Genetic Testing for Hereditary Cancer

Humana®

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Medical Coverage Policy

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Description

Genetic testing is a laboratory method that is performed to analyze an individual's deoxyribonucleic acid (DNA) to detect gene variants (mutations) associated with inherited conditions including hereditary cancer. Approximately 5 to 10 percent of all cancers are hereditary and genetic testing can help determine if a cancer is inherited. This type of testing may also be referred to as germline genetic testing. Testing is available for many cancers including, but not limited to:

- **Cutaneous melanoma:** A type of skin cancer that is very rarely inherited; most cases occur sporadically. In cases of familial melanoma, an individual may be at increased risk for developing melanoma due to variants in the *CDKN2A* gene.

- **Hereditary diffuse gastric cancer (HDGC)**: A rare, inherited type of gastric (stomach) cancer that grows in the lining of the stomach and is caused by variants in the *CDH1* gene.

- **Hereditary neuroendocrine tumor syndromes**: A group of rare genetic conditions associated with an increased risk of developing tumors in certain hormone-producing cells within the body known as neuroendocrine cells. These cells are found in several organs such as the adrenal glands, digestive system, pancreas and thyroid. Tumors originating from these cells are referred to as neuroendocrine tumors (NETs). The specific type of NET syndrome varies based on which genes are affected as well as the organs involved. An individual with any of these syndromes may develop more than one tumor during a lifetime, and the tumors may be benign or malignant. The most common syndromes include:

  - **Multiple endocrine neoplasia type 1 (MEN1)** is characterized by tumors of the pancreas, parathyroid and pituitary glands and is caused by variants in the *MEN1* gene.

  - **Multiple endocrine neoplasia type 2 (MEN2)** can cause tumors in the adrenal glands and thyroid due to variants in the *RET* gene.

  - **Multiple endocrine neoplasia type 4 (MEN4)** is similar to the other types of multiple endocrine neoplasia but is caused by variants the *CDLN1B* gene. An individual with MEN4 can develop tumors in the adrenal, parathyroid and pituitary glands.

  - **Paraganglioma (PGL) and pheochromocytoma (PCC)** are related types of rare tumors that form from the same tissue type, arising from neural crest cells. PCC develops specifically in the adrenal glands while PGL arise outside the adrenal glands, often in the abdomen, chest, head, neck or pelvis. Typically, the tumors are benign; however, some tumors can become malignant and metastasize (spread) to other body parts. These tumors can occur sporadically or as part of a hereditary syndrome such as MEN2, MEN4 or von Hippel Lindau syndrome. There are many types of hereditary PGL and PCC, each with its own genetic source, developing in different parts of the body. Variants in several genes are associated with PGL and PCC and include *MAX, SDHA, SDHAF2, SDHB, SDHC, SDHD* and *TMEM127*. It may also be appropriate to analyze the *RET* and *VHL* genes when certain features of PGL or PCC are present.

  - **von Hippel-Lindau (VHL) syndrome** is another rare, inherited disorder characterized by the development of tumors (malignant and benign) in the adrenal glands, brain, eyes, kidneys and pancreas. An individual with VHL has an increased risk of developing clear-cell renal cell carcinoma (ccRCC), a type of kidney cancer. VHL syndrome is caused by variants in the *VHL* gene.

- **Retinoblastoma**: A cancer that originates in the retina (back of the eye), predominately affecting infants and young children. Although rare, it can occur in adults as well. Retinoblastoma is caused by variants in the *RB1* gene.

Multigene panels are defined as a test that analyzes more than one gene simultaneously while single gene testing searches for variants in one specific gene. Multigene panels evaluate the DNA of an individual with a personal and/or family history of a hereditary condition. Pancancer multigene panels analyze genes associated with more than one hereditary cancer syndrome such as breast, colon, ovarian and uterine cancer. Examples of pancancer multigene panels include **CancerNext, CancerNext-Expanded and myRisk.**

Panels can be targeted or expanded. A targeted panel offers a limited number of genes associated with a specific condition while expanded panels are broad, providing analysis of a large number of genes and often include genes with unclear medical management.

