Bristol-Myers Squibb

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IMPORTANT DRUG WARNING

Subject: Increased Risk of Post-transplant Lymphoproliferative Disorder (PTLD), predominantly involving the Central Nervous System (CNS), and Progressive Multifocal Leukoencephalopathy (PML) with NULOJIX® (belatacept)

Dear Infusion Specialist:

This letter informs you of important safety information for NULOJIX® (belatacept), a selective T-cell costimulation blocker recently approved by the Food and Drug Administration (FDA) for prophylaxis of organ rejection in adult patients receiving a kidney transplant. NULOJIX is to be used in combination with basiliximab induction, mycophenolate mofetil (MMF), and corticosteroids. NULOJIX is indicated for use only in patients who are Epstein-Barr virus (EBV) seropositive. Use of NULOJIX for the prophylaxis of organ rejection in other transplanted organs has not been established.

Important information you should know about NULOJIX:

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of NULOJIX outweigh the risks, including:

- **Post-Transplant Lymphoproliferative Disorder (PTLD)**, a type of malignancy. Patients treated with NULOJIX have a higher risk of getting PTLD, predominantly involving the central nervous system (CNS). PTLD can cause death
- **Progressive Multifocal Leukoencephalopathy (PML)**, a rare, serious brain infection. This rare brain infection has been reported in patients treated with NULOJIX. PML can cause death

You play an important role by:

1) educating the patient about these risks,
2) identifying any concerning signs and symptoms associated with these risks, and
3) alerting the prescriber about any concerning signs and symptoms reported to you.

To help identify patients who are experiencing new, changed, or worsened neurological, cognitive, or behavioral signs and symptoms, a **PRE-INFUSION CHECKLIST** is available. For every patient, complete the enclosed **PRE-INFUSION CHECKLIST** before each infusion. Transplant and infusion centers should develop a systematic way to evaluate all patients treated with NULOJIX before each NULOJIX infusion is administered.

- **To download the PRE-INFUSION CHECKLIST**, go to www.NULOJIX.com/REMS.aspx. The checklist is available as an editable PDF file for easier incorporation into electronic medical record systems
- **To order tear pads of the Checklist**, call Bristol-Myers Squibb at 1-800-321-1335

Reporting Adverse Events

For any adverse event with the use of NULOJIX, healthcare professionals should contact Bristol-Myers Squibb at 1-800-721-5072 and/or the FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

This letter is not intended as a complete description of the benefits and risks associated with the use of NULOJIX. Please refer to the enclosed complete Prescribing Information and Medication Guide.

All REMS materials, including a NULOJIX® REMS webinar, are accessible at www.NULOJIX.com/REMS.aspx. For additional information, please call Bristol-Myers Squibb at 1-800-321-1335 or visit www.NULOJIX.com.

Sincerely,

Laura Bessen, MD
Bristol-Myers Squibb
Vice President, US Medical, Immunoscience and Neuroscience

Enclosure: NULOJIX® (belatacept) Pre-Infusion Checklist, full Prescribing Information and Medication Guide