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Director, Coverage & Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mailstop S3-02-01 7500 Security Blvd
Baltimore, MD 21244

Re: Coverage of NGS tumor panels-CAG-00450R

Dear Director Syrek Jensen:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the reopened process for a national coverage decision related to coverage of NGS tumor panels. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

In December 2017, the Centers for Medicare and Medicaid Services (CMS) initiated a National Coverage Decision (NCD) prompted by the parallel review and FDA approval of FoundationOne CDx as a companion diagnostic. CMS chose to expand the coverage determination more broadly to Next-Generation Sequencing (NGS) companion diagnostic panels for solid advanced tumors. Importantly, in both the draft and final NCD, CMS included language that prohibited Medicare Administrative Contractors from making local coverage determinations (LCDs) for coverage of NGS technology in any other setting. In our comment letter, we disagreed with the non-coverage provision because it indicated a mis-understanding of how the specific use of the approved NGS test fits in the overall landscape of genetic testing that may utilize NGS technology. In light of the misapplication of the NCD, we welcome the reopening of the process so that the error can be corrected. While we are grateful for the clear coverage of NGS panels as companion diagnostics for late stage cancers, the effect of this NCD is to both deny patients access to other tests that they were receiving under previous CMS policy and to block coverage of other evidence-based uses of NGS technology.

NGS represents a specific testing technology, that can be used on a number of different sample types (e.g., blood or tumor tissue), for different diseases, disease settings, and clinical uses (e.g. treatment

determination, risk assessment or disease progression). This NCD was triggered by parallel review of a diagnostic test for a specific sample type (formalin-fixed paraffin embedded tumor tissue), diseases (multiple solid cancers), disease setting (late-stage metastatic), and clinical use (companion diagnostic). In the original NCD, CMS stated its intent to not specifically review just one test, but other tests with **similar claims**: *"For this NCD analysis, we are proposing coverage for any next generation sequencing diagnostic testing with the scope of this review limited to patients with advanced cancer. This is to ensure that similar claims for these tests will be covered in the same manner under title XVIII."* In other words, the NCD explicitly sought to only review late-stage cancer diagnostic tests with similar (companion diagnostic) claims. At the conclusion of the NCD, CMS appropriately determined that the use case listed above was reasonable and necessary and should be covered not only for the FoundationOne CDx test, but any test that met the same criteria.

CMS' Previous NCD Decision Was Misguided.

We are concerned that CMS' previous NCD decision would proactively and definitively bar coverage of any other test using NGS technology in any other tissue type or disease setting without first requesting or evaluating evidence in those other use cases. The original clinical utility review executed in the NCD did not evaluate other use cases and as such we are concerned that the effect of CMS' decision precludes coverage beyond the scope of the initial analysis.

The current FDA-approved companion diagnostic claims happen to be in late-stage cancers, but it is expected that targeted therapies and diagnostics will be approved and appropriate for effectively treating early-stage cancers within the coming years. Under the current NCD, such a use would not be covered. This is only one example of where NGS technology may be appropriately used in sample types or settings other than the reviewed late-stage companion diagnostic use case.

Modifying CMS policy to allow coverage at a future time of any of these additional use cases would require opening up the NCD – or would require the creation of a new NCD – which is a rather lengthy process that can be administratively cumbersome. Rather than blocking all other coverage after only evaluating one use case for NGS technology, as CMS has done in this case, it would be more appropriate to approve coverage for the analyzed use case and leave the door open for coverage for other use cases through targeted LCDs as evidence develops. Taking this approach would require dropping the non-coverage provision from the NCD and removal of the restriction on what uses MACs are allowed to make LCDs on, a position we shared in our earlier letter to you.

CMS Should Expand the NCD to Include Both Germline and Somatic DNA Alterations.

We are also concerned that the current, reopened NCD process is restricted only to tests that serve as companion diagnostics through analysis of germline rather than somatic DNA alterations. Such a narrow reconsideration appears to indicate that CMS contemplates leaving the non-coverage provision in for a

wide variety of non-analyzed use cases and essentially freeze in time the current state of science with respect to diagnostic testing using NGS.

While we believe that the narrow question posed in the reopening of the NCD does not address the fundamental problem with the NCD, we believe that the evidence is clear that germline NGS testing of cancer susceptibility genes like BRCA1 and BRCA2 has already been demonstrated to provide value in patient treatment and disease prevention decisions. Specifically, those found at a high risk for the development of breast or ovarian cancer due to mutations in the BRCA1 or BRCA2 genes may seek prophylactic removal of the breasts or ovaries, treatments that significantly reduce cancer risk at those sites.[1] Germline testing for BRCA1 and BRCA2 has already been found through an LCD to be medically necessary when specific conditions have been met, and this coverage should be kept in place.[2]

Conclusion

On behalf of ACS CAN we ask you to take the opportunity of this NCD reopening to remove the non-coverage provisions represented in sections C and D of the NCD, both to preserve existing LCDs as well as to allow coverage policies to adapt to the ever-changing scientific and clinical landscape of genetic testing beyond single companion diagnostic testing of late-stage solid tumors. Research is rapidly driving advances in cancer care, and CMS policies should not deny cancer patients access to the fruits of that research because of an artificial block on a large swath of use cases of this emerging technology. If you have any questions, please feel free to contact me or have your staff contact Mark Fleury (mark.fleury@cancer.org).

Sincerely,

/Filed electronically/

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network

[1] Domchek SM, Friebel TM, Singer CF, et al. Association of risk-reducing surgery in BRCA1 or BRCA2 mutation carriers with cancer risk and mortality. *JAMA* 2010; 304(9):967–975.
[2] MolDX: BRCA1 and BRCA2 Genetic Testing (LCD L36082).