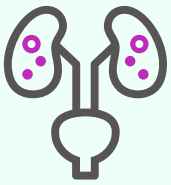
Nulojix® (belatacept)

Bristol Myers Squibb®
Access Support®

A REFERENCE GUIDE TO

Reimbursement and Coding NULOJIX® (belatacept)



NULOJIX® (belatacept)

Indication

NULOJIX (in combination with basiliximab induction, mycophenolate mofetil [MMF], and corticosteroids) is indicated for prophylaxis of organ rejection in adults receiving a kidney transplant.

- Use NULOJIX only in patients who are Epstein-Barr virus (EBV) seropositive.
- Use of NULOJIX for prophylaxis of organ rejection in transplanted organs other than kidney has not been established.

SELECT IMPORTANT SAFETY INFORMATION

- **NULOJIX is associated with increased risk for post-transplant lymphoproliferative disorder (PTLD), predominantly in the central nervous system (CNS)**
  - **NULOJIX is contraindicated in patients who are EBV seronegative or with unknown serostatus because the risk of PTLD is particularly increased in patients who are EBV seronegative**
  - **NULOJIX is to be used only in patients who are EBV seropositive**
  - Patients should be monitored for new or worsening neurological, cognitive, or behavioral signs and symptoms
  - Higher than recommended doses or more frequent dosing of NULOJIX and concomitant immunosuppressives is not recommended
- **Immunosuppression may result in increased susceptibility to infection and development of malignancies**
- **NULOJIX should be prescribed only by physicians experienced in immunosuppressive therapy and management of kidney transplant patients**
- **Use in liver transplant patients is not recommended due to an increased risk of graft loss and death**

Please see Important Safety Information on pages 12-13 and U.S. Full Prescribing Information, including **Boxed WARNINGS**.

Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-11-CM Code for NULOJIX® (belatacept)

- **ICD-11-CM** codes are used to identify a patient's diagnosis. On January 1, 2022, the newest version of these codes, ICD-11, was implemented throughout the United States. This version replaces the previous version, ICD-10-CM.
- The ICD-11-CM diagnosis codes contain **categories, subcategories,** and **codes**. Characters for categories, subcategories, and codes may be letters or numerals.
- **All categories** are 3 characters.
- **Subcategories** are either 4 or 5 characters.
- **Codes** may be 3, 4, 5, 6, or 7 characters.
- The ICD-11-CM code for the labeled indication for NULOJIX is provided below by Bristol Myers Squibb and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record.

For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**.

ICD-11-CM Code for NULOJIX[1]
Z94.0 Kidney transplant status

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Healthcare Common Procedure Coding System (HCPCS), Revenue, and Current Procedural Terminology (CPT)* Codes for NULOJIX® (belatacept)

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

The recommended HCPCS code for NULOJIX appears in the table below.

HCPCS Code[2]

HCPCS Code	Description	Billing Units
J0485	Injection, belatacept, 1 mg	1 mg = 1 billing unit

- Hospital outpatient: UB-04 (CMS-1450) [paper format] or ASC 837I (electronic format)
- **JW modifier**—Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records[3].
- **JZ modifier** – Starting no later than July 1, 2023, providers and suppliers are required to attest if there were no discarded amounts of drugs and biologicals[4].
- **JG modifier** – To be used by hospital outpatient to identify if the drug was obtained through 340B pricing. Note that use of this modifier will not trigger any differentiated payment[5].

All the coding information presented is applicable to outpatient procedures only. Please see pages 6-7 for more information.

The following revenue codes may be used in the hospital outpatient setting for NULOJIX.

Revenue Codes (for Use in the Hospital Outpatient Setting)[6]

Revenue Code	Description
0636	Drugs requiring detailed coding
0260	IV therapy

The CPT codes that may be appropriate when administering NULOJIX appear in the table below.

Recommended CPT Codes for NULOJIX[7]

CPT Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

Please contact the payer or BMS Access Support® for additional coding information regarding NULOJIX.

NDC Information, 5010 Electronic Transaction Coding & Storage for NULOJIX® (belatacept)

NDC Information

The National Drug Codes (NDCs) for NULOJIX, listed in the table below, are often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

NDC Code for NULOJIX[8]

One 250-mg vial, single use One 12-mL syringe	00003-0371-13	The red zero (red text) converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires the use of an 11-digit NDC.

5010 Electronic Transaction Coding[9]

- For electronic transactions, including 837P and 837I, the NDC is to be preceded by the qualifier N4 and followed immediately by the 11-digit NDC code for payers that require it.
- This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter), and the quantity administered.