Concurrent (paired) deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) genetic testing (also referred to as expanded RNA analysis) is a laboratory method that analyzes DNA in combination with RNA to purportedly aid with the detection, diagnosis and management of cancer as well as classification of variants of unknown significance (VUS). Paired testing may be offered to an individual who is at increased risk for hereditary cancer and is performed concurrent to DNA testing purportedly to identify additional variants (mutations). **+RNAinsight** is an example of paired genetic testing and is conducted as an add-on test for multigene hereditary cancer panels such as CancerNext and CancerNext-Expanded. **(Refer to Coverage Limitations section)**

Coverage Determination

Any state mandates for genetic testing for hereditary cancer take precedence over this medical coverage policy.

Genetic testing may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage.

Apply General Criteria for Genetic and Pharmacogenomics Tests when disease- or gene-specific criteria are not available on a medical coverage policy. For information regarding **general criteria for genetic tests**, please refer to Genetic Testing Medical Coverage Policy.

CUTANEOUS MELANOMA (*CDKN2A* GENE)

Refer to **Coverage Limitations section** for multigene panel analysis for melanoma.

Cutaneous Melanoma – Affected Individual
Humana members may be eligible under the Plan for ***CDKN2A* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for cutaneous melanoma** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
    - Individual to be tested has a personal history of 3 or more invasive cutaneous melanomas; **OR**
    - Has a personal history of a mix of invasive melanoma, pancreatic cancer and/or astrocytoma; **OR**
    - Has a personal history of invasive cutaneous melanoma and has a first-degree relative diagnosed with pancreatic cancer

Cutaneous Melanoma – Unaffected Individual
Humana members may be eligible under the Plan for ***CDKN2A* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for cutaneous melanoma** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-, second- or third-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
    - First-, second- and/or third-degree relative (on the same side of the family) has 3 or more invasive cutaneous melanomas; **OR**
    - First-, second- and/or third-degree relative (on the same side of the family) has a mix of invasive melanoma, pancreatic cancer and/or astrocytoma

Cutaneous Melanoma - Known Familial Pathogenic or Likely Pathogenic Variant
Humana members may be eligible under the Plan for **cutaneous melanoma KFV genetic testing** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has a first-, second- or third-degree relative with a pathogenic or likely pathogenic variant in the *CDKN2A* gene. Genetic testing should be limited to the KFV.

HEREDITARY DIFFUSE GASTRIC CANCER (*CDH1* GENE)

Refer to **Coverage Limitations section** for multigene panel analysis for hereditary diffuse gastric cancer (HDGC).

HDGC – Affected Individual
Humana members may be eligible under the Plan for ***CDH1* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for HDGC** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
    - Bilateral lobular breast cancer diagnosed before 70 years of age; **OR**
    - Diffuse gastric cancer (DGC) diagnosed prior to 50 years of age; **OR**

- DGC diagnosed at any age and cleft lip/cleft palate; **OR**
- DGC diagnosed at any age and is of Maori ethnicity; **OR**
- DGC and lobular breast cancer, either cancer diagnosed prior to 70 years of age

HDGC – Unaffected Individual

Humana members may be eligible under the Plan for ***CDH1*** **single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for HDGC** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-, second- or third-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
  - First-, second- or third-degree relative diagnosed with cleft lip/cleft palate; **OR**
  - First-, second- or third-degree relative diagnosed with DGC and lobular breast cancer, either cancer diagnosed before 70 years of age; **OR**
  - Two first-, second- or third-degree relatives, on the same side of the family, diagnosed with gastric cancer and one has a confirmed diagnosis of DGC; **OR**
  - Two first-, second- or third-degree relatives, on the same side of the family, diagnosed with lobular breast cancer before 50 years of age

HDGC - Known Familial Pathogenic or Likely Pathogenic Variant

Humana members may be eligible under the Plan for **HDGC known familial variant (KFV) genetic testing** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has a first- second-or third-degree relative with a pathogenic or likely pathogenic variant in the *CDH1* gene. Genetic testing should be limited to the KFV.

