CG- Drug 95 Belatacept (Nulojix)
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: CG- Drug 95 Belatacept (Nulojix)		
MNG #: 004	**☒SCO ☒One Care** **☒ MA Medicare Premier** **☒ MA Medicare Value** **☒ RI Medicare Preferred** **☒ RI Medicare Value** **☒ RI Medicare Maximum**	**Prior Authorization Needed?** **☒ Yes (always required)** **☐ Yes (only in certain situations. See this MNG for details)** **☐ No**
Clinical: ☒	**Operational: ☒**	**Informational: ☐**
Benefit Type: **☒ Medicare** **☐ Medicaid**	**Approval Date:** 1/10/2019;	**Effective Date:** **04/01/2019**
Last Revised Date: 1/25/2019; 3/26/2020; 5/11/2021; 07/01/2021; 6/2/2022, 6/8/23	**Next Annual Review Date:** 1/10/2020; 3/26/2021; 05/11/2022; 7/01/2022, 6/2/2023, 6/8/24	**Retire Date:**

OVERVIEW:

Organ transplantation is often the treatment of choice for end-stage diseases (e.g. end-stage renal disease) as it has been associated with improvement in the patient's quality of life and reduction in the risk of mortality. However, recipients require close follow-up with specialists and need to be placed on complex *maintenance immunosuppression regimens* to prevent acute rejection, to prevent deterioration of graft function, and to promote long-term patient and graft survival.

Belatacept (Nulojix) is a costimulatory blockage agent that is used as part of a triple drug maintenance immunosuppression therapy for the prophylaxis of kidney transplant rejection. It may be used as an alternative for patients who cannot continue to take a calcineurin inhibitor due to toxicity, who develop a new cancer after the procedure, and/or who are non-compliant with their current regimen.

DEFINITIONS:

Belatacept (Nulojix): An intravenous medication that is used in combination with basiliximab induction, mycophenolate mofetil, and/or a corticosteroid for the prophylaxis of kidney transplant rejection. It is a selective T-cell (lymphocyte) co-stimulation blocker that binds to CD80 and CD86 on antigen-presenting cells. By doing so, it blocks CD28 mediated co-stimulation of T lymphocytes so that it inhibits its proliferation, the production of cytokines (interleukin-2, interferon-ϒ, interleukin-4, and TNF-α), and thereby immunologic rejection.

Epstein-Barr Virus (EBV): A common asymptomatic virus known has human herpesvirus 4. It is the primary agent of infectious mononucleosis, and can be spread by intimate contact between susceptible persons and asymptomatic EBV shedders.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart

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Sheets, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations. CCA may cover Belatacept (Nulojix) for the prophylaxis of **kidney transplant** rejection when all of the following criteria are met:

- Belatacept is prescribed for kidney transplant rejection prophylaxis, AND
- Belatacept is prescribed by or with consultation with a renal transplant specialist, AND
- Belatacept is used with Basiliximab induction, mycophenolate mofetil, and/or a corticosteroid, AND
- The adult receiving a kidney transplant is documented as *Epstein-Barr virus* (EBV) seropositive

LIMITATIONS/EXCLUSIONS:

1. Commonwealth Care Alliance will not cover the use of Belatacept (Nulojix), under the following clinical conditions, including but not limited to:
   - If the member is EBV seronegative due to the increased risk of developing *post-transplant lymphoproliferative disorder*; or
   - If the member has an unknown EBV serostatus; or
   - If belatacept is used for treatment with non-transplant related diagnoses.
2. Parenteral belatacept (J0485) is not proven to be safe when administered in the home setting and therefore will be denied as not medically necessary when provided in that setting.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws (including the Plan's applicable government program contracts) that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations.

AUTHORIZATION:

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

HCPCS Code	Description
J0485	Injection, Belatacept, 1 mg [Nulojix]

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth

herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria. This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

1. Local Coverage Determination L33824. Immunosuppressive Drugs. Noridian Healthcare Solutions, Inc. Original effective date 10/1/2015, revision effective date 1/1/2020. Accessed 5/25/2022.
2. U.S. Center for Medicare & Medicaid Services. (2020). *Local coverage criteria: Immunosuppressive drugs – Policy article (A52474).* Retrieved from https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=52474&ver=26&bc=CAAAAAAAAAAA

Disclaimer

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. Dynamed. (2021). *Belatacept.* Retrieved from https://www-dynamed-com.ahs.idm.oclc.org/drug-monograph/belatacept
2. Lexicomp. (2021). *Belatacept: Drug information.* Retrieved from https://www.uptodate.com/contents/belatacept-drug-information?search=belatacept&
3. U.S. Food and Drug Administration. (2017). Nulojix (belatacept) for injection, for intravenous use. Retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125288s070lbl.pdf

REVISION LOG:

REVISION DATE	DESCRIPTION
12/31/23	Utilization Management Committee approval
6/8/23	Reviewed
6/2/2022	Updated MNG template. Added exclusion for home infusion per LCD L33824.
5/11/2021	Removed Belatacept (Nulojix) for the prophylaxis of lung transplant rejection.
5/3/2021	Added overview. Paragraph about benefit coverage was included. Authorization: format of how the codes are presented was changed (into a chart form). Added the ICD-10 diagnosis code: T86.11 Kidney Transplant rejection. Added footer and page numbers.

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3/26/2020	KH staff reviewed and updated document

APPROVALS:

David Mello	Senior Medical Director, Utilization Review and Medical Policy
CCA Senior Clinical Lead [Print]	**Title [Print]**
	12/31/23
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CCA Senior Operational Lead [Print]	**Title [Print]**
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Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee [Print]	**Title [Print]**
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