Genetic Counseling and Testing

Genetic testing for a particular disease should generally be performed once per lifetime; however, there are rare instances in which testing may be performed more than once in a lifetime (e.g., previous testing methodology is inaccurate or a new discovery has added significant relevant mutations for a disease).

Genetic Counseling

The MCO shall require counseling before and after all genetic testing. Counseling must consist of at least all of the following and be documented in the enrollee's medical record:

- Obtaining a structured family genetic history;
- Genetic risk assessment; and
- Counseling of the enrollee and family about diagnosis, prognosis, and treatment.

When performed by licensed genetic counselors, the MCO shall reimburse services using the procedure code specific to genetic counseling. Reimbursement for this service is "incident to" the services of a supervising physician and is limited to no more than 90 minutes on a single day of service.

When performed by providers other than licensed genetic counselors, the MCO shall reimburse for counseling under an applicable evaluation and management code.

Breast and Ovarian Cancer

The MCO shall cover and consider genetic testing for *BRCA1* and *BRCA2* mutations in cancer-affected individuals and cancer-unaffected individuals to be medically necessary if the enrollee meets the criteria listed below.

Eligibility Criteria

Individuals meeting one or more of the below criteria are considered eligible.

- Individuals with any blood relative with a known *BRCA1*/*BRCA2* mutation;
- Individuals meeting the criteria below but with previous limited testing (e.g., single gene and/or absent deletion duplication analysis) interested in pursuing multi-gene testing;
- Individuals with a personal history of cancer, defined as one or more of the following:
    - Breast cancer and one or more of the following:
        - Diagnosed age ≤ 45 years; or
        - Diagnosed at age 45—50 years with:
            - Unknown or limited family history; or
            - A second breast cancer diagnosed at any age; or
            - ≥ 1 close blood relative* with breast, ovarian, pancreatic, or high-grade (Gleason score ≥ 7) or intraductal prostate cancer at any age
        - Diagnosed at age ≤ 60 years with triple negative (ER–, PR–, HER2–) breast cancer;
        - Diagnosed at any age with:

                - Ashkenazi Jewish ancestry; or
                - ≥1 close blood relative* with breast cancer at age ≤ 50 years or ovarian, pancreatic, or metastatic or intraductal prostate cancer at any age; or
                - ≥3 total diagnoses of breast cancer in patient and/or close blood relatives*
            - Diagnosed at any age with male breast cancer; or
            - Epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age;
        - Exocrine pancreatic cancer at any age;
        - Metastatic or intraductal prostate cancer at any age;
        - High-grade (Gleason score ≥ 7) prostate cancer at any age with:
            - Ashkenazi Jewish ancestry; or
            - ≥1 close blood relative* with breast cancer at age ≤ 50 years or ovarian, pancreatic, or metastatic or intraductal prostate cancer at any age; or
            - ≥2 close blood relatives* with breast or prostate cancer (any grade) at any age
        - A mutation identified on tumor genomic testing that has clinical implications if also identified in the germline
        - To aid in systemic therapy decision-making, such as for HER2-negative metastatic breast cancer
- Individuals with a family history of cancer, including unaffected individuals, defined as one or more of the following:
    - An affected or unaffected individual with a 1st- or 2nd-degree blood relative meeting any of the criterion listed above (except individuals who meet criteria only for systemic therapy decision-making); or
    - An affected or unaffected individual who otherwise does not met criteria above but also has a probability > 5% of a *BRCA1/2* pathogenic variant based on prior probability models (e.g., Tyer-Cuzick, BRCAPro, Pennll)

*For the purpose of familial assessment, close blood relatives include first-, second-, and third-degree relatives on the same side of the family (maternal or paternal):

- 1st-degree relatives are parents, siblings, and children;
- 2nd-degree relatives are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings; or
- 3rd-degree relatives are great-grandparents, great-aunts, great-uncles, great grandchildren and first cousins.

Familial Adenomatous Polyposis

FAP is caused by a hereditary genetic mutation in the APC tumor suppressor gene which leads to development of adenomatous colon polyps.

The MCO shall cover and consider genetic testing for adenomatous polyposis coli (APC) gene mutations to diagnose familial adenomatous polyposis (FAP) to be medically necessary if the enrollee meets the following criteria.

Eligibility Criteria

- Personal history of ≥ 20 cumulative adenoma; or
- Known deleterious APC mutation in first-degree family member.

Lynch Syndrome

The MCO shall cover and consider genetic testing for Lynch syndrome to be medically necessary when an enrollee meets the following criteria:

- Amsterdam II criteria; or
- Revised Bethesda Guidelines; or
- Estimated risk ≥ 5% based on predictive models (MMRpro, PREMM5, or MMRpredict).

Amsterdam II Criteria

There must be at least three relatives with a Lynch Syndrome associated cancer (cancer of the colorectal, endometrium, small bowel, ureter or renal pelvis) and all of the following criteria should be present:

- One must be a first-degree relative to the other two;
- Two or more successive generations must be affected;
- One or more must be diagnosed before 50 years of age;
- Familial adenomatous polyposis should be excluded in the colorectal cancer; and
- Tumors must be verified by pathological examination.

Revised Bethesda Guidelines

One or more criterion must be met:

- Colorectal or uterine cancer diagnosed in a patient who is less than 50 years of age;
- Presence of synchronous (coexist at the same time), metachronous (previous or recurring) colorectal cancer, or other Lynch Syndrome associated tumors**;
- Colorectal cancer with the MSI-H*** histology**** diagnosed in a patient who is less than 60 years of age;
- Colorectal cancer diagnosed in one or more first-degree relatives with a Lynch syndrome related tumor, with one of the cancers being diagnosed under 50 years of age; and/or
- Colorectal cancer diagnosed in two or more first- or second-degree relatives with Lynch syndrome related tumors, regardless of age.

**Hereditary nonpolyposis colorectal cancer (HNPCC)-related tumors include colorectal, endometrial, stomach, ovarian, pancreas, ureter and renal pelvis, biliary tract, and brain (usually glioblastoma as seen in Turcot syndrome) tumors, sebaceous gland adenomas and keratoacanthomas in Muir-Torre syndrome, and carcinoma of the small bowel.

***MSI-H - microsatellite instability–high in tumors refers to changes in two or more of the five National Cancer Institute-recommended panels of microsatellite markers

****Presence of tumor infiltrating lymphocytes, Crohn's-like lymphocytic reaction, mucinous/signet-ring differentiation, or medullary growth pattern.