

5.23 PEGFILGRASTIM

Injection 6 mg in 0.6 mL single use pre-filled syringe Fulphila[®], Alphapharm Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought listing for a new biosimilar brand of pegfilgrastim (Fulphila[®]) for all indications for which the pegfilgrastim reference brand (Neulasta[®]) is currently PBS listed, on the Section 100 Highly Specialised Drugs (HSD) program.

2 Requested listing

- 2.1 The submission requested listing for pegfilgrastim (Fulphila) 6 mg in 0.6 mL single use pre-filled syringe for all indications for which the reference brand Neulasta is currently PBS listed. This includes the treatment of chemotherapy-induced neutropenia in patients who meet specified clinical criteria with the following conditions:

- Acute myeloid leukaemia
- Breast cancer
- B-cell chronic lymphocytic leukaemia
- Hodgkin disease
- Myeloma
- Inoperable stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx
- Germ cell tumours
- Non-Hodgkin lymphoma
- Sarcoma
- Central nervous system tumours
- Neuroblastoma

- 2.2 The submission anticipated that the Fulphila brand of pegfilgrastim would be brand equivalent ('a' flagged), for pharmacy level substitution, to the reference product Neulasta, and in doing so also be brand equivalent ('a' flagged) with the re-branded reference product, Ristempa. It was noted that the existing 'a' flagged brands have the same sponsor. The submission did not request the application of other biosimilar uptake drivers; however it is noted that at its March and April 2018 meetings, the PBAC considered that filgrastim and its currently listed biosimilars would be suitable for the application of biosimilar uptake drivers.

2.3 The submission requested listing under the same conditions as the current listings for pegfilgrastim, as a Section 100 Public Hospital Authority Required (STREAMLINED) and Section 100 Private Hospital Authority Required item on the PBS. An abridged version of the listing is presented below.

The submission’s proposed listings were consistent with the current PBS listings for the comparator, pegfilgrastim (Neulasta) and the re-branded reference product (Ristempa), therefore the restrictions below have not been reproduced in full.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
PEGFILGRASTIM 6 mg/0.6 mL injection, 0.6 mL syringe	1	11	\$1250.00 (Public) \$1297.15 (Private)	Fulphila®	Alpharm Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	Administered once per chemotherapy cycle
Condition:	Chemotherapy-induced neutropenia
PBS Indication:	Administered once per chemotherapy cycle for Chemotherapy-induced neutropenia
Treatment phase:	Initial and Continuing
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required – Electronic (Private) <input checked="" type="checkbox"/> Streamlined (Public)

2.4 In July 2017 the PBAC discussed the large number of restrictions for pegfilgrastim prophylaxis based on tumour type with or without requirements for specific treatment regimens. The Committee considered that the effectiveness of primary prophylaxis was largely related to the chemotherapy used rather than treatment with pegfilgrastim, thus the current restrictions may be inequitable, and potentially confusing for prescribers and patients. Therefore the PBAC “considered that it may be more appropriate to simplify the restrictions to allow primary prophylaxis for all patients where the chemotherapy treatment carries a risk of FN [febrile neutropenia] or prolonged severe neutropenia greater than 20% and is with curative intent, and to allow secondary prophylaxis for all patients who have had an episode of FN or prolonged severe neutropenia where there is clinical justification for continued therapy and an expected good response” (Neulasta PSD July 2017, para 7.5). The sponsor agreed with the Committee’s suggestion to simplify the restrictions. At its March 2018 meeting, the PBAC recommended changing the restrictions for pegfilgrastim (and for this to flow on to filgrastim and lipegfilgrastim) to broaden the

indications to primary and secondary prophylaxis of neutropenia, irrespective of chemotherapy or tumour type. The restriction is yet to be finalised, but it will be applicable to this listing if recommended.