5010 Transaction Coding for NULOJIX[9]

How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
One 250-mg vial, single use One 12-mL syringe	00003-0371-13	N4	MG	N400003037113MG250

The example given in the far right column demonstrates NDC quantity reporting for 1 vial of NULOJIX. The actual amount of drug used can vary based on factors such as indication or patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

How to store NULOJIX[8]

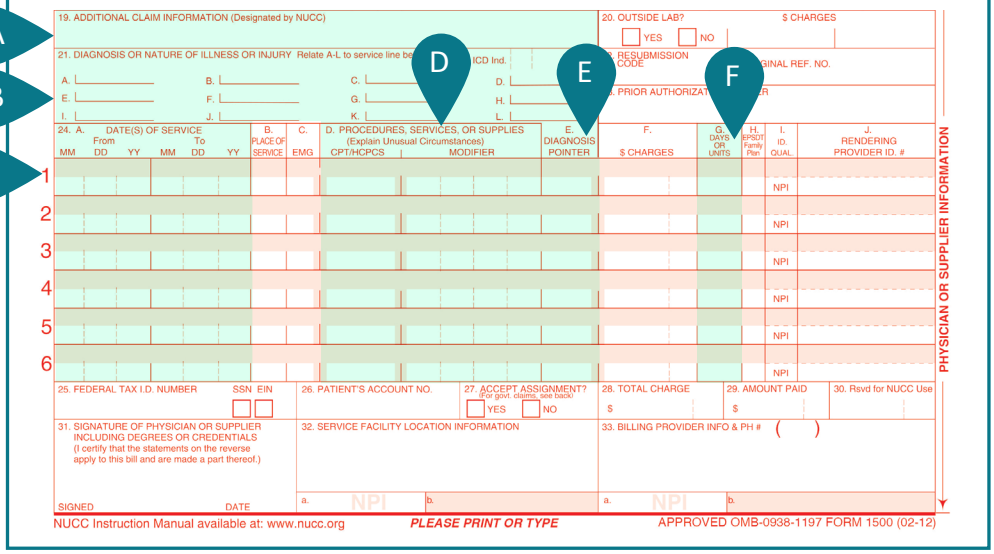
- NULOJIX lyophilized powder is stored refrigerated at 2°C to 8°C (36°F to 46°F). Protect NULOJIX from light by storing in the original package until time of use.
- The reconstituted solution should be transferred from the vial to the infusion bag or bottle immediately. The NULOJIX infusion must be completed within 24 hours of constitution of the NULOJIX lyophilized powder. If not used immediately, the infusion solution may be stored under refrigeration conditions: 2°C to 8°C (36°F to 46°F) and protected from light for up to 24 hours (a maximum of 4 hours of the total 24 hours can be at room temperature: 20°C to 25°C [68°F–77°F] and room light).

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Coding and Billing Units for NULOJIX® (belatacept)

Please contact the payer or BMS Access Support® for additional information on coding and billing units

CMS-1500 Form



This sample form is for informational purposes only.

Physician Office

A **Item 19:** Many payers require detailed information about the drug in Item 19[9]:
- Drug name: NULOJIX
- Total dosage and strength
- Method of administration
- 11-digit NDC
- Basis of measurement

B **Item 21:** Enter the site-specific ICD-11-CM code.[9]

C **Item 24A:** NDC information is required in the shaded area above the line on which a drug is reported in 24D.[9] N400003037113MG250[8].

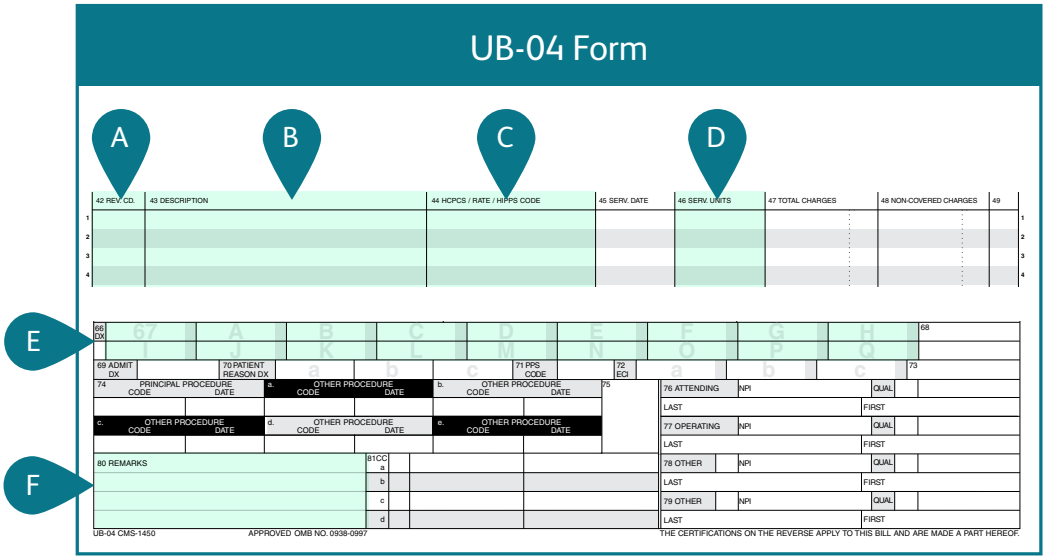
D **Item 24D:** Enter HCPCS code J0485 and CPT code 96413.[2,7,9] In addition, it is required that you enter J0485-JW on the next line to record waste[3]. If no wastage, enter J9299-JZ and J9228-JZ to attest there were no discarded amounts.[10]

