**Nulojix® (belatacept)**

**Last Review Date:** July 15, 2019  
**Number:** MG.MM.PH.157

**Medical Guideline Disclaimer**

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**Definition**

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 G1 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.

**Length of Authorization**

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

I. **INITIAL APPROVAL CRITERIA**

*Nulojix may be considered medically necessary if the below condition is met AND use is consistent with the medical necessity criteria that follows:*

1. **Prophylaxis of organ rejection in adults receiving a kidney transplant**
   a. Patient is at least 18 years of age; **AND**
   b. Nulojix is used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids; **AND**
   c. In patients who are Epstein-Barr virus (EBV) seropositive.

**Limitations/Exclusions**

Nulojix is not considered medically necessary for when any of the following selection criteria is met:

1) Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. **RENEWAL CRITERIA**

- Patient continues to meet INITIAL APPROVAL CRITERIA.
Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Prophylaxis of organ rejection in adults receiving</td>
<td>- Initial phase - 10 mg/kg IV</td>
</tr>
<tr>
<td>a kidney transplant</td>
<td>• Day 1 of transplantation, prior to implantation</td>
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<tr>
<td></td>
<td>• Day 5 (approximately 96 hours after day 1 dose)</td>
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<tr>
<td></td>
<td>• End of weeks 2, 4, 8, and 12 after transplantation</td>
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<tr>
<td></td>
<td>- Maintenance phase - 5 mg/kg IV</td>
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<tr>
<td></td>
<td>• End of week 16 after transplantation and every 4 weeks thereafter.</td>
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</tbody>
</table>

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0485</td>
<td>Injection, belatacept, 1 mg, 1</td>
</tr>
<tr>
<td></td>
<td>billable unit = 1 mg</td>
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</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>00003-0371-xx</td>
<td>Nulojix single use vial; 250 mg powder for solution</td>
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</table>

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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</thead>
<tbody>
<tr>
<td>Z29.1</td>
<td>Encounter for prophylactic immunotherapy</td>
</tr>
<tr>
<td>Z29.8</td>
<td>Encounter for other specified prophylactic measures</td>
</tr>
<tr>
<td>Z29.9</td>
<td>Encounter for prophylactic measures, unspecified</td>
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<tr>
<td>Z48.22</td>
<td>Encounter for aftercare following kidney transplant</td>
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<tr>
<td>Z48.288</td>
<td>Encounter for aftercare following multiple organ transplant</td>
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<tr>
<td>Z48.298</td>
<td>Encounter for aftercare following other organ transplant</td>
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<tr>
<td>Z94.0</td>
<td>Kidney transplant status</td>
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</tbody>
</table>

References