May 28, 2019

TO: CMS

RE: Public Comment Period for Medicare National Coverage Determinations: National Coverage Analysis (NCA) Tracking Sheet for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R)

The EndBrainCancer Initiative (formerly the Chris Elliott Fund) wishes to provide comment on the above and specifically ask for:

- A request for clarification on the language used related to does Stage 3 and Stage 4 include Grade 3 and Grade 4 for high grade gliomas because high grade gliomas (Astrocytoma Grade 3 and Glioblastoma Grade 4 brain cancer/tumors) when diagnosed often do not use the word "Stage 3" or "Stage 4" but rather use the words "Grade 3" and "Grade 4" per the World Health Organization. https://www.archivesofpathology.org/doi/full/10.5858/arpa.2016-0493-RA. Does the language CMS used for the above determination include Grade 3 and Grade 4 solid tumors meaning does the determination include coverage for an Astrocytoma Grade 3 brain tumor and a Glioblastoma Grade 4 brain tumor?
- We also ask that "repeat testing for NGS for the patients' specific disease state also be covered under Medicare. Often, solid tumors, Stage 3 and 4/Grade 3 and 4 when they come back (recurrent) are more cancerous and their genomics/biomarkers have changed due to previous treatments, radiation, or increased Stage/Grade of tumor and evolution of disease. Repeat Testing can help identify predictive health outcomes as well as help identify treatment options. Researchers use patients' DNA to inform treatment decisions. Therefore, we also request CMS to consider NGS repeat testing to provide additional insight on the genomics/biomarkers of one's specific recurrent tumor and to help predict patterns and survival.

Thank you CMS for considering clarification of language related to this NCA for NGS for Medicare Beneficiaries with Advanced Cancer (CAG-0045OR) as Medicare patients diagnosed with high grade gliomas (HGG) should not be excluded from this coverage determination and we believe they should also be covered for repeat testing for the patients specific disease state as well as this leads to identification of patterns of disease and to additional treatment options.

Blessings,

Dellann Elliott Mydland
President & CEO

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