June 2, 2006

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1055 West 7th Street, Suite 500
Los Angeles, CA 90017

Re: Draft Local Coverage Determination for Gonadotropin-Releasing Hormone Analogs (Revised DL22520 and DL22568)

Dear Dr. Quinn:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on National Heritage Insurance Company's (NHIC) draft local coverage determination (LCD) for gonadotropin-releasing hormone analogs (LCD number DL22520 and DL22568). 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.

NHIC Should Not Apply a Least Costly Alternative Policy to Gonadotropin-Releasing Hormone Analogs

We are concerned that NHIC's draft LCD would exert inappropriate control over the patient/physician decision-making process[1] that is essential to quality care

[1] Social Security Act (SSA) § 1801

and would limit or delay beneficiary access to critical, medically-accepted therapies. By applying least costly alternative (LCA) policies to gonadotropin-releasing hormone analogs, NHIC could prevent beneficiaries from receiving the most appropriate treatment for their conditions. The drugs and biological products addressed by this draft LCD – goserelin acetate, triptorelin pamoate, leuprolide acetate, histrelin implant, and histrelin acetate – 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 NHIC to adhere to the FDA's judgment and not treat these therapies as though they were interchangeable by applying an LCA policy to them.

Applying an LCA policy to these therapies not only conflicts with the FDA's conclusions that they are not therapeutically equivalent, it also disregards the Medicare statute's payment provisions. In particular, it disregards the market-based payment reforms implemented by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The draft LCD cites Social Security Act section 1862(a)(1)(A) as a source of authority for the use of LCA policies. This section governs coverage by defining the services for which Medicare will pay, however, not the amount that must be paid for those services. Section 1847A establishes the payment rates for drugs and biological products administered and billed by physicians. Under this section, reimbursement for these therapies is set at 106 percent of the drug's average sales price (ASP) or, for new drugs without established ASPs, is based on wholesale acquisition cost (WAC).[2] The statute also specifies that the reimbursement rate for each single source drug, such as the drugs addressed by the draft LCD, is to be calculated using the volume-weighted average of the ASPs reported for all National Drug Codes assigned to that drug.[3] The statute allows the ASP of one drug to be factored into calculation of the payment rate for another drug only when both drugs share the same multiple source drug billing and payment code.[4] As defined by the statute, this methodology does not allow the Centers for Medicare and Medicaid Services (CMS) or its contractors to use the payment rate for one drug as the basis for payment for another drug that does not share the same billing and payment code. The drugs addressed by the draft LCD do not share Healthcare Common Procedure Coding System (HCPCS) codes. Instead, as listed in the draft, each drug has its own code, and CMS has published a unique ASP-based rate for each code. The statute requires Medicare to reimburse these drugs at these ASP-based rates.

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2 The draft LCD incorrectly states that payment for new drugs without established ASPs is based average wholesale price (AWP).
3 Social Security Act (SSA) § 1847A(b)(4).
4 SSA § 1847A(b)(3).

Additionally, the statute permits Medicare to use an alternative payment method in only two circumstances, and neither of those circumstances applies here. The first exception applies 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.[5] In this case, the Secretary may set the drug's payment rate at the widely available market price or at 103 percent of average manufacturer price.[6] The statute offers only these two options; it does not permit the use of LCA policies. The second exception applies in the case of a public health emergency that affects access to drugs and biological.[7] In such a situation, the Secretary may use WAC instead of ASP as the basis for reimbursement, but may not use an LCA policy.[8] We urge NHIC to apply only the payment methodologies established by the statute and not apply LCA to these or any drugs or biological products.

