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POLICY Document for UDENYCA

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

Specialty Guideline Management
Neulasta and pegfilgrastim biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Neulasta	pegfilgrastim
Fulphila	pegfilgrastim-jmdb
Fylnetra	pegfilgrastim-pbbk
Nyvepria	pegfilgrastim-apgf
Stimufend	pegfilgrastim-fpgk
Udenyca	pegfilgrastim-cbqv
Ziextenzo	pegfilgrastim-bmez

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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FDA-approved Indications

Neulasta[1]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Neulasta is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Fulphila[2]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Fulphila is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

Udenyca[3]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Udenyca is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Udenyca is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Ziextenzo[4]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Ziextenzo is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Ziextenzo is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Nyvepria[5]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Nyvepria is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Fylnetra[6]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

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Fylnetra is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Fylnetra is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Stimufend[7]

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Stimufend is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Compendial Use[8-13]

- Stem cell transplantation-related indications
- Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
- Hematopoietic Acute Radiation Syndrome
- Hairy cell leukemia, neutropenic fever

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Primary Prophylaxis of Febrile Neutropenia

- Documentation must be provided of the member's diagnosis and chemotherapeutic regimen.
- If chemotherapeutic regimen has a low or intermediate risk of febrile neutropenia (20% and less), documentation must be provided outlining the member's risk factors that confirm the member is at high risk for febrile neutropenia.

Coverage Criteria

Prevention of Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy[1-9,11,13]

Authorization of 6 months may be granted for prevention of febrile neutropenia when all of the following criteria are met :

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- The requested medication will not be used in combination with other colony stimulating factors within any chemotherapy cycle.
- The member will not receive chemotherapy at the same time as they receive radiation therapy.
- The requested medication will not be administered with weekly chemotherapy regimens.
- One of the following criteria is met :
    - The requested medication will be used for primary prophylaxis in members with a solid tumor or non-myeloid malignancies who have received, are currently receiving, or will be receiving any of the following:
        - Myelosuppressive anti-cancer therapy that is expected to result in greater than 20% incidence of febrile neutropenia (FN) (See Appendix A).
        - Myelosuppressive anti-cancer therapy that is expected to result in 10 – 20% risk of FN (See Appendix B) and who are considered to be at high risk of FN because of bone marrow compromise, co-morbidities, or other patient specific risk factors (See Appendix C).
        - Myelosuppressive anti-cancer therapy that is expected to result in less than 10% risk of FN and who have at least 2 patient-related risk factors (See Appendix C).
    - The requested medication will be used for secondary prophylaxis in members with solid tumors or non-myeloid malignancies who experienced a febrile neutropenic complication or a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy, with the same dose and scheduled planned for the current cycle (for which primary prophylaxis was not received).

Other Indications[10-13]

Authorization of 6 months may be granted for members with any of the following indications:

- Stem cell transplantation-related indications
- Hematopoietic Subsyndrome of Acute Radiation Syndrome
- Treatment for radiation-induced myelosuppression following a radiological/nuclear incident
- Hairy cell leukemia
  Members with hairy cell leukemia with neutropenic fever following chemotherapy

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

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Appendix[9,13,14,15]

Appendix A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of Greater than 20%

This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

Acute Lymphoblastic Leukemia

Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)

Bladder Cancer

Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)

Bone Cancer

- VAIA (vincristine, doxorubicin, ifosfamide, and dactinomycin)
- VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
- Cisplatin/doxorubicin
- VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
- VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)

Breast Cancer

- Dose-dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel
- TAC (docetaxel, doxorubicin, cyclophosphamide)
- TC (docetaxel, cyclophosphamide)
- TCH (docetaxel, carboplatin, trastuzumab)

Head and Neck Squamous Cell Carcinoma

TPF (docetaxel, cisplatin, 5-fluorouracil)

