

## **Clinical Policy: Belatacept (Nulojix)**

Reference Number: CP.PHAR.201

Effective Date: 03.01.16

Last Review Date: 11.21

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **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**

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

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Nulojix is **medically necessary** when the following criteria are met:

#### **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 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**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Kidney Transplant (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 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):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**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.*

| <b>Drug Name</b>                    | <b>Dosing Regimen</b>   | <b>Dose Limit/<br/>Maximum Dose</b> |
|-------------------------------------|---|-------------------------------------|
| Simulect <sup>®</sup> (basiliximab) | 20 mg IV within 2 hours prior to transplantation surgery, followed by 20 mg IV 4 days after transplantation | 20 mg/dose                          |

| Drug Name  | Dosing Regimen   | Dose Limit/<br>Maximum Dose |
|--|--|-----------------------------|
| mycophenolate mofetil (Cellcept <sup>®</sup> )         | 1 g PO BID after transplantation<br>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<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): transplant recipients who are 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 | <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><br/>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; April 2018. Available at: [https://packageinserts.bms.com/pi/pi\\_nulojix.pdf](https://packageinserts.bms.com/pi/pi_nulojix.pdf). Accessed July 2, 2021.
2. Simulect Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2021. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1af01887-b69d-444b-91ed-ebfe12784440>. Accessed July 2, 2021.
3. Cellcept Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2019. Available at [https://www.gene.com/download/pdf/cellcept\\_prescribing.pdf](https://www.gene.com/download/pdf/cellcept_prescribing.pdf). Accessed July 2, 2021.
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]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>.

**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     | P&T Approval Date |
|--|----------|-------------------|
| Policy converted to new template. Added prescriber specialty requirement.<br>Modified age requirement from > 18 to ≥ 18 years. Added requirement that Nulojix is prescribed for kidney transplant rejection prophylaxis. Added requirement related to tuberculosis screening per PI. Added general efficacy statement to continued approval section. Added max dose for maintenance phase. | 03.17    | 03.17             |
| Policy converted to new template. Annual Review.<br>Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.<br>Initial approval duration extended to 6 months.   | 08.30.17 | 11.17             |
| 4Q 2018 annual review: added HIM-Medical Benefit line of business; added that member is EBV seropositive; references reviewed and updated.   | 07.31.18 | 11.18             |
| 4Q 2019 annual review: no significant changes; references reviewed and updated.  | 08.08.19 | 11.19             |

| Reviews, Revisions, and Approvals  | Date     | P&T Approval Date |
|--|----------|-------------------|
| 4Q 2020 annual review: revised HIM-Medical Benefit to HIM line of business; Cellcept dosing information adjusted per prescribing information; references reviewed and updated. | 08.11.20 | 11.20             |
| 4Q 2021 annual review: no significant changes; added Commercial line of business; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.            | 06.28.21 | 11.21             |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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