Clinical Policy: Belatacept (Nulojix)

Reference Number: ERX.SPA.182
Effective Date: 01.11.17
Last Review Date: 11.17 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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:
   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 thereafter.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Kidney Transplant (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
EBV: Epstein-Barr virus

Appendix B: Therapeutic Alternatives
N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Kidney transplant, prophylaxis of organ rejection	Initial phase: 10 mg/kg IV on day 1 (day of transplant, prior to implantation) and on day 5 (~96 hours after day 1 dose), followed by 10 mg/kg at the end of week 2, week 4, week 8, and week 12 following transplantation Maintenance phase: 5 mg/kg IV every 4 weeks thereafter (plus or minus 3 days) beginning at the end of week 16 following transplantation	10 mg/kg/dose for first 6 doses then 5 mg/kg/dose

VI. Product Availability

Lyophilized powder for injection: 250 mg per vial

VII. References

1. Nulojix Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company; May 2017. Available at: https://packageinserts.bms.com/pi/pi_nulojix.pdf. Accessed September 25, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.16	01.17
4Q17 Annual Review Converted to new template. Added requirement that Nulojix is prescribed for kidney transplant rejection prophylaxis. Added prescriber specialty. Updated max dose requirement in initial approval criteria to include max dose for maintenance phase. Extended initial approval duration from 3 to 6 months. Re-auth: Added positive response to therapy. Modified max dose requirement from 10 mg/kg to reflect maintenance phase dosing of 5 mg/kg per infusion per PI.	09.25.17	11.17

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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