ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Nulojix® (belatacept) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Nulojix® (belatacept)

Diagnosis (documentation supportive of diagnosis is required)

☐ Prophylaxis of organ rejection in adult patients receiving a **kidney transplant**

☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

☐ Patient is **EBV seropositive**

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

☐ Patient had been assessed for tuberculosis and tested for latent infections

Physician Specialty (diagnosis made by):

☐ Physician experienced in immunosuppressive therapy and management of kidney transplant patients.
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Nulojix (belatacept)

CLASSIFICATION

- Selective T-cell costimulation blocker

DESCRIPTION

- Belatacept is indicated for prophylaxis of organ rejection in EBV seropositive adult patients receiving a kidney transplant in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids.
- Belatacept use has not been established for the prophylaxis of organ rejection in transplanted organs other than the kidney.
- Belatacept 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 on antigen-presenting cells, which prevents them from binding to CD28 and costimulating the T lymphocytes. In vitro, the agent inhibits T lymphocyte proliferation and the production of various cytokines (e.g., interleukin-2, interferon-γ, interleukin-4 and tumor necrosis factor-α). Activated T lymphocytes are mediators of immunologic rejection.
- In the 3-year, multicenter, phase 3, randomized, active-controlled Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trail (BENEFIT; n=686), at month 12, belatacept (less-intensive regimen) was noninferior to cyclosporine for patient/graft survival and acute rejection and was superior to cyclosporine for the composite renal impairment endpoint in patients undergoing de novo kidney transplantation (living donor or standard criteria).
- Adverse events were similar between groups; the most common (greater than 25%) included anemia, urinary tract infection, hypertension, constipation, diarrhea, nausea, and peripheral edema. Acute infusion-related reactions (mild to moderate) were reported in the belatacept arms (4 patients in each arm) and did not occur with cyclosporine therapy. Posttransplant lymphoproliferative disorder (PTLD) at month 12 occurred in 1, 2, and 1 patient in the more-intensive regimen (MI), less-intensive regimen (LI), and cyclosporine arms, respectively.
- In the 3-year, multicenter, phase 3, randomized, active-controlled Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trail-EXTended criteria donors (BENEFIT-EXT; n=578), belatacept (less-intensive regimen) was noninferior to cyclosporine for patient/graft survival and acute rejection at month 12; belatacept (both arms combined) was superior to cyclosporine for the composite renal impairment endpoint in patients undergoing de novo kidney transplantation (extended criteria).
- Adverse events were similar between groups; the most common (greater than 20%) included anemia, graft dysfunction, constipation, and diarrhea. Acute infusion-related reactions (mild to moderate except 1 case of prolonged hypotension) were reported in the belatacept arms (MI, n=7; LI, n=9) and did not occur with cyclosporine therapy. Posttransplant lymphoproliferative disorder (PTLD) at month 12 occurred in 1, 2, and 0 patients in the MI, LI, and cyclosporine arms, respectively. Two additional patients developed PTLD after 6 months in the MI and LI arm, respectively.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Not Covered
Commercial Formulary: Not Covered
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Nulojix (belatacept) meets the definition of **medical necessity** for all FDA approved indications not otherwise excluded from part D, including the following:

- Prophylaxis for **renal** transplant rejection in EBV seropositive patients when taken in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids.

Nulojix (belatacept) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported.
- Belatacept use has not been established for the prophylaxis of organ rejection in transplanted organs other than the kidney, therefore Nulojix is **not a covered** benefit for any organ transplant that is not a kidney transplant

Required Provider Specialty:

- Physician experienced in immunosuppressive therapy and management of kidney transplant patients.

DOSAGE/ADMINISTRATION:

Adult dosing (safety and efficacy has not been established in pediatric patients):

Renal transplant rejection, EBV seropositive; in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids; Prophylaxis:

- *Initial phase:* 10 mg/kg IV on day 1 (day of transplant, prior to implantation), day 5, and end of week 2, 4, 8, and 12; median corticosteroid doses were tapered to about 15 mg daily by the first 6 weeks and remained at 10 mg daily for the first 6 months posttransplant in clinical trials.
- *Maintenance phase:* 5 mg/kg at end of week 16 and every 4 weeks thereafter

PRECAUTIONS:

- Belatacept is *contraindicated* in patients who are Epstein-Barr virus seronegative or unknown status due to increased risk for posttransplant lymphoproliferative disorder, particularly involving the CNS.
- Do not exceed recommended doses of belatacept or concomitant immunosuppressive therapy due to increased risk for posttransplant lymphoproliferative disorder (PTLD), particularly involving the CNS.
- Potentially serious or fatal infections may occur including bacterial (e.g. TB), viral (e.g. cytomegalovirus, herpes), fungal, protozoal or opportunistic. Posttransplant prophylaxis therapy is recommended for cytomegalovirus and Pneumocystis jiroveci
- Increased risk for malignancies, including the skin; recommended to use sunscreen and limit sunlight or UV light exposure including tanning beds and sunlamps.
- Avoid use of live vaccines during treatment with belatacept (e.g. intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella, TY21a typhoid vaccines).

- Cytomegalovirus infection due to increased risk for posttransplant lymphoproliferative disorder.
- Progressive multifocal leukoencephalopathy (PML), JC virus-associated, has been reported; consider reduction or withdrawal if PML is suspected or diagnosed.
- Exceeding recommended dose and frequency is not recommended due to increased risk of PTLD, PML, other malignancies, and serious infections.
- Not recommended for use in liver transplant.
- New or worsening neurological, cognitive, or behavioral signs/symptoms are potentially indicative of PTLD or PML; monitoring is recommended.
- Polyoma virus nephropathy, most due to BK virus infection, can lead to kidney graft loss and has been reported; consider immunosuppression reduction if develops.
- T-cell depleting therapy increases the risk for posttransplant lymphoproliferative disorder.
- Testing for latent infection prior to treatment is recommended; tuberculosis has been reported.

Billing/Coding information:

CPT Coding:

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

Associated HCPCS Codes:

J0485	Injection, belatacept, 1 mg (For billing prior to 1/1/13 use C9286 or J3590)

COST

AWP (October 2011):
- 250 mg vial: $1,107.50

AWP (December 2012):
- 250 mg vial: $1,107.50

COMMITTEE APPROVAL:

- November 2011

GUIDELINE UPDATE INFORMATION:

October 2011	Prior Authorization and Coverage Policy creation
May 2014	Coverage policy update

REFERENCES:

- DRUGDEX®, accessed 10/29/2011, 5/17/2014
- Product Information: Nulojix ™, (belatacept) for injection, for intravenous use. Bristol-Myers Squibb Company, Princeton, NJ. 2011.