3 Background

- 3.1 The Fulphila brand of pegfilgrastim was under TGA consideration at time of submission; however the TGA Delegate's Overview was available.
- 3.2 The TGA Delegate was not supportive of approval of the Fulphila application prior to the ACM meeting, and the ACM considered it to have an overall negative benefit-risk profile for its proposed indication. The ACM noted that the Good Manufacturing Practice (GMP) clearances were outstanding, and in their absence Fulphila could not be registered. Other issues included the study product having more aggregates than the reference product which can be associated with immunogenicity, and there were issues with the trial data, including problems with the trial population selected and that clinical conclusions on biosimilarity were drawn from populations that were considered unsuitable. The Delegate has engaged further with the sponsor post ACM consideration to resolve outstanding issues for this brand of pegfilgrastim.
- 3.3 The PBAC has not previously considered an application for the Fulphila brand of pegfilgrastim.

Brand equivalence and substitution at the pharmacist level ('a' flagging)

- 3.4 The Schedule of Pharmaceutical Benefits provide the following definition of brand equivalence:

Extract from the Explanatory Notes to the PBS Schedule¹

BRAND EQUIVALENCE

'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

- 3.5 Many medicines are available on the PBS in different brands. The Schedule of Pharmaceutical Benefits indicates where different brands are considered equivalent for the purposes of substitution at the point of dispensing by using 'a' flags.
- 3.6 The ability for prescribers and pharmacists to substitute generic or biosimilar brands for originator brands is an important part of encouraging use of generics and biosimilars in the marketplace and adds to the sustainability of the PBS.

¹ Symbols used in the Schedule - <http://www.pbs.gov.au/info/healthpro/explanatory-notes/section2/section-2-symbols>

- 3.7 For any individual prescription, a prescriber may choose to not permit brand substitution by indicating ‘substitution not permitted’ on the prescription. Likewise, when substitution is permitted, a patient may nominate which ‘a’ flagged brand they wish to receive from the pharmacist, except when State or Territory Law prohibits substitution (e.g. for Schedule 8 drugs of dependence). The substitution process allows for patient and prescriber choice and is not automatic.
- 3.8 The *National Health Act 1953* (“The Act”) makes it an offence for a pharmacist to supply a pharmaceutical benefit other than the benefit directed to be supplied in a prescription except when, amongst other criteria, the Schedule issued by the Department of Health states that the specified benefit and the substitute benefit are equivalent.
- 3.9 At the March 2018 meeting, the PBAC advised that the following revised considerations will be used to make a recommendation on brand equivalence (‘a’ flagging) of biosimilars with the reference brand;
- The Therapeutic Goods Administration has determined that the product is a biosimilar of the reference medicine as evidenced by ARTG registration documentation;
 - Availability of supportive data relating to the effects of switching between the reference product and the biosimilar product/s; and
 - Practical considerations relating to substitution by the pharmacist at the point of dispensing. This includes strength of formulation, number of units per pack and maximum quantities between the brands, which may make substitution at the pharmacy level difficult from a practical perspective.
- 3.10 The PBAC considered that where a biosimilar product could not be recommended to be brand equivalent (‘a’ flagged) at the time of PBS listing, data should be collected to support this consideration at a later point.
- 3.11 If the PBAC provides advice on brand equivalence (‘a’ flagging), the decision to apply brand equivalence to listings in the Schedule is made by the Minister for Health (or Delegate).
- 3.12 The PBAC was requested to consider whether, under Section 101(4ACD) of the National Health Act, 1953 the Minister should be advised that the Fulphila brand of pegfilgrastim and the Neulasta and Ristempa brands of pegfilgrastim could be marked as equivalent (‘a’ flagged) in the Schedule of Pharmaceutical Benefits.

Biosimilar uptake measures

- 3.13 The biosimilar uptake measures were agreed as part of the Strategic Agreements that the Government reached with Medicines Australia, the Generic and Biosimilar

Medicines Association and the Pharmacy Guild of Australia as part of the 2017 Budget process.

3.14 The PBAC will advise whether implementation of the uptake drivers is likely to raise any clinical or other concerns about appropriate use on the PBS. The PBAC may, on a case-by-case basis, provide advice relating to:

- encouraging the prescribing of a biosimilar brand for treatment naïve patients; and
- applying a lower level of authority to biosimilar brand(s) than exists for the reference brand of biological medicines.

