormalities in either can indicate changes to the DNA that result in a genetic disorder.

**Methylenetetrahydrofolate reductase (MTHFR) C677T Gene Mutation:** Mutation in the MTHFR gene which provides instruction for an enzyme that processes amino acids. Individuals with C677T mutations may have an increased risk of developing blood clots.
**Multigene Panel Tests:** Tests that evaluate more than one (1) gene or gene variant simultaneously to detect changes in gene expression most commonly associated with certain diseases and other genes that may have limited evidence of an association to the disorder. Multigene panel tests may involve traditional exon-by-exon sequencing of targeted genes to identify genetic variants or use next-generation sequencing. Each laboratory establishes its own set of criteria for selecting the genes represented in a panel, even when panels are used for the same or similar clinical indications. The lack of regulatory oversight of genetic testing means that laboratories can change the components of a panel at any time, making it difficult to evaluate the clinical utility of multigene panel tests.

**Next-Generation Sequencing (NGS or Massively Parallel Sequencing):** Genetic testing that involves sequencing of millions of DNA fragments using the following three (3) levels of molecular analysis: (1) Disease-targeted gene panels to sequence genes with an established role in the targeted disease, (2) exome sequencing of coding regions of the genome to include less common variants associated with the disease (i.e., a coding region is the segment of a gene that contains a protein-coding sequence called an exon in all 22,000 genes of the human genome); and (3) genome sequencing of both the coding and non-coding regions of the genome (i.e., the non-coding regions in between exons are called introns). Multiple sequencing platforms and different processes result in variability in test results among laboratories.

**Protein C Deficiency:** Protein C is a vitamin K-dependent protein synthesized in the liver. The gene for protein C is located on chromosome 2 (2q13-14) and appears to be closely related to the gene for factor IX. A deficiency in protein C is related to inherited thrombophilia.

**Protein S Deficiency:** Protein S is a vitamin K-dependent glycoprotein, is a cofactor of the protein C system. In the presence of protein S, activated protein C directly inhibits prothrombin activation via interactions with other coagulation factors. Two homologous genes for protein S (gene PROS1 and PROS2) map to chromosome 3. A deficiency in protein S is related to inherited thrombophilia.

**Prothrombin Gene G20210A Mutation:** A mutation in the human prothrombin gene and is a common genetic defect related to hereditary (inherited) thrombophilia. Prothrombin (factor II) is a vitamin K-dependent protein which is the precursor of thrombin, the end-product of the coagulation cascade.

**Thrombophilia:** Hereditary conditions that are risk factors for venous thrombosis.

**Whole Exome Sequencing (WES)/ Whole Genome Sequencing (WGS):** Sequencing the protein coding regions (called exons) of all of an individual’s genes (known as the exome). While exons represent only 1% of the genome, they account for approximately 85% of disease-causing variants. Through identification of variants across the exome, WES avoids the need to run multiple single-gene tests, which require prior information about variants affecting the disease. WES has been performed in a number of cancers, whereby comparison between tumor DNA and normal DNA from the same individual allows identification of variants specific to the tumor, which may provide information used for diagnosis and treatment. WES is targeted sequencing of the subset of the human genome that contains functionally important sequences of protein-coding DNA, while whole genome sequencing.
(WGS) uses next-generation sequencing techniques to sequence both coding and non-coding regions of the genome.

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

Refer to the Medical Policies page of the Provider folder at [www.bmchp.org](http://www.bmchp.org) (for BMC HealthNet Plan members, including Senior Care Options members) or [www.wellsense.org](http://www.wellsense.org) (for Well Sense Health Plan members) for information about additional, condition-specific genetic testing and gene expression profiling policies. Plan prior authorization is required for all genetic testing, even when the applicable code for the genetic test is not listed in a Plan policy.

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<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tr>
<td>81240</td>
<td>F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 20210G&gt;A variant</td>
</tr>
<tr>
<td>81241</td>
<td>F5 (coagulation factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant</td>
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Genetic Testing for Hereditary Thrombophilia

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## CPT Codes
### Description: Codes Considered Not Medically Necessary for Thrombophilia Testing

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<tr>
<th>CPT Code</th>
<th>Description: Codes Considered Not Medically Necessary for Thrombophilia Testing</th>
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</thead>
<tbody>
<tr>
<td>81291</td>
<td>MTHFR (5,10-methylene tetrahydrofolate reductase) (e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)</td>
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<tr>
<td></td>
<td>Plan note: MTHFR gene analysis is considered experimental and investigational to determine thrombophilia. See Plan policy, Genetic Testing Guidelines and Pharmacogenetics, policy number OCA 3.727, for prior authorization guidelines for MTHFR genetic testing for other indications.</td>
</tr>
<tr>
<td>81400</td>
<td>Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)</td>
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<tr>
<td></td>
<td>F5 (coagulation factor V) (e.g., hereditary hypercoagulability), HR2 variant</td>
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<td></td>
<td>Plan note: This CPT code includes numerous types of tests, including F5 HR2 variant analysis. Factor V HR2 haplotype (F5 HR2) variant testing is considered experimental and investigational to determine thrombophilia, including reflex testing of F5 HR2 following identification of member with the F5 p.Arg506Gln (FVL) variant. See Plan policy, Genetic Testing Guidelines and Pharmacogenetics, policy number OCA 3.727, for prior authorization guidelines for additional tests included in this CPT code.</td>
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### Clinical Background Information
Hypercoagulability, or thrombophilia, leads to the inappropriate formation of blood clots, and most commonly manifests as venous thromboembolism (VTE), such as deep vein thrombosis (DVT) in the legs, pulmonary embolism (PE), or in women (including individuals born with female reproductive organs and/or with typical female karyotype with two [2] X chromosomes), as adverse pregnancy outcomes. VTE affects approximately 300,000 to 600,000 individuals each year in the United States; the annual incidence of first-time VTE is approximately 1 per 1000 individuals. Typical precipitating factors for VTE include major trauma, recent surgery immobilization, medical illness, or aging. Among women (including individuals born with female reproductive organs and/or with typical female karyotype with two [2] X chromosomes), risk is increased during pregnancy and use of oral contraceptives or hormone replacement therapy (HRT). Once diagnosed, treatment options include initial short-term anticoagulation that may be extended (e.g., lifetime therapy) based on risk of recurrence balanced with risk of major hemorrhage. Heritable genetic factors also contribute to the risk of VTE.