HEREDITARY NEUROENDOCRINE TUMOR SYNDROMES (*CDKN1B, MAX, MEN1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL* GENES)

Hereditary Neuroendocrine Tumor Syndromes – Affected Individual

Humana members may be eligible under the Plan for **multigene panel sequencing (81437) and deletion/duplication analysis (81438) (performed concurrently or sequentially) for hereditary neuroendocrine tumor (NET) syndromes** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
    - A mutation identified on tumor genomic testing that has clinical implications if also identified in the germline (eg, tumor analysis shows mutation in *BRCA1* or *BRCA2* or mismatch repair [MMR] gene); **OR**
    - Clinical suspicion for multiple endocrine neoplasia type 1 (MEN1) when either of the following are present:
        - Personal history of 1 MEN1-related feature and has a first-degree relative diagnosed with at least 1 MEN1-related feature; **OR**
        - Personal history of 2 or more MEN1-related features; **OR**
    - Clinical suspicion for multiple endocrine neoplasia type 2 (MEN2) due to the presence of medullary thyroid carcinoma (MTC) or other combination of MEN2-related features (eg, pheochromocytoma [PCC], parathyroid adenoma/hyperplasia); **OR**
    - Personal history of any of the following:
        - Adrenocortical carcinoma; **OR**
        - Duodenal/pancreatic NET at any age; **OR**
        - Gastrinoma (duodenal/pancreatic or type 2 gastric NET); **OR**
        - Multifocal pancreatic NETs (PanNETs); **OR**
        - Multigland hyperplasia (without obvious secondary causes); **OR**
        - Multiple parathyroid adenomas; **OR**
        - Paraganglioma (PGL)/PCC; **OR**
        - Parathyroid adenoma or primary hyperparathyroidism diagnosed before 30 years of age; **OR**
        - Recurrent primary hyperparathyroidism

Hereditary NET Syndromes – Unaffected Individual

Humana members may be eligible under the Plan for **targeted multigene panel sequencing (81437) and deletion/duplication analysis (81438) (performed concurrently or sequentially) for hereditary NET syndromes** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
- A first-degree relative with any of the following:
  - Clinical suspicion for MEN1 when either of the following is present:
    - Personal history of 1 MEN1-related feature and a first-degree relative diagnosed with at least 1 MEN1-related feature; **OR**
    - Personal history of 2 or more MEN1-related features; **OR**
  - Clinical suspicion for MEN2 due to the presence of MTC or other combination of MEN2-related features (eg, PCC, parathyroid adenoma/hyperplasia); **OR**
  - Personal history of any of the following:
    - Adrenocortical carcinoma; **OR**
    - Duodenal/pancreatic NET at any age; **OR**
    - Gastrinoma (duodenal/pancreatic or type 2 gastric NET); **OR**
    - Multifocal pancreatic NETs (PanNETs); **OR**
    - Multigland hyperplasia (without obvious secondary causes); **OR**
    - Multiple parathyroid adenomas; **OR**
    - PGL/PCC; **OR**
    - Parathyroid adenoma or primary hyperparathyroidism diagnosed before 30 years of age; **OR**
    - Recurrent primary hyperparathyroidism

Hereditary NET Syndromes - Known Familial Pathogenic or Likely Pathogenic Variant

Humana members may be eligible under the Plan for **hereditary NET syndrome KFV genetic testing** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**

- Individual to be tested has a first-degree relative with a pathogenic or likely pathogenic variant in the *CDKN1B*, *MAX, MEN1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL* genes. Genetic testing should be limited to the KFV.

