

# Outside a Clinical Setting (OCS) Administration Checklist

## Educational Material for Healthcare Professionals (HCPs)

### For Use Prior to Administration of TYSABRI™ (Natalizumab) Subcutaneously (SC) Outside a Clinical Setting

As a pre-requisite to administer TYSABRI™ (natalizumab) SC outside a clinical setting (e.g., at home), the OCS Administration Checklist **must** be completed, and the accompanying Decision Tree **must** be referred to by the HCP for each patient, prior to each administration.

An important identified risk associated with TYSABRI treatment is Progressive Multifocal Leukoencephalopathy (PML), an uncommon brain infection which can lead to severe disability or death. It is important that the patient is assessed for signs and symptoms of PML prior to administration of TYSABRI. **The OCS Administration Checklist has been developed to aid HCPs in identifying patients with signs and symptoms of PML, and to guide escalation to the specialist physician if PML is suspected. An HCP Informational Supplement is available and included along with this OCS Administration Checklist as Appendix 5 to the Physician Information and Management Guidelines for Patients With Multiple Sclerosis Receiving TYSABRI Therapy (PID) This supplement contains relevant background information on PML, to allow for better understanding and usability of the OCS Administration Checklist by HCPs.**

The TYSABRI SC OCS Administration Checklist is not intended to replace any local pre-administration general health checks or screening protocol(s). It is recommended that the administering HCP has access to the patient's current medication list in order to complete a Medication Reconciliation in the OCS Administration Checklist.

**The OCS Administration Checklist should be read in conjunction with the EU TYSABRI SC SmPC and Package Leaflet (PL) and is not intended as replacements for these documents. Please refer to the EU TYSABRI SC SmPC and the PL for further information about the approved use of TYSABRI, available at [<https://www.ema.europa.eu/en/medicines/human/EPAR/tysabri>].**

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#### **REPORTING OF SIDE EFFECTS:**

- HCP must report all adverse events to the specialist physician for evaluation, and any suspected adverse reactions, including any possible side effects not listed in the EU TYSABRI SC SmPC or PL via the national reporting system ([www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)).
- HCP must ensure that the patient has their Patient Alert Card, and must inform the patient and/or caregiver of the following:
  - If the patient gets any side effects, talk to your neurologist (*provide phone number*).
  - This includes any possible side effects not listed in the Package Leaflet.
  - Side effects can also be reported directly via the national reporting system ([www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)).

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Patient name: \_\_\_\_\_

Specialist physician name: \_\_\_\_\_

Specialist physician's contact information / phone number: \_\_\_\_\_

HCP name (administering TYSABRI SC outside a clinical setting): \_\_\_\_\_

*Healthcare professionals should make all treatment decisions based on the context of the situation and their clinical judgment. By signing below, the HCP confirms that the OCS Administration Checklist has been completed, and that the accompanying Decision Tree has been followed. This educational tool is not intended to be a substitute for consultation with the specialist physician. For additional questions or concerns, or to discuss potential side effects, the specialist physician should be contacted.*

Signature of HCP completing this checklist: \_\_\_\_\_

Date (DD-MM-YYYY): \_\_\_\_\_

Patient name:

Date (DD-MM-YYYY):

### **Outside a Clinical Setting (OCS) Administration Checklist**

**Prior to use of this OCS Administration Checklist, the HCP must have confirmation from the specialist physician that the patient is recommended to receive the current TYSABRI SC administration outside a clinical setting:**

#### **STEP 1 – Patient Medical Status Update:**

**A) HCP should conduct an overall health check** (such as: vital signs; general health assessment) in accordance with local clinical practice)

#### **B) Confirmation of previous evaluations & investigations (if available/known):**

- Most recent MRI date (DD-MM-YYYY): \_\_\_\_\_
- Most recent JCV Antibody status (positive, negative, or pending): \_\_\_\_\_
  - Date of test (DD-MM-YYYY): \_\_\_\_\_
  - JCV Antibody Index value: \_\_\_\_\_

#### **C) Complete the OCS Administration Checklist & refer to the accompanying Decision Tree (please see next page)**

#### **‡Medication Reconciliation (to be completed with the patient when asking Question 3 in STEP 1C):**

- HCP must review the patient’s medication list and indicate below any medications used for the treatment of MS or which may weaken the immune system (such as immunosuppressants or immunomodulators). Additional pages may be added if necessary.
- **NOTE:** The specialist physician should be consulted regarding drugs that may be taken concurrently with TYSABRI. If there are any questions regarding past or concurrent therapy, such as whether or not they may weaken the immune system, do not administer TYSABRI at this time, and discuss with the specialist physician.

