

Member Name: \_\_\_\_\_ Member ID: \_\_\_\_\_ Member DOB: \_\_\_\_\_  
 Drug Name: \_\_\_\_\_ Strength: \_\_\_\_\_ Directions: \_\_\_\_\_  
 Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_  
 Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

**Horizon NJ Health**  
**Colony Stimulating Factors (G-CSF & GM-CSF) – Medical Necessity Request**

<b><u>General Information</u></b>			
Current Weight: _____	WBC count: _____	Date: _____	ANC: _____ Date: _____

<b>Please indicate the drug being requested and answer any of the corresponding questions (if any)</b>			
<input type="checkbox"/> Zarxio <input type="checkbox"/> Neulasta <input type="checkbox"/> Fulphila <input type="checkbox"/> Nivestym <input type="checkbox"/> Udenyca	<input type="checkbox"/> Leukine	<input type="checkbox"/> Granix	<input type="checkbox"/> Neupogen
None	Does the member have any of the following contraindications to therapy: <input type="checkbox"/> Excessive leukemic myeloid blasts in the bone marrow or peripheral blood (> or = 10%) <input type="checkbox"/> Concomitant use with chemotherapy and radiotherapy <input type="checkbox"/> None	Can the member try the formulary alternative, Zarxio? <input type="checkbox"/> Yes <input type="checkbox"/> No: Please provide the clinical reason why the member cannot try Zarxio: _____	

**Diagnosis Information** (please indicate diagnosis and answer related questions):

- Prevention of Chemotherapy Induced Febrile Neutropenia (FN):** Please indicate what the requested drug is being used for and answer the related questions.
- Primary Prevention
    - a. Does the member have neutropenia defined as <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours? **Yes or No.**
      - 1a. If Yes, does the member currently have a fever defined as a single temperature ≥38.3°C orally or ≥ 38.0°C for duration over 1 hour? **Yes or No.**
    - b. Is the member receiving radiation with chemotherapy? **Yes or No**
    - c. What type of cancer does the member have? \_\_\_\_\_
    - d. What chemotherapy regimen will the member be receiving? Please list all drug names.  
\_\_\_\_\_
    - e. How long is each chemotherapy cycle and how many cycles of chemotherapy are being requested? .  
\_\_\_\_\_
    - f. Please indicate if the member has any of the following risk factors/conditions.
 

<input type="checkbox"/> Age >65 receiving full chemotherapy dose intensity	<input type="checkbox"/> Poor performance or nutritional status
<input type="checkbox"/> Persistent or pre-existing neutropenia	<input type="checkbox"/> Advanced disease
<input type="checkbox"/> Tumor involvement in the bone marrow	<input type="checkbox"/> Infection or HIV
<input type="checkbox"/> Recent surgery with open wounds	<input type="checkbox"/> Is receiving curative or adjuvant treatment
<input type="checkbox"/> Liver dysfunction (bilirubin >2.0)	<input type="checkbox"/> Is at significant risk for serious medical consequences of febrile neutropenia, including death
<input type="checkbox"/> Renal dysfunction (CrCl <50)	<input type="checkbox"/> Chronic immunosuppression in the post-transplant setting
<input type="checkbox"/> Prior chemotherapy or radiation therapy	
<input type="checkbox"/> Cardiovascular disease or multiple comorbid conditions	
  - Secondary Prevention
    - a. Has the member previously experienced febrile neutropenia or dose-limiting neutropenic events on the same chemotherapy regimen? **Yes or No**
    - b. Is chemotherapy dose reduction or change in treatment regimen an option? **Yes or No**
    - c. Is the member receiving radiation together with chemotherapy concurrently? **Yes or No**

**Treatment of Chemotherapy Induced Febrile Neutropenia (FN)**

Physician office's signature\* \_\_\_\_\_ Print Name \_\_\_\_\_

\*Form must be completed and signed by physician or licensed representative from the physician's office

