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

General Information

Current Weight: _____ WBC count: _____ Date: _____ ANC: _____ Date: _____

Please indicate the drug being requested and answer any of the corresponding questions (if any)			
□ Zarxio □ Neulasta □ Fulphila □ Nivestym □ Udenyca □ Ziextenzo	□ Leukine	□ Granix	□Neupogen
None	Does the member have any of the following contraindications to therapy: □ Excessive leukemic myeloid blasts in the bone marrow or peripheral blood (> or = 10%) □ Concomitant use with chemotherapy and radiotherapy □ None	Can the member try the formulary alternative, Zarxio? □ Yes □ 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.

□ Age > 65 receiving full chemotherapy dose intensity
□ Persistent or pre-existing neutropenia
□ Tumor involvement in the bone marrow
□ Recent surgery with open wounds
□ Liver dysfunction (bilirubin >2.0)
□ Renal dysfunction (CrCl <50)
□ Poor performance or nutritional status
□ Advanced disease
□ Infection or HIV
□ Is receiving curative or adjuvant treatment and is at significant patient-specific risk for developing febrile neutropenia
□ Chronic immunosuppression in the post-transplant setting
□ Prior chemotherapy or radiation therapy
□ Cardiovascular disease or multiple comorbid conditions
□ Member previously experienced febrile neutropenia or dose-limiting neutropenic event on the same chemotherapy regimen

□ 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**

Physician office's signature*_____ Print Name_____
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