January 2022

NULOJIX (belatacept): Further extension of the temporary restriction in supply up until 3Q 2022

Dear Healthcare Professional,

Bristol Myers-Squibb (BMS) in agreement with the European Medicines Agency and {the National Competent Authority} would like to inform you of the following:

Summary

- The temporary restriction in supply of Nulojix (belatacept) will be further extended until 3Q 2022.

- Due to the restriction in supply, Nulojix can only 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, BMS Medical Information should be contacted to confirm that adequate supplies are available (see contact details below {by country}).

Background on the supply shortage

Since March 2017, distribution of Nulojix has been restricted to existing patients worldwide. 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. The temporary restriction in supply is further extended to allow for the final transition to a new, higher capacity manufacturing process. Nulojix manufactured with the new process is expected to be available in 3Q 2022, a communication will be sent to Healthcare Professionals ahead of its distribution.

Management of the supply shortage

<This section needs to be tailored to National communication:

- *In France, a system of controlled distribution to registered patients has been set up in agreement with ANSM*
- *In other countries, prescribers were invited to cooperate in avoiding initiation of a Nulojix-based regimen in new patients. Mention may be made that a finite number of vials has been allocated to each specific market based on existing demand, and HCP are expected to allocate accordingly, otherwise there is a risk of potential stock out. Specific mechanism if needed subject to agreement with National HA.*

- *The current update will be tailored to the initial National communication plan>*

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of Nulojix (belatacept) in accordance with the national spontaneous reporting system <include the details (e.g., name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

<Any schedule for follow-up action(s) by the marketing authorisation holder/competent authority, if applicable>