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## Tysabri (natalizumab) Ordering Guide

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- ❖ For **new patients**, please submit completed **Tysabri Order Form** (above) with all available supporting documentation to facilitate the approval process.
- ❖ **Please submit with Tysabri Order Form the following supporting documentation:** \*
  - Progress notes with documentation of diagnosis
  - Labs and test results supporting diagnosis, screening / monitoring (including anti-JCV antibody testing)
  - Medication history, including prior and/or concurrent therapies for primary diagnosis, prior use of immunosuppressants

*\*Specific plans may require additional documentation for prior authorization*
- ❖ Additional information for consideration:
  - To provide Tysabri, prescribers, patients, pharmacies, and infusion sites must be enrolled in the TOUCH Program
  - Risk Evaluation and Mitigation Strategy (REMS) requirements include, but are not limited to:
    - Prescriber requirements:
      - Review the TOUCH Prescribing Program's prescriber educational materials and prescribing information
      - Educate patients on the benefits/risks of Tysabri, provide patient with TOUCH educational materials
      - Evaluate patients three months after the first infusion, six months after the first infusion, every six months thereafter, and for at least six months after discontinuing
      - Assess every 6 months for continuation of therapy, and submit the Tysabri Patient Status Report and Reauthorization Questionnaire to TOUCH
      - Complete an "Initial Discontinuation Questionnaire" when Tysabri is discontinued, and a "6-Month Discontinuation Questionnaire" following discontinuation of Tysabri
      - Report cases of PML, hospitalizations due to opportunistic infections, and deaths to Biogen at 1-800-456-2255 as soon as possible
    - Pharmacy requirements:
      - Prior to dispensing, verify the prescriber, patient, and infusion center is authorized through TOUCH
      - Dispense Medication Guide
    - Infusion site requirements:
      - Obtain authorization to dispense each infusion by confirming receipt of a Notice of Patient Authorization (or by contacting the REMS program) and verify no Notice of Patient Discontinuation to ensure patient is authorized to receive Tysabri
      - Provide the patient with the Medication Guide
      - Complete the Pre-Infusion Patient Checklist. Submit within 1 day of the patient's visit, maintain copy
  - Regular **anti-JCV antibody testing** is supported by Tysabri's Prescribing Information. Frequent testing may help mitigate the risk of PML and aid in assessing suitability of starting or continuing Tysabri therapy
  - Any necessary lab draws will need to be arranged at prescriber's office or a lab facility of patient's preference
- ❖ Resources:
  - TOUCH Program educational materials, enrollment/authorization forms, and Pre-Infusion Checklist are available at [www.tysabri.com](http://www.tysabri.com), [www.touchprogram.com](http://www.touchprogram.com), as well as on the Food and Drug Administration (FDA) website