

November 28, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The undersigned organizations represent a diverse and broad community of patient advocates and providers committed to ensuring cancer patients have access to clinically appropriate, high-quality cancer care. The patients we represent and treat are benefitting from advances in the understanding of the genomic causes of cancer, both in increased access to targeted therapeutics and in innovative diagnostics that improve their ability to prevent cancer and monitor disease progression. This letter is in regard to the Centers for Medicare and Medicaid Services (CMS) reconsideration of the National Coverage Determination (NCD) on Next Generation Sequencing (NGS) for Medicare beneficiaries with Advanced Cancer in response to the concerns¹ that emerged after stakeholders reviewed the NCD's implementation instructions.

We are deeply concerned that the proposed policy is at odds with the current diagnostic landscape for germline NGS-based testing and the needs of Medicare beneficiaries with cancer. As written, this policy would reduce, rather than expand, Medicare beneficiary access to NGS-based testing for cancer.

We strongly urge the agency to make the following changes to the proposed coverage decision:

- **Allow Medicare Administrative Contractors (MACs) discretion to cover all NGS-based germline tests for cancer patients, patients with suspected/diagnosed hematologic malignancy and serial minimal residual disease assessments; and**
- **Cover multiple NGS-based tests during a patient's lifetime, when reasonable and necessary.**

Germline testing in patients has demonstrated clinical utility by informing appropriate clinical decisions and positively impacting treatment choices, leading to improved cancer outcomes and survival rates. Information provided by NGS-based germline tests for cancer patients provides treating physicians with the ability to more accurately assess the best patient management approach such as surgical decisions, prognosis, and treatment options. As currently drafted the proposed manual language will deny access to patients with ovarian or breast cancer for two reasons. First, there are currently no FDA approved or cleared germline tests for breast and ovarian cancer, and thus no tests currently contain the criteria necessary to receive national coverage outlined in the proposed decision memo. Second, in the proposed memo, MACs are not allowed to cover germline tests for breast and ovarian cancer when the tests use NGS technology. While we are supportive of MAC coverage for these tests for patients at all

¹ https://www.amp.org/AMP/assets/File/advocacy/Group_Stakeholder_Letter_NGSNCD-FINAL-1-31-2019.pdf

stages, we urge CMS to allow MACs to determine coverage for all patients with a cancer diagnosis, including breast and ovarian cancer. Since there are no FDA-cleared or approved NGS-based germline tests currently available for breast and ovarian cancer, NGS-based germline testing for early-stage breast and ovarian cancer patients remains non-covered nationally and MACs would not have the ability to cover NGS-based germline tests for these cancers. Consequently, only tests utilizing older, less-advanced, and more expensive methods would be eligible for Medicare coverage for those with early-stage hereditary breast and ovarian cancer. In order to maintain Medicare patient access to critical testing to manage cancer treatment, CMS should revise its coverage policy to include MAC discretion to cover all other NGS-based tests to ensure patients with breast and ovarian cancer continue to have access to this testing.

As written, the NCD covers a test using NGS technology in a patient with “recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer.” Hematological malignancies are not staged according to this system, nor are all myeloid malignancies staged alike. We request that the text of the NCD be clear on this issue to ensure that Medicare beneficiaries with hematological diseases have access to tests using NGS technology as these tests in patients with myeloid malignancies reflect the current standard of care and should not be denied to Medicare beneficiaries. Using NGS technology to obtain genetic variation information underlies the classification of myeloid malignancies and has aided in the correct classification and prognostic tiering of these cancers. NGS-based testing has been recognized as an optimal and comprehensive laboratory testing methodology for routine clinical evaluation of hematologic and lymphoid diseases and has emerged as the current standard to guide clinical management decisions (including indications for target-specific therapy), improve prognostic risk stratification, and provide precise diagnostic sub-classification for patients with known or suspected myeloid and lymphoid diseases.

Additionally, we are concerned about the implications of the new proposed manual language that stipulates that a patient has “not been previously tested using NGS” and fear that this new language as well as the existing similar language for somatic testing limits coverage for a medically necessary test under a number of circumstances. It is not uncommon for many such germline-tested patients to have already undergone somatic NGS testing. For example, the Palmetto GBA MolDX local coverage determination (LCD) on Genetic Testing for Lynch Syndrome acknowledges that both a germline and somatic test may be medically reasonable and necessary under certain circumstances and adopts a testing approach to reflex to germline testing in certain patients that may have already received an NGS-based somatic test.² We support such an approach and recommend the NCD be adjusted to allow for certain cancer patients to receive both an NGS-based germline and somatic test when necessary.

New evidence-based guidelines establish the value of multiple NGS-based tests during the course of a patient’s treatment. An NGS panel at the time of diagnosis and subsequent NGS panels at progression on first and subsequent lines of therapy fulfill similar and unique purposes. We encourage the agency to expand the scope of the existing NCD to cover multiple tests during a patient’s lifetime, to ensure patient access to high quality NGS testing and to ensure accurate identification of targetable mutations at diagnosis and at recurrence or progression of cancer.

² Proposed Local Coverage Determination (LCD): MolDX: Genetic Testing for Lynch Syndrome (L35024), available at <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35024&ver=50&SearchType=Advanced&CoverageSelection=Local&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=48&KeyWord=Lynch+syndrome&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&>.

As patient advocates and providers, our goal is to ensure that high quality, clinically effective NGS-based testing continues to be available to all appropriate Medicare beneficiaries. We are encouraged by CMS' willingness to reassess this policy. We look forward to CMS releasing the final NCD and welcome the opportunity to continue to work with CMS to ensure that the agency's coverage policies do not negatively impact cancer patients.

Sincerely,

A Breath of Hope Lung Foundation
AliveAndKickn
ALS Crowd
AnCan' - Answer Cancer Foundation
Bladder Cancer Advocacy Network
Cancer ABCs, Inc.
Cholangiocarcinoma Foundation
Ciitizen
CLL Society Inc.
Colon Cancer Alliance for Research and Education for Lynch Syndrome
Colorectal Cancer Alliance
Fight Colorectal Cancer
Go2 Foundation for Lung Cancer
HIS Breast Cancer Awareness
ICAN, International Cancer Advocacy Network
International Society of Nurses in Genetics
Myeloma Crowd
National Alliance of State Prostate Cancer Coalitions
Prevent Cancer Foundation
Prostate Cancer International
Prostate Health Education Network, Inc.
Sharsheret
Supporting Our Sisters International Inc.
SURVIVEiT
Susan G. Komen
The American Society of Breast Surgeons
The Clarity Foundation
Triage Cancer
Us TOO International Prostate Cancer Education & Support
Young Survival Coalition

cc: Tamara Syrek Jensen, JD, Director
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