

March 14, 2008

Katherine Tillman, RN, MA
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop S3-02-01
Baltimore, MD 21244

Re: Adding Compendia for the Purposes of Making Medicare Coverage Determinations

Dear Ms. Tillman:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the recent compendium revision requests. BIO believes that compendia serve as a vital source of information regarding novel and life-saving therapies, and we urge CMS to protect beneficiary access to these therapies by recognizing all of the current applicants. 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 health-care, agricultural, industrial and environmental biotechnology products.

As the representative of an industry dedicated to discovering new therapies and ensuring patient access to them, BIO understands 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 more tolerable treatment regimens. These new treatment options often involve the use of drugs and biologicals for indications not initially approved by the Food and Drug Administration (FDA) and offer patients and physicians renewed hope and greater



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choice in fighting illness. These advances can be particularly important for patients with advanced stages of cancer.¹ As scientific advances are publicized through peer reviewed publications, scientific compendia often incorporate this information before it appears on the FDA label. Thus, compendia are an important resource for physicians when determining the most appropriate treatment regimen for their Medicare beneficiaries.² It is imperative, therefore, that both the Centers for Medicare and Medicare Services (CMS) and Medicare contractors ensure that coverage policies keep up with the pace of innovation and clinical discovery to allow Medicare beneficiaries timely access to the most appropriate treatment options as described in the peer reviewed literature and compendia in their battles against deadly diseases.

I. The Social Security Act Provides for Numerous Compendia

Congress recognized the importance of scientific compendia in expanding treatment options for cancer patients. In 1993, it amended the Social Security Act (SSA)³ to add to the definition of drug for purposes of coverage, “any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication.”⁴ The statute further defines medically accepted indication to include:

any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—(i) the drug has been approved by the Food and Drug Administration; and (ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical

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 *Id.* at 6.

³ Section 13553(b) of the Omnibus Budget Reconciliation Act of 1993 entitled, “Uniform Coverage of ‘Off-Label’ Anticancer Drugs.”

⁴ SSA § 1861(t)(2)(A).

Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia.⁵

In amending the SSA, Congress provided Medicare beneficiaries access to state-of-the-art cancer care by requiring coverage of cancer indications listed in one of the statutorily mandated compendia. Congress also intended for CMS to use multiple publications in making coverage decisions. As it considers compendia revision requests, CMS should honor Congress's clear intent and continue to recognize at least three compendia.

II. BIO Urges CMS to Recognize the Current Applicants as Recognized Compendia for Purposes of Medicare Coverage

CMS initiated a public process by holding a Medicare Coverage Advisory Committee (MCAC) meeting on March 30, 2006, entitled, "Compendia for Coverage of Off-label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen" to discuss evidence and hear presentations regarding the desired characteristics of published authoritative compendia that may be used by CMS to determine medically accepted indications of drugs and biologicals in an anti-cancer chemotherapeutic regimen.⁶ In preparation for the MCAC, CMS reviewed the legal authority governing the addition and removal of compendia and assessed the functionality of the compendia.⁷ The agency recently finalized a public process for adding or subtracting recognized compendia that it now is implementing.⁸

⁵ SSA § 1861(t)(2)(B).

⁶ 71 Fed. Reg. 4589 (January 27, 2006).

⁷ The Agency for Healthcare Research and Quality reviewed the six current compendia and issued a technology assessment available at <https://www.cms.hhs.gov/mcd/viewtecassess.asp?where=index&tid=46>.

⁸ 42. C.F.R. § 414.930.

Although Congress clearly intended Medicare contractors to use at least three compendia to allow Medicare beneficiaries access to state-of-the-art cancer care, only one of these statutorily listed compendia – American Hospital Formulary Service-Drug Information (AHFS) – is available today. The American Medical Association Drug Evaluations (AMA-DE) no longer is in publication, and United States Pharmacopoeia-Drug Information (USP-DI) is now published by Thomson Micromedex® under the name DrugPoints®. Fortunately, Congress recognized that available compendia might change over time and included in the statute a provision permitting the Secretary to revise the list of compendia as appropriate for identifying medically accepted indications for drugs.⁹ As noted above, the statute clearly reflects Congress’s intent for Medicare contractors to use a variety of compendia for coverage determinations. Because only the AHFS is currently in publication, BIO urges CMS to recognize additional compendia – including all of the current applicants – to ensure that Congressional intent is implemented.

Recognition of additional compendia will protect beneficiary access to advanced cancer therapies by providing physicians and policymakers with a wider body of evidence to use in making treatment and coverage decisions. Although all of the compendia are evidence-based, the content of the compendia may vary due to differences in publication schedules, priorities, review processes, local practices and methods of describing the evidence for each listing. To improve the chances of a treatment option being recognized by a compendium in a timely manner, we recommend that CMS continue to recognize multiple compendia for use in Medicare’s coverage decisions and allow each compendium the needed flexibility to add new indications.

As new compendia are added, BIO looks forward to working with you to ensure that implementation is clear and consistent with statutory requirements and Congressional intent. Our overarching goal is that Medicare beneficiaries have

⁹ SSA § 1861(t).

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timely access to all appropriate treatments, and we would like to meet with you after the addition of each new compendium to ensure this objective is met.

III. Conclusion

BIO urges CMS to add all of the current applicants to the list of recognized compendia. BIO's members are at the forefront of cancer care, as we constantly strive to convert cancer from a death sentence to a chronic disease with the ultimate goal of curing all cancer. We firmly believe that by CMS providing greater access to state-of-the-art care listed in a compendia, Medicare beneficiaries have a better chance of surviving a cancer diagnosis. Please feel free to contact John Siracusa at (202) 962-9200 if you have any questions regarding this letter. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

John A. Siracusa
Manager, Medicare Reimbursement
and Economic Policy

cc: Steve Phurrough, MD