Local Coverage Article:
Pegfilgrastim (Neulasta) J2505 (A52889)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

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Article Information

General Information

Article ID
A52889

Original ICD-9 Article ID
A52799

Article Title
Pegfilgrastim (Neulasta) J2505

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Article Effective Date
10/01/2015

Revision Effective Date
01/26/2017

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

Medicare covers the use of Pegfilgrastim (Neulasta), J2505, to decrease the incidence of infection, as manifested by febrile neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. The initial 2002 FDA approval and label specified administration starting 24 hours after and no sooner than 14 days before delivery of cytotoxic chemotherapy.

Coverage of Same Day Dosing
Within two years of drug approval, presentations on the utility and non-inferiority of same day dosing of Neulasta with chemotherapeutic agents appeared as abstracts. By 2009, Whitworth and Schuman independently proclaimed the administration of "pegfilgrastim on day 1 appears to be safe, effective and convenient" and "same day…may be determined to be a convenient, safe and effective approach" respectively. A 2010 metaanalysis concluded "the results indicated that same-day administration was statistically non-inferior to next-day administration according to neutropenia duration." Based on the evidence, the administration of same-day pegfilgrastim has become an accepted standard of care and in particular, in situations where patients are believed to be a higher risk of potential non-compliance with day 2 administration.

Coverage of Less than 14 Day Dosing
In multiple trials of every other week myelosuppressive chemotherapy, pegfilgrastim given within 14 days of the next cycle has been shown to be effective in maintaining dose-density and reducing neutropenic events without any significant concerns for safety. Based on this evidence, the administration of pegfilgrastim before the traditional 14 day window has become an accepted standard of care to maintain dose-density or reduce neutropenic complications in regimens with substantial myelosuppression.

Sources:
Same Day Dosing

• Whitworth JM, Matthews KS, Shipman KA, Numnum TM, Kendrick JE, Kilgore LC, Straughn JM. The safety and efficacy of day 1 versus day 2 administration of pegfilgrastim in patients receiving myelosuppressive chemotherapy for gynecologic malignancies. Gynecol Oncol 2009; 112:601–604

• Schuman SI, Lambrou N, Robson K, et al. Pegfilgrastim dosing on same day as myelosuppressive chemotherapy for ovarian or primary peritoneal cancer. J Support Oncol. 2009; 7(6):225-8

• Burris HA, Belani CP, Kaufman PA, et al. Pegfilgrastim on the same day versus next day of chemotherapy in patients with breast cancer, non-small-cell lung cancer, ovarian cancer, and non-hodgkin's lymphoma: results of four multicenter, double-blind, randomized phase II studies. J Oncol Pract. 2010; 6(3):133-40

Less than 14 Day Dosing

• Brusamolino E, Rusconi C, Montalbetti L, et al. Dose-dense R-CHOP-14 supported by pegfilgrastim in patients with diffuse large B-cell lymphoma: a phase II study of feasibility and toxicity. Haematologica. 2006; 91(4):496-502

• Burstein HJ, Parker LM, Keshaviah A, et al. Efficacy of pegfilgrastim and darbepoetin alfa as hematopoietic support for dose-dense every-2-week adjuvant breast cancer chemotherapy. J Clin Oncol. 2005; 23(33):8340-7

• Jones RL, Walsh G, Ashley S, et al. A randomized pilot phase II study of doxorubicin and cyclophosphamide (AC) or epirubicin and cyclophosphamide (EC) given 2 weekly with pegfilgrastim (accelerated) vs 3 weekly (standard) for women with early breast cancer. Br J Cancer. 2009; 100(2):305-10

• Hecht JR, Pillai M, Gollard R, et al. A randomized, placebo-controlled phase ii study evaluating the reduction of neutropenia and febrile neutropenia in patients with colorectal cancer receiving pegfilgrastim with every-2-week chemotherapy. Clin Colorectal Cancer. 2010; 9(2):95-101

• Pirker R, Ulsperger E, Messner J, et. al. Achieving full-dose, on-schedule administration of ACE chemotherapy every 14 days for the treatment of patients with extensive small-cell lung cancer. Lung. 2006; 184(5):279-85.

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Coding Information

Bill Type Codes:

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N/A

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N/A

CPT/HCPCS Codes N/A
ICD-10 Codes that are Covered N/A
ICD-10 Codes that are Not Covered N/A
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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
01/26/2017	R2	Revised to correct the combined JEAB final MCD number from A53296, as stated in Revision 1, to A52889. No change in coverage made.
01/26/2017	R1	This JE Part A (JEA) Local Coverage article A53029 is being combined into the JE Part B (JEB) article A52889. Both JEA and JEB contract numbers will have the same final MCD article number A53296. No other change in coverage.

Back to Top **Related Local Coverage Document(s)** N/A

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

Public Version(s) Updated on 07/06/2017 with effective dates 01/26/2017 - N/A Updated on 01/20/2017 with effective dates 01/26/2017 - N/A Updated on 03/31/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

- Neulasta,
- Pegfilgrastim
- J2505

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