Clinical Policy: Belatacept (Nulojix)

Reference Number: PA.CP.PHAR.201
Effective Date: 01/2018
Last Review Date: 10/2024

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

FDA Approved Indication(s)
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.

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.

Policy/Criteria
It is the policy of PA Health & Wellness that Nulojix is **medically necessary** for members meeting the following 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 ≥ 18 years;
4. Request is for use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids;
5. Member is Epstein-Barr virus (EBV) seropositive;
6. Dose does not exceed both of the following (a and b):
   a. Initial: 10 mg/kg on 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 (± 3 days) thereafter.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Kidney Transplant (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA. PHARM.01) applies, or documentation supports that member is currently receiving Nulojix for a covered indication and has received this medication for at least 30 days;
2. Documentation of positive response 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 the first 6 doses) after transplantation and every 4 weeks (± 3 days) thereafter.

Approval Duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA. PHARM.01) applies; or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ 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 PO BID after transplantation 1 g IV over at least 2 hours BID initiated within 24 hours after transplantation for up to 14 days (recommended for patients unable to take an oral formulation).	2 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prophylaxis of organ rejection in kidney transplant recipients	Dosing for Initial Phase: • Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose): 10 mg per kg IV • End of Week 2 and Week 4 after transplantation: 10 mg per kg IV • End of Week 8 and Week 12 after transplantation: 10 mg per kg IV Dosing for Maintenance Phase: End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter: 5 mg per kg IV 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

VI. Product Availability

Vial: 250 mg

VII. References

1. Nulojix Prescribing Information. Princeton, New Jersey: Bristol-Myers Squibb Company; July 2021. Available at: https://packageinserts.bms.com/pi/pi_nulojix.pdf. Accessed July 19, 2024.
2. van Gelder T, Hesselink DA. Mycophenolate revisited. Transpl Int. 2015 May;28(5):508-15. doi: 10.1111/tri.12554.
3. Malhotra D, Jethwani P. Preventing Rejection of the Kidney Transplant. J Clin Med. 2023;12(18):5938.
4. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier.; Updated periodically. Available at: http://www.clinicalkey.com/pharmacology. Accessed August 14, 2024.

Error! Reference source not found.**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0485	Injection, belatacept, 1 mg

Reviews, Revisions, and Approvals	Date
4Q 2018 annual review: added that member is EBV seropositive; references reviewed and updated.	07/2018
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019
4Q 2020 annual review: Cellcept dosing information adjusted per prescribing information; references reviewed and updated.	10/2020
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022
4Q 2023 annual review: no significant changes; COC applied as a transplant-related indication in continued therapy section; references reviewed and updated.	10/2023
4Q 2024 annual review: no significant changes; references reviewed and updated.	10/2024