Clinical Policy: Belatacept (Nulojix)

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

Coding Implications
Revision Log

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

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 ≥ 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.
7. .

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. 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 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

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

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
4Q 2018 annual review: added that member is EBV seropositive; references reviewed and updated.	07/18	

References

1. Nulojix Prescribing Information. Princeton, New Jersey: Bristol-Myers Squibb Company; April 2018. Available at: http://packageinserts.bms.com/pi/pi_nulojix.pdf. Accessed July 24, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 24, 2018.