



**Australian Government**

**Department of Health**

## **Information for Healthcare Professionals Pharmaceutical Benefits Scheme Listing Changes - FILGRASTIM**

The Pharmaceutical Benefits Scheme (PBS) listings for filgrastim are being amended to effect changes to prescribing conditions for items under the Highly Specialised Drug (HSD) Program.

Nivestim<sup>®</sup> and Zarzio<sup>®</sup> are biosimilar brands of filgrastim and are listed on the PBS together with the reference biological medicine Neupogen<sup>®</sup>.

A summary of the filgrastim PBS listing amendments for each indication, commencing from 1 October 2019, is provided in the **tables below**. The changes bring into effect the recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC) that all brands of filgrastim may be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a'-flagged), to allow substitution by the pharmacist at the point of dispensing for all listing circumstances of filgrastim. The brands may be substituted in consultation with the patient and provided the prescriber has not written 'brand substitution not permitted' on the prescription.

Refer to the Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software, for detailed information on initial, first continuing and subsequent continuing treatment phase criteria and eligibility details.

Further information for healthcare professionals regarding the use of PBS authorities and claiming of PBS benefits is available at the [Department of Human Services](#) website.

### **More Information**

The Biosimilars Awareness Initiative webpage on the [Australian Government Department of Health website](#) provides information about biosimilar medicines.

The biosimilars regulation page on the [Therapeutic Goods Administration website](#) explains the process for approval of biosimilar medicines for use in Australia.

The PBAC recommendations on the filgrastim listing changes are available on the [PBS website](#).

## **TABLES**

**a** = brands may be substituted by the pharmacist within each PBS item listing, in consultation with the patient and provided the prescriber has not written 'brand substitution not permitted' on the prescription..

For Authority Required (Streamlined) listings, prescribers need to request authority approval from the Department of Human Services to prescribe increased quantity and/or repeats in line with the PBS restriction.

### **Filgrastim HSD (Public) PBS Listings Summary**

#### *Background*

The PBAC recommended at its March 2018 meeting that based on currently available evidence, the reference biological, Neupogen<sup>®</sup>, and the filgrastim biosimilar brands currently PBS listed could be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged), for the purposes of substitution by the pharmacist at the point of dispensing for all circumstances and indications.

#### *PBS listing changes from 1 October 2019.*

The PBS listing changes apply to the following PBS Indications:

- Chemotherapy-induced neutropenia
- Chronic cyclical neutropenia
- Severe congenital neutropenia
- Mobilisation of peripheral blood progenitor cells
- Assisting autologous peripheral blood progenitor cell transplantation
- Assisting bone marrow transplantation

Form / Strength	Brand / a flag	Authority Level	PBS Item Code for Claiming
300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	Neupogen <b>a</b> Nivestim <b>a</b>	Streamlined	5742F
300 microgram/mL injection, 10 x 1 mL vials	Neupogen <b>a</b>	Streamlined	5741E
300 microgram/0.5 mL injection, 5 x 0.5 mL syringes	Zarzio <b>a</b>	Streamlined	2758E
480 microgram/1.6 mL injection, 10 x 1.6 mL vials	Neupogen <b>a</b>	Streamlined	5743G
480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	Neupogen <b>a</b> Nivestim <b>a</b>	Streamlined	5744H
480 microgram/0.5 mL injection, 5 x 0.5 mL syringes	Zarzio <b>a</b>	Streamlined	2783L

For further detail on prescription Authority Codes which relate to specific clinical criteria, prescribing conditions and PBS Indications, please refer to the Schedule of Pharmaceutical Benefits.

## Filgrastim HSD (Private) PBS Listings Summary

*PBS listing changes from 1 October 2019.*

The PBS listing changes apply to the following PBS Indications:

- Chemotherapy-induced neutropenia
- Chronic cyclical neutropenia
- Severe congenital neutropenia
- Mobilisation of peripheral blood progenitor cells
- Assisting autologous peripheral blood progenitor cell transplantation
- Assisting bone marrow transplantation

Form / Strength	Brand / a flag	Authority Level	PBS Item Code for Claiming
300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	Neupogen <b>a</b> Nivestim <b>a</b>	Streamlined	6291D
300 microgram/mL injection, 10 x 1 mL vials	Neupogen <b>a</b>	Streamlined	6126K
300 microgram/0.5 mL injection, 5 x 0.5 mL syringes	Zarzio <b>a</b>	Streamlined	2747N
480 microgram/1.6 mL injection, 10 x 1.6 mL vials	Neupogen <b>a</b>	Streamlined	6127L
480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	Neupogen <b>a</b> Nivestim <b>a</b>	Streamlined	6292E
480 microgram/0.5 mL injection, 5 x 0.5 mL syringes	Zarzio <b>a</b>	Streamlined	2733W