MetroPlusHealth

# Policy and Procedure

| Title: Alpha-1 Antitrypsin Deficiency Part B Step Therapy | Division: Medical Management Department: Pharmacy, Utilization Management |
|---|---|
| Approval Date: 11/23/2020 | LOB: Medicare |
| Effective Date: 12/01/2020 | Policy Number: UM-MP258 |
| Review Date: 11/29/2022 | Cross Reference Number: |
| Retired Date: | Page 1 of 4 |

## 1. POLICY DESCRIPTION:

Step therapy requirement for Part B Alpha-1 Antitrypsin Deficiency. Aralast, Glassia and Zemaira require trial with Prolastin-C.

| Alpha-1 Antitrypsin Deficiency Product(s) | |
|---|---|
| **Preferred** | **Prolastin-C** (Alpha-1 Proteinase Inhibitor Human) |
| **Targeted** | **Aralast** (Alpha-1 Proteinase Inhibitor Human)<br>**Glassia** (Alpha-1 Proteinase Inhibitor Human)<br>**Zemaira** (Alpha-1 Proteinase Inhibitor Human) |

## 2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

## 3. DEFINITIONS:

Targeted: Medications that are considered non-preferred and will therefore be subject to step therapy

## 4. POLICY:

Non-preferred drugs will be considered medically necessary for beneficiaries/members when all of the following criteria are met:

1. Documented trial and failure with **all** preferred drugs listed above when indications overlap.
2. Indication, dose, frequency and duration is in accordance with FDA label, recognized compendia (for off-label uses), documented within the Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) for non-preferred drug as applicable under Medicare regulations
3. Documentation requirements are provided as listed within Local Coverage Determination (LCD) and/or National Coverage Determination (NCD)

## 5. LIMITATIONS/ EXCLUSIONS:

This policy is only applicable to members new to therapy. Members already on therapy with non-preferred drug(s) will not be subjected to this step therapy

requirement. MetroPlus will utilize a 365-day lookback period and/or documentation of medical history stating member is already on therapy with non-preferred drug(s). Additional limitations and exclusions consistent with those listed within Local Coverage Determination (LCD) and/or National Coverage Determination (NCD).

## 6. APPLICABLE PROCEDURE CODES:

| CODE | Description |
|---|---|
| J0256 | Prolastin-C |
| J0256 | Aralast |
| J0257 | Glassia |
| J0256 | Zemaira |

## 7. APPLICABLE DIAGNOSIS CODES:

| CODE | Description |
|---|---|
| E88.01 | Alpha-1 Antitrypsin deficiency |

## 8. REFERENCES:

1. Centers for Medicare and Medicaid Services, Health Plan Management System (HPMS), MA_Step_ Therapy_HPMS_Memo_8_7_18; available at http://www.cms.gov – accessed August 28, 2020 and found under Medicare > Health Plans > Health Plans - General Information > Downloads.
2. Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. http://www.cms. gov/medicare-coverage-database/search/advanced-search.aspx.
3. National Coverage Determination (NCD). Centers for Medicare & Medicare Services. http://www. cms.gov/medicare-coverage-database/search/advanced-search.aspx.
4. U.S. Food & Drug Administration. FDA Approved Drug Products. https://www.accessdata.fda.gov/ scripts/cder/daf/

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**REVISION LOG:**

| REVISIONS | DATE |
|---|---|
| Creation date | 12/1/2020 |
| Minor changes and review | 4/30/2021 |
| Annual Review | 12/17/2021 |
| Annual Review | 11/29/2022 |

| **Approved:** | **Date:** | **Approved:** | **Date:** |
|---|---|---|---|
| Glendon Henry Digitally signed by Glendon Henry Date: 2022.12.01 10:59:07 -05'00' | | Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2022.12.01 15:37:25 -05'00' | |
| **Glendon Henry, MD Senior Medical Director** | | **Sanjiv Shah, MD Chief Medical Officer** | |

## Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will

govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.
All coding and website links are accurate at time of publication.
MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.