3.15 After PBAC advice is received, a decision will be made about applying the drivers for the relevant medicine. The policy provides for lower authority requirements only for biosimilar brands, but there will be no increase in authority requirements to prescribe reference brands.

3.16 The PBAC has previously stated it had no concerns about encouraging prescribing of a biosimilar brand rather than the reference biological agent brand for treatment naïve patients, including through notes in the Schedule and prescribing software changes. (Etanercept (Brenzys) Public Summary Document, August 2017 PBAC Meeting).

3.17 The PBAC was asked to consider the appropriateness of the biosimilar uptake drivers.

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

4.1 The minor submission nominated the originator brand of pegfilgrastim, Neulasta[®], as the comparator, which was appropriate.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

5.3 The submission supported its TGA application with three studies to support its claim of bioequivalence and safety of the Fulphila brand of pegfilgrastim when compared to the originator brand Neulasta.

Table 1: Trials and associated reports presented in the re-submission

Trial ID/First Author	Protocol title/ Publication title	Publication citation
Direct randomised trial(s)		
MYL-1401H-3001	Multicenter, Double-Blind, Randomized, Comparative Efficacy and Safety Study of MYL-1401H and European Sourced Neulasta® in Stage II/III Breast Cancer Patients Receiving Neoadjuvant or Adjuvant Chemotherapy	N/A
MYL-1401H-1001	Single Center, Randomized, Double-blind, 3-Period, 3-Treatments, 3-Way Crossover Pharmacokinetics (PK)/Pharmacodynamics (PD) Trial to Assess PK, PD, Safety and Tolerability of MYL-1401H After Single Subcutaneous Injection at One Dose Level (2 mg) Comparing to an EU and US Marketed Drug Product (Neulasta®) in Healthy Volunteers	N/A
MYL-1401H-1002	Parallel-group, immunogenicity study of MYL-1401-H with US pegfilgrastim (Neulasta®) at a repeated 6 mg dose.	N/A

Source: Mylan Australia Fulphila Major PBAC Submission March 2018_Main Body.docx, p20

- 5.4 The submission was based on the MYL-1401H-3001 trial, a head-to-head trial comparing the Fulphila brand of pegfilgrastim to the Neulasta brand of pegfilgrastim in patients with Stage II/III invasive breast cancer.
- 5.5 The submission assumed that outcomes from this trial could be extrapolated to the other indications for which pegfilgrastim is PBS-listed, and claimed this to be in line with previous TGA approaches to the extrapolation of indications. In the March 2016 consideration of lipegfilgrastim, the PBAC were of the view that “evidence of comparative efficacy in one chemotherapy-induced neutropenia scenario was sufficient to enable extrapolation to other chemotherapy-induced neutropenia scenarios where evidence of efficacy of long half-life G-CSFs have previously been accepted” (Lipegfilgrastim PSD March 2016, para 7.4).
- 5.6 The TGA clinical evaluator also recommended against extrapolation of results to children on the basis of lack of generalisability of ‘comparability’ outcomes beyond the specific patient group studied in trial MYL-1401-3001.
- 5.7 Switching studies were not provided, as pegfilgrastim is not indicated for ongoing use, hence switching studies were not considered to be as relevant for this product in comparison to other biosimilars. At its April 2018 meeting, the PBAC considered the issue of brand equivalence (‘a’ flagging) across various brands of filgrastim, and considered that whilst there was limited high quality evidence specifically analysing the impact of treatment switching, it however considered the most comprehensive summary of evidence available found no evidence of major safety concerns associated with switching between different filgrastim brands [PBAC Outcomes (positive recommendations), April 2018]. Further, the PBAC noted other factors which would likely result in lower risks associated with switching between filgrastim brands, including its smaller molecule size and the nature of use of filgrastim, which is in discrete cycles when used for the neutropenia indication, and that switching brands within a treatment cycle was highly unlikely. In the case of pegfilgrastim, treatment switching within a single discrete neutropenia risk episode is even less likely, as a

single dose of pegfilgrastim provides the same treatment duration as approximately 11 days treatment with filgrastim [Filgrastim April 2018 PBAC Minutes - item 13, p8].

