

Nulojix® (belatacept)

When requesting Nulojix® (belatacept), the individual requiring treatment must be diagnosed with the following FDA-approved indication or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Nulojix is indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. Nulojix is to be used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids.

Approved Off-label Compendial Use

Prophylaxis of solid organ rejection other than kidney in a patient currently receiving Nulojix.

Coverage Guidelines

Kidney Transplantation – Prophylaxis of Organ Rejection

The individual must meet all of the following criteria for authorization:

- Is 18 years of age or older;
- Is Epstein-Barr virus (EBV) seropositive;
- Nulojix is prescribed by or in consultation with a transplant specialist physician or a physician associated with a transplant center.

Solid Organ Transplantation Other Than Kidney – Prophylaxis of Organ Rejection

The individual must meet all of the following criteria for authorization:

- Is 18 years of age or older;
- Is currently receiving Nulojix;
- Is Epstein-Barr virus (EBV) seropositive;
- Nulojix is prescribed by or in consultation with a transplant specialist physician or a physician associated with a transplant center.

Approval duration: 12 months

Dosing Recommendations

Nulojix is for intravenous infusion only. The total infusion dose of Nulojix should be based on the actual body weight of the patient at the time of transplantation and should not be modified during the course of therapy, unless there is a change in body weight of greater than 10%.

Dosing for Initial Phase	Dose
Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose)	10 mg/kg
End of Week 2 and Week 4 after transplantation	10 mg/kg
End of Week 8 and Week 12 after transplantation	10 mg/kg
Dosing for Maintenance Phase	Dose
End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter	5 mg/kg

References

1. Nulojix® intravenous infusion [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2021.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO Clinical Practice Guideline for the Care of Kidney Transplant Recipients. *Am J Transplant*. 2009;9(Suppl 3):S1 – S157.
3. Klintmalm GB, Feng S, Lake JR, et al. Belatacept-Based Immunosuppression in *De Novo* Liver Transplant Recipients: 1-Year Experience From a Phase II Randomized Study. *Am J Transplant*. 2014;14:1817-1827.
4. Budde K, Prashar R, Haller H, et al. Conversion from calcineurin inhibitor- to belatacept-based maintenance immunosuppression in renal transplant recipients: a randomized Phase 3b trial. *J Am Soc Nephrol*. 2021;32:3252-3264.