Hodgkin Lymphoma

- Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
- Nivolumab + AVD (doxorubicin, vinblastine, dacarbazine)
- Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
- BrECADD (brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone)

Kidney Cancer

Doxorubicin/gemcitabine

Non-Hodgkin's Lymphoma

- CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
- Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) ± rituximab
- ICE (ifosfamide, carboplatin, etoposide) ± rituximab

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- Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
- CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)
- MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± rituximab
- DHAP (dexamethasone, cisplatin, cytarabine) ± rituximab
- ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) ± rituximab
- HyperCVAD ± rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone ± rituximab)
- Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone)

Melanoma

Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

Multiple Myeloma

- VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
- DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)

Ovarian Cancer

- Topotecan ± bevacizumab
- Docetaxel
- Carboplatin/docetaxel

Soft Tissue Sarcoma

- MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
- Doxorubicin
- Ifosfamide/doxorubicin

Small Cell Lung Cancer

Topotecan

Testicular Cancer

- VelP (vinblastine, ifosfamide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- TIP (paclitaxel, ifosfamide, cisplatin)

Gestational Trophoblastic Neoplasia

- EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)
- EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
- TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)
- BEP (bleomycin, etoposide, cisplatin)
- TIP (Paclitaxel, ifosfamide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- ICE (ifosfamide, carboplatin, etoposide)

Wilms Tumor

- Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
- Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

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- Revised Regimen UH-1 (vincristine, doxorubicin, cyclophosphamide, carboplatin, etoposide)
- Revised Regimen UH-2 (vincristine, doxorubicin, cyclophosphamide, carboplatin, etoposide, irinotecan)

Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

Appendix B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 20%

This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

Occult Primary – Adenocarcinoma

Gemcitabine/docetaxel

Breast Cancer

- Docetaxel ± trastuzumab
- AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
- AC + sequential docetaxel + trastuzumab
- Paclitaxel every 21 days ± trastuzumab
- Sacituzumab govitecan-hziy
- TC (docetaxel, cyclophosphamide)

Cervical Cancer

- Irinotecan
- Cisplatin/topotecan
- Paclitaxel/cisplatin ± bevacizumab
- Topotecan

Colorectal Cancer

FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)

Esophageal and Gastric Cancers

Irinotecan/cisplatin

Non-Hodgkin's Lymphomas

- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
- CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
- CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin
- Bendamustine

Non-Small Cell Lung Cancer

- Cisplatin/paclitaxel
- Cisplatin/vinorelbine
- Cisplatin/docetaxel

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- Cisplatin/etoposide
- Carboplatin/paclitaxel
- Docetaxel

Pancreatic Cancer

FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)

Prostate Cancer

Cabazitaxel

Small Cell Lung Cancer

Etoposide/carboplatin

Testicular Cancer

- BEP (bleomycin, etoposide, cisplatin)
- Etoposide/cisplatin

Uterine Sarcoma

Docetaxel

Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

Appendix C: Patient Risk Factors

This list is not all-inclusive.

- Active infections, open wounds, or recent surgery
- Age greater than or equal to 65 years
- Bone marrow involvement by tumor producing cytopenias
- Previous chemotherapy or radiation therapy
- Poor nutritional status
- Poor performance status
- Previous episodes of FN
- Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
- Persistent neutropenia

Section 2: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their

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Program Description

The National Comprehensive Care Network® (NCCN®) is a not-for profit alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives. It is comprised of oncology experts who convene regularly to establish the best treatments for patients.[1]

NCCN develops resources to support stakeholders in the health care delivery system including the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

The Guidelines offer broad, high-level, evidence-based recommendations for cancer management. The Compendium extracts the drug and biologic recommendations from the Guidelines detailing their use and level of evidence category. The Templates convert the drug regimens detailed in the Guidelines and Compendium into practical, standardized order sets for safe, clinical use. [2,3]

NCCN Categories of Evidence and Consensus[4]

- **Category 1:** Based upon high-level evidence, there is uniform (defined as ≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2A:** Based upon lower-level evidence, there is uniform (≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2B:** Based upon lower-level evidence, there is NCCN consensus (50% to <85% panel support) that the intervention is appropriate.
- **Category 3:** Based upon any level of evidence, there is major NCCN disagreement (less than 50% panel support, or at least three institutions opposing the recommendation) that the intervention is appropriate.

