PART B DRUG MEDICAL/PHARMACY	ASPIRE HEALTH	Effective Date May 1, 2024	
	ONCOLOGY DRUGS / ONCOLOGY BIOSIMILARS	Policy # Oncology Drugs and Oncology Biosimilars	
		Review Date 02/27/2024	**Applicable to:** ☑ Medicare Advantage ☐ Commercial ☑ Elevance Health HMO ☑ Blue Shield Trio
	Approver's Name & Title QI & UM Drug Subcommittee		

Aspire Health Plan (AHP) applies medical drug clinical criteria as a reference for medical policy information only. Federal and state laws or requirements, contract language, and Plan benefit may take precedence over the application of these clinical criteria. Please consult the applicable certificate or contract for benefit details. This policy is subject to revision at the discretion of the Plan and is therefore subject to change. Refer to the disclaimer section below for more information.

POLICY

This policy is only applicable when no National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), or other relevant Medicare guidelines exist for the requested drug. AHP drug-specific policies also take precedence over the criteria in this policy and must be reviewed prior to applying the criteria in this policy.

1) This policy will be applied to all oncology drugs and biosimilar products specified in the 'Applicable HCPCS' that have received approval from the U.S. Food and Drug Administration (FDA).

2) Any drug or biosimilar that falls under one of the drug classes listed in the 'APPLICABLE HCPCS' section below where there is a step therapy requirement *that not listed by name in this policy* will be reviewed as follows:

   The drug will be reviewed according to the clinical criteria for this policy and considered non-preferred until it is reviewed by AHP's clinical governance committee (QI & UM Subcommittee).

APPLICABLE HCPCS

KEYTRUDA (PEMBROLIZUMAB)

- J9271: Injection, pembrolizumab, 1 mg

TECENTRIQ (ATEZOLIZUMAB)

- J9022: Injection, atezolizumab, 10 mg

BEVACIZUMAB / BIOSIMILARS (ONCOLOGY ONLY; NOT APPLICABLE TO OPTHALMOLOGY)

Bevacizumab (Alymsys, Avastin, Avzivi, Mvasi, Vegzelma, Zirabev)

- J9035 Injection, bevacizumab, 10 mg --Avastin (bevacizumab)
- Q5126 Injection, bevacizumab-maly, biosimilar (Alymsys), 10 mg
- Q5107 Injection, bevacizumab-awwb, biosimilar (Mvasi), 10 mg
- Q5129 Injection, bevacizumab-adcd, biosimilar (Vegzelma), 10 mg
- Q5118 Injection, bevacizumab-bvzr, biosimilar (Zirabev), 10 mg

Avzivi (bevacizumab tnjn): FDA approved December 2023; anticipated availability is currently unknown.

- C9399 Unclassified drugs or biologicals; bevacizumab tnjn, biosimilar (Avzivi)
- J9999 Not otherwise classified, antineoplastic drugs; bevacizumab tnjn, biosimilar (Avzivi)

For Colorectal diagnosis: Refer to NCD 110.17: Anti-Cancer Chemotherapy for Colorectal Cancer

TRASTUZUMAB / BIOSIMILARS

- J9355 Injection, trastuzumab, excludes biosimilar, 10 mg-- Herceptin (trastuzumab)
- Q5112 Injection, trastuzumab-dttb, biosimilar (Ontruzant), 10 mg
- Q5113 Injection, trastuzumab-pkrb, biosimilar (Herzuma), 10 mg
- Q5114 Injection, Trastuzumab-dkst, biosimilar (Ogivri), 10 mg
- Q5116 Injection, trastuzumab-qyyp, biosimilar (Trazimera), 10 mg
- Q5117 Injection, trastuzumab-anns, biosimilar (Kanjinti), 10 mg
- J9358 Injection, fam-trastuzumab deruxtecan-nxki biosimilar (Enhertu), 1 mg

- J9356 Injection, trastuzumab, 10 mg and Hyaluronidase-oysk-- Herceptin Hylecta (trastuzumab and hyaluronidase-oysk):

- J9316 Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg-- Phesgo (pertuzumab, trastuzumab, hyaluronidase-zzxf)

NOT APPLICABLE TO THE FOLLOWING DRUGS AND BIOSIMILARS

RITUXIMAB / BIOSIMILARS [Rituxan (rituximab); Riabni (rituximab-arrx); Ruxience (rituximab-pvvr); Truxima (rituximab-abbs); and Rituxan Hycela (rituximab/hyaluronidase)]: **Please refer to the 'Rituximab Products policy.'**

CLINICAL CRITERIA

I. INITIAL CRITERIA

The requested oncology drug may be authorized when **ALL** of the following have been met with *documentation.

*Medical record documentation by the prescriber or administering physician should substantiate the medical necessity for the use of the requested drug by clearly indicating the relevant clinical signs and symptoms related to the medical condition for which this drug is being prescribed. The documentation must also include all prior treatment regimens and the member's response to each drug or therapy.

A. PRESCRIBER SPECIALTY: Prescribed by, or in conjunction with, an oncologist, hematologist, or other specialist treating cancer.

