PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**NEULASTA**
(generic)	**(pegfilgrastim)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 153-A***

FDA-APPROVED INDICATION[1]
Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Compendial Uses
Mobilization of peripheral blood progenitor cells prior to autologous transplantation[2]

CRITERIA FOR APPROVAL

1	Is Neulasta being prescribed for the prophylaxis of chemotherapy-induced febrile neutropenia? [If no, skip to question 4.]	Yes	No
2	Is the request for a patient with a non-myeloid cancer? [If no, no further questions.]	Yes	No
3	Is the patient currently receiving or will the patient be receiving treatment with myelosuppressive anti-cancer therapy? [No further questions.]	Yes	No
4	Is Neulasta being requested for mobilization of peripheral blood progenitor cells (PBPCs)? [If no, no further questions.]	Yes	No
5	Is the mobilization of PBPCs being done prior to autologous stem cell transplantation?	Yes	No

Guidelines for Approval			
Duration of Approval		**6 Months**	
Set 1: Prophylaxis of FN		**Set 2: Mobilization of PBPC**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	4	1
2		5	
3			

Internal Use Only – Mapping Instructions		
	Yes	**No**
1	Go to 2	Go to 4
2	Go to 3	Deny
3	Approve, 6 months	Deny
4	Go to 5	Deny
5	Approve, 6 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2016.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 11, 2016.
3. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 11, 2016.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors. Version 1.2016. http://www.nccn.org/professionals/physican_gls/pdf/myeloid_growth.pdf. Accessed July 8, 2016.
5. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-3212.

DOCUMENT HISTORY

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Reviewed:	CRC 2/2002; CDPR/MM 02/2006, 08/2006; WLF 06/2007, 05/2008, 07/2009; KP 09/2010, 10/2011; DHR 09/2012; LMS 07/2013, SES 07/2014, LCB 07/2015; DR 07/2016; AN 03/2017
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