December 13, 2005

Contractor Medical Directors
Policy Development
Medicare Part B
Noridian Administrative Services
901 40th St S, Suite 1
Fargo, ND 58103-2146

Re: Part B Local Coverage Determinations Regarding Drugs and Their Covered Diagnoses (LCD numbers DL20990, DL20994, DL20996, DL21591, and DL21593)

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on Noridian Administrative Services' (NAS) draft Part A and Part B local coverage determinations (LCDs) regarding drugs and their covered diagnoses (LCD numbers DL20990, DL20994, DL20996, DL21591, and DL21593). 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 1,000 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.

We are concerned that NAS' draft LCDs would limit or delay beneficiary access to critical, medically-accepted therapies. As the representative of an industry dedicated to discovering new therapies and ensuring patient access to them, BIO understands that the practice of medicine is constantly evolving through the incorporation of new clinical evidence into the standard of care. In oncology, for example, the standard of care advances approximately every six months, if not sooner, as clinical research discovers effective new 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 new hope and greater choice in fighting illness and can be particularly important for patients with advanced stages of cancer.[1] It is imperative, therefore, that Medicare contractors ensure that their coverage policies keep up with the pace of innovation and clinical discovery to allow beneficiaries timely access to the most appropriate treatment options.

BIO strongly supports the authority and discretion Congress has granted to Medicare carriers and fiscal intermediaries to cover newly recognized, medically accepted uses of drugs and biologicals in a timely manner. Congress recognized the critical role of new clinical uses of drugs and biologicals in fighting cancer when it enacted the Medicare statute's requirement to cover indications of drugs used in anticancer regimens if they are listed in the United States Pharmacopeia-Drug Information (USP-DI) or American Hospital Formulary Service-Drug Information (AHFS).[2] Contractors also are granted the discretion to ensure beneficiary access to important drugs and biologicals if they determine that the use is supported by peer-reviewed medical literature or that the use is "medically accepted generally as safe and effective for the particular use."[3] In its longstanding guidance to contractors, CMS has expanded upon Congressional intent to protect beneficiaries' treatment choices by permitting coverage of new indications of drugs not used in an anticancer chemotherapeutic regimen if

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[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)(B)(i)(I).

[3] Social Security Act § 1861(t)(2)(B)(i)(II); Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.5.

the contractor "determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."[4]

BIO supports these standards for identifying medically accepted indications because they help to protect beneficiary access to the most appropriate treatment options. We believe it is particularly important that contractors consider the particular needs of individual patients when deciding whether to cover a specific use of a drug or biological. When new research indicates that a therapy is effective, contractors should allow patients to benefit from that treatment option by covering it without delay. For example, at the May 2005 meeting of the American Society of Clinical Oncology, researchers presented results from three clinical trials that found that Herceptin® (trastuzumab) used in combination with chemotherapy in the adjuvant setting dramatically increased breast cancer patients' chances of disease-free survival. These results demonstrated that an immediate change in clinical practice could significantly improve patient outcomes. Because Medicare allows contractors the latitude to cover new treatments that become part of accepted standards of clinical practice, Medicare beneficiaries should have the option to receive this regimen immediately, rather than having to wait until it was included in the compendia or published in peer-reviewed literature months later.[5]
Such a delay in treatment could be critical to the survival of Medicare beneficiaries with cancer.

We are concerned that NAS' draft LCDs would limit or delay beneficiary access to advanced, medically-accepted therapies because they do not reflect the full scope of Medicare's coverage requirements for uses of drugs and biologicals. We urge NAS to revise these policies to ensure that they are consistent with the Medicare statute, CMS' guidance, and each other. NAS' draft LCDs address the statutory requirements and manual guidance regarding drugs used for FDA-approved diagnoses and diagnoses that are recognized as accepted by the USP-DI or AHFS. They

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[4] Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.2.

[5] The USP-DI updated its entry for trastuzumab on September 19, 2005 to include the adjuvant use of the therapy in breast cancer treatment. See Revised Monographs at http://uspdi.micromedex.com/v1. This update occurred much more quickly than is typical. The clinical trials' results were published in the New England Journal of Medicine on October 20, 2005. E.H. Romond et al., Trastuzumab Plus Adjuvant Chemotherapy for Operable HER2-Positive Breast Cancer, 353 N. Engl. J. Med. 1673-1684 (Oct. 20, 2005); M.J. Piccart-Gebhart et al., Trastuzumab After Adjuvant Chemotherapy in HER2-Positive Breast Cancer, 353 N. Engl. J. Med. 1659-1672 (Oct. 20, 2005).

do not acknowledge the requirement in the Medicare Benefit Policy Manual that is binding on contractors, however, to cover additional medically accepted uses that are not described in the compendia.[6] Specifically, if a use does not appear in the compendia, CMS requires contractors to "contact the compendia to see if a report regarding this use is forthcoming."[7] If the report is forthcoming, the contractor shall base its decision on that report. If no report is forthcoming, the contractor shall evaluate the evidence in peer-reviewed medical literature, in consultation with local medical specialty groups.[8] NAS should revise the statements in its draft LCDs that it "has the option to consult" or "may consult" the peer-reviewed medical literature to say that it will consult such literature if a use does not appear in the compendia. Such a change is necessary to ensure NAS' policy complies with CMS' longstanding policy manual provisions and to allow contractors the opportunity to use the discretion given to them by Congress.

We also believe that the Part B draft's description of the meaning of a compendia listing is inaccurate, and we recommend that NAS use the Part A draft's language because it is clearer, more thorough, and more accurate. The Part B draft says, "NAS covers those drugs for off-label diagnoses that are approved by one of two compendia: USP DI and AHFS: Drug Information." (emphasis added.) We disagree with this description of the compendia's role in identifying medically accepted uses for drugs and biologicals. The compendia do not approve diagnoses, but instead identify diagnoses that are supported by clinical data. The Part A draft correctly describes the compendia as recognizing, not approving, additional diagnoses. BIO recommends that this language be used in both the Part A and Part B draft LCDs.

Additionally, we are concerned that NAS appears to rely on the USP-DI to provide timely summaries of recent clinical research findings rather than performing its own review of the literature or otherwise examining whether the use is medically accepted. Although both drafts appropriately recognize the importance of consulting the most up-to-date versions of the compendia, including monthly updates, the Part B draft also notes that NAS presumes that the USP-DI has consulted the relevant recent literature for

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6 Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.5.

7 Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.5.

8 Id.

its monthly updates. In our experience, we have found that the USP-DI can take months to revise their monographs to reflect new clinical literature. As such, NAS should not rely on the compendia to include all relevant recent literature, but instead should follow the procedures described in the Medicare Benefit Policy Manual, as described above. Specifically, we recommend that NAS delete the following text from paragraph A of the Part B draft LCDs: "and therefore has, NAS presumes, consulted the relevant recent literature."

We appreciate the explanation provided in the Part A draft that coverage determinations for additional uses that are not in the compendia "may be done on a one-time basis as individual considerations or may apply to all providers." We ask NAS to include this statement in the Part B draft as well. We urge NAS to continue to cover uses currently recognized in existing LCDs.

We sincerely hope that NAS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Jayson Slotnik 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 and Economic Policy
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cc:
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