Policy for Regimen Prior Authorization

Regimen prior authorization allows providers to submit a single request for all oncology drugs or biologics within an NCCN Template that require prior authorization. Regimen requests must be initiated through the provider portal. If submitted via phone or fax, each drug or biologic must be requested individually using drug-specific criteria.

Coverage is provided for a regimen request when all the following criteria are met. If all are not met, further review may be required:

1. The request is initiated through the provider portal.
2. The member is eligible for regimen review.
3. The request is for an oncology drug or biologic.
4. The requested regimen and indication align with an NCCN recommendation with a level of evidence category 1 or 2A.
5. The NCCN template is accepted by the provider without modification.
6. The indication is for a cancer type currently eligible for regimen review.
6. The indication is for a cancer type currently eligible for regimen review.

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1. Ampullary Adenocarcinoma
2. Anal Carcinoma
3. Appendiceal Neoplasms and Cancers
4. Basal Cell Skin Cancer
5. B-Cell Lymphomas
6. Biliary Tract Cancers
7. Bladder Cancer
8. Bone Cancer
9. Breast Cancer
10. Castleman Disease
11. Central Nervous System Cancers
12. Cervical Cancer
13. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
14. Chronic Myeloid leukemia
15. Colon Cancer
16. Cutaneous Lymphomas
17. Dermatofibrosarcoma Protuberans
18. Esophageal Cancer
19. Gastric Cancer
20. Gastrointestinal Stromal Tumors
21. Gestational Trophoblastic Neoplasms
22. Hairy Cell Leukemia
23. Head and Neck Cancers
24. Hepatocellular Carcinoma
25. Histiocytic Neoplasms
26. Hodgkin Lymphoma
27. Kaposi Sarcoma
28. Kidney Cancer
29. Melanoma: Cutaneous
30. Melanoma: Uveal
31. Merkel Cell Carcinoma
32. Mesothelioma: Peritoneal
33. Mesothelioma: Pleural
34. Multiple Myeloma
35. Myelodysplastic Syndromes
36. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
37. Myeloproliferative Neoplasms
38. Neuroendocrine and Adrenal Tumors
39. Non-Small Cell Lung Cancer
40. Occult Primary
41. Ovarian Cancer
42. Pancreatic Cancer
43. Penile Cancer
44. Prostate Cancer
45. Rectal Cancer
46. Small Bowl Adenocarcinoma

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47. Small Cell Lung Cancer
48. Soft Tissue Sarcoma
49. Squamous Cell Skin Cancer
50. Systemic Light Chain Amyloidosis
51. Systemic Mastocytosis
52. T-Cell Lymphomas
53. Testicular Cancer
54. Thymomas and Thymic Carcinomas
55. Thyroid Carcinoma
56. Uterine Neoplasms
57. Vaginal Cancer
58. Vulvar Cancer
59. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
60. Wilms Tumor (Nephroblastoma)

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors (G-CSFs) are recommended for primary prophylaxis based on the febrile neutropenia (FN) risk of the chemotherapy regimen. The level of FN risk varies by NCCN Template and is indicated at the top of each template. Regimens classified as high or intermediate risk of FN may include a G-CSF as part of the prior authorization

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

Duration of Approval

Authorizations may be granted for 12 months or as medically necessary, based on the member's condition and provider's clinical assessment.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. If no specific template exists for the intended maintenance therapy, the selected template can be modified to include only the appropriate maintenance agents. The modified regimen request will be submitted for further review.

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