Clinical Policy: Belatacept (Nulojix)

Reference Number: LA.PHAR.201
Effective Date: 09.15.22
Last Review Date: ~~08.22~~06.02.23 Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

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
~~***Prior authorization is required.***~~ *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 Louisiana Healthcare Connections 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 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 (± 3 days) thereafter.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. ~~Refer to the off-label use policy if~~If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
~~1.~~2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53 ~~for Medicaid.~~

II. Continued Therapy
~~A.~~ **Kidney Transplant** (must meet all)**:**
A.
~~1.~~Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
1.
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 (± 3 days) thereafter.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. ~~Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.~~
2. ~~**Approval duration: Duration of request or 6 months (whichever is less);**~~If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA ~~or~~
   a. ~~Refer to the off-label use policy for the relevant line of business if~~.PMN.255
~~3.~~2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA.PMN.53 for Medicaid.~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

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 – LA.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

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This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here 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 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~~July 2021. Available at: https://packageinserts.bms.com/pi/pi_nulojix.pdf. Accessed July ~~2, 2021~~5, 2022.
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~~5, 2022.
3. Cellcept Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; ~~December 2019.~~June 2022. Available at https://www.gene.com/download/pdf/cellcept_prescribing.pdf. Accessed July ~~2, 2021~~5, 2022.
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.~~Philadelphia, PA: Elsevier.; 2022. Available at: http://www.~~clinicalpharmacology-ip~~clinicalkey.com~~/~~/pharmacology.

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	LDH Approval Date
Converted corporate to local policy.	09.22	09.15.22
Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	

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. LHCC 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.

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 LHCC administrative policies and procedures.

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