

Prescribing Information

Neulasta® is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Rare cases of splenic rupture and sickle cell crises have been reported in postmarketing experience. Allergic reactions, including anaphylaxis, have also been reported. The majority of these reactions occurred upon initial exposure. However, in rare cases, allergic reactions, including anaphylaxis, recurred within days after discontinuing anti-allergic treatment.

In a placebo-controlled trial, bone pain occurred at a higher incidence in Neulasta® treated patients as compared to placebo-treated patients (31% vs 26%). The most common adverse events reported in either placebo- or active-controlled trials were consistent with the underlying cancer diagnosis and its treatment with chemotherapy, with the exception of bone pain. While not reported in patients receiving Neulasta®, rare events of adult respiratory distress syndrome have been reported in patients receiving the parent compound, Filgrastim.

NEUPOGEN® (Filgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.

Rare events of adult respiratory distress syndrome, splenic rupture, and sickle cell crises have been reported in postmarketing experience in patients receiving NEUPOGEN®. Allergic reactions have also been reported. In clinical trials, the most common adverse event was bone pain, reported in approximately 22% of patients. In most cases, bone pain was controlled with non-narcotic analgesics, such as acetaminophen.

Please refer to the accompanying Neulasta®, and NEUPOGEN® prescribing information.

AMGEN

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Amgen's commitment to patient support programs

Important information
and answers to
frequently asked
questions about
patient support
programs provided
by Amgen

This is not intended to be a thorough description or analysis of the subject matter discussed herein. Rather, it is intended only to provide a general summary and overview of these issues. While we believe that the information is accurate as of November 2005, we do not guarantee its accuracy. Some of the information may be subject to different interpretations, and all of the information is subject to change at any time.

Amgen's commitment to patient support programs

Amgen is committed to providing comprehensive services that help patients obtain and maintain access to medically appropriate therapies.

- For more than 15 years, Amgen's Reimbursement Connection® has been addressing the provider community's reimbursement questions regarding Amgen therapies.

- During this time, Amgen's SAFETY NET® Program has provided access to Amgen therapies for uninsured and underinsured patients.*
- As patients' needs evolve—for example, as a result of Medicare reform—Amgen will continue its efforts to help ensure that patients receive access to its medically important therapies.

Amgen programs



Reimbursement Connection®

1-800-272-9376
www.reimbursementconnection.com

- Payor policy review
- Insurance verification
- Prior authorization support
- Claims assistance and appeals
- Alternative funding referrals



SAFETY NET® Program

1-800-272-9376

- Patient assistance for the uninsured and underinsured
- Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), and NEUPOGEN® (Filgrastim) provided via product replacement to a sponsoring health care provider

Other resources

Specialty pharmacies



1-888-773-7376



1-800-237-2767



1-866-873-4502

- Personalized prescription management
- Product shipment to patient or provider
- Refill reminders
- 24-hour pharmacist availability
- Other specialty pharmacies may be available as well

Independent patient assistance foundations

- Independent, third-party, not-for-profit organizations
- Provide patient assistance and support, including assistance for underinsured patients who meet certain criteria

Foundation	Disease funded
Patient Advocate Foundation (PAF) 1-866-512-3861	Chemotherapy-induced anemia Chemotherapy-induced neutropenia
HealthWell 1-800-675-8416	Chemotherapy-induced anemia Chemotherapy-induced neutropenia
Patient Access Network Foundation (PANF) 1-866-316-7263	Chemotherapy-induced anemia Anemia of chronic disease

Other patient assistance programs may be available to provide assistance as well.

Frequently asked questions

Question: Which issues can the Reimbursement Connection® help me with?

Answer: If you or your patients experience reimbursement or access issues, call the Reimbursement Connection®. Whether you have coverage, coding, or payment questions; are experiencing claims issues; have a patient with inadequate insurance coverage; or need suggestions on where a patient might turn for alternative funding sources, the Reimbursement Connection® staff is available to help. As long as the issue is related to an Amgen therapy, Reimbursement Connection® services are likely to help resolve the issue.

Question: Can I instruct my patients to contact the Reimbursement Connection®?

Answer: Absolutely. In many cases the Reimbursement Connection® staff can work directly with patients to resolve issues. In some cases, such as when the issue relates to a problem claim or finalizing a patient assistance application, the process cannot be completed without some interaction with the health care provider's staff. However, Amgen recognizes how busy providers are and will work to make the process as efficient as possible.

Question: What are the income and other criteria patients must meet to qualify for SAFETY NET® assistance?

Answer: The eligibility criteria are not publicly available; however, the assistance criteria take into consideration the unique needs of the patient populations associated with each Amgen therapy. Further, Amgen looks at each unique patient case to determine the available options for assistance. To determine if an individual patient qualifies, call 1-800-272-9376. Staff will assess the patient's case over the phone and help complete the minimal paperwork necessary for enrollment.

Question: Do I have to use one of the specialty pharmacies listed here?

Answer: Use of these pharmacies is not a requirement. Providers can access Amgen therapies through various channels, including purchasing drugs from wholesalers, directly from Amgen in certain cases, and through specialty pharmacies other than the three listed.

Question: What are the eligibility criteria of the independent patient assistance foundations?

Answer: Each foundation establishes its own criteria. Amgen does not influence these independent, third-party, not-for-profit organizations' decisions about patient eligibility and is not privy to patient information. You can contact these foundations directly, or if you would like assistance identifying which foundations may be options for a given patient, please contact the Reimbursement Connection® at 1-800-272-9376.

*Qualifying patients are those who meet program eligibility criteria, including insurance and income requirements.