Member Name: \_\_\_\_\_ Member ID: \_\_\_\_\_ Member DOB: \_\_\_\_\_

Drug Name: \_\_\_\_\_ Strength: \_\_\_\_\_ Directions: \_\_\_\_\_

Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_

Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

a. Does the member have neutropenia defined as <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours? **Yes or No.**

1a. If Yes, does the member currently have a fever defined as a single temperature ≥38.3°C orally or ≥ 38.0°C for duration over 1 hour? **Yes or No**

b. Has the member previously received G(M)-CSF (e.g., Granix, Neupogen, Neulasta, etc.) or is currently receiving prophylaxis in the current chemotherapy cycle? Please indicate Yes or No below and answer associated questions.

Yes

a. What G-CSF did the member receive for prevention of neutropenia? \_\_\_\_\_

No

a. Does the member have a risk factor for an infection-related complication? **Yes or No.** If Yes, please describe the risk factor: \_\_\_\_\_

c. What chemotherapy regimen will the member be receiving? Please list all drug names. \_\_\_\_\_

d. How long is each chemotherapy cycle and how many cycles of chemotherapy are being requested? \_\_\_\_\_

e. What type of cancer does the member have? \_\_\_\_\_

**Acute Myelogenous Leukemia (AML):** Please indicate what the requested drug is being used for and answer the related questions

Induction treatment

a. What other medications will be member be receiving as part of the induction treatment? Please indicate what days of the treatment cycle each med will be received.  
\_\_\_\_\_

b. Does the member have non-acute promyelocytic leukemia (APL) subtype of AML, is septic, and has a life-threatening infection? **Yes or No**

Following induction chemotherapy

a. Is the requested drug being used to reduce time to neutrophil recovery and the duration of fever? **Yes or No**

Following consolidation chemotherapy

a. Is the requested drug being used to reduce time to neutrophil recovery and the duration of fever? **Yes or No**

Relapsed or Refractory AML (Salvage Therapy)

a. What other medications will be member be receiving as part of this treatment?  
\_\_\_\_\_

Post-remission AML (Consolidation)

a. Does the member have a life-threatening infection or signs and symptoms of sepsis? **Yes or No**

b. Is the leukemia believed to be in remission? **Yes or No**

**Dose Dense Chemotherapy**

a. What type of cancer does the member have? \_\_\_\_\_

b. Is the G(M)-CSF being prescribed to enable the administration of the dose-dense regimen? **Yes or No**

c. What chemotherapy drugs (including drug name, dose, and directions) is the member receiving? Please list all drug names and frequencies.  
\_\_\_\_\_  
\_\_\_\_\_

**Congenital, Cyclic or Idiopathic Neutropenia**

a. Please indicate which type of neutropenia the member has:  Congenital  Cyclic  Idiopathic

b. Does the member have severe neutropenia? **Yes or No**

c. Is the member symptomatic? **Yes or No.** If Yes, please list the symptom(s): \_\_\_\_\_

**Diffuse Aggressive Lymphoma**

Physician office's signature\* \_\_\_\_\_ Print Name \_\_\_\_\_

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Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_

Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

a. Is the drug being used for prophylaxis of neutropenia? **Yes or No.**

b. Is the member being treated with curative chemotherapy (cyclophosphamide, doxorubicin, vincristine, prednisone, and rituximab)? **Yes or No.**

**Drug-Induced Neutropenia**

a. What drug is the member taking that is causing the neutropenia? \_\_\_\_\_

**HIV/AIDS-Associated Neutropenia**

**Leukemia**

a. Has member had a relapse after an allogenic stem-cell transplant? **Yes or No**

**Myelodysplastic Syndrome (MDS):** Please indicate whether the member has anemia or neutropenia and answer the associated questions.

**Anemia**

a. What risk group is the member in?

