

PART B STEP THERAPY CRITERIA FOR APPROVAL

Lemtrada (alemtuzumab), Ocrevus (ocrelizumab), and Tysabri (natalizumab) will be approved when ALL of the following are met:

1. The requested agent is being used for ONE of the following:
 - A. An FDA approved indication

OR

 - B. An indication in CMS approved compendia

AND
2. ONE of the following:
 - A. Information has been provided that indicates the patient has been treated with the requested agent in the past 365 days

OR

 - B. There is documentation that the patient has had an ineffective treatment response to the active ingredient(s) of the preferred agent(s)

OR

 - C. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to the active ingredient(s) of the preferred agent(s)*

OR

 - D. The prescriber has submitted documentation indicating the preferred agent(s) are likely to be ineffective or are likely to cause an adverse reaction or other harm to the enrollee

Length of Approval: up to 12 months

*Preferred agent(s) may vary based upon indication. Use of TWO preferred agents is required for diagnosis of Multiple Sclerosis. Use of ONE preferred agent is required for diagnosis of Crohn's Disease.

| Targeted Part B Agent | Preferred Agent(s)* |
|---|---|
| Lemtrada (alemtuzumab) | Part D - Avonex, Betaseron, dimethyl fumarate, Gilenya, glatiramer (brand names Copaxone and Glatopa), Mayzent, Plegridy, Rebif/Rebif Rebidose, and Vumerity |
| Ocrevus (ocrelizumab) | Part D - Avonex, Betaseron, dimethyl fumarate, Gilenya, glatiramer (brand names Copaxone and Glatopa), Mayzent, Plegridy, Rebif/Rebif Rebidose, and Vumerity |
| Tysabri (natalizumab) for MS | Part D - Avonex, Betaseron, dimethyl fumarate, Gilenya, glatiramer (brand names Copaxone and Glatopa), Mayzent, Plegridy, Rebif/Rebif Rebidose, and Vumerity |
| Tysabri (natalizumab) for Crohn's Disease | Part D - Corticosteroids, methotrexate, and immunomodulators, such as azathioprine or 6-mercaptopurine |

NOTES:

- Prerequisite drugs may require prior review under Medicare Part D or Medicare Part B. Medicare Part D prerequisites will not be required for Medical Only members.
- Length of approval may be shorter due to provider network participation status.
- Coverage of one Medicare Part B Step Therapy drug could equate to multiple drug authorizations when they share the same Medicare Part B Step Therapy criteria.
- LCD/NCD criteria review completed, if applicable, in addition to the Plan's Medicare Part B Step Therapy criteria.