

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: 11/01/2020
Policy Number: PA.CP.PHAR.201	Effective Date: 01/2018 Revision Date: 10/2020
Policy Name: Belatacept (Nulojix)	
Type of Submission – <u>Check all that apply:</u> ☐ New Policy ☒ Revised Policy* ☐ Annual Review - No Revisions ☐ Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i>	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any changes or clarifying information for the policy below: 4Q 2020 annual review: Cellcept dosing information adjusted per prescribing information; references reviewed and updated.	
Name of Authorized Individual (Please type or print): Auren Weinberg, MD	Signature of Authorized Individual: 

Clinical Policy: Belatacept (Nulojix)

Reference Number: PA.CP.PHAR.201

Effective Date: 01/18

Last Review Date: 10/2020

[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 by or in consultation with a kidney transplant specialist;
2. Age $\geq$ 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. 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: 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;

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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 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

I. 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.

II. 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

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- 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

III. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prophylaxis of organ rejection in kidney transplant recipients	<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 • 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 <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 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

IV. Product Availability

Vial: 250 mg

V. 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

CLINICAL POLICY

Belatacept

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.

HCPSC 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	