PART B DRUG MEDICAL/PHARMACY	ASPIRE HEALTH	Effective Date May 1, 2024	
	PART B MEDICAL NECESSITY: • **Unlisted and Not Otherwise Classified HCPCS Codes** • **Standard Part B Drug Criteria**	**Policy #** Part B Medical Necessity	
		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 addresses the medical necessity review of physician-administered drugs covered under Medicare Part B with: 1) an Unlisted and Not Otherwise Classified HCPCS code, and for 2) drugs without an Aspire Health Plan clinical policy. For purposes of this policy, an unlisted code can be identified by the following terms:

- Non-Specified
- Not Listed
- Not Otherwise Classified (NOC)
- Not Otherwise Specified (NOS)
- Unclassified
- Unlisted
- Unspecified

This policy is only applicable when no National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant Medicare guidelines exist for the requested drug. If an AHP drug-specific policy exists for the requested drug, the AHP policy takes precedence over this policy.

FOR ONCOLOGY AGENTS: Refer to "Oncology Drugs and Oncology Biosimilars" policy

APPLICABLE HCPCS

C9399: Unclassified drugs or biologicals
Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned. C-codes are for new drugs and biologicals and are generally replaced or expire after a year. After the year, if a drug or biological does not have an established or valid HCPCS code, then it should be billed with a NOC code. NOC codes are for "Unclassified drugs" or "Not Otherwise Classified" drugs (J3490) and biologics (J3590).
J3490 Unclassified drugs
J3590 Unclassified biologics
J3591 Unclassified drug or biological used for ESRD on dialysis
J7199 Hemophilia clotting factor, not otherwise classified
J7999 Compounded drug, not otherwise classified
J9999 Not otherwise classified, antineoplastic drugs

Note: Drugs with a specific CPT or HCPCS code may not be billed using an Unlisted and Not Otherwise Classified HCPCS code.

Exception to Policy:
- J3590 Zymfentra (infliximab-dyyb): refer to AHP Clinical Policy 'Infliximab Products.'

CLINICAL CRITERIA

I. INITIAL CRITERIA

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

*Medical record documentation by the Prescriber / 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 indicated. The documentation must also include all prior treatment regimens and the member's response to that therapy.

A. The requested drug is being prescribed for a medical condition or treatment of disease state that is recognized as a Part B covered benefit by CMS (*Requested use, regardless of medical necessity,will not be covered if specifically excluded for coverage by CMS or by the member's plan benefit)*; **AND**

B. The requested drug is U.S. Food and Drug Administration (FDA) approved for at least ONE indication; **AND**

C. The requested drug and prescribed use meets the following:

1. There is an applicable NCD or LCD and the member meets all of the requirements listed within the NCD or LCD. --Please refer to NCD / LCD and do not apply the remainder of this policy.

OR

2. There is no applicable NCD or LCD for the requested drug AND it is being prescribed for:

a. An FDA-approved indication, OR

b. A "medically accepted" indication that is listed in one or more of the CMS-approved compendia with an appropriate level of evidence of efficacy. The use must not be listed as unsupported, not indicated, not recommended (or equivalent terms) in any of the CMS-approved compendia:

"Medically accepted" definitions by compendium:

- NCCN: The level of evidence for the indication is Category 1 or 2A. (If a provider chooses to use NCCN level 2B in support of a chemotherapeutic drug used for an off-label indication, AHP expects that the provider will make available to AHP significant peer reviewed phase II or phase III studies demonstrating such support.)
- DrugDex: The level of evidence for the indication is a Class I, Class IIa, or Class IIb.
- AHFS-DI or Clinical Pharmacology: The narrative text is supportive.
- Lexi-Drugs: The indication is listed as "Use: Off-Label" and rated as "Evidence Level A."

Not "medically accepted" by a compendium:

- NCCN: The level of evidence for the indication is Category 3 in NCCN.
- DrugDex: The level of evidence for the indication is Class III in DrugDex.
- AHFS-DI or Clinical Pharmacology: The narrative text is "not supportive" *(or equivalent term)*.
- Lexi-Drugs: Indication is listed as "Use: Unsupported."

The complete absence of narrative text on a use is considered neither supportive nor non-supportive.

