

November 22, 2006

Tara Turner, PharmD
Centers for Medicare and Medicaid Services
7500 Security Blvd
Mail stop: S3-02-01
Baltimore, MD 21244

**Re: Medical Literature for Local Medicare Contractors to
Determine Medically Accepted Indications for Drugs and
Biologicals Used in an Anticancer Treatment**

Dear Ms. Turner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the appropriateness of the current cancer journals listed in chapter 15 of the Medicare Benefit Policy Manual. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry dedicated to discovering new therapies and ensuring patient access to them, BIO recognizes that the practice of medicine constantly evolves through the incorporation of new clinical evidence into the standard of care. Specifically, in oncology, the standard of care can change overnight as clinical researchers discover more effective, safer or alternative treatment regimens. Many of these new treatment options involve the use of drugs and biologicals for indications not initially approved by the Food and Drug Administration (FDA). New clinical uses of FDA-approved therapies offer patients and physicians

renewed hope and greater choice in fighting illness and can be particularly important for patients with advanced stages of cancer.¹ Therefore, it is imperative that both CMS and Medicare contractors ensure that coverage policies keep up with the pace of innovation and clinical discovery to allow beneficiaries timely access to the most appropriate treatment options in their battles against deadly diseases.

This is precisely why the Medicare statute requires contractors to cover “drugs and biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication,” defined as a use approved by the FDA or use of a FDA-approved drug supported by citations in certain compendia or by peer-reviewed medical literature.² To implement this section of the statute, a basic list of 15 journals was created to assist local carriers in determining coverage for non-labeled, non-compendia indications. BIO supports these standards for identifying medically accepted indications because they help to protect beneficiary access to the most appropriate and timely treatment options. Unfortunately, this list has not been updated since initial implementation and BIO now appreciates CMS’ examination of the list’s currency.

Overall, BIO believes that the current list is not a sufficient resource for information on rare cancers and certain circulatory and organ based cancers. In addition to supporting the list of journals submitted by the American Society of Clinical Oncology,³ BIO asks that the attached list of journals be added. All of these journals use a rigorous and unbiased peer review process before publication. Furthermore, including journals on the attached list would provide a broader international scope to patient care, exposing the local carrier to a more comprehensive understanding of the standard of care while maintaining the local decision making process. BIO developed this list through extensive research with our membership regarding which scientific publications are unbiased and, furthermore, provide quality scientific and clinical information.

In addition to adding these journals, BIO asks CMS to remind the carriers that the agency requires contractors to evaluate the evidence in peer-

¹ Off-Label Use of Anticancer Therapies: Physician Prescribing Trends and the Impact of Payer Coverage Policy, Sept. 2005, at 5, available at <http://www.bio.org/speeches/pubs/CovanceReport.pdf>.

² Social Security Act § 1861(t)(2).

³ May 4 letter from Dr. Joseph Bailes to CMS.

http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?from=whatsnew&id=9

reviewed medical literature while making coverage decisions. BIO is very concerned by recent local carrier decisions that explicitly state that they will no longer evaluate peer reviewed medical literature when making coverage decisions.⁴ Many carriers are implementing policies that state that they will not even examine peer reviewed medical literature when making coverage decisions.⁵ Unfortunately, this approach harms beneficiary access to potentially life saving therapies, and we urge CMS to remind the carriers of their obligation. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions.

Please feel free to contact me at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement &
Economic Policy
Biotechnology Industry Organization (BIO)

⁴ December 13 BIO letter to Noridian Administrative Services in response to LCDs DL20990, DL20994, DL20996, DL21591, and DL21593.

⁵ Id.