OVERVIEW: Nulojix powder, lyophilized, for solution for Intravenous injection; a selective T-cell costimulation blocker indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. It is used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. Some limitations of use are that it can only be used in patients who are EBV seropositive, and it safe use has not been established for the prophylaxis of organ rejection in transplanted organs other than the kidney. Nulojix should never be used in patients with unknown aerostats or EBV seronegative. Use in patients with history of liver transplant is not recommended and only physicians experienced in immunosuppressive therapy and management of kidney transplant patients should prescribe Nulojix. See table 1 below for dosing recommendation. Doses higher than or more frequent than recommended should be avoided due to the increased risk of infection or malignancy. It should only be administered intravenously over a 30 minutes period and only the silicone-free disposable syringe enclosed in the package should be used for administration. Nulojix comes with boxed warning for Post-transplant lymphoproliferative disorder (PTLD), other malignancies, and serious infections. There is an increased risk for Progressive Multifocal Leukoencephalopathy (PML) with Nulojix. Corticosteroid utilization should be consistent with Nulojix clinical trial experience as acute rejection and graft loss might result with corticosteroid minimization

Risk Evaluation and Mitigation Strategy (REMS) for Nulojix
The Nulojix REMS program is aimed at communicating the increased risk of post-transplant lymphoproliferative disorder, predominantly involving the CNS, and progressive multifocal leukoencephalopathy (PML) associated with the agent. It also informs patients of the serious risks associated with NULOJIX. There is also an ongoing evaluation of Nulojix Safety Profile through the ENLiST (Evaluating Nulojix Long-Term Safety in Transplant) registry. ENLiST is intended to enroll all adult kidney transplant patients who are treated with agent. The objective is to determine the incidence rate of PTLD, CNS PTLD, and PML in US adult EBV seropositive kidney transplant recipients treated with Nulojix. Patient can enroll in the ENLiST Registry by calling BMS at 1-800-321-1335.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Nulojix. All approvals are provided for 1 year in duration unless otherwise noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Nulojix as well as the monitoring required for AEs and long-term efficacy. Initial and subsequent approval requires Nulojix to be prescribed by physicians experienced in immunosuppressive therapy and management of kidney transplant patients.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Nulojix is recommended in those who meet the following criteria:
Food and Drug Administration (FDA)-Approved Indications

Criteria

1. Renal transplant rejection, EBV seropositive; in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids; Prophylaxis. Approve Nulojix if the patient meets the following criteria (a, b, c, d, e, f, g and h)
   a. The patient is ≥ 18 years of age; AND
   b. The agent is prescribed by a physician experienced in immunosuppressive therapy and management of kidney transplant patients; AND
   c. The patient has an order for basiliximab, mycophenolate mofetil, and corticosteroids along with Nulojix; AND
   d. The patient is to undergo renal transplant; AND
   e. Patient has no history of liver transplant; AND
   f. Patient has EBV seropositive result; AND
   g. Patient must have been evaluated for tuberculosis and treatment for latent infection must be initiated prior to NULOJIX; AND
   h. Prescriber complies with the requirements of the REMS program.

Dosing

Initial phase:
At the initial phase, Nulojix should be dosed at 10 mg/kg IV on day 1 (day of transplant, prior to implantation), day 5, and end of weeks 2, 4, 8, and 12; Tapper corticosteroid doses to about 15 mg per day by the first 6 weeks and leave at 10 mg daily for the first 6 months post-transplant

Maintenance phase:
Dose at 5 mg/kg at end of week 16 and every 4 weeks thereafter; Tapper corticosteroid doses to about 15 mg per day by the first 6 weeks and leave at 10 mg daily for the first 6 months post-transplant

Initial Approval/ Extended Approval.
A) Initial Approval: Approve for 6 months.
B) Extended Approval: Approve for 12 months if patient is responsive and shows no sign of acute/chronic kidney rejection

REFERENCES

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<td>Nulojix (belatacept) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; September 2011</td>
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