Comparative effectiveness

5.8 The primary efficacy endpoint of the pivotal study was the duration of severe neutropenia (DSN) in Cycle 1. DSN results were taken in Cycle 1 as it was considered to be the most sensitive and relevant endpoint for evaluating the difference in efficacy between MYL-1401H (Fulphila) and Neulasta. A 95% confidence interval for the least squares (LS) mean difference in DSN between Fulphila and Neulasta within ± 1 day was elected to conclude similar efficacy between the two products. The submission claimed this was supported by European regulatory guidelines on the development of biosimilar products containing recombinant filgrastim², and that it was consistent with the evaluation of other products which pre-specified the equivalence range to be ± 1 day. The Secretariat noted the relevant EMA guideline states that absolute neutrophil count (ANC) is the relevant pharmacodynamics marker for G-CSF, and that duration of severe neutropenia is the primary efficacy variable in clinical efficacy studies. In its consideration of lipegfilgrastim, the PBAC “considered that the pre-specified non-inferiority margin, of less than one day for the duration of severe neutropenia, was appropriate” (Lipegfilgrastim PSD March 2016, para 7.6). The mean DSN in the Fulphila group was 1.2 (± 0.93) and was 1.2 (± 1.10) in the Neulasta group. The 95% CI (-0.285, 0.298) for the difference in LS mean DSN of Fulphila and Neulasta was within the equivalence range of ± 1 day.

5.9 Secondary efficacy endpoints of the pivotal trial included:

- Frequency of the worst grade (Grade 3 or 4) neutropenia by cycle;
- Depth of the absolute neutrophil count (ANC) nadir in Cycle 1;
- Time to post-nadir recovery;
- ANC-time to nadir in Cycle 1 (i.e. time from the beginning of chemotherapy to the occurrence of the ANC nadir);
- Rate of febrile neutropenia (FN);
- Percentage of scheduled chemotherapy doses that were delivered;
- Proportion of chemotherapy doses reduced, omitted, or delayed related to neutropenia, FN, or documented infections; and
- Number of days of delay of chemotherapy related to neutropenia, FN, or documented infection.

² Annex to Guideline on Similar Biological Medicinal Products Containing Biotechnology-derived Proteins as Active Substance: Non-Clinical and Clinical Issues – Guidance on Similar Medicinal Products Containing Recombinant Granulocyte-Colony Stimulating Factor. *European Medicines Agency (EMA)* (2006), London. Document EMEA/CHMP/BMWP/31329/2005.

- 5.10 The ACM noted that the secondary endpoints of grade 4 neutropenia, febrile neutropenia, and chemotherapy dose adjustment due to neutropenia differed across the Fulphila and Neulasta arms, with a greater frequency of occurrences in the Fulphila arm. The sponsor attributed the differences to chance; however the TGA Clinical Evaluator noted that the imbalance could be reflective of a real difference in the characteristics of the pegfilgrastims. The ACM did not consider the imbalances in secondary endpoints were clinically relevant because the pharmacodynamics and pharmacokinetics data, which looked at dates of neutropenia and days to recovery, were similar.
- 5.11 The TGA Clinical evaluator noted that although DSN was the numerical assessment of the laboratory parameter, the rate of FN and its consequences were the more clinically relevant parameter and was the more appropriate choice of efficacy endpoint to form the basis of the therapeutic claim for the indication.

