

TYRUKO[®]
(natalizumab-sztn) 300 mg/
15 mL IV



SANDOZ
one source[®]



ENROLL IN SANDOZ ONE SOURCE

Please complete the appropriate forms and submit them to Sandoz One Source online at www.Sandoz-OneSource.com/TYRUKO, or complete and fax to **(855) 530-1402**.

Enrollment and Prescription Checklist



As a reminder: to receive TYRUKO, the patient and their prescriber must be enrolled in TYRUKO REMS.

- ☐ For healthcare providers (HCPs), please complete **the Patient Services Enrollment and Prescription Form** and select the services you would like to request

- ☐ Have patient sign **the Patient Authorization Form**



Scan here to visit
www.Sandoz-OneSource.com/TYRUKO
to enroll online

Have questions on completing enrollment?

Please call **(855) 4TYRUKO (855-489-7856) option 2**, Monday-Friday 8 AM to 8 PM ET.

Please see full **Important Safety Information** on pages 3-4 and accompanying full **Prescribing Information**, including **Medication Guide**.



PATIENT SERVICES ENROLLMENT AND PRESCRIPTION FORM (*Required)

1 SELECT SERVICES (*Select at least one)

By completing this form, I am requesting services on behalf of the patient. I would like the following services completed:

☐ All Support Services ☐ Benefit Investigation ☐ Prior Authorization/Appeal Support ☐ Co-pay Services ☐ Bridge and/or Quick Start ☐ Sandoz Patient Assistance (SPA)

2 PATIENT INFORMATION

*First Name _____ Middle Initial _____ *Last Name _____ *Date of Birth (DD/MM/YYYY) ____/____/____ *Sex ☐ Male ☐ Female

*Address _____ *City _____ *State _____ *Zip _____ Email _____
Preferred Language: ☐ English ☐ Spanish ☐ Other _____

*Mobile Phone # _____ Additional Phone # _____ *Please check one: ☐ New to therapy ☐ Switching from other therapies _____

3 PATIENT INSURANCE

Please include front and back of insurance card(s)

☐ Please check this box if the patient has no insurance (Sandoz One Source will evaluate the patient for our free medication program Sandoz Patient Assistance [SPA])

*Primary/Medical Insurance _____ Phone # _____ *Member Name _____ *Member ID # _____ *Policy Group # _____

Member Employer _____ Pharmacy/Rx Insurance _____ Phone # _____ Member ID # _____ Rx Group # _____

Rx BIN _____ Rx PCN _____ Secondary Insurance _____ Phone # _____ Member ID _____

4 PRESCRIBER INFORMATION

*Prescriber Full Name (print) _____ Practice Name _____ PTAN # (required for Medicare) _____ Tax ID # _____ *NPI # _____

*Address _____ *City _____ *State _____ *Zip _____

*Office Contact Name _____ Office Contact Email _____ *Office Contact Phone # _____ *Office Contact Fax # _____

5 PRESCRIPTION INFORMATION

***TYRUKO Prescription**

Prescription for TYRUKO (natalizumab-sztn) NDC: 61314-0543-94 **Dose:** 1 Vial, single use - 300 mg/15 mL (20 mg/mL)

Dispense: 1 Vial **Days Supply:** 28 days **Refills:** _____ **Directions:** 300 mg infused intravenously over 1 hour, every 4 weeks. Do not give as an intravenous push or bolus

***Diagnosis Code - Please check one**

☐ ICD-10 Code: G35 (Multiple Sclerosis) ☐ ICD-10 Code: K50 (Crohn's disease)

***Procurement and Infusion Options**

Initial Infusion: ☐ Yes ☐ No (If no, date of last infusion ____/____/____)

How do you intend to procure TYRUKO? (Select only one):

☐ Buy and Bill ☐ Specialty Pharmacy to coordinate delivery

How do you intend to administer TYRUKO? (Select only one):

☐ Prescriber's office ☐ Preferred infusion site (complete below) ☐ Assist in locating an infusion center

Site Name _____ Address _____ City _____ State _____ Zip _____

Phone # _____ Fax # _____ NPI # _____ Tax ID # _____

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By completing and submitting this form, I certify that my patient is aware of the disclosure of their personal health information to Sandoz and its business partners for Sandoz's patient support services, including reimbursement and verification services and the services provided by field reimbursement professionals in my office, as part of the patient's treatment with this product. I certify that I have obtained any required patient authorization. I further certify that (a) any service provided through Sandoz One Source on behalf of any patient is not made in exchange for any expressed or implied agreement or understanding that I would recommend, prescribe, or use TYRUKO or any other Sandoz product or service for anyone, and that (b) my decision to prescribe TYRUKO was based solely on my determination of medical necessity as set forth herein, and that (c) I will not seek reimbursement for any medication or service provided by or through Sandoz One Source for any government program or third-party insurer. For the purposes of transmitting prescriptions, I authorize SPA (Sandoz Patient Assistance), Sandoz, and its affiliates, business partners, and agents to forward these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies on my behalf.

***Prescriber's Signature** (stamp signature not allowed)

Prescriber's Signature (dispense as written) _____ Date _____

Prescriber's Signature (substitution permissible) _____ Date _____

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

*Required fields.

As a reminder, patients and prescribers must be enrolled in TYRUKO REMS to receive TYRUKO.

