

Clinical Policy Title:	belatacept
Policy Number:	RxA.415
Drug(s) Applied:	Nulojix®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Belatacept (Nulojix®) is a selective T-cell costimulation blocker. It 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.

Limitation(s) of use:

- Use Nulojix® only in patients who are Epstein-Barr virus (EBV) seropositive.
- Use of Nulojix® for the prophylaxis of organ rejection in transplanted organs other than kidney has not been established.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Belatacept (Nulojix®)	Prophylaxis of organ rejection in kidney transplant recipients	<p><u>Dosing for Initial Phase:</u></p> <ul style="list-style-type: none"> • Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose): 10 mg per kg • End of Week 2 and Week 4 after transplantation: 10 mg per kg • End of Week 8 and Week 12 after transplantation: 10 mg per kg <p><u>Dosing for Maintenance Phase:</u> End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter: 5 mg per kg</p> <p>The prescribed dose must be evenly divisible by 12.5 mg in order for the dose to be prepared accurately using the reconstituted solution and provided syringe.</p>	10 mg/kg/dose for first 6 doses then 5 mg/kg/dose

Dosage Forms

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- Vial: 250 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Kidney Transplant (must meet all):

1. Prescribed for kidney transplant rejection prophylaxis;
2. Prescribed by or in consultation with a kidney transplant specialist;
3. Age \geq 18 years;
4. Request is for use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids;
5. Member is EBV seropositive;
6. Dose does not exceed the following:
 - a. Initial: 10 mg/kg for Day 1 (day of transplantation) and Day 5, end of Week 2, Week 4, Week 8, and Week 12 post-transplantation;
 - b. Maintenance: 5 mg/kg at the end of Week 16 post-transplantation and every 4 weeks thereafter.

Approval Duration

Commercial: 6 months

Medicaid/HIM: 6 months

II. Continued Therapy Approval

A. Kidney Transplant (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 5 mg/kg per infusion at the end of week 16 (after first 6 doses) after transplantation and every 4 weeks (+/- 3 days) thereafter.

Approval Duration

Commercial: 6 months

Medicaid/HIM: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

EBV: Epstein-Barr virus

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Maximum Dose
Simulect® (basiliximab)	20 mg IV within 2 hours prior to transplantation surgery, followed by 20 mg IV 4 days after transplantation	20 mg/dose

mycophenolate mofetil (Cellcept®)	1 g IV or PO at least 2 hours BID in combination with corticosteroids and cyclosporine	3 g/day
corticosteroids (e.g., prednisone, methylprednisolone)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Transplant recipients who are Epstein-Barr virus (EBV) seronegative or with unknown EBV serostatus due to the risk of post-transplant lymphoproliferative disorder, predominantly involving the central nervous system
- Boxed Warning(s):
 - Post-transplant lymphoproliferative disorder, other malignancies, and serious infections.

References

1. Nulojix Prescribing Information. Princeton, New Jersey: Bristol-Myers Squibb Company; April 2018. Available at: <http://www.nulojixhcp.bmscustomerconnect.com/index>. Accessed July 30, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/> Accessed July 30, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 3. Approval duration was updated in initial approval as well as in continued therapy approval. 4. References were updated. 	07/30/2020	09/14/2020