MVP Health Care Medical Policy

Medicare Part B: Cancer Guidance Program-Oncology Medication Coverage and Review

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **06/01/2025**
Approval Date: **12/01/2025**
Effective Date: **01/01/2026**

Related Policies: **Medicare Part B Step Therapy**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

Overview

The purpose of this policy is to define the clinical criteria that will be utilized for prior authorization review in Optum Cancer Guidance Program (CGP) determining coverage for oncology medications under medical (including, but not limited to chemotherapy, immunotherapy, targeted therapies, oral oncolytics, leucovorin, gonadotropin releasing hormonal analogs, bone modifying agents, somotostatin analogs, white blood cell growth factors, red blood growth factors, other supportive drugs).

Indications/Criteria

Preferred Product Criteria

Treatment with a non-preferred product, specified below, will be considered medically necessary for oncology indications when one of the following criteria is met AND the

provider attests that the same result is not expected to occur with the non-preferred product*:

- History of intolerance or contraindication one of the preferred products
- Previous documented failure with all of the preferred listed products for the same requested indication

If there is step therapy for bone modifying agents, criteria will be addressed in a separate policy.

Preferred Oncology Product	**Non-Preferred Oncology Product**
Zirabev Mvasi	Avastin Alymsys Vegzelma
Herceptin Trazimera Herceptin Hylecta	Kanjinti Ogivri Ontruzant Herzuma Hercessi
Neulasta Neulasta OnPro Udenyca	Fulphila Ziextenzo Fylnetra Rolvedon Stimufend Nyvepria
Nivestym Releuko	Zarxio Neupogen Granix Nypozi Ryzneuta
Ruxience Rituxan Rituxan Hycela	Truxima Riabni
Gemcitabine (Gemzar)	Infugem
Leucovorin (Wellcovorin)	Levoleucovorin (Fusilev, Khapzory)
Aranesp Retacrit Procrit/Epogen	N/A
Aloxi Emend Fosaprepitant	Akynzeo Cinvanti Sustol

	Focinvez Posfrea

Diagnosis Criteria

In additional to the above Preferred Product Criteria, oncology medications are considered medically necessary if use is listed in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium or Guidelines with Categories of Evidence of 1, 2A, and 2B. Category of Evidence of 3 uses are considered as unproven and not medically necessary. For new to market oncology drugs, coverage determination will be made if use is in accordance with FDA-approved indication(s).

Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria.

All oncology medications, for patients under the age of 19, will be considered medically necessary for oncology indications without regard to NCCN recommendations.

For Medicare Advantage plans, the Optum Cancer Guidance Program will follow Medicare hierarchy in determining medical necessity for eligible members.

- Medicare Coverage Database: National Coverage Determinations (NCD)
- Medicare Coverage Database: Local Coverage Determination (LCD)
- Medicare Coverage Database: Local Coverage Articles
- Medicare Benefit Policy Manual*
- Optum Oncology Medication Policy
- National Comprehensive Cancer Network (NCCN) Compendium and Guidelines

*Medicare Benefit Policy Manual Chapter 15-50.4.1 allows for the approval of a drug if it is being used according to the FDA-approved labeling. Additionally, Chapter 15-50.4.5 allows for the off-label use anti-cancer drugs and biologicals if use is supported by either one for more of acceptable compendia or in peer-reviewed medical literature with clinically meaningful outcomes.

Compendia:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium – Category 3 is not recognized as medically accepted
- Micromedex DrugDex – Class I, IIa, or IIb
- Clinical Pharmacology
- Lexi-Drugs – Evidence Level of A

Peer-Reviewed Medical Literature:

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal Of American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCC)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

Exclusions: N/A

References

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium®) https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed June 6,2023.

2. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) https://www.nccn.org/guidelines/category_1. Accessed June 6, 2023.

3. U.S. Food & Drug Administration. Biosimilars. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars. Accessed June 6,2023.

4. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual. Chapter 15-Covered Medical and Other Heath Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed June 6,2023.