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March 21, 2006

Empire Medicare Services
Contractor Medical Director
2651 Strang Boulevard
Yorktown Heights, NY 10598

Re: Proposed Local Coverage Determination – “Off Label Coverage of FDA –
Approved Drugs”

Dear Sir or Madam:

The American Society of Clinical Oncology (ASCO) submits these comments concerning your draft local coverage determination (LCD) for off-label uses of drugs approved by the Food and Drug Administration (FDA). As the national organization representing physicians and other health care professions that specialize in cancer care, ASCO has a strong interest in the medically appropriate uses of cancer therapies and in the correct implementation of federal law applicable to those uses.

The Proposed LCD

Under the proposed LCD, you would maintain a list of drugs approved for off-label uses not yet listed in the two compendia recognized by Medicare, *United States Pharmacopoeia - Drug Information* (USP-DI) and *American Hospital Formulary Service* (AHFS). In order to have an off-label use included in the list—and thus eligible for coverage—providers must submit data demonstrating safety and effectiveness in (1) at least two phase III clinical trials or (2) alternatively, at least two phase II trials in circumstances where small numbers of patients make phase III trials impracticable or where the phase II studies reflect overwhelming evidence of safety and effectiveness. The phase III or phase II trials supporting coverage of off-label uses must be conducted in different centers.

The proposed LCD envisions that the results of supporting studies be published in peer-reviewed medical or scientific journals and not in publications controlled by industry or in compilations of meeting abstracts.

Finally, under the proposed LCD, you, as the Medicare contractor, would utilize certain additional criteria to determine the quality and acceptability of the supporting trials. Among the variables you would consider in making the coverage decision are number of subjects, response rates and overall trial design. You would also seem to require “published recommendations from specialty societies or . . . other authoritative evidence-based guidelines” as a prerequisite to coverage.

ASCO’s Concerns

Under § 1861 (t)(2)(B)(ii)(II) of the Social Security Act, Medicare must cover an off-label use of a drug included in an anticancer chemotherapeutic regimen, even if the use is not listed in the compendia, when a carrier determines that the use is supported by evidence in the peer-reviewed medical literature. Implementing this requirement, the Medicare Policy Manual, Chapter 15, § 50.4.5.D, states:

2006 Annual Meeting
June 2–June 6, 2006
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“In determining whether there is supporting clinical evidence for a particular use of a drug, carrier medical staff (in consultation with local medical specialty groups) will evaluate the quality of the evidence in published peer reviewed medical literature.”

ASCO believes that the criteria imposed by the proposed LCD are inconsistent with the letter as well as the spirit of the statutory and manual provisions.

ASCO was intimately involved in the 1993 legislation that led to statutory support for off-label uses of cancer drugs. We are therefore aware that the Congressional sponsors of the legislation intended to provide not only the predictability and reliability that flows from reliance on the medical compendia, but also the flexibility and rapid access afforded by reliance on reports in peer-reviewed literature. The rigid and prescriptive approach reflected in the proposed LCD seriously undermines the role of peer-reviewed literature in guiding coverage determinations that are medically appropriate but not yet included in the medical compendia.

The requirements articulated in the proposed LCD for phase III and phase II trials as the basis for coverage of off-label uses exceed those that are found in many recent approvals of new anti-cancer drugs by FDA. Thus, the proposed LCD would erect a higher barrier for coverage of off-label uses than the FDA itself would expect for a new drug application (NDA) or for approval of new uses through a supplemental new drug application (SNDA). This impediment to Medicare coverage of off-label uses is inconsistent with the intent of Congress in passing the statutory provisions for protection of off-label uses of cancer drugs by Medicare beneficiaries.

ASCO urges that the proposed LCD be withdrawn or amended to omit detailed criteria regarding standards for coverage. The pace of change in cancer care is rapid, and fixed criteria for coverage may not serve the needs of cancer patients. Instead, ASCO suggests that you utilize the existing Carrier Advisory Committee (CAC) structure for consultation with affected specialties to ensure timely identification of medically appropriate off-label uses through the peer-reviewed literature.

Conclusion

ASCO and its members are eager to work with you to establish a review process that achieves the Congressional purpose by utilizing reports of clinical studies in peer-reviewed literature to ensure that Medicare beneficiaries have timely access to potentially life-extending therapies even though they may not yet have been recognized by the FDA or the medical compendia. We appreciate the opportunity to comment on the proposed LCD and look forward to working with you to achieve the results intended by Congress that will also best serve the interests of our patients and your Medicare beneficiaries.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD
Co-Chair, Government Relations Council

cc: Eileen M. Moynihan, MD
Norbert Rainford, MD
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Nancy Izzo