MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Cancer	**LAST REVIEW**	12/9/2025
THERAPEUTIC CLASS	Oncology	**REVIEW HISTORY** (MONTH/YEAR)	12/24, 3/24, 3/23, 12/21, 9/20, 9/19, 9/18, 5/17, 5/16
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

OVERVIEW

Oncology medications account for one of the largest drug spend in the United States. In more recent years, drug innovative companies have had tremendous success—releasing numerous new drugs on the market each year—with the latest goal to develop targeted cancer tumor cells as opposed to the traditional, cytotoxic chemotherapy agents. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

***Note:** This coverage policy strictly reviews the agents used specifically for the treatment or management of cancer. For **Antiemetic Agents**, please refer to Coverage Policy – Gastrointestinal Disorders – Nausea. For **ESAs** (i.e. Epogen), please refer to Coverage Policy –Renal – Anemia. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on the National Comprehensive Cancer Network (NCCN) Guidelines (https://www.nccn.org/guidelines/) and Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).*

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Please see the Prior Authorization Procedure Codes List available in the DRE provider portal (https://provider.hpsj.com/dre/forms/HPSJ%20Auth%20Required%20List.pdf) for authorization requirements for medications. Any agents with medical benefit restrictions that have specific Health Plan coverage criteria are listed below. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that require authorization and do not have established prior authorization criteria, Health Plan will make the determination based on the **National Comprehensive Cancer Network (NCCN) Guidelines** and **Medical Necessity criteria** as described in Health Plan Medical Review Guidelines (UM06)—*see below for details.*

The following general Medical Necessity criteria are used when there are no diagnosis or procedure-specific criteria applicable to the situation. All criteria below must be met for the service to be considered medically necessary.

1. The services are prescribed by a licensed health care practitioner practicing within the scope of his/her license in the context of his/her treatment of the individual.
2. The services are safe, effective, and consistent with nationally accepted standards of medical practice.
3. The services are not experimental or investigational.
4. The services are individualized, specific, and consistent with the individual's signs, symptoms, history, and diagnosis.
5. The services follow peer reviewed evidence-based literature that support medical necessity. These services are reasonably expected, in a clinically meaningful way, to:
    i. Help restore or maintain the individual's health, or
    ii. Improve or prevent deterioration of the individual's disorder or condition, or
    iii. Delay progression of a disorder or condition characterized by a progressively deteriorating course when that disorder or condition is the focus of treatment for this episode of care.
6. The individual complies with the essential elements of treatment.
7. The services are not primarily for the convenience of the individual, practitioner, caregiver, family, or another party.
8. Services are not being sought as a way to potentially avoid legal proceedings, incarceration, or other legal consequences.
9. The services are not predominantly domiciliary or custodial.
10. No exclusionary criteria are met.

IV Medications—Submitting UM (Medical) Authorization vs. Pharmacy Authorization:
Most IV medications can be covered under both medical and pharmacy benefits—depending on the setting of administration. **For IV medications that is to be dispensed through an LTC pharmacy or outpatient pharmacy, please submit a pharmacy authorization** to Medi-Cal Rx. For all other administration settings (including buy-and-bill), please submit a UM authorization.

How to submit a PHARMACY (RX) prior authorization form for review:

1. Submit a request using one of the five methods provided by Medi-Cal Rx: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/PF_5_Ways_to_Submit_a_PA_Flyer.pdf
2. Include clinic notes documenting diagnosis, past treatment history, and any pertinent laboratory tests.

How to submit a MEDICAL (UM) prior authorization form for review:

1. Submit request through Health Plan's **Medical Authorization Request form** which can be obtained from www.hpsj.com.
2. Include clinic notes documenting diagnosis, past treatment history, and any pertinent laboratory tests.
3. Fax both the completed prior authorization form and the clinic documents to Health Plan's Medical Department: 209.942.6302.

Colony Stimulating Factors
1st line— filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta, Neulasta Onpro), tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), pegfilgrastim-jmdb (Fulphila), pegfilgrastim-cbqv (Udenyca), Sargramostim *2nd line— filgrastim (Neupogen), pegfilgrastim-bmez (Ziextenzo), pegfilgrastim-apgf (Nyvepria)*

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- ❒ **Coverage Criteria:** Approval is determined by medical necessity criteria.
- ❒ **Limits:** None.
- ❒ **Required Information for Approval:** Chart notes documenting the patient's diagnosis and lab results.
- ❒ **Other Notes:** None.

2nd line— filgrastim (Neupogen)

- ❒ **Coverage Criteria:** Reserved for documentation of treatment failure of a 1st line short-acting G-CSF: filgrastim-sndz (Zarxio), tbo-filgrastim (Granix), or filgrastim-aafi (Nivestym).
- ❒ **Limits:** None.
- ❒ **Required Information for Approval:** Drug refill history showing fill(s) of a 1st line agent.
- ❒ **Other Notes:** None.

2nd line— pegfilgrastim-bmez (Ziextenzo), pegfilgrastim-apgf (Nyvepria)

- ❒ **Coverage Criteria:** Reserved for documentation of treatment failure of a 1st line long-acting G-CSF: peg-filgrastim (Neulasta, Neulasta Onpro), pegfilgrastim-jmdb (Fulphila), or pegfilgrastim-cbqv (Udenyca).
- ❒ **Limits:** None.
- ❒ **Required Information for Approval:** Drug refill history showing fill(s) of a 1st line agent.
- ❒ **Other Notes:** None.

REFERENCES

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15. Granix (tbo-filgrastim) [package insert]. North Wale, PA: Teva Pharmaceuticals USA, Inc.; 2012.
16. Neulasta (pegfilgrastim) [package insert]. Thousand Oaks, California: Amgen Inc.; 2002.
17. Fulphila (pegfilgrastim-jmdb) [package insert]. Zurich, Switzerland: Mylan GmbH; 2018.
18. Udenyca (pegfilgrastim-cbqv) [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; 2018.
19. Ziextenzo (pegfilgrastim-bmez) [package insert]. Princeton, NJ: Sandoz Inc.; 2019.
20. Nyvepria (pegfilgrastim-apgf) [package insert]. Lake Forest, IL: Pfizer; 2020.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Oncology – Cancer 2016-05.docx	5/2016	Johnathan Yeh, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2018-09.docx	9/2018	Johnathan Yeh, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2019-09.docx	9/2019	Matthew Garrett, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2020-09.docx	9/2020	Matthew Garrett, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2021-12.docx	12/2021	Matthew Garrett, PharmD
Update of Policy	Cancer	03/2023	Matthew Garrett, PharmD
Review of Policy	Cancer	03/2024	Matthew Garrett, PharmD
Review of Policy	Cancer	12/2024	Matthew Garrett, PharmD
Review of Policy	Cancer	12/2025	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy