Medical Policy

Nulojix® (belatacept)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_088
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Nulojix® (belatacept)therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Nulojix will be provided for 12 months and may be renewed.

A. Patient is 18 years of age or older; **AND**
B. Nulojix is prescribed by or in consultation with a transplant specialist physician or a physician associated with a transplant center; **AND**
C. Patient has had a kidney transplant; **AND**
D. Patient is Epstein-Barr virus (EBV) seropositive; **AND**

E. Nulojix will be used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Transplant recipients who are Epstein-Barr virus (EBV) seronegative or with unknown EBV serostatus
3. Prophylaxis of organ rejection in transplanted organs other than kidney

BACKGROUND

Nulojix, a selective T cell costimulation blocker, is a fusion protein containing modified CTLA-4 linked to a
portion of the Fc domain of human immunoglobulin GI antibody. Belatacept binds to CD80 and CD86
receptors on the antigen-presenting cell and prevents them from binding to CD28 and costimulating the
T lymphocyte, which when activated mediates immunologic rejection.

DEFINITIONS

1. NULOJIX (belatacept) for injection, for intravenous use. Initial U.S. Approval: 2011
    a. NULOJIX (belatacept) lyophilized powder for intravenous infusion is supplied as a single-use vial with a silicone-free disposable syringe.

CODING

Applicable NDC Codes	
00003-0371-13	NULOJIX, belatacept injection vial of 250 mg

Applicable Procedure Code	
J0485	Injection, belatacept, 1 mg, 1 billable unit = 1 mg

Applicable Diagnosis Codes	
Z29.1	Encounter for prophylactic immunotherapy
Z29.8	Encounter for other specified prophylactic measures
Z29.9	Encounter for prophylactic measures, unspecified
Z48.22	Encounter for aftercare following kidney transplant
Z48.288	Encounter for aftercare following multiple organ transplant
Z48.298	Encounter for aftercare following other organ transplant
Z94.0	Kidney transplant status

EVIDENCE BASED REFERENCES

1. Product Information: NULOJIX(R) intravenous injection, belatacept intravenous injection. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2021.

POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	V2 –November 8, 2022 – Annual Review and approval (no policy revisions made) V3 – March 01, 2023 – Adopted by MA UMC (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022