In addition, application of an LCA policy to these therapies also conflicts with CMS's longstanding policy by introducing cost as a factor in a coverage determination. As described in CMS's recent guidance on national coverage determinations, Medicare coverage decisions are based on the item's clinical characteristics, not its cost.[9] "The cost of an item or service is not relevant in the determination of whether [a] technology . . . should be covered for the Medicare program."[10] Furthermore, although CMS expressed intent to use cost as a factor in making coverage determinations in the past,[11] it has abandoned its efforts to establish a rule to implement such a policy. Just as cost may not be at a factor in making national coverage determinations, it should not be a factor in local coverage determinations. Yet this is precisely what is happening when contractors such as NHIC use their coverage authority to reduce payment for one drug or biological product to the rate applicable to another. Accordingly, we urge NHIC not to apply a LCA policy to these or any other drugs or biological products.

<u>If NHIC Applies LCA to These Therapies, It Should Make Exceptions When a Physician Demonstrates that the Therapy is Medically Necessary or When the Patient Received the Therapy Before the LCA Policy Became Effective</u>

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5 SSA § 1847A(d)(3).
6 Id.
7 SSA § 1847A(e).
8 Id.
9 Guidance for the Public, Industry, and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, April 11, 2006.
10 Id.
11 54 Fed. Reg. 4302 (Jan. 30, 1989); 64 Fed. Reg. 22619, 22620 (April 27, 1999); 65 Fed. Reg. 31124 (May 16, 2000).

BIO firmly believes that NHIC should not apply an LCA policy to gonadotropin-releasing hormone analogs. Nonetheless, should NHIC decide to apply LCA policies to these therapies – contrary to the Medicare statute's payment provisions and to FDA's conclusion that these drugs are not therapeutically equivalent – it must allow beneficiaries access to the medically necessary treatment for their condition. If the patient's physician demonstrates that a patient's condition requires a particular drug, NHIC should protect the patient's access to that drug by reimbursing it at its own ASP-based rate. NHIC's current LCD for these therapies includes such an exception to the LCA policy.[12] In the "Indications and Limitations of Coverage and/or Medical Necessity" section of the draft LCD, NHIC acknowledges that "differences in administration methods" may cause a "specific need to use one drug rather than the other," yet the draft LCD does not make an exception to the LCA policy when a particular drug is medically necessary. NHIC should follow the lead of other Medicare carriers[13] as well as its current policy and continue to make an exception to the LCA policy when the patient's physician demonstrates that a specific drug is medically necessary. Additionally, NHIC should not apply LCA for patients who are responding to the higher cost drug and who began treatment before the policy became effective.[14] This is consistent with NHIC's current policies in Massachusetts, Maine, New Hampshire, and Vermont.[15]

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12 NHIC, LCD for Gonadotropin-Releasing Hormone Analogs (Lupron, Leuprolide Acetate, Goserelin, Zoladex, Viadur), LCD 9933, revised Jan. 27, 2005 (Northern California); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs (Lupron, Leuprolide Acetate, Goserelin, Zoladex, Viadur), LCD 12243, revised Jan. 27, 2005 (Southern California); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 16845, revised Feb. 10, 2006 (Massachusetts); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 17602, revised Feb. 10, 2006 (Maine); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 17604, revised Feb. 10, 2006 (New Hampshire); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 17606, revised Feb. 10, 2006 (Vermont).

13 See, e.g., TrailBlazer Health Enterprises, LCD for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs, LCD L20315, revised Jan. 4, 2006; Group Health, Inc., LCD for LHRH Analogs, LCD 4308, revised Sept. 6, 2005; HealthNow, LCD for LHRH Analogs, LCD 3966, revised Jan. 1, 2006; First Coast Service Options, LCD for LHRH Analogs for Treatment of Malignant Neoplasm of the Prostate, LCD 2859, revised June 2, 2003; and Blue Cross and Blue Shield of Arkansas, LCD for Leuprolide Acetate/Goserelin, LCD 17782, revised May 31, 2005.