Inherited thrombophilias include the following abnormalities: Activated protein C resistance (factor V Leiden mutations), hyper-homocysteinemia (MTHFR mutations), protein C deficiency, protein S deficiency, prothrombin deficiency, and prothrombin gene mutation. The most common type of inherited thrombophilia is a factor V Leiden (FVL) mutation (F5 gene variant p.Arg506Gln), which
accounts for up to 50% of the inherited thrombophilia syndromes; deficiencies in protein S, protein C, and antithrombin account for most of the remaining cases.

A key part of the clotting mechanism in the factor V protein is the activation of prothrombin to thrombin, which is required for the conversion of soluble fibrinogen to insoluble fibrin. A common sequence variant of the prothrombin gene, G20210A (c.*96G>A), is associated with elevated plasma prothrombin levels, which is also a risk factor for VTE. The discovery of FVL and prothrombin G20210A as primary causes of familial thrombosis has remarkably influenced genetic testing among patients with VTE or recurrent obstetric complications.

Genetic predisposition to hyperhomocysteinemia, which is associated with vascular disease and VTE, may be caused by the C677T (c.677C>T) sequence variant of the methylenetetrahydrofolate reductase (MTHFR) gene located on chromosome 1 at band p36. There is insufficient published scientific evidence to support the clinical utility of MTHFR genetic testing to diagnose thrombophilia.

A group of gene variants linked to factor V Leiden, collectively known as the HR2 haplotype (Factor V HR2), has been studied for its possible association with thrombophilia, alone and in conjunction with p.Arg506Gln (FVL) gene variant. There is insufficient scientific evidence at this time to support factor V (F5) HR2 haplotype testing to identify hypercoagulability.

Genetic susceptibility may help explain VTE in general; however, it is important to note that many individuals who carry a genetic variant associated with thrombosis may never develop thrombotic event(s) even in the presence of an obvious precipitating factor. At the current time, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of genetic testing for thrombophilia to treat individuals taking oral contraceptives, asymptomatic individuals, or individuals with first VTE with no family history remain unproven. Additional studies are needed to establish the clinical benefits on health outcomes for these indications.

The Food and Drug Administration (FDA) only regulates genetic tests sold as kits and has practiced enforcement discretion for laboratory-developed tests (LDTs), which represent the majority of genetic tests marketed in the United States. While the Centers of Medicare & Medicaid Services (CMS) does regulation the clinical laboratories in which LDTs are performed, CMS does not evaluate whether the genetic tests are clinically meaningful.

References

Genetic Testing for Hereditary Thrombophilia

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### Original Approval Date
- Regulatory Approval: N/A

### Original Effective Date* and Version Number
- 03/01/14 Version 1

### Policy Owner
- Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)

### Approved by
- MPCTAC and QIC

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*Effective Date for the Senior Care Options Product(s): 01/01/16

### Policy Revisions History

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<tr>
<td>11/01/14</td>
<td>Review for effective date 03/01/15. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Summary, Definitions, and References sections. Changed review calendar.</td>
<td>03/01/15 Version 2</td>
<td>11/19/14: MPCTAC 12/10/14: QIC</td>
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<td>11/01/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Updated Summary and language in the Applicable Coding section without changing criteria or the applicable code list.</td>
<td>01/01/16 Version 3</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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<td>01/01/16</td>
<td>Review for effective date 05/01/16. Updated Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised criteria in the Limitations section.</td>
<td>05/01/16 Version 4</td>
<td>01/20/16: MPCTAC 02/10/16: QIC</td>
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<td>09/28/16</td>
<td>Review for effective date 11/01/16. Administrative changes to clarify language related to gender.</td>
<td>11/01/16 Version 5</td>
<td>09/30/16: MPCTAC (electronic vote) 10/12/16: QIC</td>
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### Last Review Date

09/28/16

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Next Review Date
01/01/17

Authorizing Entity
QIC

Other Applicable Policies

Medical Policy - Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies, policy number OCA 3573
Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy - Gene Expression Profiling of Tumor Tissue to Predict Cancer Recurrence and Risk Stratification (Including Oncotype DX™ and Other Tests), policy number OCA 3.572
Medical Policy - Genetic Testing for Familial Malignant Melanoma, policy number OCA 3.78
Medical Policy - Genetic Testing for Fragile X-Associated Disorders, policy number OCA 3.571
Medical Policy - Genetic Testing Guidelines and Pharmacogenetics, policy number OCA 3.727
Medical Policy - Genetic Testing for Hereditary Breast and Ovarian Cancer, policy number OCA 3.57
Medical Policy - Genetic Testing for Hereditary Colorectal Cancer, policy number OCA 3.64
Medical Policy - Medically Necessary, policy number OCA 3.14
Medical Policy - Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Pregenetic Screening), policy number OCA 3.726

Reference to Applicable Laws and Regulations

Massachusetts General Law. Chapter 111. Section 70G. (M.G.L. c. 111 sec. 70G.) Genetic information and reports protected as private information; prior written consent for genetic testing. Accessed at: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section70G

Disclaimer Information:

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

Genetic Testing for Hereditary Thrombophilia

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The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.