Clinical Policy: Belatacept (Nulojix)

Reference Number: CP.PHAR.201
Effective Date: 03.01.16
Last Review Date: 11.20
Line of Business: HIM, 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 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® 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 ≥ 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 for 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 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): HIM.PHAR.21 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 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.
   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): HIM.PHAR.21 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 – HIM.PHAR.21 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.

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum 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
- 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 • End of Week 2 and Week 4 after transplantation: 10 mg per kg • End of Week 8 and Week 12 after transplantation: 10 mg per kg Dosing for Maintenance Phase: End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter: 5 mg per kg 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; April 2018. Available at: http://www.nulojixhcp.bmscustomerconnect.com/index. Accessed July 24, 2020.
2. Simulect Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019. Available at dailymed.nlm.nih.gov. Accessed July 24, 2020.
3. Cellcept Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2019. Available at https://www.gene.com/download/pdf/cellcept_prescribing.pdf. Accessed July 24, 2020.
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.; 2020. 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
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
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

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.

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and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.