

DOCUMENTATION CHECKLIST FOR ORAL ANTICANCER DRUGS

Policy References:

- [Local Coverage Determination \(L33826\)](#)
- [Policy Article \(A52479\)](#)

Documentation References:

- [Standard Documentation Requirements Policy Article \(A55426\)](#)

The supplier must be able to provide all of these items on request:

[Standard Written Order \(SWO\)](#)

[Beneficiary Authorization](#)

[Proof of Delivery \(POD\)](#)

[Continued Need](#)

[Continued Use](#)

[Refill Requirements](#)

Medical records from treating practitioner as noted below

Medical records should contain:

ICD-10 diagnosis to support medical necessity

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 hours before the covered oral anticancer drug is administered.