# Drug Policy:

# Myeloid Growth Factors

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| **POLICY NUMBER**<br>UM ONC_1072 | **SUBJECT**<br>Myeloid Growth Factors [Neupogen (filgrastim), Granix (tbo-filgrastim), Sargramostim (leukine), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), Neulasta/Neulasta Onpro Kit (pegfilgrastim) Kit, Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv) and Ziextenzo (pegfilgrastim-bmez)] | **DEPT/PROGRAM**<br>UM Dept | **PAGE 1 OF 4** |
| **DATES COMMITTEE REVIEWED**<br>02/23/11, 03/08/12, 07/10/13, 04/09/14, 09/10/14, 10/14/15, 07/26/16, 03/08/17, 06/14/17, 06/13/18, 09/12/18, 10/10/18, 01/09/19, 07/10/19, 09/11/19, 12/11/19, 01/08/20, 02/12/20, 03/11/20, 04/08/20, 05/13/20, 08/27/20 | **APPROVAL DATE**<br>August 27, 2020 | **EFFECTIVE DATE**<br>August 28, 2020 | **COMMITTEE APPROVAL DATES**<br>(latest version listed last)<br>02/23/11, 03/08/12, 07/10/13, 04/09/14, 09/10/14, 10/14/15, 07/26/16, 03/08/17, 06/14/17, 06/13/18, 09/12/18, 10/10/18, 01/09/19, 07/10/19, 09/11/19, 12/11/19, 01/08/20, 02/12/20, 03/11/20, 04/08/20, 05/13/20, 08/27/20 |
| **PRIMARY BUSINESS OWNER:** UM<br>**APPROVED BY:** Dr. Andrew Hertler | | **COMMITTEE/BOARD APPROVAL**<br>Utilization Management Committee | |
| **URAC STANDARDS**<br>HUM 1 | **NCQA STANDARDS**<br>UM 2 | | **ADDITIONAL AREAS OF IMPACT** |
| **CMS REQUIREMENTS** | **STATE/FEDERAL REQUIREMENTS** | | **APPLICABLE LINES OF BUSINESS**<br>Commercial, Exchange, Medicaid |

## I. PURPOSE

To define and describe the accepted indications for Myeloid Growth Factors [Neupogen (filgrastim), Granix (tbo-filgrastim), Sargramostim (leukine), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), Neulasta/Neulasta Onpro Kit (pegfilgrastim) Kit, Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv) and Ziextenzo (pegfilgrastim-bmez)] usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

### A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision.
5. When available, generic alternatives are preferred over brand-name drugs AND
6. Fulphila (pegfilgrastim-jmdb) and Udenyca (pegfilgrastim-cbqv) are the PREFERRED medications whenever a long acting myeloid growth factor (pegfilgrastim) is requested AND
7. Zarxio (filgrastim-sndz) and Granix (tbo-filgrastim) are the PREFERRED medications whenever a short acting myeloid growth factor (filgrastim) is requested AND
8. Non-preferred myeloid growth factor (MGF) agent will be approved only if there is a contraindication/intolerance to the PREFERRED medication.

### B. Prophylaxis/Prevention of Febrile Neutropenia from Chemotherapy

1. NOTE: Short-acting growth factors are preferred, over long acting, when a limited number of doses (generally <10) are required/clinically indicated. Long acting growth factors are appropriate, per NCH policy, if the member is unable to self-inject or if the need for daily travel- to receive multiple (generally 10 doses) daily injections of a short acting growth factor- would cause undue hardship to the member.
2. The member has a solid tumor or non-myeloid malignancy and is receiving MGF for any of the following:
   a. MGF is being used for chemotherapy with high-risk (> 20%) for febrile neutropenia OR
   b. MGF is being used with chemotherapy with an intermediate-risk (10% to 20%) for febrile neutropenia AND the member has ONE or more of the following risk factors:
      - Age ≥ 65 years; extensive prior chemotherapy or radiation therapy; persistent/pre-existing neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction (bili > 2.0), or renal dysfunction (crcl < 50).

### C. Myelodysplastic Syndromes (MDS)

1. A short acting MGF (NCH Preferred is Zarxio) is being used in combination with lenalidomide and/or epoetin or darbepoetin alpha in members with no response to erythropoietin alone OR
2. The member has MDS and a short acting MGF (NCH Preferred is Zarxio) is being used for neutropenia AND prevention of infections.

### D. Treatment of Febrile Neutropenia

1. Member has documented febrile neutropenia as defined by the Infectious Disease Society of America as: An ANC (Absolute Neutrophil Count) of <1.0 ( 1000 cells/micoL) AND a single oral temperature of ≥ 38.3 degree C (101 degree F) or a temperature of ≥ 38.0 degree C (100.4 degree F) sustained over a 1 hour period AND
2. A short acting MGF (NCH Preferred is Zarxio) is being used with appropriate antibiotic therapy.

## III. EXCLUSION CRITERIA

A. MGF use for primary prophylaxis of febrile neutropenia in members who are receiving chemotherapy that has a low risk for febrile neutropenia.

B. MGF use for the treatment of afebrile neutropenia.

C. Member is not receiving myelosuppressive chemotherapy for non-myeloid malignancy or solid tumor.

D. For members receiving concurrent chemo-radiation, long acting MGFs are contraindicated and requests for short acting MGFs will be reviewed on a case-by case basis.

E. Pegfilgrastim use with weekly myelosuppressive chemotherapy regimens (Neupogen, Leukine, Zarxio, Nivestym, or Granix should be used in these circumstances).

F. Neupogen, Leukine, Zarxio, Nivestym, or Granix use within 7 days of Pegfilgrastim.

G. Pegfilgrastim use in myeloid malignancies or MDS, except for members with AML/ALL in remission who are receiving consolidation chemotherapy (e.g. HIDAC- High Dose Ara C).

H. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

## IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

## V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

A. None

## VII. REFERENCES

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