Clinical Criteria

Subject:	Nulojix (belatacept)		
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Overview

This document addresses the use of Nulojix (belatacept). Nulojix is a selective T-cell co-stimulation blocker indicated for the prophylaxis of organ rejection in Epstein-Barr virus (EBV) seropositive adults receiving a kidney transplant. Nulojix is used during the initial phase beginning on the day of kidney transplantation prior to implantation and for maintenance phase post kidney transplantation. It is indicated for use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. Use of this drug has not been established for the prophylaxis of organ rejection in transplanted organs other than the kidney.

Patients who are EBV seronegative are at higher risk for post-transplant lymphoproliferative disorder (PTLD) compared to patients who are EBV seropositive. EBV seropositive patients are defined as having IgG antibodies to viral capsid antigen (VCA) and EBV nuclear antigen (EBNA). Patients who are EBV seronegative or with unknown serostatus should not receive Nulojix.

Nulojix has the following black box warnings:

- Increased risk for developing PTLD, predominantly involving the central nervous system. Recipients without EBV immunity are at an increased risk; therefore, Nulojix is used only in EBV seropositive patients.
- Increased susceptibility to infection and the possible development of malignancies as a result of immunosuppression
- Use in liver transplant patients is not recommended due to increased risk of graft loss and death
- In addition, Nulojix should only be prescribed by physicians experienced in immunosuppressive therapy and management of kidney transplant patients. 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

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Nulojix (belatacept)

Requests for Nulojix (belatacept) may be approved if the following criteria are met:

I. Individual is an adult using for prevention of organ rejection in kidney transplant; **AND**
II. Individual is Epstein-Barr virus (EBV) seropositive; **AND**
III. If initiating therapy, Nulojix (belatacept) is used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids.

Requests for Nulojix (belatacept) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0485	Injection, belatacept, 1 mg [Nulojix]

ICD-10 Diagnosis

N18.6	End stage renal disease
Z48.22	Encounter for aftercare following kidney transplant
Z94.0	Kidney transplant status

Document History

Reviewed: 06/13/2022
Document History:

- 06/13/2022 – Annual Review: No change. Coding Reviewed: No changes.
- 06/14/2021 – Annual Review: Clarify combination use is for initiation of therapy. Coding Reviewed: No changes.
- 06/08/2020 – Annual Review: Wording and formatting changes. Coding reviewed: No changes.
- 06/10/2019 – Annual Review: No changes. Coding reviewed: No changes.
- 11/16/2018 – Select Review: Initial P&T review of Nulojix (belatacept); Add criteria to ensure use with basiliximab, mycophenolate mofetil, and corticosteroids per label. HCPCS and ICD-10 Coding review: No Changes.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: May 23, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.