MetroPlusHealth

Policy and Procedure

Title: CHP - Multiple Sclerosis (Infused) Step Therapy	Division: Medical Management Department: Pharmacy, Utilization Management
Approval Date: 3/28/2022	**LOB: CHP**
Effective Date: 1/1/2022	**Policy Number: UM-MP331**
Review Date: 4/4/2023	**Cross Reference Number:**
Retired Date:	**Page 1 of 3**

1. **POLICY DESCRIPTION:**
   Step therapy requirement for Multiple Sclerosis (Infused**)**. Lemtrada requires trial with Tysabri and Ocrevus.

Multiple Sclerosis (Infused) Product(s)	
Preferred	**Tysabri** (Natalizumab) **Ocrevus** (Ocrelizumab)
Targeted	**Lemtrada** (Alemtuzumab)

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.
   2. Indication, dose, frequency and duration is in accordance with FDA label and/or recognized compendia (for off-label uses).

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).

6. **APPLICABLE PROCEDURE CODES:**

CODE	Description
J2323	Natalizumab, 1mg
J0202	Alemtuzumab, 1mg
J2350	Ocrelizumab, 1mg

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
G35	Multiple Sclerosis

8. REFERENCES:

1. Ocrevus (ocrelizumab) [package insert]. South San Francisco, California: Genentech, Inc. December 2020.
2. Lemtrada (alemtuzumab) [package insert]. Cambridge, Massachusetts: Genzyme Corp. January 2022.
3. Tysabri (natalizumab) [package insert]. Cambridge, Massachusetts: Biogen Inc. December 2021.
4. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2. Accessed on March 21, 2022.

REVISION LOG:

REVISIONS	DATE
Creation date	3/28/2022
Annual review	4/4/2023

Approved:	Date:	Approved:	Date:
Glendon Henry Digitally signed by Glendon Henry Date: 2023.04.05 07:02:46 -04'00'		Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.04.18 16:39:53 -04'00'	
Glendon Henry, MD **Senior Medical Director**		**Sanjiv Shah, MD** **Chief Medical Officer**	

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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.