

## Clinical Policy: Belatacept (Nulojix)

Reference Number: PA.CP.PHAR.201

Effective Date: 01/2018

Last Review Date: 10/2023

[Coding Implications](#)[Revision Log](#)

### Description

Belatacept (Nulojix<sup>®</sup>) 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  $\geq$  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 the following:
  - 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 ( $\pm$  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.LTSS.PHAR.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;

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- 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 ( $\pm$  3 days) thereafter.

**Approval Duration: 12 months****B. Other diagnoses/indications** (must meet 1 or 2):

- Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
- Refer to PA.CP.PMN.53

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

- 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 for all relevant lines of business 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).	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

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- 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	<p><u>Dosing for Initial Phase:</u></p> <ul style="list-style-type: none"> <li>• Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose): 10 mg per kg</li> <li>• End of Week 2 and Week 4 after transplantation: 10 mg per kg</li> <li>• End of Week 8 and Week 12 after transplantation: 10 mg per kg</li> </ul> <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

## 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](https://packageinserts.bms.com/pi/pi_nulojix.pdf). Accessed June 28, 2023.
2. Simulect Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1af01887-b69d-444b-91ed-ebfe12784440>. Accessed August 6, 2023.
3. Cellcept Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; August 2022. Available at [https://www.gene.com/download/pdf/cellcept\\_prescribing.pdf](https://www.gene.com/download/pdf/cellcept_prescribing.pdf). Accessed August 6, 2023.
4. van Gelder T, Hesselink DA. Mycophenolate revisited. Transpl Int. 2015 May;28(5):508-15. doi: 10.1111/tri.12554.
5. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier.; Updated periodically. Available at: <http://www.clinicalkey.com/pharmacology>. Accessed August 6, 2023.

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-

## CLINICAL POLICY



### Belatacept

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description
J0485	Injection, belatacept, 1 mg

Reviews, Revisions, and Approvals	Date	Approval 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	