

MEDICAL POLICY

POLICY TITLE	STEP THERAPY TREATMENT OF STAGE FOUR, ADVANCED METASTATIC CANCER AND SEVERE RELATED HEALTH CONDITIONS
POLICY NUMBER	MP 2.373

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	2/1/2025

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I. POLICY

In accord with Pennsylvania Act 6 of 2020, patients with stage four, advanced metastatic cancer, are not required by Capital BlueCross to first fail to successfully respond to a different drug or prove history of failure in use of a different drug, before coverage of a covered drug is provided. When drugs are approved for sequential use (after other drugs have not sufficed), such use is dictated by the United States Food and Drug Administration (FDA) and/or the National Comprehensive Cancer Network (NCCN), not Capital BlueCross. Coverage is provided when the drug meets the following criteria:

- 1) Consistent with best clinical practices for the treatment of stage four, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage four, advanced metastatic cancer and supported by peer-reviewed medical literature, as evidenced by a level of evidence of 1 or 2A from the:
 - a) NCCN Clinical Practice Guidelines in Oncology; **or**
 - b) American Hospital Formulary System (AHFS); **or**
 - c) DrugDex
- 2) Approved by the FDA for the indication for which it is being used.

In the event of a discrepancy between the FDA indications and the NCCN guidelines, the NCCN guidelines describing best clinical practice will be followed.

In accord with the Pennsylvania Fair Access to Cancer Treatment Act (Act 6), these stages of systemic myeloid and lymphoid disease are consistent with “advanced metastatic cancer.” The affected cells circulate throughout the body, and the stages of diagnoses have a poor prognosis:

- Advanced lymphoma, stage 4
- Advanced myeloma, stage 3
- Chronic leukemias, blastic phase (CML) or Rai stage 3-4 (CLL)
- Acute leukemias, treatment not desired or active disease/relapse following treatment

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Cross-reference:

MP 2.103 Off-Label Use of Medications and Other Interventions

Abecma

Breyanzi

Carvykti

Columvi

Cosela

Denosumab

Elrexfio

Epkinly

Kymriah™

Reblozyl

Talvey

Tecartus

Yescarta

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Benefit Brochure for information on Cancer Services:

<https://www.fepblue.org/plan-brochures>.

Note for Medicare Advantage:

FDA approved drugs used for indications other than what is indicated on the FDA approved product label may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the Medicare recognized national “drug compendia, authoritative medical literature and/or accepted standards of medical practice.” Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.2- Unlabeled Use of Drug).

<http://www.cms.gov/manuals/Downloads/bp102c15.pdf>.

In accordance with CMS letter issued on September 17, 2012, entitled “[Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services](#)”. Step therapy that is not part of the FDA label does not apply to Medicare Advantage.

III. DESCRIPTION/BACKGROUND

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Over the past 25 years, NCCN has developed an integrated suite of tools to improve the quality of cancer care. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

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document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes.

The NCCN Guidelines® are the recognized standard for clinical direction and policy in cancer care and are the most thorough and frequently updated clinical practice guidelines available in any area of medicine. The intent of the NCCN Guidelines is to assist in the decision-making process of individuals involved in cancer care—including physicians, nurses, pharmacists, payers, patients, and their families—with the ultimate goal of improving patient care and outcomes.

The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. In addition, separate guidelines provide recommendations for some of the key cancer prevention and screening topics as well as supportive care considerations.

The NCCN Guidelines provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards.

The NCCN Guidelines contain the following components:

- Panel members providing institutional affiliations and specialties.
- Algorithms or flowcharts to provide guidance for clinical decision-making process.
- Discussion text describing the data and clinical information that supports the recommendations in the algorithms.
- Listing of references providing the evidence for the recommendations; and
- Disclosure of potential conflicts of interest of panel members and NCCN headquarters staff.

The NCCN Guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions. These panel members are multidisciplinary, disease- and issue-specific subspecialists who are both clinicians, researchers, and advocates. In addition, each guideline undergoes annual institutional review where it is circulated for comment among the multidisciplinary faculty at each NCCN Member Institution.

Further details on the Development and Update of the NCCN Guidelines are available, which provide information on the composition and roles of the NCCN Guidelines development group, policies for transparency and management of potential conflicts of interest, and the Guidelines development and updates process. <https://www.nccn.org/professionals/default.aspx>

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NCCN Categories of Evidence and Consensus

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise indicated.

<https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines>

IV. RATIONALE

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The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

World-renowned experts from NCCN Member Institutions diagnose and treat patients with a broad spectrum of cancers and are recognized for dealing with complex, aggressive, or rare cancers. NCCN Member Institutions pioneered the concept of the multidisciplinary team approach to patient care and conduct innovative research that contributes significantly to understanding, diagnosing, and treating cancer. NCCN programs offer access to expert physicians, superior treatment, and quality and safety initiatives that continuously improve the effectiveness and efficiency of cancer care globally.

The NCCN ORP fosters innovation and knowledge discovery that improve the lives of patients with cancer.

Guiding Principles:

1. Study both FDA-approved and investigational agents/devices, to seek novel enhanced, effective, and efficient cancer therapy.
2. Develop new insights into cancer care delivery outcomes and quality, as well as identify solutions to barriers affecting optimal cancer management.
3. Increase opportunities for NCCN Member Institution faculty to participate in oncologic investigation and support those who are, or will become, leaders in cancer research.

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4. Demonstrate that constructive, appropriate, and transparent collaboration between academia and industry results in valuable knowledge and improved cancer management.
5. Ensure the dissemination of knowledge gained through the program to the medical community at large through presentations at meetings and/or publication in peer-reviewed journals.

V. DEFINITIONS

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CHEMOTHERAPY-Drug therapy used to treat infections, cancers, and other diseases and conditions.

STAGE FOUR, ADVANCED METASTATIC CANCER- Cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes or other areas or parts of the body.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

➤ ***Specific codes do not apply to this policy.***

IX. REFERENCES

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1. *Federal Employee Program (FEP) Benefit Brochure 2023*
2. McPhail, S., Johnson, S., Greenberg, D., Peake, M., & Rous, B. (2015). Stage at diagnosis and early mortality from cancer in England. *British journal of cancer*, 112 Suppl 1(Suppl 1), S108–S115.
3. *National Comprehensive Cancer Network®. NCCN clinical practice guidelines in oncology (NCCN Guidelines®). NCCN Clinical Practice Guidelines in Oncology.*
4. *National Comprehensive Cancer Network®. About NCCN.*
5. *Pennsylvania Act 6 of 2020 (General Assembly. House Bill 427), Fair Access to Cancer Treatment Act.*

Other Sources:

Taber's Cyclopedic Medical Dictionary, 19th edition.

X. POLICY HISTORY

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MP 2.373	03/31/2020 New Policy. Policy developed in accord with PA Act 6 of 2020 to state that step therapy will not apply to any patient with Stage IV metastatic disease. Effective 4/10/2020.
	05/04/2021 Consensus Review. No change to policy statement. Background and References updated. NCCN language added.
	07/19/2021 Consensus Review. Added defining language regarding Act 6 and advanced metastatic cancer.
	01/19/2022 Consensus Review. No changes to policy statement.
	07/27/2023 Consensus Review. No changes to policy statement. Rationale and background updated. References reviewed.
	01/19/2024 Administrative Update. Clinical benefit added.
	10/11/2024 Consensus Review. No change to policy statement. Cross referenced policies and references updated.
	01/08/2024 Administrative Update. Removed NCCN statement.

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