Subject: Specialised Services Circular (SSC)
Sent on behalf of: Chair of the SW Specialised Service Circular Group
Dear Colleagues,

Please find attached the following Specialised Services Circular(s):

SSC Number	SSC Title	Trusts approved to prescribe in accordance with the SSC, providing appropriate internal governance arrangements are in place
2747	**SSC 2747 Treatment of adults with relapsing remitting multiple sclerosis - switching from Tysabri® to Tyruko®**	Gloucester Hospitals Foundation Trust Great Western Hospitals Foundation Trust North Bristol Trust Royal Cornwall Hospital Trust Royal Devon University Hospital Trust Royal United Hospitals of Bath Salisbury Foundation Trust Somerset Foundation Trust Torbay and South Devon Foundation Trust University Hospitals Plymouth Trust University Hospitals Dorset Trust

Is an implementation plan required from all SW trusts (regardless of commissioned status) for this SSC? No

For all other South West region trusts this is for information only.

Trusts should ensure that use is registered on the Blueteq system (if appropriate).

Treatment will only be funded where the drugs minimum dataset is fully and accurately populated.

Please direct any queries to: england.speccomm-southwest@nhs.net

NHS England South West

All Chief Executives

All Medical Directors

All Chief Pharmacists

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11 December 2024

Dear Colleagues,

Treatment of adults with relapsing remitting multiple sclerosis: switching from Tysabri® to Tyruko®

NHS England commissions natalizumab in line with NICE guidelines (TA127) for the treatment of rapidly evolving severe relapsing–remitting multiple sclerosis in adults.

Some patients with relapsing remitting multiple sclerosis (RRMS) are currently being switched between two versions of the drug natalizumab - from Tysabri® to the biosimilar Tyruko®. There are no meaningful differences between the two medicines in terms of quality, safety and how effective they are.

NHS England has received some concerns from patients and clinicians highlighting potential side effects and potential discrepancies with the associated antibody testing for John Cunningham (JC) virus.

Reported side effects

All versions of natalizumab can cause similar side effects and should be reported via the Yellow Card scheme as with all medicines (https://yellowcard.mhra.gov.uk/). Individuals experiencing side effects are being advised to discuss these with their clinician.

The side effect profiles of Tysabri® and Tyruko® are described as the same in the Summary of Product Characteristics:

- Tyruko 300 mg concentrate for solution for infusion - Summary of Product Characteristics (SmPC) - (emc)
- TYSABRI 300 mg concentrate for solution for infusion - Summary of Product Characteristics (SmPC) - (emc).

John Cunningham virus testing for Progressive Multifocal Leukoencephalopathy

John Cunningham (JC) virus is a common virus in the general population. JC virus usually causes no symptoms and is normally kept under control by the immune system. However, if the immune system is weakened, JC virus can reactivate. It can then cause inflammation and damage to the brain resulting in a serious illness called progressive multifocal leukoencephalopathy (PML). Treatment with natalizumab can increase the risk of developing PML.

Quantitative assessment of antibody status for JC virus can be used to stratify risk of PML in patients receiving natalizumab. This then determines the need for additional monitoring or consideration of alternative treatment options.

For patients receiving Tysabri®, the StratifyJCV® test is used. For patients receiving Tyruko®, then the ImmunoWELL® JCV test is used.

Recent reports indicate that patients may see a change in their JC virus test result when switching to the biosimilar Tyruko®. This is because of an increased sensitivity of the ImmunoWELL® test used with Tyruko®. For most people, this does not mean an increased risk of developing PML but is causing patient concern and challenges for clinicians.

Patient Communications

Trusts should ensure appropriate patient information is available and have adequate arrangements in place to inform patients of any planned medication changes. Patients should be offered the opportunity to discuss any queries regarding planned medication changes with their clinical team prior to switching medications.

To support this process, NHS England has developed a Patient Information Sheet (see attached) explaining the switching from Tysabri® to Tyruko® for patients with relapsing remitting multiple sclerosis.

Action to take

Clinical and pharmacy teams managing patients with relapsing remitting multiple sclerosis should take the following actions:

- Share the attached Patient Information Sheet with patients whose medication has been switched to Tyruko®
- Share the attached Patient Information Sheet with patients receiving natalizumab who the team is planning to switch to Tyruko®, as part of shared decision making.
- Continue to monitor any side effects or changes in JC virus test results and be prepared to discuss these with their patients if necessary
- Report any side effects or adverse incidents relating to JC virus tests via the Yellow Card scheme (https://yellowcard.mhra.gov.uk/)

Further Work

NHS England has undertaken the following actions in response to the issues that have been raised. These include:

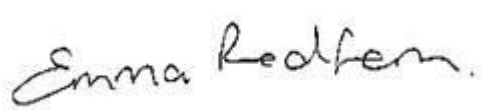
- Setting up an expert working groups to consider further actions that may be required in relation to prescribing or monitoring guidelines.
- Notifying the Medicines & Healthcare products Regulatory Agency (MHRA) of the correspondence we have received, raising concerns regarding side effects and the issue around JC virus antibody testing.
- Discussing matters with National Institute of Health and Care Excellence (NICE) to ensure any relevant updates to guidance are appropriately considered.
- Producing a patient information sheet explaining the switch from Tysabri® to Tyruko® for patients with relapsing remitting multiple sclerosis.
- Discussing engagement and information sharing with patient groups regarding biosimilar medicines.

Further Information

- NHS England Patient Information Sheet 'Switching from Tysabri® to Tyruko® for patients with relapsing remitting multiple sclerosis'.
- Medicines & Healthcare products Regulatory Agency website: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- National Institute of Health and Care Excellence (NICE) technology appraisal guidance of natalizumab for the treatment of adults with highly active relapsing remitting multiple sclerosis: https://www.nice.org.uk/Guidance/TA127
- NHS England Treatment Algorithm for Multiple Sclerosis disease-modifying therapies: https://www.england.nhs.uk/publication/treatment-algorithm-for-multiple-sclerosis-disease-modifying-therapies/
- The Patient's Association website: https://www.patients-association.org.uk/switchingtobiosimilars
- Biosimilar medicines: NHS England » What is a biosimilar medicine?
- Shared decision making: NHS England » Shared decision-making

I would be grateful if you could cascade this information to Neurology teams within your organisation, specifically asking that these are shared with both clinical and pharmacy teams managing patients with multiple sclerosis.

With best wishes,



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