



MEDICARE FORM

Tysabri® (natalizumab) Medication Precertification Request

Page 1 of 3

All fields must be completed and legible for precertification review.)

For Illinois MMP: FAX: 1-855-320-8445 PHONE: 1-866-600-2139

For other lines of business: Please use other form.

Note: For the treatment of Crohn's disease, Tysabri is non-preferred. Entyvio, Inflectra, and Remicade are preferred for MA plans and Humira and Skyrizi are preferred for MAPD plans. For the treatment of multiple sclerosis, Tysabri is preferred.

Please indicate: [ ] Start of treatment: Start date \_\_\_/\_\_\_/\_\_\_ [ ] Continuation of therapy: Date of last treatment \_\_\_/\_\_\_/\_\_\_

Precertification Requested By: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

A. PATIENT INFORMATION

Form section A containing fields for Patient Information: First Name, Last Name, Address, City, State, ZIP, Home Phone, Work Phone, Cell Phone, DOB, Allergies, E-mail, Current Weight, Height.

B. INSURANCE INFORMATION

Form section B containing fields for Insurance Information: Member ID #, Group #, Insured, Does patient have other coverage?, If yes, provide ID#, Carrier Name, Insured.

C. PRESCRIBER INFORMATION

Form section C containing fields for Prescriber Information: First Name, Last Name, Address, City, State, ZIP, Phone, Fax, St Lic #, NPI #, DEA #, UPIN, Provider Email, Office Contact Name, Phone.

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Form section D containing fields for Dispensing Provider/Pharmacy: Place of Administration (Self-administered, Outpatient Infusion Center, Home Infusion Center, Administration code(s)), Dispensing Provider/Pharmacy (Physician's Office, Retail Pharmacy, Specialty Pharmacy, Other), Name, Address, City, State, ZIP, Phone, Fax, TIN, PIN, NPI.

E. PRODUCT INFORMATION

Form section E containing fields for Product Information: Request is for Tysabri, Dose, Frequency, HCPCS Code.

F. DIAGNOSIS INFORMATION - Please indicate primary ICD Code and specify any other where applicable.

Form section F containing fields for Diagnosis Information: Primary ICD Code, Secondary ICD Code, Other ICD Code.

G. CLINICAL INFORMATION - Required clinical information must be completed in its entirety for all precertification requests.

For All Requests (clinical documentation required for all requests):

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- Has the patient had prior therapy with Tysabri (natalizumab) within the last 365 days?
Has the patient had a trial and failure, intolerance, or contraindication to any of the following? (select all that apply)
Entyvio (vedolizumab) Inflectra (infliximab-dyyb) Remicade (infliximab)
Has the patient had a trial and failure, intolerance, or contraindication to any of the following? (select all that apply)
Humira (adalimumab) Skyrizi (risankizumab-rzaa)

Please explain if there are any other medical reason(s) that the patient cannot use any of the following preferred products when indicated for the patient's diagnosis (select all that apply).

Form section G containing checkboxes for Entyvio, Inflectra, and Remicade.

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

Please explain if there are any other medical reason(s) that the patient cannot use any of the following preferred products when indicated for the patient's diagnosis (select all that apply).

- Humira (adalimumab)     Skyrizi (risankizumab-rzaa)

Yes     No    Does the patient have a documented anti-JCV antibody test with ELISA prior to initiating treatment?

→ Please indicate the date of the anti-JCV antibody test: \_\_\_\_/\_\_\_\_/\_\_\_\_

Please indicate the results of the anti-JCV antibody test with ELISA:  positive     negative

Yes     No    Will the patient have documented anti-JCV antibody testing with ELISA annually after initiating treatment with Tysabri (natalizumab)?

Yes     No    Is this infusion request in an outpatient hospital setting?

→  Yes     No    Is the patient medically unstable for infusions at alternate levels of care?

Yes     No    Does the patient have a history of any cardiopulmonary conditions?

→ Please provide the description of the condition: \_\_\_\_\_

Yes     No    Does this condition cause an increased risk of severe adverse reactions?

Yes     No    Does the patient have documentation of unstable vascular access?

Yes     No    Is there clinical evidence that the patient has an inability to safely tolerate intravenous volume load (including from unstable renal function)?

→  Yes     No    Is the inability to tolerate intravenous volume load due to unstable renal function?

