Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: CG- Drug 95 Belatacept (Nulojix)		
MNG #: 004	**☒SCO ☒One Care**	**Prior Authorization Needed?** **☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☐Yes ☒No**	**Approval Date:** 1/10/2019;	**Effective Date:** **04/01/2019**
Last Revised Date: 1/25/2019; 3/26/2020	**Next Annual Review Date:** 1/10/2020; 3/26/2021	**Retire Date:**

OVERVIEW:
This document addressed the use of belatacept (Nulojix) (Bristol-Myers, Squibb, Princeton, New Jersey).

DEFINITIONS:
- Belatacept (Nulojix) - An intravenous drug that is a selective T-cell co-stimulation blocker indicated for the prophylaxis of organ rejection in Epstein-Barr virus (EBV) seropositive adults receiving a kidney transplant.

DECISION GUIDELINES:
Clinical Coverage Criteria:
- Belatacept is considered **medically necessary** for prevention of organ rejection in adults receiving a kidney transplant who are Epstein-Barr virus (EBV) seropositive.
- Belatacept is considered **medically necessary** for the prevention of lung transplant rejection who are Epstein-Barr virus (EBV) positive.
- Belatacept is considered **not medically necessary** when the above criteria are not met.

AUTHORIZATION:
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not signify whether 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. Other Policies and Coverage Determination Guidelines may apply. This Medical Necessity Guideline is subject to all applicable laws and regulations, 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**
  - J0485 Injection, belatacept, 1 mg [Nulojix]
- **ICD-10 Diagnosis**
  - N18.6 End stage renal disease
  - Z48.22 Encounter for aftercare following kidney transplant
  - Z94.0 Kidney transplant status

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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.

ATTACHMENTS:

EXHIBIT A: CG-Trans-02 Kidney Transplantation	CG-Trans-02 Kidney Transplantation

REVISION LOG:

REVISION DATE	DESCRIPTION
3/26/2020	KH staff reviewed and updated document

APPROVALS:

Stefan Topolski MD	Medical Director, Medical Affairs
CCA Senior Clinical Lead [Print]	**Title [Print]**
[signature]	3/26/2020
Signature	**Date**
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**

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Lori Tishler, MD	Vice President, Medical Affairs
CCA CMO or Designee [Print]	**Title [Print]**
[signature]	1/10/2018
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