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INDICATION AND IMPORTANT SAFETY INFORMATION

What is TYRUKO?

TYRUKO (natalizumab-sztn) is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. TYRUKO increases the risk of progressive multifocal leukoencephalopathy (PML). When starting and continuing treatment with TYRUKO, it is important to discuss with your doctor whether the expected benefit of TYRUKO is enough to outweigh this risk.

It is not known if TYRUKO is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TYRUKO?

TYRUKO (natalizumab-sztn) increases your risk of getting a rare brain infection—called progressive multifocal leukoencephalopathy (PML)—that usually leads to death or severe disability.

- **There is no known treatment, prevention, or cure for PML**
- **You should not take certain medicines that weaken your immune system at the same time you are taking TYRUKO. Even if you use TYRUKO alone to treat your multiple sclerosis (MS), you can still get PML**
- **Your risk of getting PML is higher if you:**
 - have been infected by the John Cunningham Virus (JCV). JCV is a common virus that can cause PML in people who have weakened immune systems, such as people taking TYRUKO. Before or while you receive TYRUKO, your doctor may do a blood test to check if you have been infected by JCV
 - have received TYRUKO for a long time, especially for longer than 2 years
 - have received certain medicines that can weaken your immune system before you start receiving TYRUKO
- **Your risk of getting PML is greatest if you have all 3 risk factors listed above. There may be other risk factors that have not yet been identified**
- Patients who are anti-JCV antibody negative are still at risk for the development of PML due to the potential for a new JCV infection or a false negative test result. Therefore, patients with a negative test result should be retested periodically
- **While you receive TYRUKO, and for 6 months after you stop receiving TYRUKO, it is important that you call your doctor right away if you have any new or worsening medical problems that have lasted several days**
 - These may include problems with your thinking, eyesight, balance, or strength; weakness on 1 side of your body; and problems using your arms and legs
 - Tell all of your doctors that you are getting treatment with TYRUKO
- **Because of your risk of getting PML while you receive TYRUKO, TYRUKO is available only through a restricted distribution program called the TYRUKO REMS program**

Who should not receive TYRUKO?

Do not receive TYRUKO if you have PML or are allergic to natalizumab products or any of the ingredients in TYRUKO.

What should I tell my doctor before receiving each dose of TYRUKO?

Before receiving TYRUKO, it is important to tell your doctor if you:

- have a medical condition that can weaken your immune system, such as HIV (human immunodeficiency virus) infection or AIDS (acquired immunodeficiency syndrome), leukemia or lymphoma, or organ transplant
- have any new or worsening medical problems that have lasted several days
- are pregnant or plan to become pregnant. TYRUKO may cause low platelets, and in some cases also low red blood cells (anemia), in your newborn baby if you take TYRUKO while you are pregnant. It is not known if TYRUKO can cause birth defects
- have had hives, itching, or trouble breathing during or after receiving a dose of TYRUKO
- have a fever or infection (including shingles or any unusually long-lasting infection)
- are breastfeeding or plan to breastfeed. TYRUKO can pass into your breast milk. It is not known if the TYRUKO that passes into your breast milk can harm your baby. Talk to your doctor about the best way to feed your baby while you receive TYRUKO

Tell your doctor about all of the medicines and supplements you take. Especially tell your doctor if you take medicines that can weaken your immune system. Ask your doctor if you are not sure.



INDICATION AND IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION *(continued)*

What are the possible side effects of TYRUKO?

TYRUKO can cause serious side effects. If you have any of the symptoms listed below, call your doctor right away:

- **Herpes infections.** TYRUKO may increase your risk of getting an infection of the brain or the covering of your brain and spinal cord (encephalitis or meningitis) caused by herpes viruses that may lead to death. Symptoms include sudden fever, severe headache, or confusion. Infection of the eye caused by herpes viruses leading to blindness in some patients has occurred. Call your doctor if you have changes in vision, eye redness, or eye pain
- **Liver damage.** Symptoms include yellowing of the skin and eyes (jaundice), unusual darkening of the urine, nausea, feeling tired or weak, or vomiting
- **Allergic reactions including serious allergic reactions.** Symptoms of an allergic reaction can include: hives, itching, trouble breathing, chest pain, dizziness, wheezing, chills, rash, nausea, flushing of skin, low blood pressure

Serious allergic reactions usually happen within 2 hours of the start of your infusion, but they can happen any time after receiving TYRUKO. Contact your doctor right away if you have any symptom of an allergic reaction, even if it happens after your infusion.

- **Infections.** TYRUKO may increase your risk of getting an unusual or serious infection because TYRUKO can weaken your immune system
- **Low platelet counts.** TYRUKO may cause the number of platelets in your blood to be reduced. Symptoms include easy bruising, small scattered spots on your skin that are red, pink or purple, heavier menstrual periods than are normal, bleeding from your gums or nose that is new or takes longer than usual to stop, or bleeding from a cut that is hard to stop

The most common side effects of TYRUKO are:

- Headache, feeling tired, urinary tract infection, joint pain, lung infection, depression, pain in your arms or legs, diarrhea, vaginitis, rash, stomach area pain. If you experience any side effect that bothers you or does not go away, tell your doctor

These are not all of the possible side effects with TYRUKO. Always contact your doctor if you have questions or experience any side effects that bother you or do not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Sandoz at 1-800-525-8747.

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