

TYSABRI▼ Treatment Initiation Form

TYSABRI (natalizumab) 300 mg concentrate solution for infusion

This form should be read carefully before starting treatment with **TYSABRI**. Please follow the advice in this form to ensure that you are fully informed of, and understand the risk of **PML** (progressive multifocal leukoencephalopathy), **IRIS** (Immune Reconstitution Inflammatory Syndrome) and other important adverse effects of **TYSABRI**.

Before starting treatment with **TYSABRI** you should:

- Read the **Package Leaflet** which is included in each box of **TYSABRI**
- Read the **Alert Card** given to you by your doctor
- Discuss with your doctor the benefits and the risks associated with this treatment

The **Package Leaflet** and the **Alert Card** contain important safety information about **PML**, a rare brain infection that has occurred in patients who have been given **TYSABRI**, and which may lead to severe disability or death.

JC virus is a common virus which infects many people but does not normally cause noticeable illness. **PML** is associated with an uncontrolled increase of the **JC virus** in the brain, although the reason for this increase in some patients treated with **TYSABRI** is unknown.

The risk of **PML** with **TYSABRI** is higher:

- If you have antibodies to the **JC virus** in your blood
- The longer that you are on treatment with **TYSABRI**, especially if you have been on treatment for more than two years
- If you have taken an immunosuppressant (a medicine that reduces the activity of your body's immune system) at any time before starting **TYSABRI** treatment

Your doctor should discuss the potential risk of developing **PML** with you before you start treatment with **TYSABRI**.

Your doctor may test your blood to check if you have antibodies to the **JC virus** before you start treatment with **TYSABRI**. Your doctor may repeat the test while you are on **TYSABRI** treatment to check if anything has changed. The risk of **PML** is higher if you have all the risk factors described above, or if you have not taken an immunosuppressant medication prior to starting **TYSABRI** and have higher levels of antibodies to the **JC virus** and you have been on **TYSABRI** for more than 2 years. Your doctor will monitor you more closely if you are at higher risk for **PML**.

You should discuss with your doctor if **TYSABRI is the most suitable treatment for you before you start taking **TYSABRI** and when you have been taking **TYSABRI** for more than two years.**

In patients with **PML**, a reaction known as **IRIS** (Immune Reconstitution Inflammatory Syndrome) is likely to occur after treatment for **PML**, as **TYSABRI** is removed from your body. **IRIS** may lead to your condition getting worse, including worsening of brain function.

The **Package Leaflet** should be read each time that you take **TYSABRI** because it may have new information that is important to your treatment.

You should keep the **Alert Card** with you to remind you of the important safety information, in particular any symptoms you may develop which could possibly indicate **PML**. If appropriate, you should show the **Alert Card** to your partner or caregiver.

If you do not have the **Package Leaflet** or the **Alert Card** then please ask your doctor to provide them to you before you receive your infusion of **TYSABRI**.

Patient's Name (print)

Patient's Signature

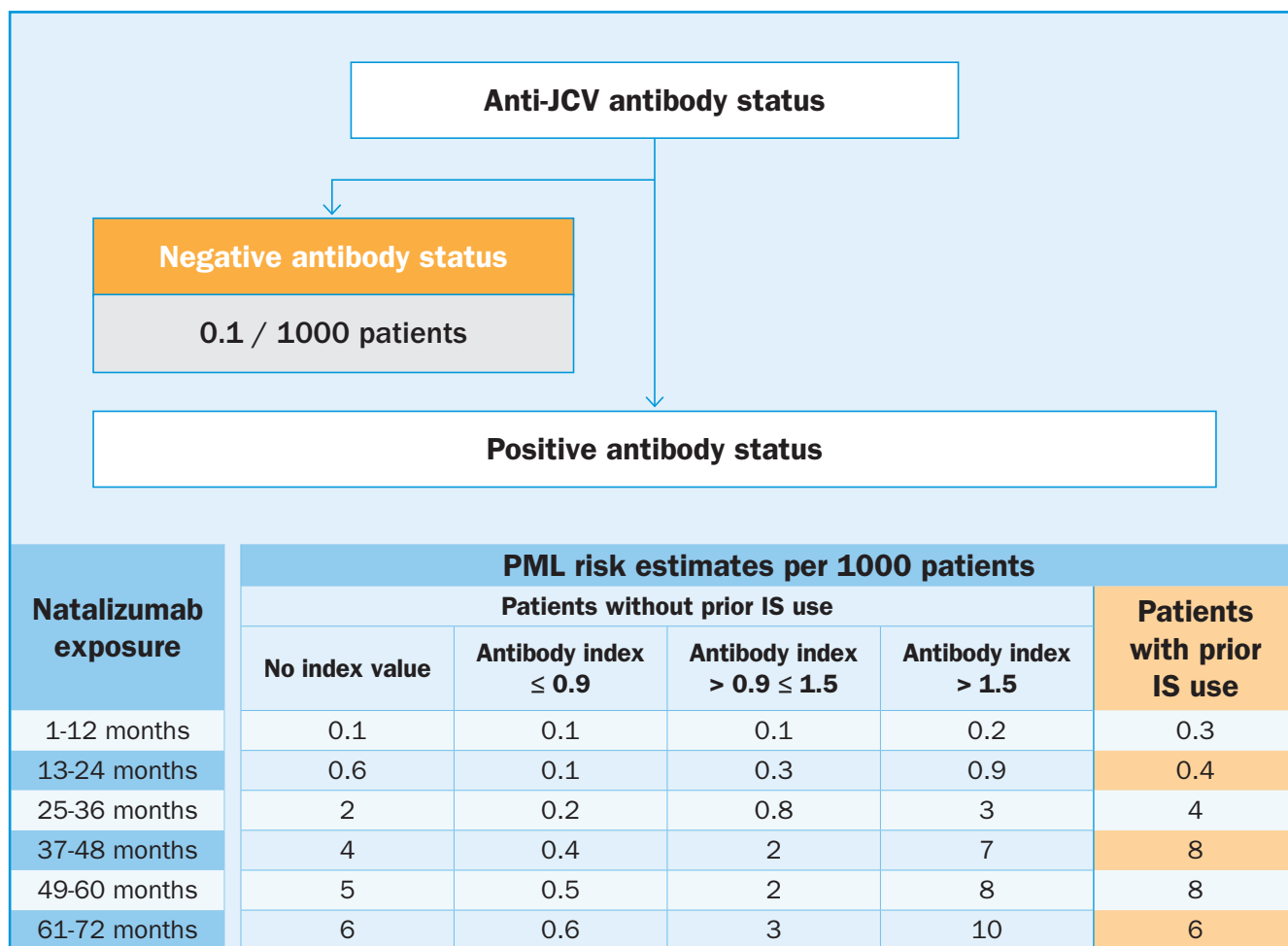
Date

Doctor's Name (print)

Doctor's Signature

Date

PML risk estimate:



Patients who are anti-JCV antibody negative

Based on global data, if you do not have antibodies to JCV your chance of getting PML is 0.1/1000 (or 1 in 10,000) patients.

Patients who are anti-JCV antibody positive

If you do have antibodies to JCV, your risk of developing PML will vary depending on the duration of treatment with TYSABRI, the level of anti-JCV antibodies in your blood and whether you have received prior treatment with an immunosuppressant medication. Your doctor will discuss the potential risk before you start treatment.

Reporting of side effects

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard (UK) or, if in Ireland, via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.