**Combination chemotherapy medicines**

**Frequently Asked Questions**

This factsheet provides information on the changes to the Pharmaceutical Benefits Scheme (PBS) listing for combination chemotherapy medicines, Opdualag® (nivolumab with relatlimab) and Vyxeos® (liposomal daunorubicin with cytarabine), 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’:
	+ **Opdualag** (nivolumab with relatlimab); and
	+ **Vyxeos** (liposomal daunorubicin with cytarabine).
* This is the first time that ‘combination items’ for the treatment of cancer have been recommended by the PBAC for listing on the PBS section 100 (s100) Efficient Funding of Chemotherapy (EFC) Program.
* 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 currently listed on the PBS for the treatment of patients with unresectable Stage III or Stage IV malignant melanoma.
* Vyxeos is currently 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).

**What is happening with** **Opdualag and Vyxeos?**

* These medicines were temporarily listed on the Highly Specialised Drugs (HSD) Program to prioritise patient access while updates were made to legislation and administrative systems to support the listing of combination medicines on the EFC Program.
* On 1 December 2024, Opdualag and Vyxeos are being transitioned from the HSD Program to the EFC Program.

## PBS section 100 programs

**What is the PBS s100 Efficient Funding of Chemotherapy (EFC) Program?**

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

**What is the PBS s100 Highly Specialised Drugs (HSD) Program?**

* The HSD Program provides access to specialised PBS medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied.

## Patients

**How will moving Opdualag and Vyxeos from the HSD Program to the EFC Program impact patients?**

* Under the HSD Program, patients pay the relevant PBS patient co-payment for their original prescription and each repeat prescription.
* Under the EFC Program, patients only pay one PBS patient co-payment for each original prescription. There is no cost to the patient for repeat prescriptions.
* The current PBS patient co-payment amounts are available on the [PBS website](http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee).

## Prescribers

**Are there changes to who can prescribe Opdualag and Vyxeos?**

* There will be no change to the medical practitioners who are authorised prescribers of these medicines.

**Why do the PBS restrictions for Opdualag and Vyxeos under the EFC Program look different to the previous PBS restrictions for these medicines under the HSD Program?**

* An EFC medicine is listed as a dose amount (e.g. 480 milligrams). An HSD medicine is usually listed as a quantity amount (e.g. 2 vials).
* Due to the different way the maximum amount for these medicines is expressed under the EFC Program, updated prescriber instructions are available within the relevant PBS restrictions on the [PBS website](https://www.pbs.gov.au/pbs/home).
* The clinical and treatment criteria for these medicines under the EFC Program remain the same as they were under the HSD Program.

**Can a prescription for Opdualag or Vyxeos still be written under the HSD Program from 1 December 2024?**

* No, as of 1 December 2024, prescribers will no longer be able to write new prescriptions for these medicines under the HSD Program.
* All new prescriptions written on or from 1 December 2024 must be written under the EFC Program.

**Will Opdualag and Vyxeos need to be prescribed differently under the EFC Program?**

* Prescribing of these 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 these 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

**If an HSD Program prescription was written for Opdualag or Vyxeos before 1 December 2024, can it still be supplied and claimed after 1 December 2024?**

* Yes, these medicines will remain available on the HSD Program under special supply arrangements for a period of 12 months.
* This means that pharmacies can continue to supply these medicines under the HSD Program for prescriptions that were written before 1 December 2024.

**Can an HSD Program prescription for Opdualag or Vyxeos be used to claim under the EFC Program?**

* No, an HSD Program prescription must be claimed under the HSD Program arrangements.
* These medicines will have different PBS item codes under the EFC Program.
* Claiming these medicines under the EFC Program will require the prescriber to write a new PBS prescription from 1 December 2024.

**W****hat changes are being made to the claiming of Opdualag and Vyxeos under the EFC Program?**

* There are administrative changes to the listed maximum amount for dispensing and claiming purposes.
* These medicines contain 2 active ingredients in the one vial:
	+ 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 will be made in relation to the first active ingredient that is listed for each of these medicines:
	+ **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** **Opdualag and Vyxeos 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 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 daunorubicin dose).

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

* Prescription (for consolidation): 52 mg 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 daunorubicin dose).

**A PBS Approved Supplier will claim for supplies of Opdualag and Vyxeos 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 used for Opdualag and Vyxeos under the EFC Program.

**Who should I contact for further enquiries on combination chemotherapy medicines?**

* The EFC team at the Department of Health and Aged Care may be contacted via email at s100programs@health.gov.au.