
Medicare

Intermediary Manual

Part 3 - Claims Process

Department of Health and
Human Services (DHHS)
HEALTH CARE FINANCING
ADMINISTRATION (HCFA)

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
3660.13 - 3660.14	6-344.6A - 6-344.6B (2 pp.)	6-344.6A - 6-344.6B (2 pp.)

**NEW/REVISED PROCEDURES--*EFFECTIVE DATE:* January 1, 2000
IMPLEMENTATION DATE: July 1, 2000**

Section 3660.13, Oral Cancer Drugs, is revised to reflect the addition of three HCPCS codes, J8510, J8520, and J8521 for oral cancer drugs effective January 1, 2000. These HCPCS codes were included in the 2000 HCFA Common Procedure Coding System (HCPCS) Update that was released in October 1999. Providers must report a cancer diagnosis code when billing for these HCPCS codes in FLs 67-75.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

3660.11 Self-Administered Drugs and Biologicals.--Drugs and biologicals furnished to outpatients for therapeutic purposes that are self-administered are not covered by Medicare unless those drugs and biologicals must be put directly into an item of durable medical equipment or a prosthetic device, the statute provides for such coverage (including blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin (EPO), certain oral anti-cancer drugs and their associated antiemetics), or **the ordinarily non-covered, self-administered drug insulin is administered in an emergency situation to a patient in a diabetic coma.** (See §3112.4.)

3660.12 Self-Administered Drug Administered In An Emergency Situation.--Pay for the ordinarily non-covered, self-administered drug insulin administered in an emergency situation to a patient in a diabetic coma. The provider bills for the aforementioned drug on Form HCFA-1450 or its electronic equivalent with bill type 13X, 83X, or 85X, as appropriate. The provider reports value code A4 and its related dollar amount (the amount included in covered charges for the ordinarily non-covered, self-administrable drug insulin administered to the patient in an emergency situation) in FLs 39-41 under revenue code 637 (self-administrable drugs not requiring detailed coding) in FL 42. The provider completes the remaining items in accordance with regular billing instructions.

NOTE: Do not utilize revenue code 637 (self-administrable drugs not requiring detailed coding) for the reporting of those self-administered drugs and biologicals that are statutorily covered. (See §3112.4.) Providers should continue to follow existing reporting requirements for those self-administered drugs and biologicals.

3660.13 Oral Cancer Drugs.--Pay for self-administrable oral versions of covered injectable cancer drugs prescribed as an anti-cancer chemotherapeutic agent when the oral drugs are furnished on or after January 1, 1994. To be covered, an oral cancer drug must:

- o Be prescribed by a physician or practitioner as an anti-cancer chemotherapeutic agent;
- o Be a drug or biological approved by the FDA for the prescribed use;
- o Have the same active ingredients as a non-self administrable, anti-cancer drug or biological that is covered when furnished incident to a physicians service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's Approved Drug and Products (Orange Book), Physician's Desk Reference (PDR), or an authoritative drug compendium; or

-- Effective January 1, 1999, be a FDA-approved oral anti-cancer Prodrug, an oral drug ingested into the body that metabolizes into the same active ingredient that is found in the non-self-administrable form of the drug;

- o Be used for the same indications (including off label uses) as the non-self-administrable form of the drug; and
- o Be reasonable and necessary for the individual patient.

<u>Generic/Chemical Name</u>	<u>How Supplied</u>	<u>HCPCS</u>
Busulfan	2 mg/ORAL	J8510
Capecitabine	150mg/ORAL	J8520
Capecitabine	500mg/ORAL	J8521
Methotrexate	2.5 mg/ORAL	J8610

Cyclophosphamide	25 mg/ORAL	J8530	
	50 mg/ORAL	J8530	(Treat 50 mg. as 2 units)
Etoposide	50 mg/ORAL	J8560	
Melphalan	2 mg/ORAL	J8600	
Prescription Drug, Chemotherapeutic, NOS	ORAL	J8999	

Part B of Medicare pays 80 percent of the reasonable cost of oral cancer drugs furnished by a provider. Deductible and coinsurance apply. The provider bills for these drugs on Form HCFA-1450 or its electronic equivalent. The provider enters revenue code 636 in FL 42 of the UB-92, the name and HCPCS of the oral drug in FL 43 of the UB-92 (revenue description), and the number of tablets or capsules in FL 46 of the UB-92. Each tablet or capsule is equal to one unit, except for 50 mg./ORAL of cyclophosphamide (J8530), which is shown as 2 units. Notify providers of the names and HCPCS of the covered drugs. Providers report oral anti-cancer Prodrugs under revenue 636 in FL 42 and HCPCS code J8999 in FL 44. The provider completes the remaining items in accordance with regular billing instructions. Do not pay for oral cancer drugs or oral anti-cancer Prodrugs unless a diagnosis of cancer appears in FLs 67, 68, 69, 70, 71, 72, 73, 74, or 75 of the HCFA-1450.

A. EOMB Messages.--If the claim for an oral cancer drug is denied because it was not approved by FDA, is not considered to be a medically accepted treatment for cancer, or is not the chemical equivalent of a covered injectable cancer drug, state the appropriate message on the EOMB:

- o "Medicare does not pay for oral cancer drugs that are not approved by the U.S. Food and Drug Administration."

- o "Medicare does not pay for this type of oral drug because it has not been proven to be medically acceptable for treating this type of cancer."

- o "Medicare does not pay for oral cancer drugs that do not have the same active ingredients as the drug would have if given by injection."

3660.14 Self-Administered Anti-emetic Drugs.--Effective with dates of service on or after January 24, 1996, pay for self-administrable oral or rectal versions of self-administered anti-emetic drugs when they are necessary for the administration and absorption of primary Medicare covered oral anti-cancer chemotherapeutic agents when a high likelihood of vomiting exists. The self-administered anti-emetic drug is covered as a necessary means for the administration of the oral anti-cancer drug (similar to a syringe and needle necessary for injectable administration). Self-administered anti-emetics which are prescribed for use to permit the patient to tolerate the primary anti-cancer drug in higher doses for longer periods are not covered. In addition, self-administered anti-emetics used to reduce the side effects of nausea and vomiting brought on by the primary drug are not included beyond the administration necessary to achieve drug absorption. (See §3112.4.)

A. Billing Requirements.--The provider bills for these drugs on Form HCFA-1450 or its electronic equivalent. The cost of the drug is billed under revenue code 636 in FL 42. For claims with dates of service on or after January 24, 1996 through March 31, 1996, the provider will report HCPCS code J3490 in FL 44. For dates of service on or after April 1, 1996, one of the following HCPCS codes is reported in FL44, as appropriate:

K0415 Prescription anti-emetic drug, oral, per 1 mg, for use in conjunction with oral anti-cancer drug, not otherwise specified; or

K0416 Prescription anti-emetic drug, rectal, per 1 mg, for use in conjunction with oral anti-cancer drug, not otherwise specified.