Drug Reimbursement Issues Surrounding the Implementation of Medicare Part D What community cancer centers need to know

by Marie C. Infante, Esq., and Stephen R. Bentfield, Esq.

Prior to 2006, Medicare Part B was the primary reimbursement vehicle for prescription drug medications prescribed by oncologists for the treatment of cancer and its many side effects. Today, oncology practitioners (physicians, nurses, and pharmacists) must now answer, on a regular basis, the question of whether coverage for certain prescription drug costs is under Part B or Part D. As a general rule, chemotherapeutic agents given incident to a physician service are still covered under Part B. For drugs prescribed to manage the side effects of anticancer treatment, the answer is not as clear cut. Instead, the individual circumstances of each patient, and the timing by which the drugs are prescribed and administered, determine which program should be billed for the drug. Because these determinations are specific to individual patients, payment conclusions must be made on a case-by-case basis.

What the MMA Says

Using four criteria, the MMA defines a Part D covered drug as one that is:

- Available only by prescription
- Approved by the Food and Drug Administration
- Used and sold in the United States
- Used for a medically accepted indication.

Excluded from this definition, however, is any drug for which, as prescribed and dispensed or administered to an individual, payments would be available under Medicare Part A or Part B for that individual, even though a deductible may apply.

Typically, anticancer and antiemetic drugs prescribed by oncologists are paid for under Medicare Part B. The Part B program makes payments to physicians for drugs or biologicals which are not usually self-administered by the patient and are administered "incident to" a physician's service. Payments to physicians for oncology drugs (including anticancer and antiemetic drugs) constitute a large portion of Medicare outpatient drug spending under the Part B program ($3.8 billion in 2002) and, consequently, a substantial portion (72 percent) of the revenue to oncology practices.

The rules governing physician reimbursement for drugs used in the treatment of cancer, and the side effects associated with such treatment, are highly technical and carefully defined. Medicare Part B covers oral chemotherapy drugs *provided* they have the same active ingredients and are used for the same indications as other chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service. Part B also covers oral antiemetic drugs that are used as part of an anticancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous antiemetic drug *within 48 hours of chemotherapy administration*. Starting this year, CMS has stated that any antiemetics taken *after* the 48-hour window are to be covered under Part D rather than Part B.

The Centers for Medicare & Medicaid Services (CMS) has long wrestled with the interplay in coverage for prescription drugs under the Part B and Part D programs. In April 2005 testimony before Congress, Health and Human Services Secretary Michael Leavitt stated that, with certain exceptions, most drugs covered by Part B would *not* be suitable for shifting to Part D. According to Secretary Leavitt's written testimony, good candidates for shifting to Part D include blood clotting factors, as well as certain oral anticancer and antiemetic agents.

Soon thereafter, in June 2005, CMS provided some additional clarification on the Part B/Part D coverage issue by way of a Q&A document posted on its web site (*www.cms.hhs.gov*). Specifically, CMS stated that Part D plans must include in their formularies "all or nearly all drugs" in several categories, including anticancer drugs. CMS' rationale for this policy decision is to ensure that Medicare beneficiaries have access to clinically appropriate medications and that formularies not be discriminatory toward any one class of beneficiaries, including cancer patients. In addition, CMS is seeking to avoid any interruption in ongoing therapies using these drugs.

Although Part D plans are required to include anticancer medications on their respective formularies, it is important to understand that this does not mean that coverage for these drugs will be provided by Part D. Medicare Part B will remain the *primary* reimbursement system for oncology medications prescribed for cancer patients following the implementation of the Part D benefit. CMS clarified, however, that anticancer drugs that have medically accepted indications in addition to anticancer agents, can be paid under Part D when prescribed and used for indications *other than* cancer treatment (i.e., immunosuppressive drugs, parenteral nutrition drugs, IVIGs). To achieve this outcome, CMS recommends the Part D sponsor use a prior authorization approach, or similar mechanism, in their formularies. Therefore, when administering drugs or providing medications to patients, physicians must include precise, clear documentation in their clinical records to support drug payments from the appropriate program. Starting in 2006, oncologists *should not* dispense drugs covered by Part D from their offices because only contract pharmacies can submit claims to the Part D program.

