



# Association of Pathology Chairs

## Promoting Excellence In Academic Pathology

100 West 10th Street, Suite 603, Wilmington, DE 19801  
Tel: 302-660-4940 Email: info@apcprods.org Web: www.apcprods.org

### President

Barbara Ducatman, MD

### President-Elect

Lydia Howell, MD

### Past President

Peter Jensen, MD

### Secretary-Treasurer

David Roth, MD, PhD

### Councilor-at-Large

Michael Laposata, MD, PhD

### Chair, Advocacy Committee

Debra Leonard, MD, PhD

### Chair, Graduate Medical Education Committee

Karen Kaul, MD, PhD

### Chair, Leadership Development & Diversity Committee

Dani Zander, MD

### Chair, Practice & Management Committee

Chen Liu, MD, PhD

### Chair, Research Committee

Jeffrey Golden, MD

### Chair, Undergraduate Medical Education Committee

Jennifer Baccon, MD, PhD

### Chair, Senior Fellows Group

Fred Sanfilippo, MD, PhD

### Chair, PRODS Section

Scott Anderson, MD

### Chair, UMEDS Section

Barbara Knollmann-Ritschel, MD

### Chair, PDAS Section

Kristen Kolb

### Executive Director

Priscilla Markwood, CAE

November 27, 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 Association of Pathology Chairs represents academic departments of pathology and laboratory medicine in academic medical centers throughout the U.S. and Canada. Our members are committed to providing the best care possible, including high quality, clinically-proven Next Generation Sequencing (NGS)-based testing, when appropriate. We are concerned that the recent proposed change to the National Coverage Determination for NGS for Medicare Beneficiaries with Advanced Cancer will compromise the quality of care we are able provide to patients. Below, are comments with our specific concerns about the Proposed Decision, as written.

#### **Point 1. Regarding "...the evidence is sufficient to expand coverage of Next Generation Sequencing (NGS) as a diagnostic laboratory test when performed in a CLIA-certified laboratory..."**

Next Generation Sequencing is a method used to determine the sequence of nucleotides in a region of DNA or RNA. Newer methods of determining a genetic DNA or RNA sequence may be developed in the future that could be more effective. Also, NGS is used for non-cancer testing, such as infectious disease tests, germline genetic tests for diseases other than cancer, bone marrow engraftment analysis, and other medically important testing. *We recommend specifying germline cancer risk testing using NGS technology as the focus of this Proposed Decision, or even just specifying germline cancer risk testing without specifying the method.*

#### **Point 2. Regarding "The patient has...not been previously tested using NGS"**

Our understanding of the genes that can cause an inherited cancer risk is expanding. For example, inherited breast cancer risk genes began with two genes (BRCA1 and BRCA2). We now have evidence of 14 genes that cause an increased lifetime risk of breast cancer, with an additional 14 with preliminary evidence which may become clinically relevant in the future as evidence increases. This is true for many other inherited cancers by organ system. Therefore, if CMS wants to limit medically unnecessary testing using next generation sequencing methods, the Proposed Decision should not allow repeat germline testing of the same gene, unless the first test did not provide full gene sequence coverage. However, testing for genes not included in a first test, as

our knowledge increases, would be considered medically necessary. *We recommend coverage of multiple NGS-based tests over the course of a patient's lifetime, as medically reasonable and necessary.*

**Point 3. Regarding “The diagnostic laboratory test using NGS must have all the following...Food and Drug Administration (FDA) approval or clearance...”**

Since testing must be performed in a CLIA-certified laboratory, and the oversight of laboratory-developed tests remains controversial, requiring that a germline test for inherited cancer risk be FDA cleared or approved basically means that this testing will not be possible for Medicare Beneficiaries because no NGS germline inherited cancer risk tests are FDA cleared or approved. *We recommend allowing CLIA regulatory standards for laboratory-developed tests to be acceptable to allow access to this testing.*

**Point 4. General**

*We encourage CMS to allow Medicare Administrative Contractors (MACs) to retain discretion to cover any germline tests for Medicare Beneficiaries with any stage of cancer that are deemed to be medically reasonable and necessary.*

Thank you for this opportunity to provide comments on the National Coverage Determination for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer Proposed Decision prior to finalization. We welcome continued dialog and are available to provide more information and/or answer questions regarding this important initiative. To coordinate, please contact Priscilla Markwood, APC's Executive Director, at [pmarkwood@apcprods.org](mailto:pmarkwood@apcprods.org) or at (302) 660-4945.

Sincerely,



Barbara Ducatman, MD

President, Association of Pathology Chairs

Chief, Pathology and Laboratory Medicine Service Line, Beaumont Health

Chair, Department of Pathology and Laboratory Medicine, Beaumont Hospital, Royal Oak

Chair, Department of Pathology, Oakland University William Beaumont School of Medicine

Physician Executive, Beaumont Medical Group