Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization

Title: belatacept (Nulojix)

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived:

   3.1 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
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Background Information, continued:

Medication Summary

- Nulojix (belatacept) is a selective T cell costimulation blocker used for rejection prophylaxis in kidney transplant patients who are seropositive for Epstein-Barr virus. Belatacept binds to CD80 and CD86 on antigen presenting cells which blocks the CD28-mediated costimulation of T lymphocytes.
- Nulojix is used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids in patients undergoing kidney transplant who are EBV seropositive. Members without immunity to EBV have an increased risk of developing post-transplant lymphoproliferative disorder (PTLD) while on Nulojix therapy.
- Nulojix is administered as a 10 mg/kg dose rounded to the nearest 12.5 mg increment intravenous (IV) infusion over 30 minutes on the day of transplantation (day 1), day 5, day 14, day 28, and day 84. Then maintenance dosing begins at 5 mg/kg rounded to the nearest 12.5 mg increment infused over 30 minutes every 4 weeks thereafter.

Coverage Guidelines

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Members less than 18 years of age, as safety and efficacy have not been established.
- Members who have undergone liver transplant.
- Members who are EBV seronegative or unknown status.
- Members with a history of hypersensitivity to Nulojix or any of its ingredients.
- Members experiencing clinically important, active infections including, but not limited to, sepsis, tuberculosis without treatment, aplastic anemia, or opportunistic infections.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

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Procedure:

1.0 Request for initial therapy with Nulojix for kidney transplant rejection prophylaxis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Requesting independent practitioner must be an immunologist or transplant specialist; **AND**

1.2 Member must be scheduled to undergo kidney transplant; **AND**

1.3 Member must be at least 18 years of age; **AND**

1.4 Laboratory results indicating an Epstein-Barr Virus (EBV) seropositive status; **AND**

1.5 Member must not be a candidate for tacrolimus or cyclosporine due to previous allergic reaction; **AND**

1.6 Member must be getting concurrent mycophenolate mofetil and corticosteroids; **AND**

1.7 Current weight for weight-based dosing;

1.8 If criteria are met, may approve Nulojix for up to one (1) year.

2.0 Request for continuation of therapy beyond initial authorization period for Nulojix requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the Member’s current weight for weight-based dosing:

2.1 If criterion is met, Nulojix may be approved for up to one (1) year.
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References:


