



October 31, 2006

Contractor Medical Directors
Policy Development
Attention: Part B J3 LCD Comments
Noridian Administrative Services
901 40th St. S, Suite 1
Fargo, ND 58103-2146

**Re: Local Coverage Determinations Regarding Drugs and Their
Covered Diagnoses and Gonadotropin Releasing Hormone Analogs**

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 and the draft Part B LCD for gonadotropin releasing hormone (GnRH) analogs for Medicare Administrative Contractor (MAC) Jurisdiction 3. 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.

I. Draft Consolidated Policies for Drugs Used Incident to a Physician's Service

BIO understands that NAS was selected by the Centers for Medicare and Medicaid Services (CMS) in July as the first Part A/B MAC for Jurisdiction 3, a region consisting of Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming. Prior to assuming the claims processing functions for the Jurisdiction 3, NAS has been instructed to consolidate the existing LCDs in each state so that the same policies apply throughout the entire MAC region. NAS has posted draft consolidated Part A and Part B policies for a number of coverage topics, including the covered diagnoses for drugs used “incident to” a physician’s service. The draft consolidated Part A and Part B LCDs for “incident to” drugs are a restatement of policies in effect in states for which NAS currently serves as either the carrier or fiscal intermediary or both. BIO’s comments reiterate some of our concerns on the initial NAS draft LCDs, as well as raise additional concerns based on the final NAS LCDs that are now proposed for Jurisdiction 3.

BIO previously submitted comments on NAS draft LCDs concerning Part B drugs and their covered diagnoses, expressing our concern that these policies would limit or delay beneficiary access to critical, medically-accepted therapies.¹ We also understand that, in proposing the consolidated LCDs for Jurisdiction 3 on this topic, NAS has largely elected to maintain the same Part B policy currently in place in five of the six Jurisdiction 3 states and the Part A policy in place in two of the six states. BIO continues to believe that aspects of these policies may harm Medicare beneficiary access to innovative therapies, and urges NAS to make revisions prior to their adoption throughout the entire MAC Jurisdiction.

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

¹ BIO Letter to NAS Regarding LCDs for Drugs and Their Coverage Diagnoses, Dec. 2005, available at: <http://www.bio.org/healthcare/medicare/20051214.pdf>

can be particularly important for patients with advanced stages of cancer.² 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.

As stated in our previous comments,³ BIO strongly supports the authority and discretion Congress has granted to Medicare contractors 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).⁴ The importance of the compendia used for this purpose was reaffirmed by CMS through a meeting of the Medicare Coverage Advisory Committee held in March, which focused on desirable characteristics of compendia used for Medicare coverage decisions. 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."⁵ 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 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."⁶

While BIO appreciates that NAS has attempted to address several issues raised in our previous comments, we remain concerned that elements of the NAS' draft consolidated LCDs for Jurisdiction 3 would limit or delay beneficiary access to advanced, medically-accepted therapies. BIO urges NAS to further revise these policies to ensure that they are consistent with the Medicare statute, CMS' guidance, and each other.

² 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>.

³ BIO Letter to NAS, Dec. 2005.

⁴ Social Security Act § 1861(t)(2)(B)(i)(I).

⁵ Social Security Act § 1861(t)(2)(B)(i)(II); Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.5.

⁶ Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.2.

A. NAS should affirm its obligation to consult the peer-reviewed medical literature for additional medically-accepted uses.

NAS' draft consolidated LCDs address the statutory requirements and manual guidance regarding drugs used for FDA-approved indications/treatments and indications/treatments that are recognized as accepted by the USP-DI or AHFS. However, as BIO has commented previously, NAS does not acknowledge the requirement in the Medicare Benefit Policy Manual that is binding on contractors to cover additional medically accepted uses that are not described in the compendia.⁷ 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.”⁸ 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 literature, in consultation with local medical specialty groups.⁹ Thus, we again urge NAS to revise the statement in its Part B draft that it “has the option” to say that it will include additional medically-accepted off-label indications/treatments identified in the peer-reviewed medical literature that USP-DI and AHFS do not appear to have taken into account. NAS should also revise the Part A draft to say that it will consult the relevant peer-reviewed literature if a use does not appear in the compendia. These revisions are necessary to ensure NAS' policies comply with CMS' longstanding policy manual provisions and to allow contractors the opportunity to use the discretion given to them by Congress.

B. NAS should conduct its own review of the peer-reviewed medical literature for additional medically-accepted diagnoses rather than rely on physicians to provide supporting publications.

