



November 18, 2004

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Request for Comment Period Extension on Draft Decision
Memorandum for Anticancer Chemotherapy for Colorectal
Cancer (CAG-00179N)**

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) respectfully requests an extension of the comment period on the Centers for Medicare and Medicaid Services' (CMS) draft coverage decision memorandum for anticancer chemotherapy for colorectal cancer (CAG-00179N).

Currently, the comment period for this proposed coverage decision is only 30 days. Given the impact this decision would have on patient access to our member companies' products, as well as on the development of future therapies, we request an extension of 60 days so that we may assess this complex proposal thoroughly before providing detailed comments.

As CMS recently acknowledged, the agency has developed a new role for Medicare by using its coverage decisions to expand clinical research of drugs and biologicals.¹ This proposed national coverage determination (NCD) is a significant component of this new interpretation of Medicare's

¹ Gina Kolata, Medicare Covers New Treatments With a Catch, New York Times, Nov. 5, 2004 (quoting Dr. Sean Tunis on a "whole new role for Medicare").

responsibilities. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe, and we are committed to ensuring that patients have access to our therapies. Although we appreciate that the NCD appears to expand coverage for the therapies it addresses, we are concerned about its longer term implications as well as resolving the numerous questions raised by this draft.

Specifically, the proposed NCD offers us only 30 days to comment not only on the coverage of the four colorectal cancer therapies, but also on several other complex issues that relate to patient access to other innovative therapies. These issues include guidance to contractors regarding off-label uses of these and other therapies, methods of incorporating public input in the trial selection process, beneficiary participation in selected clinical trials, programs to cover and collect data on off-label uses of drugs and biologicals in non-clinical trial settings, and improving the timeliness of local coverage determinations regarding off-label uses. We believe that the 30-day comment period is insufficient for us, or other interested parties, to provide thoughtful comments on all of the significant issues raised by this draft NCD.

In addition to the significant number of complex topics to address in our comments, BIO believes that the late addition of these issues to the NCD's scope warrants an extension to the comment period. Although CMS initiated the review process for this NCD 20 months ago, the salient issues of the draft decision memorandum were not introduced into the review process until very recently. CMS added bevacizumab (Avastin™) and cetuximab (Erbix™) to the review only two months ago, and none of the clinical trial matters in the draft NCD were subject to public comment previously in the review process. In fact, CMS' summary of the comments filed in 2003 reveals that few, if any, of the topics raised by the draft NCD were part of the review's original scope. To fully consider all of the recent, substantial changes in the NCD's focus, we need more than 30 days.

CMS can extend the comment period for this proposed NCD without concern about violating the statutory timeframe. CMS has indicated that the Medicare Modernization Act's amendments to the NCD development

process are “effective for NCDs undertaken on or after January 1, 2004.”² Because CMS initiated this NCD on February 12, 2003, it does not appear to be subject to the statutory deadlines. CMS therefore can choose to extend the comment period for an additional 60 days, and postpone the NCD’s effective date if necessary.

Alternatively, if CMS determines that the statutory deadlines apply to this NCD, it could extend the comment period and still conclude the NCD review process on time. Social Security Act section 1862(l) requires CMS to issue a draft NCD within 6 months of a request for an NCD, followed by a 30-day comment period and a 60-day decision period. The statute demonstrates Congress’ understanding of the importance of public input into CMS’ coverage decisions, while also requiring CMS to act promptly on requests for NCDs. Ordinarily, the statute’s timeline would allow interested parties up to 7 months to study and evaluate the issues involved in the proposed NCD. This might be enough time for meaningful comments when an NCD request is externally generated and the public has been involved in the process from the beginning. However, CMS initiated this NCD process through an internal request, and the agency should take particular care to ensure that all affected parties have adequate time to assess the draft NCD. Here, CMS set the final scope of the NCD review only two months ago, and the agency raised several issues for comment for the first time in this draft NCD. In the interests of allowing meaningful public comment, we respectfully request that CMS extend the comment period for an additional 60 days. The additional time would provide CMS with more substantial comments, while also giving the agency time to fully consider and respond to those comments.

Historically, CMS has extended its comment periods to allow for additional public comment on significant policy proposals. For example, in January 2004, CMS extended the comment period for its proposed rule regarding prospective payment systems for inpatient psychiatric facilities for an additional 30 days. CMS explained that it granted the extension “due to the scope and complexity of [the] proposed rule” and because commenters requested additional time “so that they may provide meaningful comments

² CMS, Changes to the National Coverage Determination Process, [available at](http://www.cms.hhs.gov/coverage/8a4.asp) <http://www.cms.hhs.gov/coverage/8a4.asp>.

on its provisions.”³ CMS also extended the comment periods in the development of this NCD twice.⁴ We ask CMS to call upon previous precedent to extend this courtesy once again. We believe that an additional 60 days would help us and other interested parties to respond thoughtfully with comments that will help CMS’ implementation of this NCD and other coverage decisions.

Thank you for your consideration of this request.

Sincerely,

/s/

Michael Werner
Chief of Policy,
Biotechnology Industry Organization

cc: Sean Tunis, Director, Office of Clinical Standards and Quality
Steve E. Phurrough, MD, MPA, Director, Coverage and Analysis
Group
James A. Rollins, MD, Coverage and Analysis Group
Gay W. Burton, Coverage and Analysis Group

³ 69 Fed. Reg. 4464 (Jan. 30, 2004).

⁴ NCA Tracking Sheet for Anticancer Chemotherapy for Colorectal Cancer (CAG-00179N), [available at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=90](http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=90).