MULTIPLE ENDOCRINE NEOPLASIA TYPE 1 (*MEN1* GENE)

Multiple Endocrine Neoplasia Type 1 – Affected Individual

Humana members may be eligible under the Plan for ***MEN1* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for multiple endocrine neoplasia type 1 (MEN1)** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Clinical suspicion for MEN1 when either of the following is present:
  - Personal history of 1 MEN1-related feature and a first-degree relative diagnosed with at least 1 MEN1-related feature; **OR**
  - Personal history of 2 or more MEN1-related features

MEN1 – Unaffected Individual

Humana members may be eligible under the Plan for ***MEN1* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for MEN1** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
- Has a first-degree relative with either of the following:
  - Personal history of 1 MEN1-related feature and a first-degree relative diagnosed with at least 1 MEN1-related feature; **OR**
  - Personal history of 2 or more MEN1-related features

MEN1 - Known Familial Pathogenic or Likely Pathogenic Variant

Humana members may be eligible under the Plan for ***MEN1* KFV genetic testing** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has a first-degree relative with a pathogenic or likely pathogenic variant in the *MEN1* gene. Genetic testing should be limited to the KFV.

MULTIPLE ENDOCRINE NEOPLASIA TYPE 2 (*RET* GENE)

Multiple Endocrine Neoplasia Type 2 – Affected Individual

Humana members may be eligible under the Plan for ***RET* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for multiple endocrine neoplasia type 2 (MEN2)** (S3840) when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has a personal history at least 1 of the following features of MEN2:
  - MTC; **OR**
  - Parathyroid adenoma or hyperplasia; **OR**
  - PCC

MEN2 – Unaffected Individual

Humana members may be eligible under the Plan for ***RET* single gene sequencing and deletion and duplication analysis (performed concurrently or sequentially) for MEN2 (S3840)** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
- Has a first-degree relative with a confirmed diagnosis of any of the following:
  - MTC; **OR**
  - Parathyroid adenoma or hyperplasia; **OR**
  - PCC

MEN2 – Known Familial Pathogenic or Likely Pathogenic Variant

Humana members may be eligible under the Plan for **RET KFV genetic testing** (S3840) when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has a first-relative with a pathogenic or likely pathogenic variant in the *RET* gene. Genetic testing should be limited to the KFV.

MULTIPLE ENDOCRINE NEOPLASIA TYPE 4 (*CDLN1B* GENE)

Multiple Endocrine Neoplasia Type 4 – Affected Individual

Humana members may be eligible under the Plan for ***CDLN1B* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for multiple endocrine neoplasia type 4 (MEN4)** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Personal history of 1 of the following:
  - Pancreatic or duodenal NETs; **OR**
  - Papillary thyroid carcinoma; **OR**
  - Parathyroid adenoma/hyperplasia; **OR**
  - Pituitary adenomas

MEN4 – Unaffected Individual

Humana members may be eligible under the Plan for ***CDLN1B* single gene sequencing and deletion/duplication analysis (performed concurrently or sequentially) for MEN4** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
- Has a first-degree relative with a personal history of any of the following:
  - MEN4; **OR**
  - Pancreatic or duodenal NETs; **OR**
  - Papillary thyroid carcinoma; **OR**
  - Parathyroid adenoma/hyperplasia; **OR**
  - Pituitary adenomas

MEN4 – Known Familial Pathogenic or Likely Pathogenic Variant
Humana members may be eligible under the Plan for ***CDLN1B* KFV genetic testing** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has a first-degree relative with pathogenic or likely pathogenic variant in the *CDLN1B* gene. Genetic testing should be limited to the KFV.

RETINOBLASTOMA (*RB1* GENE)

Retinoblastoma – Affected Individual

Refer to **Coverage Limitations section** for multigene panel analysis for retinoblastoma.

Humana members may be eligible under the Plan for ***RB1* single gene sequencing and deletion/duplication analysis (S3841) (performed concurrently or sequentially) for retinoblastoma** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested has been diagnosed with retinoblastoma by ophthalmoscopic examination and confirmed by imaging studies (eg, magnetic resonance imaging [MRI], ocular ultrasonography or optical coherence tomography [OCT])

Retinoblastoma – Unaffected Individual
Humana members may be eligible under the Plan for ***RB1* single gene sequencing and deletion/duplication analysis (S3841) (performed concurrently or sequentially) for retinoblastoma** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
- Individual to be tested is unaffected; **AND**
- An affected first-, second- or third-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**
- Has a first-degree relative with a confirmed diagnosis of retinoblastoma

Retinoblastoma – Known Familial Pathogenic or Likely Pathogenic Variant

Humana members may be eligible under the Plan for ***RB1* KFV genetic testing (S3841)** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**

- Individual to be tested has a first-degree relative with a known familial pathogenic or likely pathogenic variant in the *RB1* gene. Genetic testing should be limited to the KFV.

