RX.PA.024.MPC Nulojix® (Belatacept)

The purpose of this policy is to define the prior authorization process for Nulojix® (belatacept).

Nulojix® (belatacept) is a selective T-cell costimulation blocker indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplantation in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. Nulojix® (belatacept) is recommended to be used only in patients who are EBV seropositive.

DEFINITIONS

EBV Serology – laboratory tests which detect the presence of EBV antibodies

Epstein Bar Virus (EBV) – a member of the herpes virus family and one of the most common human viruses with as many as 95% of adults between the ages of 35-40 in the United States having been infected at some point during their lives, most often during childhood. Symptoms of the virus in children may be absent or indistinguishable from other mild, brief illnesses. Infections during adolescence will present as mononucleosis 35-50% of the time. Patients undergoing organ transplants who have not been exposed to EBV, and therefore do not have immunity, are at increased risk of post-transplant lymphoproliferative disorder (PTLD, found to be the most common malignancy in transplant recipients) due to chronic immunosuppression since EBV can infect B cells and cause them to proliferate.

T Lymphocyte (T-cell) – activated T-cells are the predominant mediators of immunologic rejection

The drug, Nulojix® (belatacept), is subject to the prior authorization process.

PROCEDURE

A. <u>Initial Authorization Criteria:</u>

Must meet all of the criteria listed below:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-tb Gold In-Tube test (QFT-GIT) or T-SPOT®. TB test (T-Spot)]

- Must be at age 18 years or older
- Must be prescribed by a physician who specializes in immunosuppression or renal transplantation
- Must be undergoing or have undergone a renal transplant
- Must meet at least ONE of the following:
    - Be at increased risk of renal failure before transplant
    - Have tried and failed, have an intolerance to, or have a contraindication to tacrolimus or cyclosporine
- Must be used in conjunction with basiliximab induction [if giving Nulojix at time of transplant], mycophenolate mofetil, and corticosteroids
- Must be EBV seropositive as demonstrated by EBV serology
- Must not have any evidence of infection including, but not limited to:
    - Progressive multifocal leukoencephalopathy (PML)
    - Cytomegalovirus (CMV)
    - Polyoma virus-associated nephropathy (PVAN)
- Must not have history of or currently active malignancy

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Nulojix will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>
All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

<u>Limitations:</u>

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J0485	Injection, belatacept, 1 mg

REFERENCES

1. Epstein-Barr Virus and Infectious Mononucleosis. http://www.cdc.gov/ncidod/diseases/ebv.htm
2. Lymphoproliferative disorders following solid organ transplantation. UpToDate; accessed June 2011.
3. Nulojix [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2011.
4. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis infection – United States 2010. Department of Health and Human Services Centers for Disease Control and Prevention [U.S.]. vol 59, RR-5. 2010 June 25.
5. Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm. Accessed 10/29/2012.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*