

References: L33826, A52479

All Oral Anticancer Drugs

- Dispensing Order, if applicable
- Detailed Written Order (DWO)
- Beneficiary Authorization
- Refill Requirements
- Proof of Delivery (POD)
 - Method 1 - Direct Delivery to the Beneficiary by the Supplier
The date the beneficiary/designee signs for the supplies is to be the date of service of the claim.
 - Method 2 - Delivery via Shipping or Delivery Service
The shipping date is to be the date of service of the claim.
 - Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary
- Continued Need
- Continued Use

Medical Records

- For an oral anticancer drug to be covered, all of the following criteria must be met:
 - Drug or biological has been approved by the FDA; **and**
 - It has the same active ingredients as a non-self-administrable anticancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anticancer drug and non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's Approved Drug Products (Orange Book), Physician's Desk Reference (PDR), or an authoritative drug compendium, or it is a prodrug which, when ingested, is metabolized into the same active ingredient which is found in the non-self-administrable form of the drug; **and**
 - It is used for the same anticancer chemotherapeutic indications, including unlabeled or "off label" uses, as the non-self-administrable form of the drug; **and**
 - It is prescribed by a physician or other practitioner licensed under state law to prescribe such drugs as anticancer chemotherapeutic agents.

Note: A drug that is not available in an injectable form does not meet the second criterion. If an oral anticancer drug is used for immunosuppression (rather than treatment of cancer), the third criterion is not met.

Antiemetic Drugs (J8498, J8597)

- Antiemetic drug is used in conjunction with a covered oral anticancer drug; **and**
- It is likely that administration of the covered oral anticancer drug will induce emesis if the antiemetic drug is not administered; **and**
- Antiemetic drug is administered within two (2) hours before the covered oral anticancer drug is administered.

Billing Reminders

- ICD code(s) (see the PA for covered ICD codes) that justifies the need for the drug(s) must be included on each claim.
- The National Drug Code (NDC) that matches the product dispensed must be used.
- For NDC numbers, 1 unit of service = 1 tablet or capsule.
- NDCs may only be billed when the drug is used as an oral anticancer drug.
- Claims for codes J8498 or J8597 must identify the name of the drug, manufacturer, and dosage strength of each tablet/suppository etc. and must also include which oral anticancer drug is being used and the prescribed frequency of administration of the anticancer drug.
- For codes J8498 and J8597, 1 unit of service = 1 mg.
- Claims using code J8999 must include the name of the drug, manufacturer, NDC number, dosage strength of each tablet/suppository etc., and number of tablets or capsules dispensed.
- A new DWO is required whenever there is a change in dosage or directions for administering the drug.
- Supply fees
 - One unit of supply code Q0511 is covered for the first covered oral anticancer drug that is dispensed in a 30-day period.
 - If covered drugs are dispensed by more than one pharmacy during a 30 day period, one unit of Q0511 is covered for each pharmacy.
 - One unit of supply fee code Q0512 is covered for each subsequent covered oral anticancer drug that is dispensed in that 30-day period.
 - If two dosage strengths of the same drug are dispensed on the same day, one unit of service of the appropriate supply fee is payable for each one.
 - More than one unit of service of code Q0511 billed per 30 days by a single pharmacy will be denied as incorrect coding.
- Supply fee code(s) must be billed on the same claim as the drug(s). If it is not, the supply fee will be denied as incorrect billing.
- J8498 is not eligible for payment of a supply fee.

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