TYSABRI (natalizumab) Treatment Initiation Form

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 Patient 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 Patient 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 2 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 2 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 Patient 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 Patient Leaflet or the Alert Card, then please ask your doctor to provide them to you before you initiate your TYSABRI treatment.

Patient's Name (print) _____

Patient's Signature _____ **Date** _____

Doctor's Name (print) _____

Doctor's Signature _____ **Date** _____

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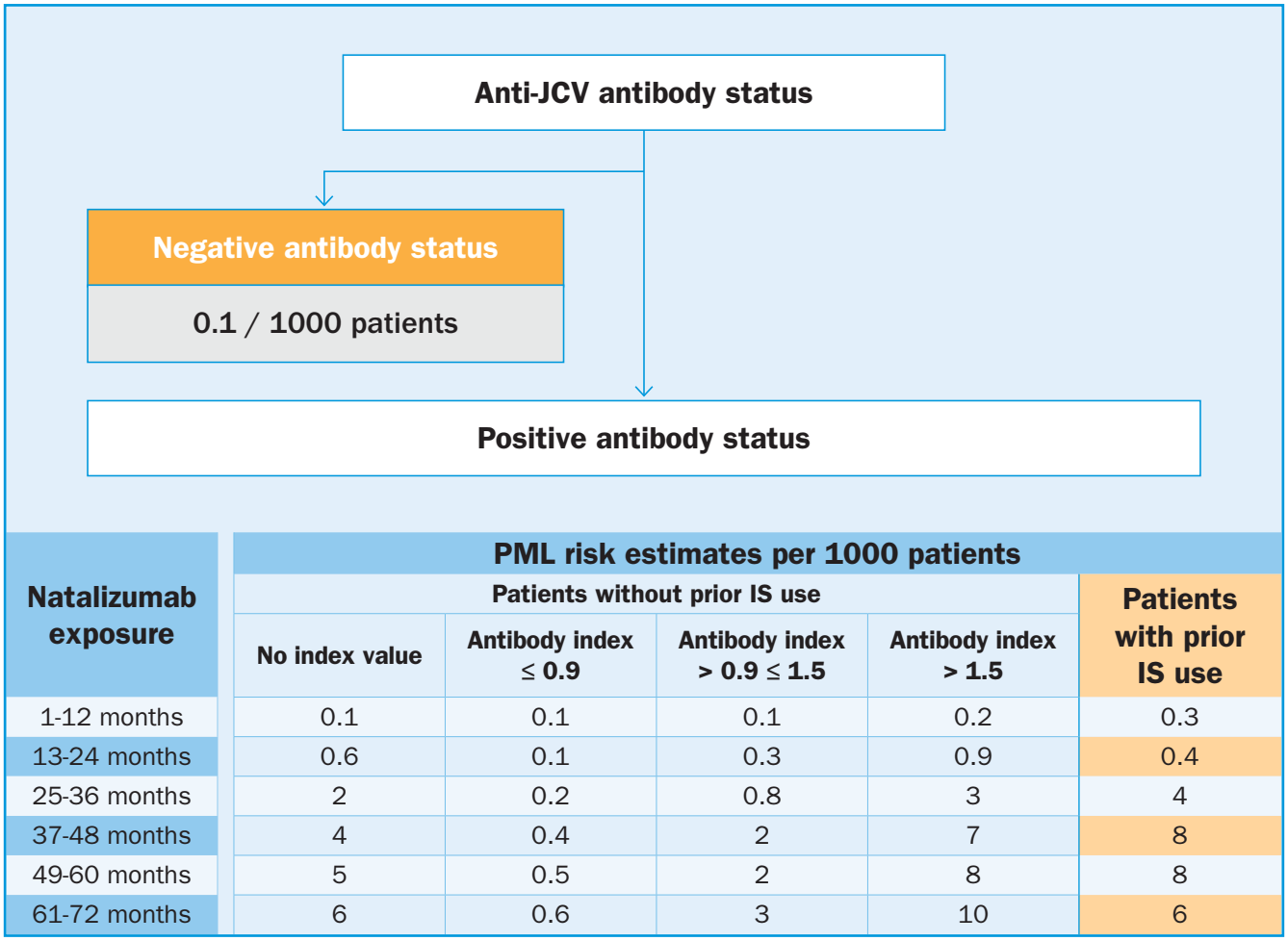
PML risk estimate:



Natalizumab exposure	PML risk estimates per 1000 patients				
	Patients without prior IS use				Patients with prior IS use
	No index value	Antibody index ≤ 0.9	Antibody index > 0.9 ≤ 1.5	Antibody index > 1.5	
1-12 months	0.1	0.1	0.1	0.2	0.3
13-24 months	0.6	0.1	0.3	0.9	0.4
25-36 months	2	0.2	0.8	3	4
37-48 months	4	0.4	2	7	8
49-60 months	5	0.5	2	8	8
61-72 months	6	0.6	3	10	6

IS: Immunosupressant

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

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in the patient leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store, or if in Ireland, via HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2; Tel:+353 16764971; Fax: +353 16762517. 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.

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