

Stakeholder Feedback to Proposed Genetic Testing Policy

K. Swan, MS, MA, CGC

Thank you for taking time to review coverage of genetic testing within the state of Colorado. I'm writing to voice several concerns over the proposed policy for genetic testing and to highlight areas of improvement with this policy.

Born and raised in Colorado, I've been a certified genetic counselor specializing in cancer genetics for the past 5 years. While in graduate school, I also obtained a master's degree in bioethics. This combination of genetics and ethics has certainly provided me with an interesting perspective in this ever growing, ever changing field of genetics. As part of this ethics training, I firmly believe that Colorado Medicaid patients deserve the same standard of care services as any other patient in the state of Colorado.

While I appreciate the attempt of the CDC to stratify genetic testing into various tiers, this categorization of genetic testing into these arbitrary tiers is outdated and has not kept up with what is currently the standard of care. In fact, many of the guidelines referenced on this website are not the most current version of those guidelines. Following these tiers would hinder Colorado Medicaid patients from receiving the same care as every other patient in the state.

It is outside my scope to comment on anything outside of the cancer genetics so I will leave those comments to medical providers who do specialize in those areas. Offering genetic testing to all appropriate patients who have a family history of cancer and meet current national testing guidelines is extremely important as it dictates appropriate cancer screening *and* cancer treatment options for patients and all of their family members. These tests are cost effective to the health care system as cancer prevention is much cheaper than cancer treatment.

A few opportunities for improvement that I'd like to highlight include:

- **Coverage of multi-gene panel testing for hereditary cancers.** Single syndrome testing has quickly become replaced by multi-gene panel testing as the new standard of care. Recently, many professional organizations have come out in support of multi-gene panel testing. Benefits of this type of testing include it being more cost effective than ordering multiple rounds of single syndrome testing, more time efficient and most importantly, offering the ability to find more mutations and prevent more cancers.
- **Coverage of BRCA1/2 testing as consistent with the most recent version of the NCCN guidelines for both unaffected and affected patients.** These guidelines are updated annually with 2014 being the most current set of guidelines.
- **Coverage of Lynch syndrome testing as consistent with the most recent version of NCCN guidelines for both affected and unaffected patients.** These guidelines are updated annually with the 2014 guidelines being the most current set of guidelines. The Lynch syndrome criteria outlined in the draft is inconsistent with appropriate testing. With the proposed draft, a newly diagnosed colon cancer patient diagnosed at age 70 would be covered for Lynch while testing for a patient who's dad died from colon cancer

at age 40 would not be covered. The first situation is not appropriate for genetic testing, would be covered and would be an irresponsible use of healthcare dollars. The second situation is very suspicious for Lynch Syndrome, very appropriate and would not be covered.

- **Coverage of testing for the colorectal polyposis syndromes (APC, MUTYH) as supported by NCCN guidelines.**
- **Coverage of FDA approved companion diagnostic tests (BRACAnalysis CDx).** In this tiered testing categorization, the CDC has not kept up to date with the importance of using genetic information to treat certain cancers. In December, the FDA approved a PARP inhibitor, Lynparza to treat advanced stage ovarian cancers due to germline mutations in BRCA1/2. The FDA specifically requires that this BRCA test be done by an FDA approved lab. Without this as a covered service, Colorado Medicaid patients with ovarian cancer would not be able to determine if they are eligible for certain therapeutic options.

Thank you for taking the time to consider these aspects of coverage in helping to make sure Colorado Medicaid patients receive the same standard of care as other Colorado patients. In my letter, I referenced many guidelines but have not attached them here. Please let me know if I can provide you with any additional information, data or guidelines.

D. Apdekar, MD

Thank you for the opportunity to participate in the Benefits Collaborative Public Meeting. You run a very orderly meeting and the process you explained in your slides is well thought out and inclusive and effective.

In the spirit of only contributing with new information and points I chose to remain silent during the meeting but would like to make a few points directly to you.

