

TO: ALL PROVIDERS

FROM: CAREFIRST OF MARYLAND INC., MEDICARE PART A

DATE: AUGUST 8, 2005

SUBJECT: SELF-ADMINISTERED DRUGS

The Social Security Act does not provide a comprehensive drug benefit for Medicare beneficiaries. Drugs provided during acute inpatient stays and qualified skilled nursing facility stays are generally covered under Part A if Medicare requirements are met. For Part B (outpatient, including outpatient hospital such as the emergency department), drug coverage has traditionally been limited to the type of drugs that cannot be self-administered, that are medically necessary and reasonable, that are Food and Drug Administration (FDA) approved, and that are incident to the physicians' services as defined in the Medicare manuals. Payments for drugs and supplies used in the performance of procedures are not separately billable to Medicare or the beneficiary as they are included in the fee for the procedure.

With passage of the 2002 Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act (BIPA), Congress changed the Medicare definition for covered drugs, from the type of drugs that *cannot* be self-administered to the type of drugs that *are usually not* self-administered. As a result of this benefit change, self-administered drugs and biologicals (oral or injectable) are not covered in the outpatient setting except where Congress has provided for additional coverage. Examples of such coverage include specific blood clotting factors, drugs used in immunosuppressive therapy, renal dialysis-related erythropoetin, osteoporosis drugs for certain homebound patients, some oral anti-cancer drugs, and some anti-nausea drugs in combination with oral or intravenous chemotherapy.

The Centers for Medicare & Medicaid Services (CMS) has published two Program Memoranda on this issue: Transmittal AB-02-072, Change Request 2200, released on May 15, 2002, which provides clarification of Section 112 of the BIPA; and, Transmittal AB-02-139 Change Request 2311, released on Oct. 11, 2002, which provides additional guidance for applying the Medicare Self-Administered Drug Exclusion. These transmittals instruct contractors to define "usually not self-administered" as more than 50 percent of the time for all Medicare beneficiaries who use the drug. In other words, if more than 50 percent of Medicare beneficiaries self-administer the drug, it is excluded from coverage. The Medicare exclusion is clear for oral drugs, suppositories and topical medications. The issues arise with drugs administered by intravenous (IV), intramuscular (IM), subcutaneous (SQ) or multiple routes. Note: There is no change for drugs covered as an integral part of a procedure (e.g., a topical ophthalmic anesthetic) which are not separately reimbursed.

The transmittals above instruct Medicare contractors to develop a process for determinations on each drug. For drugs that have multiple indications and administration routes, contractors will consider all of these indications and administration routes while making a single determination for each drug. In making these determinations, the contractor must use the transmittal guidelines, peer-reviewed medical literature, standards of medical practice, FDA-approved language, package inserts, drug compendia as appropriate, evidence-based practice guidelines and other information from interested individuals or groups. Medicare has instructed Fiscal Intermediaries that they may use the Self-Administered Drug list of their corresponding primary Carrier to promote consistency within a region. CareFirst of MD, INC., has chosen to take this approach, and therefore uses the Self-Administered Drug list of TrailBlazer Health Enterprises, LLC., which can be found at:

<http://www.trailblazerhealth.com/coverage/druglist.asp>

CareFirst's list of drugs excluded from Medicare coverage as self-administered reproduces the list developed by TrailBlazer Health Enterprises, LLC., and can be found at:

http://www.marylandmedicare.com/pages/mdmedicare/drugs_biologicals/pdf/SA_D%20Exclusions.pdf

The CMS Manual Instructions for Determining Self-Administration of a Drug or Biological can be found in the Medicare Benefit Policy Manual 100-2, Chapter 15, Section 50-2:

http://www.cms.hhs.gov/manuals/102_policy/bp102c15.pdf

Billing Self-Administered Drugs Under the Correct Revenue Code

Our Medical Review department has detected claims in which non-covered drugs have been billed under improper revenue codes, such as 0250. The self-administered drug should be reported under revenue code 0637. CMS has also instructed that self-administered medications be billed using revenue code 0637. Refer to February 23, 2000 Medi-760-00.

If you have any questions you can contact our Provider Service line at 1-866-488-0545.

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ARE AVAILABLE AT NO COST FROM OUR WEBSITE AT www.marylandmedicare.com.