MetroPlus Health

Policy and Procedure

Title: Medicare - Autoimmune Drug Policy	Division: Medical Management Department: Pharmacy, Utilization Management
Approval Date: 11/23/2020	LOB: Medicare, UltraCare
Effective Date: 12/01/2020	Policy Number: UM-MP259
Review Date: 11/29/2022	Cross Reference Number:
Retired Date:	Page 1 of 4

1. POLICY DESCRIPTION:

Step therapy requirement for Part B Autoimmune. Actemra, Cimzia, Ilumya, Inflectra, Orencia, Renflexis, and Stelara IV require trial with Avsola, Entyvio, Simponi Aria, and Remicade, where indications overlap.

Prior Authorization requirement for Remicade (infliximab)

Autoimmune Product(s)	
Preferred	**Entyvio** (Vedolizumab) **Simponi Aria (**Golimumab) **Remicade** (Infliximab) ***PA Required*** **Inflectra** (Infliximab-dyyb) **Infliximab**
Targeted	**Actemra (**Tocilizumab) **Avsola** (Infliximab-axxq) **Cimzia** (Certolizumab pegol) **Ilumya** (Tildrakizumab-asmn) **Orencia** (Abatacept) **Renflexis** (Infliximab-abda) **Stelara IV** (Ustekinumab)

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. **For Cimzia**, when **any** of the following criteria are met:
   a. Member has a documented inadequate response or intolerable adverse event with each of the following where the product's indications overlap:
      i. Avsola, Inflectra, or Renflexis
      ii. Entyvio
      iii. Ilumya
      iv. Simponi Aria
   b. Member is currently pregnant or breastfeeding

2. For all other non-preferred products when any of the following criteria are met:
   a. Member has a documented inadequate response or intolerable adverse event with each of the following where the product's indications overlap:
      i. Avsola or Remicade
      ii. Entyvio
      iii. Simponi Aria
   b. Member has a documented inadequate response or intolerable adverse event with Entyvio where the product's indications overlap and there is a documented clinical reason to avoid TNF inhibitors such as:
      a) History of demyelinating disorder
      b) History of congestive heart failure
      c) History of hepatitis B virus infection
      d) Autoantibody formation/lupus-like syndrome
      e) Risk of lymphoma
3. 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
4. Documentation requirements are provided as listed within Local Coverage Determination (LCD) and/or National Coverage Determination (NCD)

For Remicade (infliximab) only:
Per CMS regulation, Metroplus Health Plan follows the following Local Coverage Determination (LCD) and Local Coverage Article (LCA):
1. LCD: L33394
2. LCA: A52423

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
Q5121	Avsola
J3380	Entyvio

CODE	Description
J3245/ J3590	Ilumya
J1602	Simponi Aria
J3357/ J3358	Stelara
Q5102/ Q5103	Inflectra
Q5102/ Q5104	Renflexis
J3490/J3590/ J3262	Actemra
J0717	Cimzia
J0129	Orencia
J1745	Remicade

7. 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/

REVISION LOG:

REVISIONS	DATE
Creation date	11/23/2020
Review date	12/15/2020
Review date	4/30/2021
Annual review & update to preferred/non-preferred products	12/17/2021
Addition of Rituxan LCD/LCA criteria	2/28/2022
Annual review & update to preferred/non-preferred products	11/29/2022

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Approved:	Date:	Approved:	Date:
Glendon Henry Digitally signed by Glendon Henry Date: 2022.12.01 11:08:32 -05'00'		Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2022.12.01 15:38:19 -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.