



Pharmaceutical Benefits Scheme (PBS) Efficient Funding of Chemotherapy (EFC) Program – Combination chemotherapy medicines

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This frequently asked questions (FAQ) document provides information on the PBS listing for combination chemotherapy medicines, nivolumab with relatlimab (Opdualag®) and liposomal daunorubicin with cytarabine (Vyxeos®), and an overview of the prescribing and claiming arrangements.

Combination chemotherapy medicines

What are combination chemotherapy medicines?

- The Pharmaceutical Benefits Advisory Committee (PBAC) recommended the PBS listing of two 'combination items' on the PBS section 100 (s100) EFC Program:
 - nivolumab with relatlimab (**Opdualag®**) and
 - liposomal daunorubicin with cytarabine (**Vyxeos®**).
- The *National Health Act 1953* defines 'combination items' as 'a pharmaceutical item that has a drug that contains at least 2 other drugs or medicinal preparations, at least one of which is a listed drug'.
- Opdualag is listed on the PBS for the treatment of patients with unresectable Stage III or Stage IV malignant melanoma.
- Vyxeos is listed on the PBS for the treatment of patients with therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC).

PBS section 100 programs

What is the PBS s100 EFC Program?

- The EFC Program provides funding for chemotherapy medicines used for the treatment of cancer that are administered at public or private hospitals.

Prescribers

How can combination chemotherapy medicines be prescribed under the EFC Program?

- Prescribing of combination chemotherapy medicines under the EFC Program should be in accordance with the patient's required dose for their treatment regime or protocol.
- A PBS prescription for combination chemotherapy medicines under the EFC Program should align with all other EFC medicines, where prescriptions should be written for the patient's dose in milligrams.

Claiming

What is the process for claiming combination chemotherapy medicines under the EFC Program?

- Combination chemotherapy medicines contain more than one active ingredient in the one vial. For example:
 - Opdualag® contains nivolumab with relatlimab and
 - Vyxeos® contains liposomal daunorubicin with cytarabine.
- The EFC Program only allows for one maximum amount to be entered with each claim.
- Claims must be made in relation to the first active ingredient that is listed. For example:
 - **for Opdualag®, this will be the nivolumab dose amount.**
 - **for Vyxeos®, this will be the liposomal daunorubicin dose amount.**
- Further details on one active ingredient claiming can be found in the administrative note for each medicine listing on the PBS website.

Examples of prescribing and claiming of combination chemotherapy medicines under the EFC Program are outlined below:

Example 1: Opdualag® (nivolumab with relatlimab, 240 mg/80 mg per vial)

- Prescription: 480 mg nivolumab with 160 mg relatlimab administered as an intravenous infusion over 30 minutes.
- Claim: the amount to enter for a PBS claim will be 480 mg (relative to the nivolumab dose).

Example 2: Vyxeos® (liposomal daunorubicin with cytarabine, 44 mg/100 mg per vial)

- Prescription (for induction): 88 mg liposomal daunorubicin with 200 mg cytarabine administered as an intravenous infusion over 90 minutes for a patient with a body surface area (BSA) of 2.0 m².
- Claim: the amount to enter for a PBS claim will be 88 mg (relative to the liposomal daunorubicin dose).

Example 3: Vyxeos® (liposomal daunorubicin with cytarabine, 44 mg/100 mg per vial)

- Prescription (for consolidation): 52 mg liposomal daunorubicin with 117 mg cytarabine administered as an intravenous infusion over 90 minutes for a patient with a BSA of 1.8 m².
- Claim: the amount to enter for a PBS claim will be 52 mg (relative to the liposomal daunorubicin dose).

A PBS Approved Supplier will claim for supplies of combination chemotherapy medicines under the EFC Program using the maximum amount of one active ingredient. Will a PBS Approved Supplier be remunerated in accordance with the price on the PBS Schedule?

- Yes, remuneration will be linked to the relevant PBS item code for the combination chemotherapy item under the EFC Program.

WHERE CAN I SEEK FURTHER INFORMATION?

Any further queries on combination chemotherapy medicines can be emailed to the [PBS s100 Programs mailbox](#).