Clinical Policy Title:	belatacept
Policy Number:	RxA.415
Drug(s) Applied:	Nulojix®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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	<u>Dosing for Initial Phase:</u> • 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. <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. 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.	10 mg/kg/dose for first 6 doses then 5 mg/kg/dose

Dosage Forms

- 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 ≥ 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: 6 months

II. Continued Therapy Approval

A. Kidney Transplant (must meet all):

1. Member is 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: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
EBV: Epstein-Barr Virus
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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

Drug Name	Dosing Regimen	Maximum Dose
(mycophenolate mofetil) Cellcept®	1 g IV or orally at least 2 hours twice daily in combination with corticosteroids and cyclosporine	3 g/day
corticosteroids (e.g., prednisone, methylprednisolone)	Varies	Varies
cyclosporine (Gengraf®, Neoral®, Sandimmune®)	Varies	Varies

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

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.

APPENDIX D: General Information

Not Applicable.

References

1. Nulojix® Prescribing Information. Princeton, New Jersey: Bristol-Myers Squibb Company; April 2018. Available at: http://www.nulojixhcp.bmscustomerconnect.com/index. Accessed June 25, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/ Accessed June 25, 2021.
3. Nulojix®, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed June 25, 2021.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Available at: https://www.micromedexsolutions.com/micromedex2/librarian/CS/745188/PFActionId/pf.HomePage/ssl/true. Accessed June 25, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized	07/30/2020	09/14/2020

by RxAdvance…”. 3. Approval duration was updated in initial approval as well as in continued therapy approval. 4. References were updated.		
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving the medication that has been authorized by..." 4. Appendix B, therapeutic alternative verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance..". 5. Appendix B: Therapeutic Alternatives was updated to include “cyclosporine (Gengraf®, Neoral®, Sandimmune®)…” 6. Appendix B footnote was updated to,” Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only”. 7. References were reviewed and updated.	06/25/2021	09/14/2021