Because antiemetics are effective against vomiting and nausea and are prescribed to treat a variety of condi-

tions in addition to chemotherapy-induced nausea and vomiting, this class of drugs will frequently trigger the Part B/Part D payment dilemma. As such, antiemetics present a good model for highlighting some of the practical problems associated with this issue. Several factors, including the clinical indications for an individual beneficiary, will factor into whether the drug will be covered under Part B or Part D.

For an antiemetic drug to be covered under Part B, three conditions must be met:

1. The drug must be used as part of an anticancer chemotherapeutic regimen
2. The drug must constitute a full therapeutic replacement for an intravenous antiemetic drug
3. The drug must be given within 48 hours of a chemotherapy administration.

The analysis, however, does not stop at these three conditions. To complicate matters further, CMS has stated that one of the determining factors is whether the drug *could* be covered under Part B as prescribed and dispensed or administered. If the drug could be covered under Part B, CMS has advised prescription drug plans to view coverage as "available" under Part B— regardless of whether or not the individual patient is actually enrolled in Part B. In addition, CMS has informed Part D plans *not* to include oral anticancer drugs covered by Part B on their formularies that have *no other medically accepted indication* besides cancer treatment.

This analysis also applies to certain growth factors currently covered under Part B. For example, Leukine® (sargramostim) is a growth factor used following certain chemotherapies, as well as bone marrow transplantation. Leukine is commonly administered by injection incident to a physician's service, and, therefore, covered under Part B. However, some physicians may instruct patients to self-administer Leukine outside the office, and provide the patient with a prescription. In this instance, where the patient fills the prescription at a pharmacy and self-administers the drug outside the physician's office, coverage may be provided under Part D. Again, the particular facts and circumstances of the particular drug, and the means and location of administration will factor into whether the drug will be covered under Part B or Part D.

Practical Steps for Physicians

So how will physicians navigate this myriad of Part B/Part D rules? For starters, some working knowledge of the fundamental differences between Medicare Part B and Part D is essential. For example, Part D requires prescriptions for covered drugs to be filled at network pharmacies and will not honor claims submitted by physician practices. Physicians must use greater clarity and precision when charting in their clinical records to provide sufficient documentation for reimbursement purposes. The prescription should clearly state the condition for which the drug is being prescribed, the manner in which the drug is prescribed, and the timing in which it is administered. Prescription clarity is particularly important given the regulatory constraints associated with anticancer and antiemetic agents.

As an intake matter, physicians should modify their admissions policies to confirm whether a patient is enrolled in a Part D plan, and specifically identify in which plan the patient is enrolled. This information should be obtained from both new and existing patients.

In addition, physicians must determine the boundaries of each patient's particular Part D plan when making prescription decisions. Each Part D plan has its own unique formulary that may include utilization management tools, such as a prior authorization or step therapy.

These suggested steps should help oncologists identify potential Medicare coverage issues at the earliest point possible, and, most importantly, properly document the treatment and prescription process to support medical necessity and reimbursement under the Part B program or the Part D program, as appropriate. Many serious issues such as the Part B/Part D coverage dilemma have emerged since CMS undertook the task of implementing the Medicare prescription drug benefit. Against tremendous pressure to make changes, CMS has requested Congress to withhold acting on this issue for at least two years to allow the agency to gain experience administering the Part D drug benefit. Clearly, the Part B/Part D debate has only begun. Stay tuned.

PHOTOGRAPH/ COMSTOCK

Significant 2006 Changes

- While most anticancer drugs continue to be covered under Medicare Part B, anticancer drugs that have medically accepted indications in addition to anticancer agents *can* be paid under Part D when prescribed and used for indications *other than* cancer treatment.
- Only contract pharmacies can submit claims to the Part D program, so oncologists *should not* dispense *any* drugs covered by Part D from their offices.
- Antiemetics will frequently trigger the Part B/Part D payment dilemma because these drugs are effective against vomiting and nausea and are prescribed to treat a variety of conditions *in addition to* chemotherapy-induced nausea and vomiting.
- Starting this year, any antiemetics taken more than 48 hours *after* chemotherapy administration are covered under part D rather than Part B.

Marie C. Infante, Esq., and Stephen R. Bentfield, Esq., are with the Washington, D.C., office of Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.