

November 4, 2015

Dear Ms. Kimberley Smith:

Thank you for giving us the opportunity to make comment on the latest draft of the Genetic Testing Benefit Coverage Standard, version 9/11/2015 and the Benefits Collaborative FAQs: Genetic Testing, version 9/29/2015. We appreciate the chance to respond once again to the items we feel are most relevant to appropriate coverage of genetic testing for Coloradoans.

On behalf of the Colorado Genetic Counselors Network – Oncology Practice Group who represents the cancer genetic counselors throughout the state, we respectfully re-submit the following:

Item #1:

Per FAQ Item #10 regarding Adenomatous Polyposis Syndromes, “The Department will not cover testing for the purpose of identifying Adenomatous Polyposis Coli (*APC*) or *MUTYH* (MutY Homolog (E. coli)) gene mutation at this time but will revisit this decision in a year’s time, as more evidence of clinical utility becomes available.” *MUTYH* is also commonly referred to as *MYH*.

We strongly ask that coverage for this testing be reconsidered, based on evidence that has previously been provided (please see proposal by Myriad Laboratories: <https://www.colorado.gov/pacific/sites/default/files/Benefits%20Collaborative%20Genetic%20Testing%20Feedback%20Myriad%20Genetics%20February%2012%2C%202015.pdf>).

Additionally, we would like to re-emphasize that **The Benefit Coverage Standard is primarily based on the CDC Tier 1 criteria, which includes tests that are covered by CMS** (Centers for Medicare and Medicaid Services). CMS guidelines state the following:

***APC* and *MYH* gene testing** for Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP), or *MYH*-associated polyposis (MAP) is covered for the following individuals;

- A beneficiary with ≥ 20 cumulative colorectal adenomas over a lifetime.
- Testing for *APC* gene mutations should precede testing for the less common *MYH* mutation.

Further evidence of clinical utility is included in the CMS National Coverage Policy*:

Familial Adenomatous Polyposis (FAP) is an autosomal dominant syndrome caused by a germ-line mutation of the *APC* gene. Characteristically, affected patients develop multiple adenomas diffusely throughout the colon beginning in their teens. Colorectal cancer is inevitable in patients with FAP if colectomy is not performed. The average age at symptomatic diagnosis ranges from 34 to 45 years of age. However, the average age of colonic adenoma appearance is 16 years and of cancer diagnosis is 39 years. The FAP gene mutation occurs in approximately 1/10,000 - 1/30,000 live births in the United States, affects both sexes equally, and accounts for up to 1% of colorectal cancers.

MYH-associated polyposis (MAP) is an autosomal recessive syndrome linked to germ-line mutations of the *MYH* gene. The full clinical picture of *MYH*-associated polyposis (MAP) is incompletely understood at this time. Current evidence suggests it is associated with about 0.4-1.0% of colorectal cancers.

CMS has long been covering *APC* and *MYH* testing for individuals with multiple colorectal adenomas. Evidenced-based guidelines including NCCN, American Gastroenterological Association (AGA), and ASCRS guidelines support this type of genetic testing for individuals with multiple colorectal adenomas. Therefore, based upon the CDC definition of tiers, *APC* and *MYH* testing should be considered a covered testing service for individuals with concerning histories (as outlined above) as non-coverage would significantly deviate from the standard of care for patients as outlined by CMS coverage and societal guidelines.

Furthermore, CMS policy covers upper endoscopies (EGDs), which is a specific management guideline for individuals with Familial Adenomatous Polyposis (and is also recognized as an appropriate recommendation by Colorado Medicaid).**

*Colorado specific Medicare policy regarding coverage of polyposis can be found at: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35062&ContrId=331&ver=25&ContrVer=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCD%7cMCD&PolicyType=Both&s=8&Keyword=polyposis&KeywordLookUp=Doc&KeywordSearchType=Exact&kq=true&bc=IAAABAAAAAAAAA%3d%3d&>

**Colorado specific Medicare policy regarding coverage of EGDs can be found at: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35350&ContrId=331&ver=16&ContrVer=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCD%7cMCD&PolicyType=Both&s=8&Keyword=polyposis&KeywordLookUp=Doc&KeywordSearchType=Exact&kq=true&bc=IAAABAAAAAAAAA%3d%3d&>

Item #2:

Per FAQ Item #12 regarding coverage of Lynch syndrome to include endometrial cancer under the age of 50, “The Department has determined not to expand the criteria for Lynch syndrome testing, at this time, beyond the criteria previously listed.”

