

Sample Letter of Medical Necessity

Practice Letterhead

(Date)

(Insurer Name)

(Insurer Company Name)

(City, State ZIP Code)

ATTN: (Name, Claims Department)

Re: Treatment authorization request for (patient's name)
(Policy #/Group #/Patient ID #)
(DOB)

To whom it may concern:

I am writing on behalf of my patient, (patient's name) to request coverage for Neulasta[®] (pegfilgrastim) therapy. This letter documents the medical necessity for Neulasta[®] therapy to decrease the incidence of infection, as manifested by febrile neutropenia. Details about the patient's medical condition, planned chemotherapy treatment, and information from the product's labeling are indicated below.

(Mr./Ms.) (patient's last name) is receiving a myelosuppressive anti-cancer regimen associated with a clinically significant incidence of febrile neutropenia to treat (his/her) (patient's diagnosis). (His/Her) medical history and treatment pattern are as follows:

- List type of myelosuppressive chemotherapy regimen that the patient is to receive
- List applicable risk factors

Neulasta[®] is indicated 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.

Rare cases of splenic rupture in some patients and sickle cell crises in patients with sickle cell disease have been reported in post-marketing 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.

In summary, Neulasta[®] therapy is medically necessary and reasonable for (Mr./Ms.) (patient's last name)'s medical condition and planned chemotherapy regimen, and would provide significant clinical benefit. Please contact me if any additional information is required to ensure prompt approved coverage of this course of Neulasta[®] therapy.

Sincerely,

(Physician Name)