MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: PA.097.MH
Last Review Date: 06/07/2021
Effective Date: 09/01/2021

PA.097.MH – Molecular Genetic Testing

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **molecular/genetic tests** medically necessary for the following indications:

1. The member demonstrates signs/symptoms of a genetically-linked disease, or the member/member's fetus has a direct and documented risk factor for development of a genetically-linked disease, or the member has a malignancy or physical condition for which an established treatment is associated with a specific mutation.
2. A molecular/genetic test, specific mutation, or set of mutations have been established in peer-reviewed scientific literature to be reliably associated with the specific diseases being evaluated for (condition or response to treatment identified).
3. The results of the molecular/genetic test will specifically determine medication, treatment, and/or clinical management decisions. Results are furnished for the diagnosis, direct care, and treatment of a medical condition and not mainly for the convenience of the member, provider, or laboratory.
4. The ordered test must directly impact clinical decision making and patient management.

Or

Any molecular/genetic test which is state mandated (*see Variations section below*).

Requests for molecular/genetic testing billed using unlisted codes or emerging technology will be evaluated on a case by case basis. Documentation must be provided by the requesting physician satisfying the criteria listed above.

Genetic testing for FMR1 Mutations, including Fragile X syndrome is medically necessary for:

1. Members with an intellectual disability, developmental delay, or autism spectrum disorder; OR
2. Members with a family history of fragile X syndrome seeking reproductive counseling; OR
3. Fetal testing of known carrier mothers; OR

4. Members who have ovarian failure before the age of 40 in whom fragile-X associated failure is suspected; OR
5. Members with neurological symptoms and findings consistent with Fragile X associated tremor and ataxia syndrome.

Genetic testing for FMR1 mutations is considered investigational in the absence of the above clinical indications.

Genetic testing for the determination of metastatic risk of Uveal Melanoma is medically necessary for:

1. Members with primary, localized uveal melanoma; OR
2. Members with primary, localized uveal melanoma without evidence of metastatic disease.

Genetic testing for Uveal Melanoma is considered investigational in the absence of the above clinical indications.

Genetic testing for Epilepsy is medically necessary for:

1. Members with infantile and early childhood onset epilepsy syndromes where test results may lead to:
    a. Changes in medication regiment; OR
    b. Changes in diagnostic testing where alternative invasive tests may be avoided; OR
    c. Changes in reproductive decision making.

Genetic testing for Epilepsy is considered investigational in the absence of the above clinical indications.

Genetic testing for Huntington's Disease (HD) is medically necessary for:

1. Predictive testing in asymptomatic members who have familial history of HD to define risk of transfer; OR
2. Prenatal testing in members who have familial history of HD.

Genetic testing for Huntington's Disease is considered investigational in the absence of the above clinical indications.

Genetic testing for Duchenne and Becker Muscular Dystrophy (DMD) is medically necessary for:

1. Confirming diagnosis and direct treatment in members with symptoms of dystrophinopathy; OR
2. Excluding or confirming the need for cardiac surveillance of members with familial history of DMD; OR
3. Members with familial history of DMD seeking reproductive counseling; OR
4. Excluding or confirming the need for cardiac surveillance of male members with familial history of DMD.

Genetic testing for DMD is considered investigational in the absence of the above clinical indications.

Genetic testing for Tay-Sachs Disease is medically necessary for:

1. Members who of Ashkenazi Jewish, French-Canadian, or Cajun descent and are considering pregnancy or are pregnancy;
2. Members who have familiar history of Tay-Sachs Disease.

Genetic testing for Tay-Sachs Disease is considered investigational in the absence of the above clinical indications.

Limitations

1. Molecular/genetic testing for a germ line or constitutional mutation is allowed only one time per member's lifetime.
2. Using molecular/genetic testing for risk selection or risk classification purposes in providing health coverage is prohibited and not covered.
3. Molecular/genetic testing for asymptomatic general screening of a disease/condition is not covered unless specifically provided under a specific benefit plan.
4. Molecular/genetic testing for identification of late onset adult disorders will be covered only if an effective treatment exists that has documented better efficacy if initiated prior to onset of symptoms.
5. Direct-to-consumer (DTC) self-testing home kits and other DTC genetic tests are not covered.
6. Storing or using stored human biological specimens for molecular/genetic testing is considered experimental/not covered and should be under the purview of the responsible IRB (Institutional Review Board) or other comparable body.
7. Testing of anonymous human biological samples is considered not medically necessary/not covered.

Variations

Any molecular/genetic test which is state mandated such as newborn screen (e.g. phenylketonuria (PKU), cystic fibrosis or congenital hypothyroidism) does not require prior authorization under this policy.

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Background

The emergence of personalized laboratory medicine has been characterized by a multitude of testing options which can more precisely pinpoint management needs of individual patients. As a result, the growing compendium of products described as biomarkers requires a careful evaluation by both clinicians and laboratorians as to what testing configurations are reasonable and necessary.

There are a plethora of burgeoning tools, including both gene-based (genomic) and protein-based (proteomic) assay formats, in tandem with more conventional (longstanding) flow cytometric, cytogenetic, etc. biomarkers. There are also highly-diverse approaches ranging from single mutation biomarkers to multiple biomarker platforms, the latter of which often depend upon sophisticated biomathematical interpretative algorithms.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
81171	Aff2 gene detc abnor alleles
81172	Aff2 gene charac alleles
81173	Ar gene full gene sequence
81174	Ar gene known famil variant
81177	Atn1 gene detc abnor alleles
81178	Atxn1 gene detc abnor allele
81179	Atxn2 gene detc abnor allele
81180	Atxn3 gene detc abnor allele
81181	Atxn7 gene detc abnor allele
81182	Atxn8os gen detc abnor allel
81183	Atxn10 gene detc abnor allel
81184	Cacna1a gen detc abnor allel
81185	Cacna1a gene full gene seq
81186	Cacna1a gen known famil vrnt
81187	Cnbp gene detc abnor allele
81188	Cstb gene detc abnor allele
81189	Cstb gene full gene sequence
81190	Cstb gene known famil vrnt

81204	Ar gene charac alleles
81233	Btk gene common variants
81234	Dmpk gene detc abnor allele
81236	Ezh2 gene full gene sequence
81237	Ezh2 gene common variants
81239	Dmpk gene charac alleles
81271	Htt gene detc abnor alleles
81274	Htt gene charac alleles
81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)
81284	Fxn gene detc abnor alleles
81285	Fxn gene charac alleles
81286	Fxn gene full gene sequence
81289	Fxn gene known famil variant
81305	Myd88 gene p.leu265pro vrnt
81306	Nudt15 gene common variants
81312	Pabpn1 gene detc abnor allel
81320	Plcg2 gene common variants
81329	Smn1 gene dos/deletion alys
81333	Tgfbi gene common variants
81336	Smn1 gene full gene sequence
81337	Smn1 gen nown famil seq vrnt
81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)
81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10
81343	Ppp2r2b gen detc abnor allel
81344	Tbp gene detc abnor alleles
81345	Tert gene targeted seq alys
81347	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)

81348	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)
81351	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence
81352	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)
81353	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant
81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)
81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)
81419	Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2
81443	Genetic tstg severe inh cond
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])
The following codes are MA only:	
81479	Unlisted molecular pathology procedure

81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure
87999	Unlisted microbiology procedure
88299	Unlisted cytogenetic study

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Disclaimer:
MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies

for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.