

Clinical Policy: Belatacept (Nulojix)

Reference Number: CP.PHAR.201

Effective Date: 03.01.16

Last Review Date: 11.17

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

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

Description

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

FDA Approved Indication(s)

Nulojix, in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids, is indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant.

Limitation(s) of use:

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

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation[®] 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. Dose does not exceed (a or b):
 - a. Initial: 10 mg/kg for Day 1 (day of transplantation) and Day 5, Week 2, Week 4, Week 8, and Week 12 post-transplantation;
 - b. Maintenance: 5 mg/kg for Week 16 post-transplantation and every 4 weeks thereafter.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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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 (e.g., no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed 5 mg/kg every 4 weeks.

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 CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.PHAR.57 evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prophylaxis of organ rejection in kidney transplant recipients	<p><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</p> <p>End of Week 2 and Week 4 after transplantation: 10 mg per kg</p> <p>End of Week 8 and Week 12 after transplantation: 10 mg per kg</p> <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>	10 mg/kg per infusion

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VI. Product Availability

Vial, lyophilized powder for injection: 250 mg per vial

VII. References

1. Nulojix Prescribing Information. Princeton, New Jersey: Bristol-Myers Squibb Company; February 2017. Available at: http://packageinserts.bms.com/pi/pi_nulojix.pdf. Accessed August 30, 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. 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 developed	03.16	03.16
Policy converted to new template. Added prescriber specialty requirement. 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. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Initial approval duration extended to 6 months.	08.30.17	11.17

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

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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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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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