Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: CG- Drug 95 Belatacept (Nulojix)		
MNG #: 004	**☒SCO ☒One Care** **☒ MAPD-MA Medicare Preferred** **☒ MAPD-MA Medicare Value** **☒ MAPD-RI Medicare Preferred** **☒ MAPD-RI Medicare Value** **☒ DSNP-RI Medicare Maximum**	**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; 5/11/2021; 07/01/2021	**Next Annual Review Date:** 1/10/2020; 3/26/2021; 05/11/2022; 7/01/2022	**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-Ɣ, 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.

Maintenance Immunosuppression Regimen: Therapy that is administered to almost all kidney transplant recipients at the time of transplantation and continued long-term for the duration of the allograft. This may include a combination of glucocorticoids, calcineurin inhibitors, antimetabolic agents, mammalian target of rapamycin inhibitors, and/or costimulatory blockage agents.

Post-transplant Lymphoproliferative Disorder: Rare complication of solid organ or allogeneic hematopoietic cell transplantation characterized by lymphoid and/or plasmocytic proliferation and overproduction of cells. It is

related to Epstein-Barr virus and immunosuppression therapy.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance 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:

Commonwealth Care Alliance will not cover the use of Belatacept (Nulojix), under the following conditions, including but not limited to:

- If the member is EBV seronegative due to the increased risk of developing *post-transplant lymphoproliferative disorder*,
- If the member has an unknown EBV serostatus,
- If belatacept is used for treatment with non-transplant related diagnoses

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

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 ourcriteria, 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:

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ATTACHMENTS:

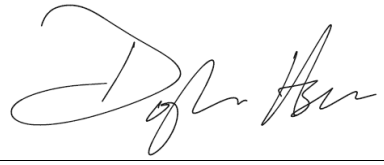
EXHIBIT A: CG-Trans-02 Kidney Transplantation	CG-Trans-02 Kidney Transplantation

REVISION LOG:

REVISION DATE	DESCRIPTION
5/11/2021	Removed Belatacept (Nulojix) for the prophylaxis of lung transplant rejection, as it is considered experimental and investigational.
5/3/2021	Overview: added that belatacept is for immunosuppression to prevent kidney transplant rejection, can be a part of the maintenance immunosuppression therapy regimen, and is an alternative to calcineurin inhibitor. Definitions: provided more background information for belatacept, and included more definitions (Epstein-Barr Virus, maintenance immunosuppressive regimen, and post-transplant lymphoproliferative disorder). Decision Guidelines: added that belatacept should be prescribed by or in consultation with a transplant specialist, and should be used in combination with basiliximab induction/mycophenolate mofetil/corticosteroid. Limitations/Exclusions: added this section, and included that members serostatus must be known and positive, and for transplant-related diagnoses. 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.
3/26/2020	KH staff reviewed and updated document

Medical Necessity Guideline

APPROVALS:

Douglas Hsu, MD, MPH	Vice President, Medical Policy and Utilization Review
CCA Senior Clinical Lead [Print]	**Title [Print]**
	3/26/2020
Signature	**Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Lori Tishler, MD	Senior Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	3/26/2020
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