BIO is also concerned with NAS' statement in the draft consolidated Part B LCD that it will “exercise” its option to consult additional off-label indications in the medical literature when such publications are provided by a “physician or other resource.” BIO believes that this statement does not adhere to the intent of the Medicare Benefit Policy Manual, which requires Medicare contractors to consult the peer-reviewed literature, rather than shifting this responsibility to physicians or other entities to identify and provide information regarding relevant publications. BIO urges NAS to revise this statement to reflect the contractor's obligation to perform this review.

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

⁸ Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 15, § 50.4.5.

⁹ Id.

C. NAS should finalize language in the draft LCDs regarding the meaning of a compendia listing.

BIO applauds NAS for revising the language from its original Part B draft LCD to describe the meaning of a compendia listing. We believe that both the Part A and Part B draft consolidated LCD descriptions of the meaning of a compendia listing are more accurate than the original NAS draft LCDs. By referring to treatments listed in the compendia, rather than approved by the compendia, we believe that the Jurisdiction 3 draft policies more accurately capture the role of the compendia of identifying, rather than approving, medically-accepted uses for drugs and biologicals. BIO recommends that NAS adopt this language in the final Jurisdiction 3 policies.

D. NAS' should follow the procedures described in the Medicare Benefit Policy Manual to determine additional medically-accepted uses rather than rely on monthly compendia updates.

BIO reiterates our concern 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 consolidated LCD 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 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, BIO recommends that NAS delete the following text from paragraph A of the Part B draft consolidated LCD: “and therefore has, NAS presumes, consulted the relevant recent literature.”

E. NAS should clarify the scope of the LCD.

BIO appreciates the explanation provided in the Part A draft consolidated LCD 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 again ask NAS to include this statement in the Part B draft as well. In addition, to avoid confusion, NAS should clearly state that these LCDs would

only apply to drugs not recognized in other LCDs or otherwise explicitly covered under Part B statute. For example, the Part B draft states that NAS will cover those drugs that are “not usually self-administered.” However, this statement does not address existing statutory Part B coverage for certain self-administered drugs, such as transplant-related immunosuppressive drugs and oral anti-emetics. Therefore, BIO urges NAS to amend this language to reflect the fact that these policies would not apply to Part B coverage afforded to certain drugs under the other statutory provisions, including special delivery formats or formulations.

F. NAS should continue to rely on the CAC process.

BIO believes in the value of the CAC process and we encourage NAS to quickly employ it into their LCD process. BIO urges NAS to allow the CAC to have some oversight during the LCD transition process to help ensure that Medicare beneficiaries’ best interests are met during this process.

BIO also encourages NAS to make the CAC a central part of their long term LCD process to maintain the link between the practicing physician and the policy process so that policy can keep pace with the ever evolving “practice” of medicine at the local level.

II. Draft Policies for GnRH Analogs

BIO also is concerned that the draft LCD for GnRH analogs will limit beneficiary access to critical therapies that are used to treat cancer and other serious conditions. In the draft LCD, NAS proposes to apply a “least costly alternative” (LCA) policy to several GnRH analog therapies. Under this policy, NAS “will pay for the dosage administered for any of these drugs only at the rate approved for the lowest-priced drug approved for the given indication.”¹⁰ If the physician believes that a different drug is more appropriate for the patient, and the patient signs an advanced beneficiary notice, the patient may be charged for the difference between the reimbursement of the more expensive medication and the less expensive medication.¹¹ The draft LCD makes no exceptions for medical necessity or for patients who are already receiving a drug at the time the policy becomes applicable.

¹⁰ NAS, Gonadotropin Releasing Hormone Analogs, Draft LCD J3 CB2006.16.

¹¹ Id.

We urge NAS to reconsider this LCD. NAS has failed to comply with CMS' instructions and NAS' own policy of using the "least restrictive" approach to consolidating LCDs.¹² The Statement of Work instructs carriers to consolidate LCDs by selecting the "least restrictive LCD from the existing LCDs on a single topic."¹³ Of the three LCDs in place in the Jurisdiction 3 states, NAS selected the most restrictive policy – one that applies LCA to all covered GnRH analogs – instead of one of the two less restrictive policies that either do not apply LCA¹⁴ or that apply LCA to only two drugs and allow exceptions for medical necessity and for patient who began GnRH analog therapy before the policy became applicable.¹⁵