B. AGE RESTRICTIONS: Member meets FDA or compendia-supported labeled age recommendation.

C. FOR WEIGHT-BASED OR BSA-DOSED DRUGS: Member's current weight (within the last 30 days) or BSA.

D. FOR ALL INDICATIONS:

1. Requested drug is FDA-approved *(Note: The FDA indication alone does not determine the medical necessity of a specific drug for an individual patient. AHP reserves the right to review all treatments for medical necessity.);* **and**

2. Documented diagnosis is an FDA-labeled indication OR recognized as a "Medically Accepted Indication" according to a CMS-approved compendia:
    a. American Hospital Formulary Service-Drug Information (AHFS-DI); or
    b. National Comprehensive Cancer Network (Categories 1 or 2A only); or
    **An exception may be granted by an Aspire Medical Director for a category 2B therapy or regimen in there are no appropriate therapy alternatives.*
    c. Micromedex DrugDex; or
    d. Clinical Pharmacology; or
    e. Lexi-Drugs.

and

3. Therapy will be administered with concomitant treatment according to FDA indication or NCCN category 1 or 2A recommendation (as applicable).

AND

E. The appropriate *succession of the therapies have been tried and failed (i.e., intolerance, contraindication, or progression), or not clinically appropriate for member. Submit documentation of ALL previous treatments and the resulting outcomes where applicable, including dose and dates.

*The recommended succession of therapies can be found within compendia monographs, FDA label or NCCN guidelines. **If the requested agent is at therapeutic parity with the preferred product according to CMS compendia monographs, FDA labeling, or NCCN guidelines, the PREFERRED product will be authorized unless clinical documentation is submitted to support the medical necessity of the requested (non-preferred) product.**

AND

F. Documentation of ALL the following:
1. Previous treatments and the resulting outcomes where applicable, including dose and dates; **AND**
2. Relevant lab tests, clinical markers, or assays supporting the diagnosis and/or continuation of treatment (for new members).

II. REAUTHORIZATION / CONTINUATION OF THERAPY CRITERIA

The request oncology drug may be authorized for continuation of therapy when initial criteria have been met AND there is documentation of beneficial response from previous course of treatment:

A. Member continues to meet the GENERAL and CONDITION-SPECIFIC criteria in the 'Initial Therapy' section above; **AND**

B. Adherence to therapy at least 85% of the time (as verified by the prescriber or member medication fill history), OR adherence less than 85% of the time due to the need for surgery, treatment of an infection or adverse event mitigation, causing temporary discontinuation: Review with Prescriber and Aspire Clinical Reviewer may be required, **AND**

C. Positive response to therapy: Stabilization or clinically significant improvement in disease state or decrease in size of tumor or tumor spread; **AND**

D. Prescriber attests to, or clinical reviewer has found, no evidence of intolerable adverse effects or unacceptable toxicity with the requested oncology drug; **AND**

E. FOR WEIGHT-BASED OR BSA-DOSED DRUGS: Member's current weight (within the last 30 days) or BSA.

STEP THERAPY

Step therapy criteria do not apply for members who are currently being treated with the requested medications. Step therapy is only applied for members that are new to therapy (have not received the requested drug in the last 365 days.

A. **PREFERRED PRODUCT(S): Refer to Step Therapy Drug List** (no step therapy required for preferred drugs)

- There is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs; therefore, the **PREFERRED** biosimilar products listed that is FDA-approved for the same indication(s) as the reference product will be authorized UNLESS the PREFERRED biosimilar is recommended unless the NCCN guidelines specifically recommend against this.

- The **NON-PREFERRED** product may be authorized if there are no **PREFERRED** FDA-approved biosimilar that share the prescribed FDA-labeled or the "Medically Accepted Indication" according to a CMS-approved compendia.

B. **NON-PREFERRED PRODUCTS** may be authorized when all of the clinical criteria above are met **AND** ONE of the following:

1. Information has been provided that indicates the member has been treated with the request medication in the past 365 days; **OR**

2. Member has had an ineffective treatment response to **at least TWO preferred biosimilar drug(s)** Provide specific clinical documentation and description of therapeutic failure and dates/duration of therapy to support the requested product for a complete and timely review**; OR**

3. Documentation of intolerance, hypersensitivity, or FDA labeled contraindication **to at least TWO preferred biosimilar drug(s)**. Provide specific clinical documentation of intolerance, hypersensitivity, or FDA labeled contraindication and dates/duration of therapy to support the requested product for a complete and timely review; **OR**

4. Clinical rationale from Prescriber indicates preferred medication(s) are likely to be ineffective, likely to cause an adverse reaction or harm, or likely to be of no clinical benefit; **OR**

5. BOTH of the following:

    a. NCCN does NOT specify the preferred medication(s) as a preferred regimen for the requested indication; AND

    b. NCCN specifies the requested medication as a preferred regimen for the requested indication.

DOSAGE AND AUTHORIZATION TIMEFRAMES

1. Recommended Dosage: Must be prescribed within the recommended range of, and does not exceed, the FDA-approved labeling, CMS-approved compendia, or NCCN (based on diagnosis, weight, condition, etc.). Prescriber submit supporting evidence for off-label use as requested by Plan.

