TYRUKO▼(natalizumab)
TREATMENT INITIATION FORM

SANDOZ

This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

This form should be read carefully before starting treatment with TYRUKO. 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 TYRUKO.

Before starting treatment with TYRUKO you should:
- **Read the Patient Leaflet which is included in each box of TYRUKO**
- **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 NATALIZUMAB, 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 NATALIZUMAB is unknown.

The risk of PML with natalizumab-treated patients is higher:
- If you have antibodies to the JC virus in your blood
- The longer that you are on treatment with NATALIZUMAB, 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 NATALIZUMAB treatment

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

Your doctor may test your blood to check if you have antibodies to the JC virus before you start treatment with TYRUKO. Your doctor may repeat the test while you are on TYRUKO 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 NATALIZUMAB and have higher levels of antibodies to the JC virus and you have been on NATALIZUMAB 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 TYRUKO is the most suitable treatment for you before you start taking TYRUKO and when you have been taking TYRUKO 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 TYRUKO 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 TYRUKO 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 TYRUKO treatment.

Patient's Name (print) _____

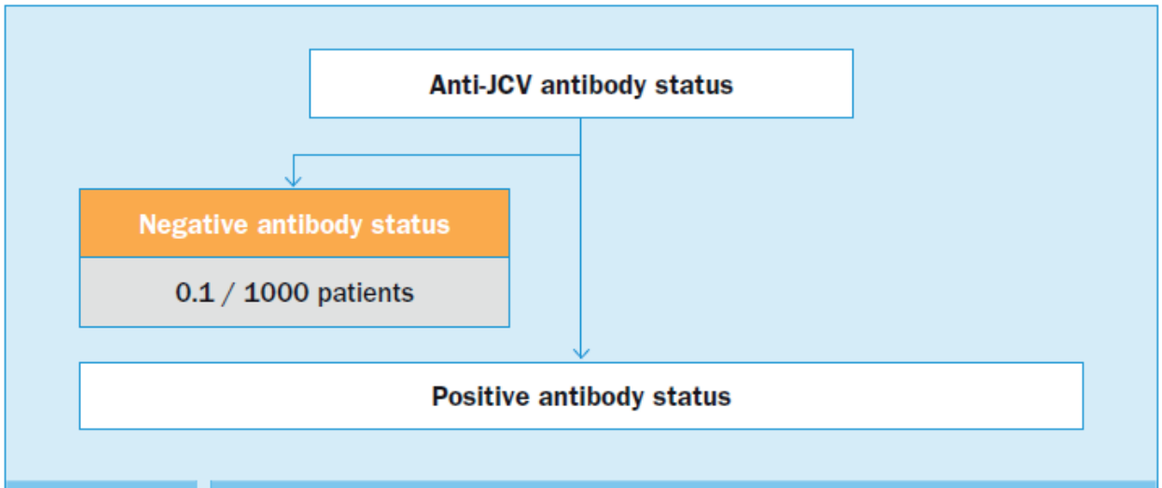
Patient's Signature _____ **Date** _____

Doctor's Name (print) _____

Doctor's Signature _____ **Date** _____

Date of MHRA Approval: April 2025

PML risk estimation:



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

Anti-JCV antibody index values may depend on the assay used. The PML Risk Estimates provided above are based on anti-JCV antibody index data obtained from use of the STRATIFY JCV DxSelect assay.

An additional anti-JCV antibody assay, ImmunoWELL™ JCV IgG test, has been developed. The comparison between STRATIFY JCV® DxSelect® *, and ImmunoWELL JCV IgG tests indicates a potential offset of up to 0.1 in index values (e.g. lower range: 0.8, higher range: > 1.4 in the table above) when using the ImmunoWELL™ JCV IgG test.
*STRATIFY JCV® is a trademark of Biogen MA Inc. DxSelect® is a trademark of DIASORIN S.p.A.

Patients who are anti-JCV antibody negative

Based on the available 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 NATALIZUMAB, 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. You can help by reporting any side effects you may get. Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.yellowcard.mhra.gov.uk.
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours. When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

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Artwork Proof Box:

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Proof no:	002.0
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SKUs:	00000000
SZ codes:	SZ0000000000
Item codes:	TF1.1706.002.0d
Pharma codes:	00000000

Technical Colours:	
	Legend:
Colours:	
	Pantone 541
	Cyan
	Magenta
	Yellow
	Black

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