# MRI protocol and surveillance in Multiple Sclerosis (MS) patients receiving Tysabri

**Descriptor:**

Assessment of compliance with the European Medicines Agency (EMA) recommendations for MRI screening for progressive multifocal leukoencephalopathy (PML) in patients being treated with Natalizumab (Tysabri) for multiple sclerosis (MS).

**Background:**

Natalizumab is a monoclonal antibody approved for the treatment of adults with highly active multiple sclerosis. PML is a rare, but potentially fatal, demyelinating condition caused by reactivation of the John Cunningham (JC) virus. The risk of developing PML is increased in patients treated with Tysabri. Some patients have additional risk factors (including known JC virus antibody positive, treatment with Tysabri for more than 2 years and prior immunosuppressant use). Early detection of PML improves prognosis. MRI can detect asymptomatic PML.

## The Cycle

**The standard:**

The EMA recommendations are reflected in the Summary of Product Characteristics for Tysabri. This states that all patients with multiple sclerosis treated with Tysabri:

-should have a baseline MRI scan within 3 months prior to starting treatment

-should have an annual MRI surveillance scan (with some patients requiring more frequent imaging)

The recommended protocol for annual scans includes:

Sagittal and axial 2D FLAIR or 3D FLAIR

Axial FSE PD/T2

Axial DWI

Axial T1W spin echo pre and post contrast

Higher risk patients may undergo more frequent (3-6 monthly imaging), often with an abbreviated protocol but should still undergo annual imaging with the full protocol as described above.

**Target:**

100% to receive a baseline scan

100% to receive an annual surveillance scan

100% of annual surveillance scans to include T1, T2/proton density, FLAIR, DWI and T1 post contrast

## Assess local practice

**Indicators:**

% of relevant patients receiving a baseline scan within 3 months prior to starting treatment

% of relevant patients receiving annual follow-up MRI (the authors suggest an 11-13 months window of acceptability)

% of relevant annual follow-up MRI studies adhering to the recommended protocol

**Data items to be collected:**

Cohort of patients on Tysabri treatment for MS

Date started treatment

Date of baseline scan

Dates of annual surveillance MRI studies (higher risk patients may undergo more frequent abbreviated imaging but should have a complete protocol study annually)

Protocol employed for annual surveillance studies

**Suggested number:**

The adult cohort of multiple sclerosis patients on Tysabri treatment. (30-100 depending on hospital size)

**Suggestions for change if target not met:**

Present data to clinicians who refer for, and protocol these studies locally (likely neurologists and neuroradiologists respectively)

Create a referral proforma including the required information

Create a specific local protocol for Tysabri PML screening in MS

Re-audit annually to ensure compliance in the requesting, and appropriate protocolling of studies

**References:**

1. Summary of product characteristics (SPC) for Tysabri <https://www.medicines.org.uk/emc/medicine/18447/SPC/TYSABRI+300+mg+concentrate+for+solution+for+infusion/>
2. Natalizumab for the treatment of adults with highly active relapsing–remitting multiple sclerosis.Technology appraisal guidance [TA127] Published date: 22 August 2007 <https://www.nice.org.uk/guidance/ta127>

**Editor's comments:**

The protocol described is the recommended protocol in the EMA guidelines. Some centres are opting to use an abbreviated protocol. When carrying out this audit check initially what the local agreement is and that all involved are aware of what is being done.

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