Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number: PA.CP.PHAR.201	**Effective Date: 01/2018** **Revision Date: 10/2021**
Policy Name: Belatacept (Nulojix)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Belatacept (Nulojix)

Reference Number: PA.CP.PHAR.201
Effective Date: 01/18
Last Review Date: 10/2021

Coding Implications
Revision Log

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
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Nulojix is **medically necessary** for members meeting the following criteria:

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 Epstein-Barr virus (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: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Documentation of positive response 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.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 policies – PA.CP.PMN.53

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
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: 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. 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	Approval Date
4Q 2018 annual review: added that member is EBV seropositive; references reviewed and updated.	07/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: Cellcept dosing information adjusted per prescribing information; references reviewed and updated.	10/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	