→ Please document the following:     GFR: \_\_\_\_ mL/min/1.73m<sup>2</sup>    Date Collected: \_\_\_\_/\_\_\_\_/\_\_\_\_

BUN: \_\_\_\_ mg/dL    Date Collected: \_\_\_\_/\_\_\_\_/\_\_\_\_

Creatinine: \_\_\_\_ mg/dL    Date Collected: \_\_\_\_/\_\_\_\_/\_\_\_\_

**For Initiation Requests:**

**Crohn's Disease**

Yes     No    Does the patient have a diagnosis of fistulizing Crohn's disease?

→ Please indicate how long the patient has been diagnosed with fistulizing Crohn's disease:

Please select:  Less than 1 month     1 month     2 months     3 months or greater

Yes     No    Does the patient have a diagnosis of Crohn's disease?

→ Please indicate the severity of the patient's disease:  mild     moderate     severe

Yes     No    Does the patient have a documented diagnosis of active Crohn's disease?

→ Please select all signs/symptoms that apply:

abdominal pain     arthritis     bleeding     diarrhea     internal fistulae     intestinal obstruction

megacolon     perianal disease     spondylitis     weight loss     None of the above

Yes     No    Have symptoms remained active despite treatment with conventional Crohn's disease therapies (e.g., sulfasalazine, corticosteroids, or immunosuppressive agents (e.g., 6-mercaptopurine, azathioprine)?

→ Please check all medications that apply:  6-mercaptopurine (6-MP)     azathioprine     sulfasalazine

corticosteroids     Other, please explain: \_\_\_\_\_

Please indicate the length of the medication trial:  Less than 1 month     1 month     2 months     3 months or greater

Yes     No    Will Tysabri (natalizumab) be used concomitantly with immunosuppressants?

Yes     No    Will Tysabri (natalizumab) be used concomitantly with tumor necrosis factor inhibitors (TNF inhibitors) (e.g., adalimumab, infliximab)?

**Multiple Sclerosis**

Which of the following types of MS has the patient been diagnosed with:

Relapsing-Remitting MS (RRMS)     Primary-Progressive MS (PPMS)     Progressive-Relapsing MS (PRMS)     Secondary-Progressive MS (SPMS)

Yes     No    Has the patient discontinued other medications used for treating MS (not including Ampyra (dalfampridine))?

How many of the following preferred alternatives have treatment with an adequate trial been ineffective, not tolerated or is contraindicated?

Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Gilenya (fingolimod), Glatopa/Copaxone/glatiramer, Lemtrada (alemtuzumab), Plegriid (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate)

0     1     2     3     4 or more

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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**G. CLINICAL INFORMATION (continued) – Required clinical information must be completed in its entirety for all precertification requests.**

**For Continuation Requests (clinical documentation required for all requests):**

Please indicate the length of time on Tysabri (natalizumab): \_\_\_\_\_

Yes  No Is this continuation request a result of the patient receiving samples of Tysabri (natalizumab)?

Yes  No Has the patient had a documented anti-JCV antibody test with ELISA within the last 12 months?

→ Please indicate the date of the last anti-JCV antibody test with ELISA: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Please indicate the results of the anti-JCV antibody test with ELISA:  positive  negative

Yes  No Has the patient received Tysabri (natalizumab) within the past 6 months?

→  Yes  No Does the patient have a documented severe and/or potentially life-threatening adverse event that occurred during or following the previous infusion?

→  Yes  No Could the adverse reaction be managed through pre-medication in the office setting?

Yes  No Is there clinical documentation supporting disease stability?

Yes  No Is there clinical documentation supporting disease improvement?

**For Crohn's Disease:**

Please indicate the severity of the disease at baseline (pretreatment with Tysabri (natalizumab)):  mild  moderate  severe

**For Crohn's Disease or Fistulizing Crohn's Disease:**

Yes  No Will Tysabri (natalizumab) be used concomitantly with immunosuppressants or TNF inhibitors (e.g., adalimumab, infliximab)?

**For Multiple Sclerosis:**

Which of the following types of MS has the patient been diagnosed with:

Relapsing-Remitting MS (RRMS)  Primary-Progressive MS (PPMS)  Progressive-Relapsing MS (PRMS)  Secondary-Progressive MS (SPMS)

Yes  No Has the patient discontinued other medications used for treating MS (not including Ampyra (dalfampridine))?

**H. ACKNOWLEDGEMENT**

**Request Completed By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.