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United States Senate

WASHINGTON, DC 20510-0609

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Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Ms. Frizzera,

I write to you to express concern for denial of coverage by Trailblazer Health for our citizens in Colorado. Trailblazer is the Medicare contractor for Region 8, which includes Oklahoma, Colorado, New Mexico and Texas.

It has come to our attention that Trailblazer is refusing to cover the medically necessary treatments of Avastin (bevacizumab) for patients with epithelial ovarian cancer (EOC), despite being ordered by the respective physicians. It has also come to my attention that there is a variation in coverage of Avastin across the United States based primarily on the region of the patient, which results in some Medicare recipients receiving reimbursement for Avastin, and others being denied coverage of treatment.

As you know, Medicare is required to pay for drugs and biologics that are “reasonable and necessary”, which does not limit therapies to on-label use. In fact, approximately 40 percent of cancer treatment is off-label, but evidence based. Avastin is an anti-angiogenesis biologic approved by the Food and Drug Administration to treat some types of colorectal, lung and breast cancers. Although Avastin has not been determined to treat EOC for on-label use, numerous peer-reviewed studies have been conducted on the use of Avastin for EOC, with the vast majority showing positive results. This has led to a positive determination of off-label coverage use of Avastin in other Medicare regions of the country.

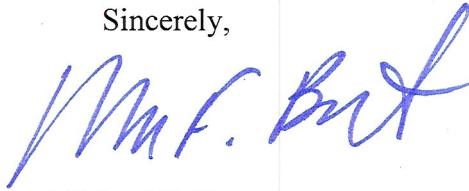
Even more important, Avastin has been included as a preferred treatment of EOC on the National Comprehensive Cancer Network (NCCN) compendium, approved as a reference by CMS in the Social Security Act § 1861(t)(1). This compendium includes treatment that is evidence-based, using scientific literature as its foundation. The inclusion of a therapy on the NCCN compendium meets the criteria that the level of scientific research has been completed to conclude that the therapy is safe and effective and thus, meets the definition of “reasonable and necessary”.

Even without referencing the NCCN compendium, the evidence is clear that Avastin is safe and effective in the treatment of EOC. Indeed, studies have been published showing Avastin's activity against ovarian cancer since 2005. There are currently numerous trials ongoing as well as a body of evidence in the form of published papers showing its efficacy.

The determination of Medicare coverage in other regions of the country for this treatment only speaks to the validity of making a coverage determination using the federally-recognized NCCN compendium—which in this case, validates scientific literature showing that Avastin is reasonable and necessary as a treatment for epithelial ovarian cancer. As such, we believe that Trailblazer's refusal to cover Avastin is improper and we ask that CMS require TrailBlazer to approve the drug as reasonable and necessary.

I look forward to your timely response in this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "M.F. Bennet", is written over the typed name.

Michael F. Bennet
United States Senator

Cc: Jonathan Blum, Director, Office of Medicare Management