DeanHealthPlan
A member of SSM Health

Coverage of any medical intervention discussed in a Dean Health Plan 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 for Cowden Syndrome - PTEN Gene MP9488

Covered Service: Yes

Prior Authorization Required: Yes

Additional Information: 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. See Genetic Testing MP9012 for additional information.

Pre and post-test genetic counseling is required for any individual undergoing genetic testing.

For ASO members pre and post-genetic counseling is not required. Please reference the ASO Summary Plan Description (SPD).

A first-degree relative is defined as an individual's parents, full siblings, and children.

A second-degree relative is defined as an individual's grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.

A third-degree relative is defined as first cousins, great-aunts, great-uncles, great-grandchildren, or great-grandparents

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 our Medicare Replacement products.

BadgerCare Plus Policy: Dean Health Plan covers when BadgerCare Plus also covers the benefit.

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Dean Health Plan Medical Policy:

1.0 Genetic testing for **Cowden Syndrome (CS) requires prior authorization** through the Health Services Division. **PTEN** gene testing is considered medically necessary in individuals with a suspected or known clinical diagnosis of Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome (BRRS), or a known family history of a PTEN mutation who meet **ANY** of the following criteria:

- 1.1 Individual from a family with a known PTEN mutation pathogenic/likely pathogenic variant
- 1.2 Individual with a personal history of Bannayan-Riley-Ruvalcaba Syndrome
- 1.3 Individual meeting clinical diagnostic criteria for Cowden Syndrome/PTEN Hamartoma Tumor Syndrome (PHTS)
- 1.4 Individual **not** meeting clinical diagnostic criteria for CS/PHTS with a personal history of at least **ONE** of the following:
  - 1.4.1 Adult Lhermitte-Duclos disease (cerebellar tumors)
  - 1.4.2 Autism spectrum disorder and macrocephaly
  - 1.4.3 Two (2) or more biopsy-proven trichilemmomas
  - 1.4.4 Two (2) or more major criteria (one (1) must be macrocephaly)
  - 1.4.5 Three (3) major criteria without macrocephaly
  - 1.4.6 One (1) major and three (3) or more minor criteria
  - 1.4.7 Four (4) or more minor criteria
- 1.5 At-risk individual with a relative with a clinical diagnosis of CS/PHTS or BRRS for whom testing has not been performed. The at-risk individual must have **EITHER** of the following:
  - 1.5.1 Any one major criteria; **OR**
  - 1.5.2 Two minor criteria
- 1.6 PTEN pathogenic/likely variant detected by tumor profiling on any tumor type in the absence of germline analysis

***Criteria for PTEN genetic testing purposes are:**

Major	Breast cancer Mucocutaneous lesions • One biopsy-proven trichilemmoma • Multiple palmoplantar keratoses

	• Multi-focal or extensive oral mucosal papillomatosis • Multiple cutaneous facial papules (often verrucous) Macrocephaly (97th percentile or greater; 58 cm in adult women, 60 cm in adult men) Endometrial cancer Follicular thyroid cancer Multiple GI hamartomas or ganglioneuromas Macular pigmentation of glans penis
Minor	Colon Cancer Esophageal glycogenic acanthosis (≥3) Thyroid structural lesions (e.g. adenoma, nodule(s), goiter) Testicular lipomatosis Vascular anomalies (including multiple intracranial developmental venous anomalies) Papillary or follicular variant of papillary thyroid cancer Intellectual disability (e.g. IQ ≤ 75) Autism spectrum disorder Single gastrointestinal hamartoma or ganglioneuroma Lipomas Renal cell carcinoma

2.0 There is insufficient evidence to include fibrocystic disease of the breast, fibromas, and uterine fibroids as diagnostic criteria so these are considered experimental and investigational and therefore are not medically necessary.

CPT/HCPCS Codes Related to MP9488

* 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
0101U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])
0130U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure)
0235U	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions (e.g. Genomic Unity PTEN Analysis)
81321	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis
81322	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant
81323	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant
81403	Molecular Pathology Procedure Level 4
81435	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11
81436	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g.,

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CPT Code	Description
	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

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