

Medical Policy: Nulojix® (belatacept) intravenous infusion

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|------------------|-------------|
| MG.MM.PH.301 | January 31, 2024 | 2018 |

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Nulojix, a selective T-cell costimulation blocker, is indicated for **prophylaxis of organ rejection** in patients ≥ 18 years of age receiving a kidney transplant. Nulojix is to be used in conjunction with basiliximab, mycophenolate mofetil, and corticosteroids.

The prescribed dose must be evenly divisible by 12.5 mg. Use of higher than recommended doses or more frequent administration is not recommended due to the increased risk of post-transplant lymphoproliferative disorder predominately of the central nervous system (CNS), progressive multifocal leukoencephalopathy, and serious CNS infections. The dose is based on actual body weight of the patient at the time of transplantation and should not be modified during the course of treatment unless the patient’s weight changes by $> 10\%$.

Length of Authorization

12 months

Dosing Limits [Medical Benefit]

Approve the following dosing regimen (A and B):

- A. Each individual dose must not exceed 10 mg/kg administered by intravenous infusion; **AND**
- B. Nulojix is administered no more than four times in the first 4 weeks (day of transplant, Day 5, end of Week 2, and end of Week 4), and then no more frequently than once every 4 weeks.

Guideline

1. **Kidney Transplantation – Prophylaxis of Organ Rejection.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
 - A. Patient is \geq 18 years of age; **AND**
 - B. Patient is Epstein-Barr virus (EBV) seropositive; **AND**
 - C. Nulojix is prescribed by or in consultation with a transplant specialist physician or a physician associated with a transplant center
2. **Solid Organ Transplantation Other Than Kidney – Prophylaxis of Solid Organ Rejection in a Patient Currently Receiving Nulojix.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
 - A. Patient is \geq 18 years of age; **AND**
 - B. Patient is Epstein-Barr virus (EBV) seropositive; **AND**
 - C. Nulojix is prescribed by or in consultation with a transplant specialist physician or a physician associated with a transplant center.

Applicable Procedure Codes

| Code | Description |
|-------|-----------------------------|
| J0485 | Injection, belatacept, 1 mg |

Applicable NDCs

| Code | Description |
|---------------|--------------------------------------|
| 00003-0371-13 | Nulojix 250MG Solution Reconstituted |

ICD-10 Diagnoses

| Code | Description |
|--------|---|
| T86.11 | Kidney Transplant Rejection |
| T86.91 | Unspecified transplanted organ and tissue rejection |

Revision History

| Company(ies) | DATE | REVISION |
|-----------------------------|------------|---|
| EmblemHealth & ConnectiCare | 1/31/2024 | Annual Review: no criteria changes |
| EmblemHealth & ConnectiCare | 04/05/2023 | Transfer from CCUM Template to CoBranded Medical Template Retired MG.MM.PH.157 |
| EmblemHealth & ConnectiCare | 7/20/2022 | Annual Revision: No criteria changes |

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|-----------------------------|-----------|--------------------------------------|
| EmblemHealth & ConnectiCare | 7/21/2021 | Annual Revision: No criteria changes |
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References

1. Nulojix® intravenous infusion [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2021.