

| Market Applicability | | | | | | | |
|----------------------|----|----|----|----|----|----|----|
| Market | DC | GA | KY | MD | NJ | NY | WA |
| Applicable | X | X | X | X | X | X | X |

Nulojix (belatacept)

| Override(s) | Approval Duration |
|---------------------|-------------------|
| Prior Authorization | 1 year |

| Medications |
|----------------------|
| Nulojix (belatacept) |

APPROVAL CRITERIA

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. 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.

Note:

Nulojix (belatacept) has the following black box warnings:

Increased risk of developing post-transplant lymphoproliferative disorder (PTLD), predominately involving CNS. Recipients without immunity to EBV 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

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resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: June 3, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

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

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.