VON HIPPEL-LINDAU SYNDROME (*VHL* GENE)

Von Hippel-Lindau Syndrome – Affected Individual

Humana members may be eligible under the Plan for ***VHL* single gene sequencing and deletion/duplication analysis (S3842) (performed concurrently or sequentially) for von Hippel Lindau (VHL) syndrome** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**

- Individual to be tested exhibits any of the following characteristics of VHL and a clinical diagnosis cannot be established:

  - Clear cell RCC (ccRCC) diagnosed before 40 years of age; **OR**
  - Endolymphatic sac tumor; **OR**
  - Hemangioblastoma of the brain, retina or spine; **OR**
  - Multiple (more than 1) bilateral ccRCC tumors diagnosed at any age; **OR**
  - Multiple (more than 1) pancreatic cysts; **OR**
  - Pancreatic NET; **OR**
  - Pancreatic serous cystadenoma (more than 1); **OR**
  - Papillary cystadenoma of the epididymis or broad ligament; **OR**
  - PCC; **OR**
  - PGL of abdomen, neck or thorax; **OR**
  - Retinal angioma

VHL – Unaffected Individual

Humana members may be eligible under the Plan for ***VHL* single gene sequencing and deletion/duplication analysis (S3842) (performed concurrently or sequentially) for VHL** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**

- Individual to be tested is unaffected; **AND**
- An affected first-, second- or third-degree relative is unavailable for genetic testing (eg, deceased, declines genetic testing or unable to contact); **AND**

- A first-, second- or third-degree relative has been diagnosed with any of the following:

- Clear cell RCC (ccRCC) diagnosed before 40 years of age; **OR**
- Endolymphatic sac tumor; **OR**
- Hemangioblastoma of the brain, retina or spine; **OR**
- Multiple (more than 1) bilateral ccRCC tumors diagnosed at any age; **OR**
- Multiple (more than 1) pancreatic cysts; **OR**
- Pancreatic NET; **OR**
- Pancreatic serous cystadenoma (more than 1); **OR**
- Papillary cystadenoma of the epididymis or broad ligament; **OR**
- PCC; **OR**
- PGL of abdomen, neck or thorax; **OR**
- Retinal angioma

VHL – Known Familial Pathogenic or Likely Pathogenic Variant
Humana members may be eligible under the Plan ***VHL* KFV genetic testing (S3842)** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**

- Individual to be tested has a first- second-or third-degree relative with a pathogenic or likely pathogenic variant in the *VHL* gene. Genetic testing should be limited to the KFV.

Note: The criteria for **genetic testing for hereditary cancer** are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **genetic testing for hereditary cancer** for the following:

- Deletion/duplication information is obtained as part of the sequencing procedure but submitted as an independent analysis

- Individual to be tested has an affected first-, second- or third-degree relative with a negative genetic testing result for the associated condition

- Individual to be tested is unaffected and an affected first-, second- or third-degree relative who is available for genetic testing

- KFV analysis using a multigene panel that includes the KFV

- Sequencing, deletion/duplication analysis and large genomic rearrangement analysis of a single gene, multigene panel or sequentially for the detection of a KFV without the KFV results of a relative

These are considered **not medically necessary** as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **genetic testing for hereditary cancer** for genes, indications or tests other than those listed above including, but may not be limited to:

- Concurrent (paired) DNA and RNA genetic testing (eg, +RNAinsight for CancerNext [0134U])

- Pancancer multigene panels that analyze genes associated with multiple hereditary cancer syndromes including, but may not be limited to:

  - Ambry Genetics hereditary cancer *Next* panels including, but may not be limited to:

