Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 93.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Nulojix (belatacept)

I. Policy:
Nulojix (belatacept)

II. Purpose/Objective:
To provide a policy of coverage regarding Nulojix (belatacept)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Nulojix (belatacept) is a selective T-cell costimulation blocker indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Nulojix (belatacept) will be considered medically necessary for all lines of business for the prophylaxis of organ rejection in adult patients with:

- Physician provided documentation of kidney transplant; **AND**
- Documentation of Epstein-Barr virus (EBV) seropositivity; **AND**
- Documentation of planned use in combination with a complete immunosuppressive regimen including basiliximab induction (for patients new to immunosuppressive therapy), corticosteroids, AND mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus)

AUTHORIZATION DURATION: Initial approval will be for 1 year or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 1 year or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued use in combination with mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus) & corticosteroids, lack of organ rejection, and lack of toxicity. The medication will no longer be covered if patient discontinues mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus) and/or corticosteroids, experiences toxicity, or symptoms of organ rejection.

NOTE: According to Lexi-Drugs, phase 2 and 3b randomized controlled trials showed that patients 6 to 60 months post kidney transplant can be safely converted from a calcineurin inhibitor to Nulojix. Patients had stable kidney function (eGFR 30 to 75 mL/minute/1.73 m^2) or absence of proteinuria (≤500 mg/day in diabetic patients or ≤1,000 mg/day in nondiabetic patients) for at least 3 months without a history of rejection. In clinical trials, mycophenolate or other immunosuppressant was continued in combination with Nulojix.

LIMITATIONS:

- Nulojix® (belatacept) is contraindicated in transplant recipients who are EBV seronegative or are of unknown serostatus.
- Nulojix® (belatacept) is contraindicated for all transplants other than kidney.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/14/11

Revised: 1/2014 (add criteria), 1/20/15 (added reauth criteria), 9/23/22 (Medicaid PARP statement), 3/21/23 (Medicaid Business Segment, Immunosuppressive regimen change, LOB carve out)

Reviewed: 3/2016, 3/30/17, 3/29/18, 1/30/19, 11/1/19, 9/30/20, 9/23/21