March 29, 2018

ACMG Advocacy Alert - Advocacy Works!

Center for Medicare and Medicaid Services (CMS) Releases Final National Coverage Determination on Next Generation Sequencing

On March 16, CMS released the final National Coverage Determination (NCD) for Next Genera[tion] Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer. The final policy, availabl[e] significantly different than the proposed policy, in large part due to the direct efforts of the Ame[rican] College of Medical Genetics and Genomics and many of you who individually heeded our call t[o] your concerns directly to CMS.

As you recall, ACMG sent members an Advocacy Alert on January 12 about the pending Medic[are] coverage policy decision regarding coverage of laboratory tests using Next Generation Sequenc[ing] major concern was that the proposed NCD would limit coverage to only those tests which have [FDA] approval or clearance. This effectively would have eliminated coverage for NGS Laboratory De[veloped] Tests (LDTs), leading to serious consequences for laboratories performing these tests and for pa[tients who] would have been unable to benefit from the full range of genetic tests. ACMG's formal commer[ts can be] read here.

As a result of our communal efforts along with many others, our voices were heard by CMS. Th[e final] NCD clarified their coverage policy *vis-à-vis* FDA-approved or cleared tests. The final NCD po[licy also] included a new section, allowing Medicare Administrative Contractors to make Local Coverage Determinations about non-FDA-approved or cleared tests, essentially providing a pathway for c[overing] LDTs in CLIA-certified laboratories.

Submission of public comments by ACMG and our members is a critical step in advocating for [sound] policies that protect and benefit patients. We thank all of our members who took time to submit [formal] comments to CMS. ACMG will continue to review the CMS decision in more detail and will fo[llow up] with CMS as needed.