Comparative harms

- 5.12 Safety endpoints of the MYL-1401H-3001 trial included adverse events, which encompassed adverse drug reactions, bone pain, infections, injection site tolerance, and incidence of antibodies. Treatment emergent adverse events (TEAEs) were similar across arms, and the submission claimed Fulphila to have a similar adverse event profile to Neulasta in the prophylaxis of chemotherapy-induced neutropenia. The TGA Delegate's overview noted an imbalance in the rates of thrombocytosis, with 6.3% in the Fulphila patient group versus 0% in the Neulasta group, though the sponsor noted that laboratory values were consistent across arms, rather than AE reports. There was also an imbalance in serious AEs, mainly due to an imbalance in reporting of febrile neutropenia. Overall the safety profile of Fulphila was considered to be similar to Neulasta, and the ACM did not have any major objections to its safety outcomes.
- 5.13 The ACM considered that immunogenicity was not well established, as the MYL-1401H-1002 trial found that there was a greater frequency of anti-drug antibodies in the Fulphila arm, and more aggregates were found in the Fulphila product, although they were at levels lower than those associated with a heightened risk of immunogenicity. The ACM considered that there was no evidence to conclude that Fulphila was more immunogenic than the originator brand, however it noted that the clinical trials were not conducted in an appropriate population, hence any immunogenic differences could not be identified based on the available data.

Clinical claim

- 5.14 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of pegfilgrastim (Fulphila) compared with originator branded pegfilgrastim (Neulasta) and by extension, the re-branded reference product, Ristempa®.
- 5.15 The PBAC questioned the claim of non-inferior comparative effectiveness as the secondary endpoints were not met, particularly for higher rates of febrile neutropenia

within the Fulphila arm of the trial, however also noted the TGA Delegate was supportive of registering Fulphila pending resolution of GMP issues. The Committee considered that the differences in clinical endpoints may have some impact on consideration of biosimilar uptake drivers and ‘a’ flagging for this agent.

- 5.16 The PBAC noted the ACM was satisfied that there were no major differences between the safety profiles of the Fulphila brand of pegfilgrastim in comparison to the reference brand and were satisfied the claim of non-inferior comparative safety was reasonable.

Financial implications

- 5.17 The submission presented a cost-minimisation analysis to the Neulasta brand of pegfilgrastim, and it stated that their proposed price will result in no net cost to Government. The Secretariat noted that pegfilgrastim was recommended by the PBAC at its March 2018 meeting to broaden its indications, with a price reduction to ensure a cost-effective listing in the expanded population. It would be expected that the pegfilgrastim biosimilar would meet the new lower price of pegfilgrastim at time of listing, which would result in no net cost to government.
- 5.18 The Secretariat noted that although Fulphila would be the first biosimilar brand of pegfilgrastim to be listed on the PBS, it will not result in a statutory price reduction to the reference brand of pegfilgrastim, as Neulasta already received a price reduction when the Ristempa brand of pegfilgrastim was PBS listed.

For more detail on PBAC’s view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC deferred making a recommendation regarding the listing of biosimilar pegfilgrastim (Fulphila) pending TGA approval. The PBAC noted that as the Good Manufacturing Practice (GMP) clearances were still outstanding, the TGA was not in a position to register Fulphila at this time and as such the product could not be recommended for listing on the PBS.
- 6.2 The PBAC agreed in principle that the extrapolation of outcomes of the pivotal trial in patients with Stage II/III invasive breast cancer to the other indications was acceptable, consistent with the TGA Delegate’s advice.
- 6.3 The PBAC noted that although the ACM and TGA were satisfied that Fulphila met the agreed level of non-inferiority for clinical efficacy for the primary endpoint, there were residual concerns regarding the results of the secondary efficacy outcomes which may require further consideration pending the final TGA conditions of registration.
- 6.4 The PBAC also noted the imbalance in the rates of thrombocytosis and other serious adverse events, and also noted the ACM and TGA did not find these differences in clinical safety to be sufficient to prevent their assessment that Fulphila be considered a biosimilar of the reference product. The PBAC considered it was reasonable to await

the final TGA outcome and conditions of registration prior to making a recommendation.

- 6.5 The PBAC considered that switching between biosimilar agents was unlikely in this scenario in comparison to other agents for other chronic conditions, as pegfilgrastim is likely to be used in discrete cycles and has a long half-life with substantially fewer injections than filgrastim in a treatment cycle.

