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CRX-ALL-0330-19
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CRX-ALL-0330-19
A. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; or

B. Use in adult individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML; or

C. Treatment of moderate to severe aplastic anemia; or

D. Treatment of severe neutropenia in individuals with hairy cell leukemia; or

E. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophils count (ANC) less than or equal to 500 mm$^3$) or experiencing recurrent infection; or

F. In an individual receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer; or

G. Chronic administration to reduce the incidence and duration of sequelae of neutropenia (for example, fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia; or

H. Treatment of (non-chemotherapy) drug-induced neutropenia; or

I. Treatment of low neutrophil counts in individuals with glycogen storage disease type 1b; or

J. Treatment for neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy; or

K. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected; or

L. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome); or

M. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:
   1. To promote myeloid reconstitution; or
   2. When engraftment is delayed or has failed; or

N. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT); or

O. Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.
III. Requests for pegfilgrastim (Neulasta, Neulasta on-body injector delivery kit), pegfilgrastim-jmdb (Fulphila) or pegfilgrastim-cbqv (Udenyca) may be approved for individuals who meet any of the following criteria:

A. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; or
B. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophils count (ANC) less than or equal to 500 mm$^3$ or experiencing recurrent infection; or
C. In an individual receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer; or
D. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome); or
E. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:
   1. To promote myeloid reconstitution; or
   2. When engraftment is delayed or has failed.

IV. Requests for sargramostim (Leukine) may be approved for individuals who meet any of the following criteria:

A. In an individual receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer; or
B. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; or
C. For administration shortly after the completion of induction or repeat induction chemotherapy of acute myeloid leukemia (AML) for individuals over 55 years of age; or
D. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophils count (ANC) less than or equal to 500 mm$^3$ or experiencing recurrent infection; or
E. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected; or

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CRX-ALL-0330-19
Market Applicability

| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
|--------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | X | NA | NA | X | X | X | X | X | X | NA | NA | NA | X |

*FHK- Florida Healthy Kids

F. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome); or

G. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:
   1. To promote myeloid reconstitution; or
   2. When engraftment is delayed or has failed; or

H. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT).

V. Requests for Tbo-Filgrastim (Granix) may be approved for individuals who meet any of the following criteria:

I. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:
   1. To promote myeloid reconstitution; or
   2. When engraftment is delayed or has failed; or

J. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT).

May not be approved:

The use of CSFs (filgrastim, filgrastim-aafi, filgrastim-sndz, pegfilgrastim, pegfilgrastim-jmdb, pegfilgrastim-cbqv, sargramostim and tbo-filgrastim) may not be approved for any of the following:

1. As prophylaxis for FN, except when criteria above are met; or
2. As treatment in neutropenic individuals who are afebrile, except when criteria above are met; or
3. As adjunctive therapy in individuals with uncomplicated febrile neutropenia, defined as: fever less than 10 days duration, no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection; and no uncontrolled malignancies; or
4. Chemo sensitization of myeloid leukemias; or
5. As prophylaxis for FN during concomitant chemotherapy and radiation therapy; or
6. Continued use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders); or
7. For uses not meeting the criteria above.

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