

Government Health Plan (GHP) of Puerto Rico

Authorization Criteria

Natalizumab (Tysabri®) – Crohn’s Disease Managed by MCO

Section I. Prior Authorization Criteria

1. Physician must submit evidence of a NEGATIVE intradermal tuberculin (PPD) test result, or Negative results of a chest X-ray, or a certification of negative tuberculosis risk.
 2. Patient must meet all criteria / requisites according to diagnosis (see *Section II for Specific criteria per diagnosis*)
- C. Assess clinical response after the first three months of treatment.
- D. Treatment should be discontinued if failure to therapy or toxicity is documented.
- E. Follow Package insert instructions for dose administration.

Sección II. Specific Criteria per Diagnosis

A. Crohn’s Disease

1. Prescriber restriction: Gastroenterologists (Applies to 1st prescription and every 12 months).
2. The physician that administers the therapy, as well as the pharmacy and the infusion center where patient is to be treated must be registered in the TOUCH™ Prescribing Program.
3. Prescriber must document the diagnoses on the prescription:
 - a. Moderate to severe active Crohn's disease with evidence of inflammation and inadequate response or intolerance to treatment with conventional therapies for Crohn's disease and to tumor necrosis factor inhibitors. (ICD-10-CM K50.00, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918 o K50.919).
4. Physician must certify the following:

a. Patient has been treated with the following drugs and there is evidence of intolerance or failure to therapy:

- i. Corticosteroids (e.g. Budesonide, Hydrocortisone) and,
- ii. TNF- α Antagonist on formulary (Adalimumab, Infliximab).

B. Multiple Sclerosis

- 1. Prescriber restriction: neurologist
- 2. Additional Criteria
 - 1. The patient, the physician that administers the infusion, the pharmacy and the infusion center are registered in the TOUCH™ Prescribing Program.
 - 2. Physician certifies that the patient has relapsing forms of multiple sclerosis. (ICD-9: 340; ICD-10: G35)

Section II. References

- 1. Tysabri [package insert]. Cambridge, MA: Biogen Idec; May 2016

Section III. Review Log

Approved:	December 1, 2009
Revised:	December 1, 2011
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GPI	GPI NAME
62405050001320	NATALIZUMAB FOR IV INJ CONC 300 MG/15ML