

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

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

Please indicate the drug being requested and answer any of the corresponding questions (if any)			
<input type="checkbox"/> Zarxio <input type="checkbox"/> Neulasta <input type="checkbox"/> Fulphila <input type="checkbox"/> Nivestym <input type="checkbox"/> Udenyca <input type="checkbox"/> Ziextenzo <input type="checkbox"/> Nyvepria <input type="checkbox"/> Releuko <input type="checkbox"/> Fylnetra	<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

1. What type of cancer does the member have? _____
2. What chemotherapy regimen will the member be receiving? Please list all drug names.

3. Is the member receiving dose-dense chemotherapy (regimen that requires G-CSF to maintain dose intensity/schedule)? **Yes or No.**
4. How long (days) is each chemotherapy cycle? _____
5. How many cycles of chemotherapy are being requested? _____
6. 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"/> Persistent neutropenia <input type="checkbox"/> Bone marrow involvement by tumor <input type="checkbox"/> Recent surgery with open wounds <input type="checkbox"/> Liver dysfunction (bilirubin >2.0) <input type="checkbox"/> Renal dysfunction (CrCl <50) <input type="checkbox"/> Poor performance or nutritional status	<input type="checkbox"/> Advanced disease <input type="checkbox"/> Infection or HIV <input type="checkbox"/> Is receiving curative treatment and is at significant patient-specific risk for developing febrile neutropenia <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 <input type="checkbox"/> Member previously experienced febrile neutropenia or dose-limiting neutropenic event on the same chemotherapy regimen
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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 dose dense chemotherapy (regimen that requires G-CSF to maintain dose intensity/schedule)? **Yes or No**

Physician office's signature* _____ Print Name _____

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Treatment of Chemotherapy Induced Febrile Neutropenia (FN)

1. Does the member have febrile neutropenia following chemotherapy? **Yes or No.**
2. Has the member previously received or is currently receiving Colony Stimulating Factor (CSF -e.g., Granix, Neupogen, Neulasta, etc.) prophylaxis in the current chemotherapy cycle? Please indicate Yes or No below and answer associated questions.

Yes

a. Which CSF did the member receive for prevention of neutropenia? _____

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

No

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

3. What chemotherapy regimen will the member be receiving? Please list all drug names. _____

4. How long (days) is each chemotherapy cycle? _____

5. How many cycles of chemotherapy are being requested? _____

6. 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**

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

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

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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

1. Which of the following risk groups 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)
- Other (please specify) _____

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

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

4. What is the member's serum EPO in IU/ml? _____

5. What is the member's ring sideroblast %? _____

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

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

8. Does the member have an SF3B1 mutation? **Yes or No**

Neutropenia

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

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

1. 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

2. Does the member have Rituximab-related Neutropenia?

Yes

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

No

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

Yes

a. Does the member have either Polymorphic PTLD or B-cell type Monomorphic PTLD? **Yes or No.**

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

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

If Yes,

i. . What chemotherapy regimen will the member be receiving? Please list all drug names.

ii. How often will this cycle be given (ie, how many weeks between each cycle given?) _____

iii. How many cycles of chemotherapy will member receive? _____

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

No

4. What specific type of lymphoma does the member have? _____

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Acute Radiation Syndrome (ARS)

a. Does the member have radiation-induced myelosuppression following a radiologic/nuclear incident (hematopoietic acute radiation syndrome [H-ARS])? **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 allogeneic donors: for mobilization of allogeneic hematopoietic cells or for 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 (Unituxin®), 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**

Chimeric antigen receptor (CAR) T-Cell Related Toxicities

- a. Does member have Cytokine Release Syndrome (CRS)? **Yes or No**
- b. Is this being used as supportive care for this diagnosis? **Yes or No**
- c. Is the member neutropenic? **Yes or No**

Wilm's Tumor (Nephroblastoma)

- a. Is this being used as supportive care for this diagnosis? **Yes or No**
 - b. What other chemotherapy will the member also be receiving?
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