Belatacept (Nulojix®)

<u>Place of Service</u> Office Administration Outpatient Facility Administration

HCPCS: J0485 per 1 mg

Condition listed in policy (see criteria for details)

• <u>Kidney transplant</u>

AHFS therapeutic class: Immunosuppressive Agents

Mechanism of action: Belatacept is a selective T-cell (lymphocyte) co-stimulation blocker used for prophylaxis of organ rejection in kidney transplant patients.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information forprior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Nulojix® (belatacept) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Kidney transplant

- 1. Being used for prophylaxis of organ rejection in an adult patient with kidney transplant, AND
- 2. Patient is EBV seropositive

Covered Doses

Induction: Up to 10 mg/kg IV for up to six doses (over the first 12 weeks) Maintenance: up to 5 mg/kg IV every 4 weeks

Coverage Period

Cover indefinitely

ICD-10:

Z94.0, Z48.22

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Nulojix[®] (belatacept) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

<u>Blue Shield's research indicates there is inadequate clinical evidence to support off-labeluse of this</u> <u>drug for the following conditions (Health and Safety Code1367.21):</u> • Liver Transplant

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

<u>How supplied</u>: 250 mg (single-use vial of lyophilized powder for intravenous infusion)

Administration:

Per prescribing information for Nulojix (belatacept), "Only physicians experienced in immunosuppressive therapy and management of kidney transplant patients should prescribe Nulojix. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient."

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at
 <u>http://www.micromedexsolutions.com/home/dispatch</u>
- Nulojix (belatacept) [Prescribing information]., Princeton, NJ: Bristol Myers Squibb Company; 7/2021.

(7) Policy Update

Date of initial review: 3Q2022 Date of next review: 3Q2023

Changes from previous policy version:

New policy

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

PHP Medi-Cal

Effective: 01/03/2024

belatacept (Nulojix®)