| Medication Name | Date Initiated | Date Discontinued (if applicable) | Treatment Ongoing? (Yes / No) | Additional Notes (if applicable) |
|-----------------|----------------|-----------------------------------|-------------------------------|----------------------------------|
|                 |                |                                   |                               |                                  |
|                 |                |                                   |                               |                                  |
|                 |                |                                   |                               |                                  |
|                 |                |                                   |                               |                                  |
|                 |                |                                   |                               |                                  |

#### **STEP 2 – Record TYSABRI (natalizumab) SC Information:**

- TYSABRI SC Administered**
- Date of Administration (DD-MM-YYYY): \_\_\_\_\_
  - LOT #: \_\_\_\_\_ Expiration Date (DD-MM-YYYY): \_\_\_\_\_
- TYSABRI SC NOT Administered** → The specialist physician must be contacted. Please refer to Decision Tree.
- Has the patient’s specialist physician been contacted? (indicate one): YES / NO
  - Reason(s) TYSABRI SC **NOT** Administered: \_\_\_\_\_
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#### **STEP 3 – OPTIONAL Data Recording (if available/known):**



- Most Recent In-Person Appointment with Specialist Physician (DD-MM-YYYY): \_\_\_\_\_
- Next Scheduled Appointment Date with Specialist Physician (DD-MM-YYYY): \_\_\_\_\_
- Next Scheduled Appointment Date Outside a Clinical Setting (DD-MM-YYYY): \_\_\_\_\_

Patient name:

Date (DD-MM-YYYY):

**STEP 1C: Complete the OCS Administration Checklist & refer to the accompanying Decision Tree**

Ask the patient and/or caregiver the following questions and refer to Decision Tree guidance based on responses:

| OCS ADMINISTRATION CHECKLIST   |   | DECISION TREE  |   |
|--|---|--|---|
| #  | QUESTION  | IF RESPONSE IS YES   | IF RESPONSE IS NO   |
| 1  | <p>Since your last dose of TYSABRI, have you had any new or worsening medical problems that have persisted over several days, such as a new or sudden change in your:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> thinking, concentration, memory, personality, or behavior (such as confusion, delirium, or loss of consciousness)</li> <li><input type="checkbox"/> ability to speak</li> <li><input type="checkbox"/> vision / eyesight</li> <li><input type="checkbox"/> balance / coordination</li> <li><input type="checkbox"/> strength</li> <li><input type="checkbox"/> sensation</li> </ul> <p>or have you developed any other significant or sustained symptoms, such as:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> seizures</li> <li><input type="checkbox"/> headaches</li> <li><input type="checkbox"/> nausea / vomiting</li> <li><input type="checkbox"/> or others? (Please specify: _____)</li> </ul> | <p>Do <b>NOT</b> administer TYSABRI SC.</p> <p>The specialist physician must be contacted. Record details in STEP 2.</p>   | <p>Proceed to Question 2</p>  |
| 2  | <p>Since your last dose of TYSABRI, have you been diagnosed with a new medical condition that can weaken your immune system (for example: a new infection or cancer) or have you had any surgeries that may suggest your body is not able to fight infections well?</p>   | <p>Do <b>NOT</b> administer TYSABRI SC.</p> <p>The specialist physician must be contacted. Record details in STEP 2.</p>   | <p>Proceed to Question 3</p>  |
| 3  | <p>Since your last dose of TYSABRI, have you taken medicines to treat cancer or multiple sclerosis (MS) or any other medicines that weaken your immune system? (HCP must complete a <b>Medication Reconciliation</b><sup>†</sup> for each patient, prior to each administration. Please refer to previous page.)</p>  | <p>Do <b>NOT</b> administer TYSABRI SC.</p> <p>The specialist physician must be contacted. Record details in STEP 2.</p>   | <p>Proceed to STEP 2</p>  |
| <p style="text-align: center;"><b>DECISION TREE OUTCOME</b></p> <p style="text-align: center;"><i>Guidance is provided based on patient/caregiver responses.</i></p> <p style="text-align: center;"><i>This educational tool is <u>not</u> intended to be a substitute for consultation with the specialist physician.</i></p> <p style="text-align: center;"><i>HCPs should make all treatment decisions based on the context of the situation and their clinical judgment.</i></p> |   | <p style="text-align: center;"></p> <p style="text-align: center;"><b>TYSABRI SC <u>not immediately</u> administered.</b></p> <p style="text-align: center;"><b>The HCP must consult with the specialist physician regarding responses.</b></p> <p style="text-align: center;"><b>It is the responsibility of the specialist physician to determine next steps regarding the appropriateness and timing of TYSABRI administration.</b></p> | <p style="text-align: center;"></p> <p style="text-align: center;"><b>HCP may administer TYSABRI SC.</b></p> |