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Association of Community Cancer Centers

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Michelle Atkinson
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Medicare Coverage Advisory Committee
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7500 Security Boulevard
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**Re: Characteristics of Compendia Used for
Medicare Part B Coverage of Drugs and
Biologicals Employed in an Anti-Cancer
Chemotherapeutic Regimen**

Dear Ms. Atkinson:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the desired characteristics of published authoritative compendia that may be used by the Centers for Medicare and Medicaid Services (CMS) to determine the medically accepted indications of drugs and biologicals employed in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program. ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 65% of all U.S. cancer patients.

ACCC is committed to ensuring that Medicare beneficiaries have access to quality cancer care. Cancer is a deadly disease, and patients often require treatment with the most innovative and cutting-edge therapies to win their battles against it. Although some advances in cancer care are made by developing new drugs,¹ many involve the discovery of new uses for drugs already approved for other indications by the Food and Drug Administration (FDA). This “off-label” use of cancer drugs is a common medical practice that is a critical component of many treatment regimens and is integral to the discovery of new cures.

The Medicare statute recognizes the importance of innovation in cancer care by requiring carriers to cover off-label uses of cancer drugs that are supported by citations in the American Hospital Formulary Service-Drug Information (AHFS-DI), the United States Pharmacopoeia-Drug Information (USP-DI) or its successor publications, or the American Medical Association Drug Evaluations or by clinical evidence in peer-reviewed literature.² This requirement protects beneficiary access to innovative therapies, used in conformity with evolving standards of care.

The statute also allows the Secretary to revise the list of compendia “as is appropriate for identifying medically accepted indications for drugs.”³ The statute also allows the Secretary to recognize a successor publication if the name of a statutorily designated publication is changed.⁴ The American Medical Association Drug Evaluations ceased publication, so only two of the compendia listed in the statute are available in updated forms for use in Medicare coverage decisions.

ACCC thanks the Medicare Coverage Advisory Committee (MCAC) for calling this meeting to evaluate the desirable characteristics of any additional compendia used for Medicare coverage decisions. The questions published on the CMS website for discussion at this meeting address the compendia in general as well as the AHFS-DI and USP-DI. Because the AHFS-DI and the USP-DI and its successor publications are identified specifically in the Medicare statute, we have

¹ We use the term “drugs” throughout these comments to refer to both drugs and biologicals.

² Social Security Act (SSA) § 1861(t)(2), as amended by the Deficit Reduction Act, S. 1932, § 6001(f) (signed by President Bush on Feb. 8, 2006).

³ SSA § 1861(t)(2)(B).

⁴ SSA § 1873.

addressed our comments to the criteria for identifying additional compendia for use in Medicare coverage decisions. Although we do not endorse any particular compendia, we have identified the following characteristics that any additional compendium should have.

The compendium must include an extensive breadth of listings that reflect the widely varied nature of cancer. There are hundreds of types of cancer, and most have multiple treatment regimens. The compendium's listings must be broad enough to encompass the full range of accepted treatment options for different forms and stages of tumors.

The compendium must demonstrate the flexibility to rapidly integrate literature, and the updates must be readily accessible. Delays of months, and sometimes years, between the announcement of significant clinical research outcomes and their inclusion in the compendia can obstruct Medicare beneficiaries' access to care. The compendium must review applications for new listings and revisions to listings in a timely manner and must be revised frequently to incorporate the latest developments in cancer care. The updated listings must be made available in a convenient and readily accessible location, such as on a website.

The compendium must use a clearly described and transparent application and review process for new listings and revisions to listings. As new treatment options are developed, researchers, physicians, and patients will need to know how to request that the regimens be included in the compendium. The compendium must describe the application process, including the information required to submit a request, the criteria for review of that information, and the process used to determine what the published listing for the request will be. Additionally, the compendium should employ a transparent process for reviewing applications, including opportunity to respond to reviewers' questions. If the reviewers find the evidence supporting a request to be not validated or equivocal, the reviewers should explain why.

The compendium must consider data from various types of trials. While randomized controlled trials (RCTs) are recognized as the gold standard for clinical research, they cannot be performed for every condition. Small patient populations and the high cost of RCTs often prevent therapies for rare cancers from being studied in these trials. In these cases, data from Phase II trials can be very important, and in fact may be the only data available. Accordingly, the compendium must not limit its review to large RCTs, but instead must consider data from other types of trials as well. This premise similarly extends to acknowledging negative trial findings.


The compendium must provide clearly written entries that describe the evidence for each use. A publication is useful to physicians and carriers only if it presents information on treatment options in clear language and an easily understood format. In addition to indicating whether a use is accepted, the compendia should describe the evidence reviewed for each listing. This will help readers understand the publisher's basis for its recommendation and will allow physicians and carriers to determine whether the listing incorporates the latest research. If the compendium uses a rating system for the strength or quantity of evidence supporting a use, it must explain what each rating means. Each time a listing is revised, the date of the revision should be clearly noted in the listing so that physicians and carriers can be sure that they are relying on the most recent edition.

Finally, the Secretary should continue to recognize at least two publications for use in Medicare carriers' coverage decisions. Because cancer care is constantly changing, it is highly unlikely that any one publication could describe all of the medically accepted treatment options for every variety of cancer at any given point in time. Each publication applies slightly different standards for inclusion and different methods of indicating whether a use is supported by clinical evidence and the weight of that evidence. Each publication also has a unique review and publication schedule. Medicare's recognition of multiple compendia will provide physicians and carriers with more data regarding current treatment options. By recognizing multiple compendia, CMS will increase the likelihood that at least one compendium will recognize a new development in a timely manner.

ACCC is aware that the MCAC has been tasked with determining, and possibly ranking, additional characteristics that are desirable and of high priority in a robust, evidence-based compendium. ACCC is concerned about several of the characteristics identified in the MCAC's questions for this meeting, and indeed believe them to be totally irrelevant. For example, it would be inappropriate for the compendium to establish explicit recommendations on the sequential use of therapies or combination in relation to other therapies because different sequences for different patients are appropriate, and indeed needed. Additionally, the compendium should not be expected to provide net benefit analysis based on harm and potential benefit. This analysis is impossible to perform meaningfully because individual comorbidities require a different assessment for each patient. For the same reason, we argue against any type of stratification of the risks of available therapies. ACCC also believes that the compendium should remain silent when the evidence on a use is equivocal. Issuing a "not recommended" listing when the evidence supporting a use is equivocal could cause carriers to deny coverage of that use for all patients. If the compendium remains silent, however, carriers could continue to cover the use on a case-by-case basis until more data are available.

We appreciate the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact ACCC's staff person, Deborah Walter, at (301) 984-5067, if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "E. Strode Weaver". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

E. Strode Weaver, FACHE, MBA, MHSA
President, Association of Community Cancer
Centers