Outcome:

Deferred

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.

Addendum to the July 2018 PBAC Minutes:

MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT FOR CONSIDERATION BY THE COMMITTEE

4.01 PEGFILGRASTIM

**Injection 6 mg in 0.6 mL single use pre-filled syringe
Fulphila[®], Alphapharm Pty Ltd.**

9 Purpose of application

- 9.1 Following deferral at the July 2018 PBAC meeting, the minor submission sought listing for a new biosimilar brand of pegfilgrastim (Fulphila[®]) for all indications for which the pegfilgrastim reference brand (Neulasta[®]) is currently PBS listed, on the Section 100 Highly Specialised Drugs program.

10 Background

- 10.1 At its July 2018 PBAC meeting, the PBAC deferred making a recommendation regarding the listing of biosimilar pegfilgrastim, pending TGA approval. Further details on the deferral are available in section 6 of the July 2018 minutes.
- 10.2 The minor submission for the November 2018 meeting included the TGA approval letter (dated 6 August 2018) and requested the listing of biosimilar pegfilgrastim be progressed. The sponsor confirmed that the GMP clearances had been granted and that no significant conditions were applied to the registration. *The Secretariat confirms that TGA registration of biosimilar pegfilgrastim has occurred and that no significant conditions of registration were applied.*

11 PBAC Outcome

- 11.1 The PBAC recommended the listing of the biosimilar brand of pegfilgrastim, Fulphila[®], on the Section 100 Highly Specialised Drugs (HSD) program, for all indications for which the pegfilgrastim reference brand (Neulasta[®]) is currently PBS listed.
- 11.2 The PBAC advised that the Fulphila[®], Neulasta[®] and Ristempa[®] brands of pegfilgrastim should be considered equivalent for the purpose of substitution (i.e., ‘a’ flagged).
- 11.3 The PBAC advised that there were no clinical or other concerns about appropriate use of medicines, if the policy decision were made to apply the following biosimilar uptake drivers to the requested listing:
- encouraging the prescribing of biosimilar pegfilgrastim for treatment naïve patients by the addition of a note in the schedule; and
 - in principle, applying a lower level of authority to biosimilar pegfilgrastim than exists for the reference brand. The PBAC noted that applying a lower level of authority for the Fulphila[®] brand cannot be implemented at this time, as listings in Section 100 must be either Authority Required or streamlined authority items (i.e. cannot be a Restricted Benefit or unrestricted listings), and pegfilgrastim is already a streamlined authority listing.

Outcome:

Recommended

12 Recommended listing

- 12.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
PEGFILGRASTIM 6 mg/0.6 mL injection, 0.6 mL syringe	1	11	Fulphila [®] Alphapharm Pty Ltd

Public Summary Document – July 2018 PBAC Meeting

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Chemotherapy-induced neutropenia
PBS Indication:	Chemotherapy-induced neutropenia
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic (Private) <input checked="" type="checkbox"/> Streamlined (Public)
Clinical criteria:	Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.
Administrative Advice	Note Biosimilar prescribing policy Prescribing of the biosimilar brand FULPHILA® is encouraged for treatment naïve patients. Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
PEGFILGRASTIM 6 mg/0.6 mL injection, 0.6 mL syringe	1	11	Alphapharm Pty Fulphila® Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Chemotherapy-induced neutropenia
PBS Indication:	Chemotherapy-induced neutropenia
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic (Private) <input checked="" type="checkbox"/> Streamlined (Public)

<u>Clinical criteria:</u>	<p>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission;</p> <p>AND</p> <p>Patient must be at greater than 20% risk of developing febrile neutropenia;</p> <p>OR</p> <p>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.</p>
<u>Administrative Advice</u>	<p><u>Note</u></p> <p><u>Biosimilar prescribing policy</u></p> <p>Prescribing of the biosimilar brand FULPHILA® is encouraged for treatment naïve patients. Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).</p>

13 Context for Decision

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14 Sponsor’s Comment

The sponsor had no comment.