

Instructions for Use

White Blood Cell Colony Stimulating Factors (for Ohio Only)

Policy Number: CSOH2025D0061.B Effective Date: May 1, 2025

| Table of Contents | Page |
|-------------------------------------|------|
| Application | 1 |
| Coverage Rationale | 1 |
| Applicable Codes | 2 |
| Policy History/Revision Information | 2 |
| Instructions for Use | 2 |

Related Policy

 Oncology Medication Clinical Coverage (for Ohio Only)

Application

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This Medical Benefit Drug Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

This policy refers to the following white blood cell colony stimulating factors (CSFs) for **non-oncology** conditions:

- Long-acting pegfilgrastim agents:
 - Fulphila[®] (pegfilgrastim-jmdb)
 - Fylnetra[®] (pegfilgrastim-pbbk)
 - Neulasta[®] (pegfilgrastim)
 - Nyvepria[™] (pegfilgrastim-apgf)
 - Udenyca[®] (pegfilgrastim-cbqv)
 - Stimufend[®] (pegfilgrastim-fpgk)
 - Ziextenzo[®] (pegfilgrastim-bmez)
- Short-acting filgrastim agents:
 - Granix[®] (tbo-filgrastim)
 - Neupogen[®] (filgrastim)
 - Nivestym[®] (filgrastim-aafi)
 - Nypozi[™] (filgrastim-txid)
 - Releuko[®] (filgrastim-ayow)
 - Zarxio[®] (filgrastim-sndz)
- Leukine[®] (sargramostim)
- Rolvedon[™] (eflapegrastim-xnst)
- Any FDA-approved white blood cell colony stimulating factor product not listed here

White blood cell colony stimulating factors (CSFs) are considered medically necessary in certain circumstances. For medical necessity clinical coverage criteria for non-oncology conditions, refer to the <u>Ohio Department of Medicaid Unified</u> <u>Preferred Drug List Criteria</u>.

For **oncology** indications, refer to the Medical Benefit Drug Policy titled <u>Oncology Medication Clinical Coverage (for Ohio</u> <u>Only</u>) for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium[®] (NCCN Compendium[®]).

 White Blood Cell Colony Stimulating Factors (for Ohio Only)
 Page 1 of 3

 UnitedHealthcare Community Plan Medical Benefit Drug Policy
 Effective 05/01/2025

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS Code | Description |
|------------|---|
| C9173 | Injection, filgrastim-txid (Nypozi), biosimilar, 1 mcg |
| J1442 | Injection, filgrastim, (G-CSF), excludes biosimilars, 1 microgram |
| J1447 | Injection, tbo-filgrastim, 1 microgram |
| J1449 | Injection, eflapegrastim-xnst, 0.1 mg |
| J2506 | Injection, pegfilgrastim, 0.5 mg |
| J2820 | Injection, sargramostim (GM-CSF), 50 mcg |
| J3490 | Unclassified drugs |
| J3590 | Unclassified biologics |
| J9999 | Not otherwise classified, antineoplastic drug |
| Q5101 | Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 microgram |
| Q5108 | Injection, pegfilgrastim-jmdb (Fulphila), biosimilar, 0.5 mg |
| Q5110 | Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram |
| Q5111 | Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg |
| Q5120 | Injection, pegfilgrastim-bmez (ZIEXTENZO), biosimilar, 0.5 mg |
| Q5122 | Injection, pegfilgrastim-apgf (Nyvepria), biosimilar, 0.5 mg |
| Q5125 | Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg |
| Q5127 | Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg |
| Q5130 | Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg |

Policy History/Revision Information

| Date | Summary of Changes |
|------------|---|
| 05/01/2025 | Coverage Rationale |
| | Revised list of applicable white blood cell colony stimulating factors (CSFs)/short-acting filgrastim agents; added Nypozi[™] (filgrastim-txid) |
| | • Replaced coverage guidelines with language to indicate white blood cell colony stimulating factors (CSFs) are considered medically necessary in certain circumstances; for medical necessity clinical coverage criteria for non-oncology conditions, refer to the <i>Ohio Department of Medicaid Unified Preferred Drug List Criteria</i> |
| | Applicable Codes |
| | • Added HCPCS codes C9173, J3490, J3590, and J9999 |
| | Supporting Information |
| | Removed <i>Definitions, Background, Clinical Evidence, FDA,</i> and <i>References</i> sections |

Archived previous policy version CSOH2024D0061.A

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and

 White Blood Cell Colony Stimulating Factors (for Ohio Only)
 Page 2 of 3

 UnitedHealthcare Community Plan Medical Benefit Drug Policy
 Effective 05/01/2025

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Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.