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February 9, 2009

Barry M. Straube, MD
Director and Chief Clinical Officer
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Straube:

We are writing on behalf of the American Society of Clinical Oncology (ASCO) to request that the Centers for Medicare & Medicaid Services advise National Government Services (NGS), an A/B Medicare Administrative Contractor, that its recently announced policy disfavoring coverage of intravenous antiemetics is inconsistent with national Medicare policy and must be rescinded. ASCO is the national organization representing physicians who specialize in the treatment of cancer, and NGS's new policy is contrary to the interests of our patients as well as contrary to national Medicare policy.

On January 13, 2009, NGS posted the following announcement on its web site (emphasis added):

> **Use of Injectable Medications When an Oral Equivalent is Available**
>
> National Government Services would like to remind providers that the use of injectable medications when an oral form of the same medication is available must meet medical necessity requirements for use of the drug, and for the route of administration. <u>Documentation should indicate that the patient was unable to tolerate the oral preparation prior to initiation of the intravenous form of the medication.</u>
> An example is a failed course of the oral anti-emetic before starting an intravenous form of the same anti-emetic.
>
> <u>Instruction regarding this topic is from the Centers for Medicare & Medicaid Services (CMS) and is national not a local determination</u>.
>
> Please refer to the following references used for this article:

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Alexandria, VA 22314
T: 571-483-1300
F: 571-366-9530
www.asco.org

> The Medicare Benefit Policy Manual, CMS Publication 100-2, Chapter 15, Section 50.2 & 50.5.4
> National Government Services Local Coverage Determination Supplemental Instruction Article for Drugs and Biologicals, Coverage of, for Label and Off-Label Uses - Supplemental Instructions Article (A44930)

As noted in the announcement, NGS takes the position that this policy – under which intravenous antiemetics will ordinarily not be covered by Medicare – is mandated by provisions of the Medicare Benefit Policy Manual that were issued years ago. No other Medicare contractor takes this position.

NGS cites section 50.5.4 of the Manual, but this section does not support its position. This provision relates to Part B coverage of oral antiemetics when they are a "full replacement" for intravenous antiemetics. It provides that, notwithstanding the "full replacement" requirement, Medicare will cover supplemental intravenous antiemetics if the oral antiemetics were ineffective.

Section 50.2.A, K of the Manual, also cited by NGS, provides that the route of administration must be medically reasonable and necessary. It states further that "if a drug is available in both oral and injectable forms, the injectable form of the drug must be reasonable and necessary as compared to using the oral form." We do not believe that this language was intended to deny coverage to injectable drugs whenever an oral version exists. Instead, we believe that his language is intended to reflect the policy stated in section 50.4.3:

> Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. Carriers exclude the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.

In other words, intravenous antiemetics are to be denied coverage in favor of oral antiemetics only if use of oral antiemetics – rather than intravenous antiemetics – is the established medical practice in the circumstance at issue.

In the case of antiemetics administered in conjunction with anticancer chemotherapy, the standard practice is to use intravenous antiemetics, although oral antiemetics may sometimes be used instead. Thus, ASCO believes that NGS's policy, under which Medicare coverage of intravenous antiemetics will usually be denied, is not consistent with national Medicare policy.

Moreover, NGS's policy, if allowed to be implemented, will adversely affect Medicare patients. Most physicians do not dispense oral drugs, which means that cancer patients must obtain their

oral antiemetics from a pharmacy and bring them to the oncologist on the days of chemotherapy. In the case of oral antiemetics covered by Part B, however, the Medicare Claims Processing Manual (Ch. 17, § 80.2) provides:

> The oral anti-emetic drug(s) should be prescribed only on a per chemotherapy treatment basis. For example, only enough of the oral anti-emetic(s) for one 24- or 48-hour dosage regimen (depending upon the drug) should be prescribed/supplied for each incidence of chemotherapy treatment.

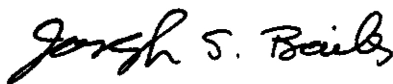
This Manual provision precludes physicians from writing a prescription for antiemetics for the entire course of chemotherapy, thus requiring only a single trip to the pharmacy. Instead, cancer patients, who are often seriously ill, could be required to fill prescriptions for antiemetics prior to every chemotherapy encounter. This is a burden that should not be imposed on these patients.

In the case of oral antiemetics that do not meet the conditions for Part B coverage, patients will be subject to the prior authorization and quantity limits that the Medicare Part D plans may impose. Again, these requirements could be highly disruptive to the care of cancer patients.

ASCO sees no basis for the new NGS policy, which purports to be simply an implementation of longstanding Manual provisions even though no other contractor has interpreted the Manual in this manner. ASCO respectfully requests that CMS direct NGS to rescind its recent policy announcement and to cover medically necessary intravenous antiemetics without requiring a showing that the patient has failed on oral antiemetics.

We are available for a meeting or conference call to discuss this issue should you feel it necessary. Please let us know if you need any further information. Thank you for your consideration of this request.

Sincerely,



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