Low or intermediate-1 risk category based on International Prognostic Scoring System (IPSS)

Very low, low, or intermediate risk category based on Revised IPSS (IPSS-R)

Very low, low, or intermediate risk category based on WHO-based prognostic scoring system (WPSS)

b. Does the member have symptomatic anemia? **Yes or No**

c. Does the member have the del(5q) abnormality? **Yes or No**

d. What is the member's serum EPO in IU/ml? \_\_\_\_\_

e. What is the member's ring sideroblast %? \_\_\_\_\_

f. Will the member be receiving an erythropoietin alfa or darbepoetin alfa therapy (requires prior approval) concurrently? **Yes or No.**

g. Has the member failed to respond to erythropoietin alfa or darbepoetin alfa therapy despite adequate iron stores? **Yes or No.**

**Neutropenia**

h. Does the member have a recurrent or resistant infection? **Yes or No**

**Non-Hodgkin's Lymphoma: AIDS-related B-Cell Lymphoma**

a. Does the member have HIV/AIDS?

Yes

a. Does the member have any of the following (please indicate all that apply)? **Yes or No**

Burkitt Lymphoma

Diffuse large B-cell lymphoma (DLBCL)

Human Herpes Virus 8 (HHV8)-positive DLBCL (formerly known as Lymphoma associated with Castleman's disease)

Primary effusion lymphoma

No

b. Does the member have Rituximab-related Neutropenia?

Yes

a. Has the member had prolonged neutropenia? **Yes or No**

No

c. Does the member have Post-Transplant Lymphoproliferative Disorder (PTLD)?

Yes

a. Does member have a positive positron emission tomography/computerized tomography (PET/CT) scan after treatment with Rituximab? **Yes or No**

b. Will the member be receiving chemotherapy along with the requested drug? **Yes or No.**

If Yes, how often will this cycle be given (ie, how many weeks between each cycle given)? \_\_\_\_\_

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2b. How many cycles of chemotherapy will member receive?  
\_\_\_\_\_  
\_\_\_\_\_

2c. On which days of the cycle will the member receive this chemotherapy regimen with Granulocyte Colony Stimulating Factor (G-CSF) therapy? \_\_\_\_\_  
\_\_\_\_\_

No

d. What specific type of lymphoma does the member have? \_\_\_\_\_

**Acute Radiation Syndrome (ARS)**

a. Does the member have suspected or confirmed exposure to radiation levels of  $\leq 10$  grays (Gy)? **Yes or No**

b. Does the member have suspected or confirmed exposure to radiation levels of  $\geq 2$  grays (Gy)? **Yes or No**

c. Does the member have a significant decrease in the absolute lymphocyte count? **Yes or No**

d. Does member have neutropenia of  $< 0.5 \times 10^9$  cells/L that is anticipated to persist for  $\geq 7$  days? **Yes or No**

**Transplant: Mobilization (Bone marrow transplant (BMT)/ Hematopoietic stem cell transplant (HSCT), Peripheral Blood Progenitor Cells (PBPC) transplant, Granulocyte transplant).** Please indicate what the G(M)-CSF is being used for.

For mobilization of autologous hematopoietic progenitor cells (HSCT/BMT/PBPC )

For mobilization of autologous PBPC into peripheral blood for collection by leukapheresis

For mobilization of allogeneic donors: for mobilization of allogeneic cells or granulocyte transfusion

**Transplant: Supportive Care (Myeloid Recovery, Delayed/ Failed Engraftment).** Please indicate what the G(M)-CSF is being used for.

After autologous hematopoietic cell transplant (HSCT/ BMT/PBPC)

Reduce duration of neutropenia in members undergoing myeloablative chemotherapy followed by allogeneic HSCT/BMT

To accelerate myeloid recovery in members undergoing allogeneic HSCT/BMT from HLA-mated related donor

For delayed or failed hematopoietic engraftment after transplant

After haploidentical/cord blood transplant

**Dinutuximab (Unituxin)**

a. Is the member receiving Dinutuximab, granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2) and 13-cis-retinoic acid (RA) for the treatment of high-risk neuroblastoma? **Yes or No**

b. Has the member achieved at least a partial response to prior first-line multiagent, multimodality therapy? **Yes or No**

Physician office's signature\* \_\_\_\_\_ Print Name \_\_\_\_\_

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