Bristol Myers Squibb™

23 September 2020

Direct Healthcare Professional Communication

NULOJIX (belatacept): Extension of the temporary restriction in supply up until 4Q 2021 (initiated in March 2017)

Dear Healthcare Professional,

Bristol Myers-Squibb (BMS) in agreement with the European Medicines Agency and the Medicines & Healthcare products Regulatory Agency would like to inform you of the following:

Summary:

- As of 11 March 2019, Nulojix can be prescribed to new patients if the following two criteria are met:
  1. Nulojix is the best treatment option for the patient;
  2. BMS has confirmed that supplies are adequate for new and existing patients.

- Before initiating Nulojix treatment in new patients, a member of the transplant team should contact BMS Medical Information to confirm that adequate supplies are available (see contact details below).

- **As of September 2020, the requirement to confirm available supplies before initiating treatment for new patients is expected to remain in place until the fourth quarter (4Q) of 2021.**

Background on the supply shortage

The supply shortage is related to a temporary production capacity issue. It is not related to a quality defect of the product or a safety issue. Because of the supply shortage, distribution of Nulojix has been restricted since March 2017: only existing patients worldwide, or patients with an urgent medical need for Nulojix who have exhausted all other options, were permitted to start Nulojix. As production of Nulojix returned to normal capacity, supply restrictions were eased in March 2019 to allow for additional new patients meeting the two above-mentioned criteria to be treated with Nulojix.

This DHPC letter (dated September 2020) is to inform you that these relaxed restrictions continue to be in place, and are extended until 4Q 2021. This will allow for a final transition to a new, higher capacity manufacturing process.

Management of the supply shortage

In the United Kingdom, prescribers are requested to cooperate in avoiding initiation of a Nulojix-based regimen in new patients, unless the above criteria are met. A finite number

Bristol-Myers Squibb Pharmaceuticals Limited
Uxbridge Business Park
Sanderson Road
Uxbridge, Middlesex
UB8 1DH United Kingdom
bms.com/gb
Office +44 (0)1895 523000
Fax +44 (0)1895 523010
Medical Information 0800 731 1736
medical.information@bms.com

of vials has been allocated to each specific market based on existing demand, and healthcare professionals are expected to allocate accordingly to prevent a potential stock out.

Indication

NULOJIX, in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adults receiving a renal transplant (see section 5.1 of the SPC for data on renal function). It is recommended to add an interleukin (IL)-2 receptor antagonist for induction therapy to this belatacept-based regimen.

Company contact point

If you have any questions or require additional information regarding this extension of the temporary restriction in Nulojix supply, please contact the BMS Medical Information Department via phone 0800 731 1736 or email medical.information@bms.com.

Reporting of suspected adverse reactions

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- 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.

Adverse events should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

Yours Sincerely,

Dr Usman Ali Farooqui, MBBS, MBA, MSc, FFPM
UK/IE Disease Area Head for Innovative Medicines

Bristol Myers Squibb
Uxbridge Business Park,
Sanderson Road,
Uxbridge UB8 1DH
United Kingdom

Bristol Myers Squibb™

Job bag no. IMSUK2000919-01
September 2020