With respect to multi-gene panels, they have become very helpful to me in my OBGYN practice. Many patients have family histories that overlap between BRCA and Lynch other syndromes. Many Lynch patients present with ovarian cancers as well as endometrial cancers and sometimes deciding which test between BRCA and Lynch can be confusing. The MyRisk panel offered by Myriad, is no more expensive than either test alone and includes 25 genes that can identify many mutations that impact patient care. I have detected other genes to explain family histories for breast cancer like PalB and Chek2 which are now included in some of the multigene panels.

This year the American Congress of OBGYN also came out with their recommendations for all family histories to take into account Lynch syndrome associated cancers. So I agree with the speaker who recommended that all of the family history indications listed in Tier 2 should be included in Tier 1.

Finally, I would like to thank the committee for allowing those of us who are educated and experienced in counselling and identifying appropriate patients to test, to be allowed to perform these genetic tests directly from our offices. It was clear from the meeting that there are many dedicated genetic professionals and counselors in our community that do a wonderful job at counselling patients who need these diagnostic genetic tests. In addition there are many equally

committed physician and physician extender providers who have become dedicated and educated to provide safe, comprehensive and effective counselling for our patients.

I look forward to the continued process.

J. Pollard, Assurex Health

We wish to thank the Department of Health Care Policy & Financing for giving us a forum to participate in the policy development for Genetic Testing. We also appreciate the opportunity to both understand the process undertaken by the Department and the Departments need for reliance on a standardized method of establishing coverage criteria as noted in the selection of the Center for Disease Control (CDC) guidelines for genetic testing.

As noted in comments made during the Benefits Collaborative meeting of 2-12-15 for genetic testing, the use of CDC guidelines alone, has limitations in its ability to evaluate and address the rapidly changing world of genetic testing and to effectively examine the wide range of applications and methodologies used. To address a portion of this need, we recommend the evaluation and use of the Palmetto GBA MoIDX Technical Assessment process used in the evaluation of diagnostic testing for consideration of coverage by CMS. The Technical Assessment process includes a review of all submitted requests to determine if the assay is reasonable and necessary, and demonstrates clinical utility (CU) and analytical and clinical validity (AVCV). CMS has directed Palmetto to focus on these two broad categories of evidence and to follow the ACCE criteria developed by the Centers for Disease Control and Prevention (the first publicly-available analytical process for evaluating scientific data on emerging genetic tests). For this reason, we request that the MoIDX Technical Assessment process, and the results of the process, be considered as an additional method of evaluating technologies for coverage determinations.

The following link provides access to the Palmetto GBA MoIDX Technical Assessment process.

[http://www.palmettogba.com/Palmetto/Moldx.nsf/docsCat/MoIdx~Browse%20By%20Topic~General~Technical%20Assessment%20\(TA\)%20Process%20\(M00095\)?open&Expand=1](http://www.palmettogba.com/Palmetto/Moldx.nsf/docsCat/MoIdx~Browse%20By%20Topic~General~Technical%20Assessment%20(TA)%20Process%20(M00095)?open&Expand=1)

Please also find attached the following;

- GeneSight Clinical Dossier,(which contains much of the information utilized in the Palmetto GBA MoIDX Technical Assessment)
- Referenced peer reviewed publications (4)
- Medicare LCD providing a positive coverage determination for the GeneSight pharmacogenomic test.
- Medicare LCD non-coverage determination using single gene testing

We hope this information is informative and provides evidence sufficient to encourage the utilization of the process and the results of the MoIdx Technical Assessment as part of your coverage determination.

E. D. Crawford, MD

I understand that Colorado Medicaid has issued a draft policy for genetic testing utilizing the Center for Disease Control's Genetic Testing tier system. As some background, I have an intense interest in these biomarkers. Over the past several years we have been involved in a number of the pivotal trials. I have been guided by the concept that use of a number of these biomarkers improves the outcome of men with prostate cancer and that the results are actionable. In other words it changes what we do. Appended, please find several articles I have written on this subject. Regarding the Prolaris marker, this is an extremely important one to help us navigate through who to treat and who not to treat for prostate cancer.

