Belatacept

(Nulojix®) J0485 (1mg)

Covered with prior authorization

Belatacept (Nulojix®) may be authorized when the following criteria are met:

Prophylaxis of Organ Rejection

- **Individual meets ALL of the following criteria:**
  - Individual is 18 years of age or older
  - Individual is Epstein-Barr virus (EBV) seropositive
  - Medication is being prescribed by, or in consultation with, a transplant specialist physician or a physician associated with a transplant center

Exclusion criteria:

- **Liver Transplantation:**
  - Nulojix has a boxed warning stating that use in liver transplant recipients is not recommended due to an increase risk of graft loss and death
  - Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
  - Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial approval duration:

- Initial approval duration is up to 4 months.

Reauthorization approval duration:

- Reauthorization approval duration is up to 12 months.

Reauthorization Criteria:

- Belatacept for intravenous infusion (Nulojix®) is considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Nulojix®, a soluble fusion protein, is indicated for prophylaxis of organ rejection in adults ≥ 18 years of age receiving a kidney transplant. Nulojix® is to be used in conjunction with basiliximab, mycophenolate mofetil, and corticosteroids.

References:

1. Nulojix® for injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; 2018.
2. Klintmalm GB, Feng S, Lake JR, et al. Belatacept-Based Immunosuppression in De Novo Liver Transplant Recipients: 1-Year Experience From a Phase II Randomized Study. Am J Transplant. 2014; 14:1817-1827.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team.

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