14 See, e.g., Empire Medicare Services, LCD for LHRH Analogs, LCD 3751, revised March 2, 2006; HGSAdministrators, LCD for LHRH Analogs for Prostatic Cancer Treatment, LCD 20430, revised Oct. 15, 2005; Group Health, Inc., LCD for LHRH Analogs, LCD 4308, revised Sept. 6, 2005; HealthNow, LCD for LHRH Analogs, LCD 3966, revised Jan. 1, 2006; and Blue Cross and Blue Shield of Arkansas, LCD for Leuprolide Acetate/Goserelin, LCD 17782, revised May 31, 2005.

15 NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 16845, revised Feb. 10, 2006 (Massachusetts); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 17602, revised Feb. 10, 2006 (Maine); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 17604, revised Feb. 10, 2006 (New Hampshire); NHIC, LCD for Gonadotropin-Releasing Hormone Analogs, LCD 17606, revised Feb. 10, 2006 (Vermont).

If NHIC Applies LCA to These Therapies, It Should Clarify Key Elements of the LCD

If NHIC decides to finalize this policy, we also recommend that NHIC clarify key elements of the draft LCD. First, NHIC states, "pricing will be crosswalked only among similar interval drugs; e.g., one-month pricing will not be crosswalked to 1/12 of one-year pricing." We ask NHIC to clarify precisely how this crosswalking will be performed, particularly given the complexities of distinguishing equivalent courses of therapy from similar administration intervals. For example, two drugs could have the same administration interval, e.g., once each week, but a full course of treatment with one drug is 4 weeks while the other drug is administered for 8 weeks. The drug with the 8-week course of therapy could have a lower weekly cost than the drug with the 4-week course of therapy, but the total cost of that drug would be higher because it is administered over more weeks. This scenario, coupled with differing physician administration costs and concerns regarding uninterrupted patient access to care (particularly for patients in rural areas) underscores why the application of LCA is inappropriate for drugs and biologicals not rated as therapeutic equivalents by the FDA.

Second, NHIC states that a drug with less than 20 percent of market share, in terms of dollars allowed, in the previous quarter will not be used to set the LCA price for this drug class. This raises several questions. Why was 20 percent selected? Would it be the market share nationwide or just in California? Of Medicare beneficiaries or all patients? Of NHIC's market only? Would drugs supplied through the Competitive Acquisition Program be included? Moreover, NHIC neither identifies the source of its data nor explains if this data will be made available to the public for an independent analysis. This is particularly troubling because CMS does not typically collect this information, and there are a wide variety of sources for it, some more reliable than others. In addition, NHIC does not explain how this policy will be applied to drugs with different indications. Specifically, it is not clear whether the "drug class" includes all of the drugs covered by this therapy, regardless of the drugs' indications, or if the market share criterion will be applied only to drugs that share an indication. A drug may have more than 20 percent of the market share for all of the drugs in the class, yet not be used for a specific indication. It would be inappropriate to conclude that such a drug is a "least costly alternative" for another therapy when the two drugs do not treat the same conditions. Although we appreciate NHIC's general sensitivity about using the price of a drug that is not widely available to set the LCA price for the drug class, we are deeply concerned about precisely how this proposal will be implemented. Because NHIC has not described how it will perform this analysis,

the draft LCD fails to create a predictable, transparent, and logical process for determining reimbursement rates for these therapies.

Finally, the draft LCD states that Medicare contractors may apply LCA on a case-by-case basis. We urge NHIC to apply LCA through LCDs only. The LCD process helps to protect beneficiary access to care by ensuring that all coverage decisions are made in a transparent and predictable manner, with opportunity for input from patients, physicians, and other stakeholders. Applying LCA on a case-by-case basis offers none of these protections and could unfairly limit beneficiaries' treatment options.

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We sincerely hope that NHIC will give thoughtful consideration to our comments and decide not to apply an LCA policy for gonadotropin-releasing hormone analogs or any other drugs or biological products. Nonetheless, should NHIC decide to finalize this LCA policy, we urge it to make an exception when the patient's physician demonstrates that a specific drug is medically necessary and for patients who began treatment before the LCA policy became effective. In addition, we request that NHIC clarify key elements of the LCD as discussed above and 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
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cc:
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