    - CancerNext
    - CancerNext-Expanded
    - CustomNext-Cancer

  - BROCA Cancer Risk Panel

  - Color hereditary cancer panels including, but may not be limited to, Color Extended Hereditary Cancer

  - Empower Hereditary Cancer Test

  - Invitae hereditary cancer panels including, but may not be limited to:

    - Invitae Cancer Screen
    - Invitae Common Hereditary Cancers Panel
    - Invitae Multi-Cancer Panel

  - Myriad myRisk Hereditary Cancer Panel

  - myVantage Hereditary Comprehensive Cancer Panel

  - PreSENTIA Comprehensive Cancer Panel

  - Preventest
  - Quest Diagnostics hereditary cancer panels including, but may not be limited to:

    - Comprehensive Hereditary Cancer Panel
    - Guideline-Based Hereditary Cancer Panel

- Tempus xG+

- VistaSeq hereditary cancer panels including, but may not be limited to:

  - Hereditary Cancer Panel
  - Hereditary Cancer Panel without *BRCA*

- Multigene panel to analyze a single gene including, but may not be limited to:

  - *CDH1* gene analysis using a multigene panel for the evaluation of gastric cancer
  - *CDKN2A* gene analysis using a multigene panel for the evaluation of melanoma
  - *RB1* gene analysis using a multigene panel for the evaluation of retinoblastoma

- Multigene panel that includes genes that are not relevant to the individual's personal and family history

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81406	MOLECULAR PATHOLOGY PROCEDURE LEVEL 7	**Not Covered if used to report any tests outlined in Coverage Limitations section**
81437	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL	**Not Covered if used to report any tests outlined in Coverage Limitations section**
81438	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL	**Not Covered if used to report any tests outlined in Coverage Limitations section**

81479	Unlisted molecular pathology procedure	**Not Covered if used to report any tests outlined in Coverage Limitations section**
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family	
0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure)	**Not Covered**
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
S0265	Genetic counseling, under physician supervision, each 15 minutes	
S3840	DNA analysis for germline mutations of the RET proto-oncogene for susceptibility to multiple endocrine neoplasia type 2	
S3841	Genetic testing for retinoblastoma	
S3842	Genetic testing for Von Hippel-Lindau disease	

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Appendix

Appendix A
Pre- and Post-Test Genetic Counseling Criteria

Pre- and post-test genetic counseling performed by any of the following qualified medical professionals
Genetic counselor who is board-certified or board-eligible by the American Board of Medical Genetics and Genomics (ABMGG) or American Board of Genetic Counseling, Inc (ABGC) and is not employed by a commercial genetic testing laboratory; **OR**
Genetic clinical nurse (GCN) or advanced practice nurse in genetics (APNG) who is credentialed by the Genetic Nursing Credentialing Commission (GNCC) or the American of Nurses Credentialing Center (ANCC) and is not employed by a commercial genetic testing laboratory; **OR**
Medical geneticist who is board-certified or board-eligible by ABMGG; **OR**
Treating physician who has evaluated the individual to be tested and has completed a family history of three generations

Appendix B
Family Relationships

Degree of Relationship	Relative of the Individual to be Tested
First-degree	Child, full-sibling, parent
Second-degree	Aunt, uncle, grandchild, grandparent, nephew, niece, half-sibling

Third-degree	First cousin, great aunt, great-uncle, great-grandchild, great-grandparent, half-aunt, half-uncle

Appendix C
MEN1-Related Features[84]

Adrenal adenomas
Bronchial/thymic carcinoids
Duodenal/pancreatic neuroendocrine tumor
Foregut carcinoid (bronchial, thymic or gastric)
Gastric carcinoids
Pancreatic (functioning) or duodenal neuroendocrine tumors (gastrinoma, glucagonoma, insulinoma, VIPoma/somatostatinoma)
Parathyroid adenoma or hyperplasia
Pituitary adenoma
Primary hyperparathyroidism

Change Summary

- 01/25/2024 Annual Review, Coverage Change. Updated Coding Information.