NAS should apply Montana's LCD, which does not include an LCA policy, to Jurisdiction 3 because it is the least restrictive of the LCDs currently in place and will best protect beneficiary access to care. We believe that the LCDs with LCA policies would restrict beneficiaries' access to the most appropriate drug for their condition. This is a concern particularly for low-income beneficiaries who cannot afford to pay the difference in reimbursement for the preferred drug. By encouraging physicians and beneficiaries to select a therapy on the basis of its reimbursement, not its clinical qualities, an LCA policy also could interfere with the physician-patient decision-making process and deny access to the most appropriate care, particularly for low-income beneficiaries. The drugs and biological products addressed by this draft LCD – goserelin acetate, triptorelin pamoate, leuprolide acetate, and histrelin implant – are unique therapies, with different active ingredients, indications, dosage forms, and dosage schedules. The Food and Drug Administration (FDA) recognizes no therapeutic equivalents for any of these therapies. We urge NAS to adhere to the FDA's judgment and not treat these therapies as though they were interchangeable by applying an LCA policy to them.

Additionally, by not applying an LCA policy, the Montana LCD complies with the market-based payment reforms implemented by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This LCD allows

¹² See Jurisdiction 3 Local Coverage Determinations, https://www.noridianmedicare.com/maci3/lcd_policies/index.html ("our objective has been to create medically sound and appropriate policies based on the policies currently in place. One of the key concepts in this process is to take the "least restrictive" approach to the consolidation.")

¹³ Centers for Medicare and Medicaid Services, Department of Health and Human Services. "Part A and Part B Medicare Administrative Contractor Statement of Work: Draft. § C.5.1.1.7 (May 3, 2006).

¹⁴ Blue Cross and Blue Shield of Montana, LCD for Leuprolide Acetate, L11327 (LCD applicable in Montana).

¹⁵ Noridian Administrative Services, LCD for Gonadotropin-Releasing Hormone Analogs, L9951 (LCD applicable in Utah).

each drug or biological product to be reimbursed at its own payment rate of 106 percent of the drug's average sales price (ASP), as required by the MMA.¹⁶ In contrast to these clear instructions, LCA policies disregard the statute's methodology by using the payment rate for one drug as the basis for payment for another drug that does not share the same billing and payment code.¹⁷ We urge NAS to apply the Montana LCD to ensure that each drug is reimbursed at its own ASP-based rate.

In the alternative, if NAS decides to apply an LCA policy to GnRH analogs, it should adopt Utah's LCD for Jurisdiction 3. This LCD allows exceptions to the LCA policy when a particular therapy is medically necessary or if the patient received the therapy before the effective date of the policy or before becoming eligible for Medicare. These exceptions are critical to protecting beneficiary access to appropriate care. The Utah LCD also applies LCA to 12-month implantable GnRH analogs only. While all of the GnRH analogs are unique therapies, the 12-month implantable therapies are administered on a common schedule, use the same method of administration, and are prescribed for patients with the same illness. In contrast, the other GnRH analogs are used to treat several conditions as highlighted in FDA approved product labeling and compendia, and even when used for the same condition, are administered through different techniques, such as an implant or intramuscular or subcutaneous injection. These therapies also are administered at different frequencies for varying lengths of time, such as monthly, every three months, every four months, and for one to six months or more. Because these therapies have such great variations in indications, administration techniques, dose, dosage frequencies, and length of course of treatment, treating these therapies as if they were interchangeable by applying an LCA policy is particularly troubling.

III. Conclusion

In conclusion, BIO urges NAS 1) to affirm its obligation to consult the peer-reviewed literature for additional medically-accepted diagnoses, 2) to conduct its own review of the peer-reviewed medical literature, 3) to finalize language in the

¹⁶ The draft LCD incorrectly states that payment for new drugs without established ASPs is based average wholesale price (AWP).

¹⁷ In fact, the statute allows only two exceptions to the ASP-based payment methodology, which neither allow for the use of LCA policies nor apply here. These exceptions are (1) use of the widely available market price or 103 percent of average manufacturer price if the Inspector General finds that the ASP for a drug or biological exceeds the widely available market price or average manufacturer price for such drug or biological by an applicable threshold percentage (SSA § 1847A(d)(3)), and (2) use of WAC instead of ASP during a public health emergency that affects access to drugs and biological products (SSA § 1847A(e)).

draft LCDs regarding the meaning of a compendia listing, 4) to follow the procedures described in the Medicare Benefit Policy Manual to determine additional medically accepted uses, and 5) to clarify the scope of the LCDs. We also urge NAS to protect beneficiary access to appropriate care by not applying an LCA policy to GnRH analogs. If NAS decides to apply an LCA policy, it must limit it to 12-month implantable therapies and allow exceptions for medical necessity and patients already receiving care.

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/

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