Refer to the 'Appendix' section for CMS-approved compendia.

AND

D. PRESCRIBER SPECIALTY: Not required unless determined medically necessary by Aspire Medical Director that the requested drug is prescribed by, or in conjunction with, a Provider of the respective specialty for specific diagnosis; **AND**

E. AGE RESTRICTIONS: Member meets FDA or compendia-supported labeled age recommendation; **AND**

F. DOSAGE: The requested drug is prescribed within the manufacturer's published dosing guidelines, or as published in the current CMS-approved compendia; and

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

AND

G. IF REQUESTED DRUG IS AN INFUSED PRODUCT WITH AN ORAL OR SELF- ADMINISTERED DOSAGE FORM AVAILABLE: Clinical rationale and supporting documentation that the member is unable to switch to an oral dosage form or self-administer. **Refer to CMS Article A53032: Self-Administered Drug Exclusion List.**

AND

H. Baseline disease activity assessment and goals for treatment to be used to evaluate efficacy of therapy at time of reauthorization / continuation of therapy; **AND**

I. Prescriber attestation that the member does not have a FDA-labeled contraindication for member or pose a clinical risk to member's condition.

II. REAUTHORIZATION / CONTINUATION OF THERAPY CRITERIA

The requested 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 with the same FDA-approved indication(s) as the reference product will be authorized. EXCEPTION: A CMS-approved compendia or NCCN guidelines specifically recommend against the biosimilar product.

- 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 (if applicable to requested drug):

    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 or CMS-approved compendia (AHFS-DI; NCCN; Micromedex DrugDex; Clinical Pharmacology; or Lexi-Drugs) based on prescribed indication, member's weight, condition, etc.

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:

    - Initial authorization: May authorize up to 6 months OR up to the limit of the appropriate FDA-labeled course of treatment.

    - Continuation of therapy: May authorize up to 12 months OR up to the limit of the appropriate FDA-labeled course of treatment.

4. Reauthorization: Must meet continuation of therapy criteria

5. Authorization for the requested 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

Refer to FDA-approved label or CMS-approved compendia for requested drug

CLINICAL SUMMARY / APPENDIX

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §110.3 for coverage of drugs, which are necessary to the effective use of Durable Medical Equipment (DME) or prosthetic devices.)
Reference: Medicare Benefit Policy Manual, Chapter 15. Section 50.4.5.)

The following are currently the authoritative compendia for CMS approved clinical decision support tools to determine FDA approved and medically accepted indication:

1. American Hospital Formulary Service-Drug Information (AHFS-DI)
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
3. Micromedex DrugDex Compendium (DrugDex)
4. Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology)
5. Wolters Kluwer Lexi-Drugs (Lexi-Drugs)

REFERENCES

Government Agency
Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National Coverage Determination (NCD) (search: 'for requested drug'). Available from CMS.

Centers for Medicare and Medicaid Services (CMS). CMS IOM, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.4.5.

Centers for Medicare and Medicaid Services (CMS). CMS Transmittal 96, Change Request (CR) 6191 dated October 24, 2008.

Centers for Medicare and Medicaid Services (CMS). CMS IOM, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 50.2, Determining Self-Administration of Drug or Biological. Accessed on January 2024.

U.S. Food and Drug Administration (FDA). Orphan Product Designations and Approval Search. Available at: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm. Accessed on January 2024.

Medicare Part B Administrative Contractor (MAC) for CA (Jurisdiction E): Noridian Healthcare Solutions. Jurisdiction E - Medicare Part B. Determination of Approved and Accepted Off-label Drug Indications. Available at: https://med.noridianmedicare.com/web/jeb/topics/drugs-biologicals-injections/determination-of-approved-and-accepted-off-label-drug-indications. Last Updated Oct 31, 2022. Accessed on January 2024.

Medicare Part B Administrative Contractor (MAC) for CA (Jurisdiction E): Noridian Healthcare Solutions. Jurisdiction E - Medicare Part B. Hemophilia Clotting Factor Billing. Available at: https://med.noridianmedicare.com/web/jeb/topics/drugs-biologicals-injections/hemophilia-clotting-factor-billing. Last Updated Dec 11, 2023. Accessed on January 2024.

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