A prospective study conducted by colleagues and myself assessed the impact of the Prolaris test on physician recommendations for treatment (Crawford et al. 2014 *Curr Med Res Opin.*). This study assessed pre-Prolaris treatment recommendations with post-Prolaris recommendations, and actual treatment selections were verified via a third-party audit of patient charts. This study showed that overall, 65% of patients had a change between intended therapy options pre- and post-Prolaris testing that were directionally aligned with test results (tests results indicating lower risk led to reductions in treatment and higher risk led to increases in interventional treatment). Interestingly, there was a 49.5% reduction in surgical interventions and a 29.6% reduction in radiation treatment. This is important to consider as these therapies, while important for patient care when used appropriately, do come with high levels of associated morbidity.

Quite honestly, I don't understand or really need to all of the intricacies of approval. It is my understanding that a number of these tests including Prolaris did get local coverage determination and work through the molecular diagnoses issues.

A. Patterson, MD

I am an obstetrician gynecologist in the community and writing on behalf of all the patients who meet current societal guidelines for Lynch syndrome testing. The National Cancer Comprehensive Network (NCCN) has published guidelines supporting the genetic evaluation of patients which I have been utilizing in my clinical practice. Furthermore, we have advanced technology with panel tests, which covers a wide range of genes associated with common cancers. I am able to test for several syndromes at once, particularly when the literature demonstrates overlapping syndromes and cancers. Single syndrome testing may be too narrow, and provide a false sense of security for my patients.

As a physician specializing in women's health it is my obligation, per the American Congress of Obstetrician Gynecologists, that I obtain a thorough cancer family history and act on the information provided, as is standard of care. Limiting access to Lynch syndrome testing and/or a panel tests for these patients with high-risk histories, would disrupt the current standard of care. I am able to offer appropriate management (surveillance and prophylactic surgery) to manage cancer risks. [*Specific patient case removed*]

It is my understanding, that there are proposed changes for Medicaid patients, which includes not covering unaffected patients with a family history suggestive of Lynch syndrome. NCCN currently indicates patients who have personal or family history suggestive of Lynch syndrome

are appropriate for Lynch syndrome evaluation. It is my job to make optimal medical recommendations with informed consent, and I cannot adequately do that without all the answers genetic testing offers me. Let's go forward with the technology available to us, not backward limiting Lynch testing to just those with colon cancer. Uterine and ovarian cancer plays a significant role in Lynch syndrome, and my patients rely on me to PREVENT gynecological cancers. Testing patients only after a Lynch cancer, is a real failure in prevention, especially when a cancer family history is present.

I am requesting that Colorado Medicaid utilize the well-recognized current NCCN guidelines for Lynch syndrome testing criteria, and cover my Risk panel testing that provides me with much more information. Thank you in advance for your consideration.

E. Spector, PhD, FACMG

I am not sure that this program would be helpful to most of the patients that we perform testing for and that our physicians see. Pharmacogenetics is a very small part of genetic testing, Tier 1 tests. None of the tests that we perform are associated with a drug/treatment suggested on an FDA label.

I would be happy to provide more feedback or meet with your committee in person. You need more trained geneticists to work through the process to ensure that the appropriate tests will be covered.

R. Rogers MSN, CNP

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As a Nurse Practitioner, specializing in OB/Gyn services, it is my obligation (per ACOG) that I practice standard of care, obtaining a thorough cancer family history, and acting on the information provided. Limiting access to Lynch syndrome testing and/or a panel test for these patients with high-risk histories, would disrupt the current standard of care. I am able to offer appropriate management (surveillance and prophylactic surgery) to manage cancer risks.

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When I have tested and detected a mutation it is the most rewarding feeling in the world to help a family stay a family and not lose their mother or sister to a very awful and often slow death of a cancer that could have been avoided. Thank you for taking the time to read this and consider our concerns.