2. Quantity: Align with FDA-labeled dose, compendia recommended dosing for indication requested for a maximum of course of therapy, 30 days whichever is shorter, or per J-code billing limits.

3. Authorization Period

    a. Initial Authorization: May authorize for up to 6 months OR up to the limit of the appropriate FDA-labeled or NCCN guideline course of treatment.

    b. Continuation of Authorization: May authorize for up to 12 months or maximum duration per FDA label or NCCN guideline, whichever is shorter.

4. Reauthorization: Must meet continuation of therapy criteria

5. Authorization for the requested oncology drug is limited to the submitted request that was reviewed. Any modifications to the diagnosis or prescribed indication necessitates a new prior authorization request.

DRUG INFORMATION

PHARMACOLOGIC CATEGORY: Antineoplastic Agents

PRODUCTS: Oncology Drugs

ROUTE OF ADMINISTRATION: Varies by drug

FDA-APPROVED INDICATIONS: Refer to the FDA-approved product information or labeling for respective drug.

COMPENDIAL APPROVED (OFF-LABELED) USES: Refer to CMS-approved compendia for the relevant off-label use.

CONTRAINDICATIONS: Refer to individual drug monographs for contraindications for requested drug.

OTHER CONSIDERATIONS: Refer to individual drug monographs for monitoring and other considerations for requested drug.

CLINICAL SUMMARY / APPENDIX

Biosimilars are a class of drugs designed to increase access for patients who need treatment with a biologic medicine. The U.S. Food and Drug Administration (FDA) defines a biosimilar as "a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product" in terms of safety, purity, and potency. In other words, biosimilars are, equivalent to the biologic medications they were developed to mimic. A biosimilar may be used in treatment-experienced patients who have previously been treated with the reference product, as well as in treatment-naïve patients who have not previously received the reference product (FDA, 2022)

REFERENCES

Government Agency

Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination (NCD) (search: bevacizumab; pembrolizumab**;** trastuzumab). Available from CMS.

- NCD 110.17: Anti-Cancer Chemotherapy for Colorectal Cancer: Oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), and bevacizumab (Avastin™)

Biosimilars. U.S. Food and Drug Administration. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars. Updated 03/01/2023. Accessed January 2024.

Biosimilar development, review, and approval. U.S. Food and Drug Administration. https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval. Last updated 12/13/2022. Accessed January 2024.

Prescribing Information

1. Alymsys (bevacizumab) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
2. Avastin (bevacizumab) [prescribing information]. South San Francisco, California: Genentech, Inc; September 2022.
3. Avzivi (bevacizumab-tnjn) [prescribing information]. Basking Ridge, New Jersey: Bio-Thera Solutions, Ltd.; December 2023.
4. Mvasi (bevacizumab-awwb) [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2023.
5. Vegzelma (bevacizumab) [prescribing information]. Jersey City, NJ: Celltrion USA Inc; February 2023.
6. Zirabev (bevacizumab-bvzr) [prescribing information]. New York, NY: Pfizer Inc; February 2023.

IMPORTANT REMINDER

This Medicare Part B Step Therapy Medical Necessity Guideline is provided for informational purposes only and neither constitutes nor replaces professional medical advice. Physicians, hospitals, and other providers are expected to administer or use drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and other health care providers are solely responsible for all medical care decisions. In accordance with the member's Evidence of Coverage (EOC), every benefit plan has its own coverage provisions, limitations, and exclusions. In the event of a conflict between this policy and the member's EOC, the member's EOC provisions will take precedence.

Aspire Health Plan (AHP) adheres to Medicare guidelines, including National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant Medicare manuals established by CMS. Compliance with these guidelines is required when applicable. Refer to the CMS website at http://www.cms.hhs.gov. For the most up-to-date Medicare policies and coverage, please search the Medicare Coverage Database. All LCDS are the same for each state within a Jurisdiction. Medicare Part B Administrative Contractor (MAC) for CA [Jurisdiction E (1)]: Active LCDs - JE Part B – Noridian (noridianmedicare.com). In the event of a discrepancy between this policy and the Medicare NCD or LCD, the Medicare NCD/LCD will govern.

This policy is utilized by AHP to determine coverage in the absence of applicable CMS Medicare guidelines. Please refer to the links provided in the References section below to access the Medicare source materials that were used for developing this resource document. This document does not serve as a substitute for the official Medicare source materials that provide detailed information on Medicare coverage requirements. In the event of a conflict between this document and Medicare source materials, the Medicare source materials will take precedence.

The inclusion of a code in this policy does not imply that the health service it describes is covered or not covered. Benefit coverage for health services is determined by the member-specific plan document and applicable laws that may mandate coverage for a particular service. Inclusion of a code does not imply or guarantee reimbursement or payment of a claim. Other Policies and Standards may also apply. Providers are expected to retain or have access to the necessary documentation when requested in order to support coverage.

The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.

POLICY HISTORY

Version	Committee Approval Date	Revision Author/Title	Summary of Changes
1	02/27/2024		New Policy