Clinical Policy: Belatacept (Nulojix)

Reference Number: CP.PHAR.201
Effective Date: 03/16
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of belatacept (Nulojix®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Nulojix is **medically necessary** for members meeting the following criteria:

I. Initial Approval Criteria

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

1. Prescribed by or in consultation with a kidney transplant specialist;
2. Age ≥ 18 years;
3. Prescribed for kidney transplant rejection prophylaxis;
4. Request is for use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids;
5. Member is Epstein-Barr virus (EBV) seropositive;
6. Tuberculosis (TB) test within past 12 months is negative, or if positive, active TB has been ruled out and member has received treatment for latent TB infection;
7. Requested dose is no more than 10 mg/kg per infusion.

Approval Duration: 3 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response to therapy;
3. Requested 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: 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; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Belatacept, a selective T-cell (lymphocyte) costimulation blocker, binds to CD80 and CD86 on antigen-presenting cells thereby blocking CD28 mediated costimulation of T lymphocytes. In vitro, belatacept inhibits T lymphocyte proliferation and the production of the cytokines interleukin-2, interferon-γ, interleukin-4, and TNF-α. Activated T lymphocytes are the predominant mediators of immunologic rejection.

Formulations:
Lyophilized powder for injection: 250 mg per vial

FDA Approved Indications

Nulojix (belatacept) is a selective T-cell costimulation blocker/injection for intravenous use indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. It is to be used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids.

Limitations of use:

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

Appendices

Appendix A: Abbreviation Key

EBV: Epstein-Barr virus
TB: tuberculosis

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	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

References

1. Nulojix Prescribing Information. Princeton, New Jersey: Bristol-Myers Squibb Company; August 2016. http://packageinserts.bms.com/pi/pi_nulojix.pdf. Accessed February 6, 2017.

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.

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.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.