(1) Does the application adequately address the issue of the public health need for the medicine?

Yes ☒ No ☐

Granulocyte stimulating agents CSF’s are very effective adjuncts to facilitate the administration of chemotherapy, particularly dose-intensive regimens where the limiting factor is granulocyte recovery. The application details circumstances where CSF’s are indicated, and conversely where CSF’s either should not be administered or where they are not cost-effective.

(2) Have all important studies that you are aware of been included in the application?

Yes ☒ No ☐

The application relies on review papers and guidelines for CSF use published by ASCO and other organizations. Randomized comparisons of filgrastim and pegfilgrastim are also cited. Cost effectiveness studies are also included. These are sufficient to make the case for including G CSF on essential medicine lists for adults and children with cancer.

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?

Yes ☒ No ☐

Febrile neutropenia is a life-threatening complication of chemotherapy administration. A number of factors increase this risk. Numerous studies have demonstrated the efficacy of CSF’s to mitigate this risk and limit deaths from this complication. Evidence-based guidelines have been published that provide a rational basis for use of CSF’s, and clinical scenarios where CSF administration is and is not indicated. These have been incorporated in the application as guidelines for use of these agents for patients undergoing cancer chemotherapy.

(4) Is there evidence of efficacy in diverse settings and/or populations?

Yes ☒ No ☐
The efficacy of CSF’s have been demonstrated in children, adults, and the elderly, for mitigation of adverse effects of chemotherapy, for facilitating dose-intensive regimens where indicated, and for mobilizing hematopoietic stem cells for use in stem cell transplantation.

(5) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?

Yes ☒ No ☐

Adverse effects of CSF’s are generally mild in comparison to the toxicities of chemotherapy. The key issues are appropriate use of these agents, and selection of patients for whom CSF administration can be beneficial.

ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

Yes ☒ No ☐

CSF’s can be self-administered safely by patients, but appropriate patient selection and patient education are key components of successful use of these agents.

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)

Yes ☐ No ☒

The various granulocyte stimulating agents have been available for several decades. Filgrastim biosimilars are now becoming available which should lower the cost of these agents.

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?

Yes ☐ No ☐

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(9) Please comment briefly on issues regarding cost and affordability of this medicine.
Filgrastim biosimilars are now becoming available which should lower the cost of these agents. Prior analyses have demonstrated that cost savings from prevention of febrile neutropenia outweigh the costs of these relatively expensive medicines. The impact in resource poor settings may be even more dramatic.

(10) Any additional comments?

(11) Please summarise the action you propose the Expert Committee takes.

Addition of Granulocyte stimulating agents to the List of Essential cytotoxic and adjuvant medicines for use in appropriately selected patients with cancer undergoing myelosuppressive chemotherapy.