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Peg Skelly

To cite this article: Peg Skelly (1999) Billing for Oral Chemotherapy Drugs, Oncology Issues, 14:6, 14-14, DOI: 10.1080/10463356.1999.11905268

To link to this article: https://doi.org/10.1080/10463356.1999.11905268

Published online: 17 Oct 2017.

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by Peg Skelly

Q: *What is the basis for Medicare to cover oral drugs?*

A: Under the Medicare program, oral drugs are generally not covered because of Medicare program exclusions for drugs and biologicals that can be self-administered and the incident-to requirements. HCFA is in the process of reviewing the policy for drugs that can be self-administered and changes may be implemented. Currently under Medicare Part B there are several statutory and HCFA administrative decisions that allow outpatient coverage for select oral agents, including anti-cancer drugs and anti-emetics. Oral drugs administered to hospital inpatients or furnished by a SNF are included in the Part A payment and are not separately reimbursed.

Q: *Which oral chemotherapy drugs are covered?*

A: Effective January 1994, Medicare Part B began coverage for select oral, anti-cancer drugs. These provisions limited coverage to anti-cancer chemotherapeutic agents. Five oral anti-cancer drugs currently meet these requirements: cyclophosphamide, etoposide, melphalan, methotrexate, and capecitabine. The coverage requirements state that the drug must:

- be prescribed by a physician or practitioner licensed under state law to prescribe chemotherapy agents
- be approved by the Federal Drug Administration
- have the same active ingredients as a non-self-administered anti-cancer drug that is covered when furnished as an incident-to a physician's service, have the same chemical/generic name, or, effective January 1999, be a prodrug, which metabolizes into the same active ingredient found in the non-self-administered form of the drug
- be used for the same indications, including off-label uses, as the non-self-administered form of the drug (i.e., cancer diagnosis)
- be reasonable and necessary for the individual patient.

Q: *What are coverage conditions for oral anti-emetics?*

A: Effective January 1998, Medicare Part B extended oral drug coverage to include oral anti-emetics that meet the following requirements.

- Only oral drugs approved by the FDA for use as anti-emetics are covered.
- Oral anti-emetic(s) must either be administered by the treating physician or prescribed by the physician as part of a cancer chemotherapy regimen.
- Administration of the oral anti-emetic drug(s) must be initiated within two hours of the administration of chemotherapy and may be continued for a time period of up to forty-eight hours (or twenty-four hours for HCPCS codes Q0163 and Q0180 based on FDA labeling).
- The oral anti-emetic drug(s) must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of chemotherapy.
- Effective July 1999, more than one oral anti-emetic drug may be covered for concurrent use if more than one oral anti-emetic is needed to fully replace intravenous anti-emetic drugs.

There are additional medical necessity rules that may affect coverage of oral anti-emetics. For example, with concurrent oral anti-emetics, a supplier may only dispense a single course of drugs at one time. Also, intravenous anti-emetics can be covered subject to medical necessity when administered to patients who fail oral anti-emetic therapy. However, claims containing both oral and intravenous formulations will require appeal to establish medical necessity.

Q: *How are oral chemotherapy drugs billed?*

A: HCFA has assigned HCPCS codes J8530-J8999 for oral chemotherapy drugs. National Drug Codes (NDCs) may be billed only when the drug is used as an oral anti-cancer drug. Oral anti-emetics are billed with HCPCS codes Q0163-Q0181 and/or miscellaneous code K0415 (prescription anti-emetic drug, oral, per 1mg, for use in conjunction with oral anti-cancer drug, not otherwise specified).

Peg Skelly is vice president of consulting services with Comprehensive Reimbursement Consultants in Minneapolis, Minn.