Genetic Testing **MP9012**

Covered Service:	Yes
Prior Authorization Required:	Please reference hyperlinks found 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
Medicare Policy:	Prior authorization is dependent on the member's Medicare coverage. Prior authorization is not required for Medicare Cost (Dean Care Gold) and Medicare Supplement (Select) when this service is provided by participating providers. Prior authorization is required if a member has Medicare primary and Dean Health Plan secondary coverage. This policy is not applicable to Dean Health Plan Medicare Replacement products.
BadgerCare Plus Policy:	Dean Health Plan covers when BadgerCare Plus also covers the benefit.

Dean Health Plan Medical Policy:

General Information and Medical Necessity Guidelines for Genetic Testing:

1.0 Genetic testing is covered for a Dean Health Plan member if the test results provide a direct medical benefit or guides reproductive decision-making for the Dean Health Plan 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 Somatic Tumor Markers MP9486

3.29 Genetic Testing: General Approach to Genetic Testing MP9610

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 order 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 panels used to predict risk for the development of many hereditary cancers are considered not medically necessary.

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

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

8.0 The following genetic tests require prior authorization and are considered medically necessary when criteria has been met:

8.1 Retinal disorder gene panel testing is considered medically necessary for confirmation of diagnosis in member with clinical manifestations (physical examination, electroretinogram) suggestive of nonsyndromic hereditary retinal disorder (eg, early-onset retinitis pigmentosa, Leber congenital amaurosis/severe early-onset retinal dystrophy

9.0 Genetic testing for heritable disorders of a Dean Health Plan member's non-Dean Health Plan relative **requires** prior authorization through the Health Services Division and is considered medically necessary when **ALL** of the following conditions are met:

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

9.2 The information will be used in the immediate care plan of the Dean Health Plan 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 Dean Health Plan 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 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.

12.4 Whole Genome Sequencing

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

12.6 Growth stimulation expressed gene ST2 Assay

12.7 Pulmonary disease (idiopathic pulmonary fibrosis, mRNA, gene expression analysis (e.g. Envisia Genomic Classifier, Veracyte)

12.8 Epi proColon colorectal cancer screening blood based biomarker

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 Dean Health Plan. Inclusion of a code above does not imply any right to reimbursement or guarantee claim payment. Other medical policies may also apply.

CPT Code	Description
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)
81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence
81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant
81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)

CPT Code	Description
81243	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81244	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles (eg, expanded size and methylation status)
81256	HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D)
81332	SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z)
81401	Molecular Pathology Procedure Level 2
81407	Molecular Pathology Procedure Level 8
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)
81432	Hereditary breast cancer-related disorders (eg, 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
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81434	Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA

CPT Code	Description
	analysis, and RNA analysis when performed, 5-50 genes (eg, 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
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])
81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score (e.g. Allomap)
81479	Unlisted molecular pathology procedure
82103	Alpha-1-antitrypsin; total
82104	Alpha-1-antitrypsin; phenotype
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection
0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)
0112U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA
0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness (e.g. PedictSURE IBD Test)
0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements (e.g. Vita Risk)
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of

CPT Code	Description
	homozygosity for chromosomal abnormalities
0224U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue (e.g. Oncotype MAP™ Pan-Cancer Tissue Test)
0230U	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
G0237	Colorectal cancer screening; blood-based biomarker
S3841	Genetic testing for retinoblastoma

	Committee/Source	Date(s)
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	Utilization Management Committee/ Health Services	March 10, 1999
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	Utilization Management Committee/ Genetics Testing Work Group	August 9, 2000
	Utilization Management Committee/Dean Genetics Counsel.	November 11, 2000
	Utilization Management Committee/Medical Affairs	May 12, 2004
	Utilization Management Committee/Medical Affairs	January 14, 2009
	Medical Director Committee/Medical Affairs	January 18, 2012
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Committee/Source	Date(s)
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Medical Policy Committee/Quality and Care Management Division	January 17, 2018
Medical Policy Committee/Quality and Care Management Division	April 18, 2018
Medical Policy Committee/Quality and Care Management Division	June 20, 2018 December 19, 2018
Medical Policy Committee/Health Services Division	May 15, 2019
Medical Policy Committee/Health Services Division	June 19, 2019
Medical Policy Committee/Health Services Division	July 17, 2019
Medical Policy Committee/Health Services Division	November 20, 2019
Medical Policy Committee/Health Services Division	December 18, 2019
Medical Policy Committee/Health Services Division	March 18, 2020
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Medical Policy Committee/Health Services Division	October 21, 2020
Medical Policy Committee/Health Services Division	November 18, 2020
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Medical Policy Committee/Health Services Division	March 17, 2021
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Medical Policy Committee/Health Services Division	July 21, 2021
Medical Policy Committee/Health Services Division	April 20, 2022
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Medical Policy Committee/Health Services Division	October 19, 2022
Medical Policy Committee/Health Services Division	

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	Committee/Source	Date(s)
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	UM Committee (UMC)/Director UM/UMC Chair	March 10, 2004
	UM Committee (UMC)/Director UM/UMC Chair	March 9, 2005
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	UM Committee (UMC)/Director UM/ UMC Chair	March 14, 2007
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	UM Committee (UMC)/Director UM/UMC Chair	April 8, 2009
	Medical Director Committee/Medical Affairs	February 24, 2011
	Medical Director Committee/Medical Affairs	January 18, 2012
	Medical Director Committee/Medical Affairs	April 18, 2012
	Medical Director Committee/Medical Affairs	August 15, 2012
	Medical Director Committee/Medical Affairs	September 19, 2012
	Medical Director Committee/Medical Affairs	January 16, 2013
	Medical Director Committee/Medical Affairs	June 13, 2013
	Medical Director Committee/Medical Affairs	January 15, 2014
	Medical Director Committee/Medical Affairs	February 19, 2014
	Medical Director Committee/Medical Affairs	January 21, 2015
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Reviewed:	Medical Director Committee/Quality and Care Management Division	December 16, 2015
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	Medical Policy Committee/Quality and Care Management Division	April 3, 2017
	Medical Policy Committee/Quality and Care Management Division	July 19, 2017
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	Medical Policy Committee/Quality and Care Management Division	April 18, 2018
	Medical Policy Committee/Quality and Care Management Division	June 20, 2018
	Medical Policy Committee/Health Services Division	December 19, 2018
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