Again, we would like to re-iterate that **this has long been a CMS guideline** that specifically states the following:

Hereditary Colorectal and Endometrial Cancer Syndromes

The tests are covered for a **beneficiary who has or has had colorectal or endometrial cancer and meets one of the following criteria:**

4. Endometrial cancer diagnosed in a beneficiary at less than 50 years of age

Per the previously submitted document from Myriad, several publications were cited as having addressed the significance of endometrial cancer in Lynch syndrome. As testing for those with early onset colorectal cancer has been proven, testing those with endometrial cancer may be equally as important if not more so, especially in cases of *MSH6* mutations. Additionally, the following article describes the risk for a second cancer in women diagnosed with endometrial cancer. The mean age of diagnosis was 46.3 years and the median age was 46 years. This speaks to the clinical utility of surveillance in these individuals in the prevention of additional cancers.

Win AK et al. Risks of colorectal and other cancers after endometrial cancer for women with Lynch syndrome. *J. Natl Cancer Inst.* 2013 Feb 20;105(4):274-9.

We strongly encourage a re-review of the presented data and a review of the evidence that has been provided by CMS.

Item #3:

Per FAQ Item #8 regarding the guidelines used for the basis of the Department policy, we would like to call attention to the fact that many of the CDC Tiers are based off of other national guidelines, including NCCN, EGAPP and USPFTF. However, upon review, **the bodies of evidence used by the CDC are from 2014 or earlier**, despite the last update being noted as May 2015.

Also, per FAQ Item #5, the question was asked, “How might stakeholders engage with CDC regarding the development of this list?” One of the responses includes the following statement, “...the CDC is open to anyone contacting them to let them know of key sources that may be missing from the list (e.g., a guideline or systematic review).”

We respectfully ask for **access to the designated contact person(s) at the CDC** for further appropriate discussion, as listed above (guideline and systematic review). We further request the **opportunity to receive more specific education regarding the CDC process** of weekly research and guideline review (i.e. horizon scan).

Item #4:

Per FAQ Item #5 and Item #7, it is stated that the Department will review both the CDC list and any and all additional policy criteria placed in the coverage standard, on an annual basis and will amend Colorado Medicaid policy as needed.

It has been noted that the Medicaid Evidence Based Decisions Program (part of the Oregon Health Science University) has been engaged by the Department to review information pertaining to clinical utility of additional policy coverage suggestions. Given this collaboration, we would like to encourage the Department to consider the coverage guidelines that Oregon state Medicaid (which participates in the MED Program) policy follows. Oregon follows the NCCN guidelines and is also in the process of reviewing coverage of multi-gene panels (Next Generation Sequencing).

We understand and acknowledge that further research is needed in order to determine the overall effectiveness of Next Generation Sequencing (NGS), particular as it pertains to clinical utility. However, as a Colorado state policy Benefit Coverage Standard, we feel it is important to provide evidence regarding the cost-saving aspect of NGS as well. We have included several publications pertaining to this, as well as the impact on medical management (clinical utility).

If this evidence will not be considered for this current version of the Benefit Coverage Standard, **we ask for the opportunity to provide feedback in a timely manner prior to the next iteration of the policy.**

Item #5:

Under “Eligible Providers”, we request that the statement regarding Genetic Counselors be corrected to read “certified through the American Board of Genetic Counseling” (currently stated as American Board of Genetic Counselors).

We appreciate your consideration once again of these recommendations. We welcome open dialogue regarding these issues as the field of genetic testing is rapidly changing and thank you for the opportunity to work in collaboration in development of appropriate Colorado state policy.

Sincerely,

The Colorado Genetic Counselors Network – Oncology Practice Group

Contact:

Lisa Ku, MS, CGC*

Instructor, Certified Genetic Counselor

University of Colorado Hereditary Cancer Clinic

303-724-0685

303-724-0488 (fax)

Lisa.ku@ucdenver.edu

*Contact person on behalf of the Colorado Genetic Counselors Network and not as a representative of the University of Colorado