

August 14, 2015

Dear Ms. Kimberley Smith:

We were encouraged to see the incorporation of stakeholder feedback in the current version of the draft policy addressing hereditary cancer testing.

On behalf of the cancer genetic counselors in Colorado, we would like to strongly recommend the following with regards to coverage of hereditary cancer germline genetic testing for patients with Colorado Medicaid:

- To ensure clarity in coverage criteria for BRCA1/BRCA2 testing, we encourage the use of the most current version of the National Comprehensive Cancer Network's (NCCN) testing criteria (please see copy of the current NCCN BRCA1/BRCA2 criteria at the end of this document)
- Incorporate "endometrial cancer under age 50" and "synchronous or metachronous colorectal or other Lynch syndrome-related tumors, at any age" as covered criteria for Lynch syndrome as these are well-recognized indications for Lynch syndrome evaluation that are covered by Medicare
- Coverage for both patients affected with a personal history of cancer and unaffected patients without a personal history of cancer who have a family history of cancer, meeting current NCCN BRCA1/BRCA2 and/or Lynch syndrome guidelines
- Ability to appeal a coverage denial for genetic testing based on the ordering health care provider's clinical judgment of medical necessity and for situations in which NCCN guidelines are not available
- We support the Department's plan to review the Genetic Testing Benefits Standard annually

We look forward to an opportunity for on-going dialogue between our organizations in relation to this rapidly evolving field to ensure equality in care between Medicaid and non-Medicaid patients within the state of Colorado.

We appreciate your consideration of these recommendations. Thank for your providing a format for feedback and collaboration in ensuring appropriate access to genetic services for Colorado Medicaid patients.

Sincerely,

16 Clinical Cancer Genetic Counselors in Colorado

List of genetic counselors who have signed this letter and the organizations that they work for:

Melissa Gilstrap, MS, CGC	Parker Adventist Hospital	Mary Freivogel, MS, CGC	Invision Sally Jobe
Breanna Roscow, MS, CGC	Lutheran Medical Center	Michelle Springer, MS, CGC	University of Colorado Health
Elena Strait, MS, CGC	Penrose Cancer Center	Erin Hoffman, MS, CGC	Littleton Adventist Hospital
Leslie Ross, MS, CGC	University of Colorado-Ft. Collins	Joy Stern, MS, CGC	Callaway Young Cancer Center
Shonee Lesh, MS, CGC	Saint Joseph Cancer Center	Christine Barth, MA, CGC	St. Mary's Medical Center
Josie Kagey, MS, CGC	Porter Adventist Hospital	Lisa Ku, MS, CGC	University of Colorado Health
Jessamyn Nazario, MS, CGC	Invision Sally Jobe	Janet Talbert, MS, CGC	University of Colorado Health
Brittany Goetsch, MS, CGC	Rocky Mountain Cancer Centers	Lisen Axell, MS, CGC	University of Colorado Health

Current NCCN criteria for BRCA testing:

HEREDITARY BREAST AND/OR OVARIAN CANCER SYNDROME TESTING CRITERIA^{a,b}

Meeting one or more of these criteria warrants further personalized risk assessment, genetic counseling, and often genetic testing and management. Testing of unaffected individuals should only be considered when an appropriate affected family member is unavailable for testing.

- Individual from a family with a known deleterious *BRCA1/BRCA2* mutation
- Personal history of breast cancer^b + one or more of the following:
 - ▶ Diagnosed ≤45 y
 - ▶ Diagnosed ≤50 y with:
 - ◊ An additional breast cancer primary^c
 - ◊ ≥1 close blood relative^d with breast cancer at any age
 - ◊ ≥1 close relative with pancreatic cancer
 - ◊ ≥1 relative with prostate cancer (Gleason score ≥7)
 - ◊ An unknown or limited family history^a
 - ▶ Diagnosed ≤60 y with a:
 - ◊ Triple negative breast cancer
 - ▶ Diagnosed at any age with:
 - ◊ ≥1 close blood relative^d with breast cancer diagnosed ≤50 y
 - ◊ ≥2 close blood relatives^d with breast cancer at any age
 - ◊ ≥1 close blood relative^d with invasive ovarian^e cancer
 - ◊ ≥2 close blood relatives^d with pancreatic cancer and/or prostate cancer (Gleason score ≥7) at any age
 - ◊ A close male blood relative^d with breast cancer
 - ◊ For an individual of ethnicity associated with higher mutation frequency (eg, Ashkenazi Jewish) no additional family history may be required^f
- Personal history of prostate cancer (Gleason score ≥7) at any age with ≥1 close blood relative^d with breast (≤50 y) and/or invasive ovarian^e and/or pancreatic or prostate cancer (Gleason score ≥7) at any age
- Personal history of pancreatic cancer at any age with ≥1 close blood relative^d with breast (≤50 y) and/or invasive ovarian^e and/or pancreatic cancer at any age
- Personal history of pancreatic cancer, and Ashkenazi Jewish ancestry
- Family history only (significant limitations of interpreting test results for an unaffected individual should be discussed):
 - ▶ First- or second-degree blood^d relative meeting any of the above criteria
 - ▶ Third-degree blood^d relative who has breast cancer^b and/or invasive ovarian^e cancer and who has ≥2 close blood relatives^d with breast cancer (at least one with breast cancer ≤50 y) and/or invasive ovarian^f cancer

HBOC testing criteria met

See Follow-up (HBOC-2)

If HBOC testing criteria not met, consider testing for other hereditary syndromes

If criteria for other hereditary syndromes not met, then cancer screening as per [NCCN Screening Guidelines](#)

^aFor further details regarding the nuances of genetic counseling and testing, see [BR/OV-A](#).

^bFor the purposes of these guidelines, invasive and ductal carcinoma in situ breast cancers should be included.

^cTwo breast cancer primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or asynchronously.

^dClose blood relatives include first-, second-, and third-degree relatives on same side of family. (See [BR/OV-B](#))

^eIncludes fallopian tube and primary peritoneal cancers. *BRCA*-related ovarian cancers are associated with epithelial non-mucinous histology. Other cancer genetic syndromes may be associated with mucinous ovarian cancer. Non-epithelial ovarian cancer may be associated with PJS and possibly other cancer syndromes. Ovarian/fallopian tube/primary peritoneal cancers are component tumors of Lynch syndrome; be attentive for clinical evidence of this syndrome. See [NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal](#).

^fTesting for Ashkenazi Jewish founder-specific mutation(s) should be performed first. Comprehensive genetic testing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or if other HBOC criteria are met. Founder mutations exist in other populations.

Note: All recommendations are category 2A unless otherwise indicated.

Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.