E **Item 24E:** Enter the diagnosis code reference letter or number from Box 21 that relates to the date of service and the services or procedures performed that is entered on that same line under 24D[9].

F **Item 24G:**
- Billing units are reported here[9]
- For NULOJIX, 1 mg = 1 billing unit

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Coding and Billing Units for NULOJIX® (belatacept) (cont.)



This sample form is for informational purposes only.

Outpatient Hospital

A

Form Locator (FL) 42:

- Enter a 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.[10]
- For IV drug administration, code 0260 (IV therapy) could be used.[6]
- CMS recommends using revenue code 0636 (drugs requiring detailed coding).[6,11]

B

FL 43:

- Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.[10]
- Report the quantity qualifier (MG) followed by the quantity (250 mg/vial).[10] For example, use "N400003037113MG250" for the 250-mg vial[8].

C

FL 44:

- Enter HCPCS code J0485 and CPT code 96413.[7,9]
- In addition, it is required that you enter J0485-JW on the next line to record waste[3].

D

FL 46: Billing units are called service units and are placed here.[10]
1 mg = 1 billing unit

E

FLs 67A-67Q: Enter the site-specific ICD-10-CM diagnosis code for the condition being treated.[10]

F

FL 80: Some payers require detailed information about the drug in FL 80.[9,10]

- Drug name: NULOJIX
- Total dosage and strength
- Method of administration
- 11-digit NDC
- Basis of measurement

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Dosing for NULOJIX® (belatacept)

NULOJIX should be administered in combination with basiliximab induction, mycophenolate mofetil (MMF), and corticosteroids. In clinical trials the median (25th to 75th percentile) corticosteroid doses were tapered to approximately 15 mg (10 to 20 mg) per day by the first 6 weeks and remained at approximately 10 mg (5 to 10 mg) per day for the first 6 months post-transplant. Corticosteroid utilization should be consistent with the NULOJIX clinical trial experience.

Due to an increased risk of post-transplant lymphoproliferative disorder (PTLD) predominantly involving the central nervous system (CNS), progressive multifocal leukoencephalopathy (PML), and serious CNS infections, administration of higher than the recommended doses or more frequent dosing of NULOJIX is not recommended *[see Warnings and Precautions (5.1, 5.4, 5.5) and Adverse Reactions (6.1)]*.

NULOJIX is for intravenous infusion only. Patients do not require premedication prior to administration of NULOJIX.

- The total infusion dose of NULOJIX should be based on the actual body weight of the patient at the time of transplantation and should not be modified during the course of therapy unless there is a change in body weight of greater than 10%.
- The prescribed dose of NULOJIX must be evenly divisible by 12.5 mg in order for the dose to be prepared accurately using the reconstituted solution and the silicone-free disposable syringe provided. Evenly divisible increments are 0, 12.5, 25, 37.5, 50, 62.5, 75, 87.5, and 100.

For example[8]:

- A patient weighs 64 kg. The dose is 10 mg per kg.
- Calculated dose: 64 kg × 10 mg per kg = 640 mg.
- The closest doses evenly divisible by 12.5 mg below and above 640 mg are 637.5 mg and 650 mg.
- The nearest dose to 640 mg is 637.5 mg.
- Therefore, the actual prescribed dose for the patient should be 637.5 mg.

Dosing Recommendations in Adult De Novo Kidney Transplant Recipients[8]

Dosing for Initial Phase	Dose
Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose)	10 mg per kg
End of Week 2 and Week 4 after transplantation	10 mg per kg
End of Week 8 and Week 12 after transplantation	10 mg per kg
Dosing for Maintenance Phase	**Dose**
End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter	5 mg per kg

Medicare Drug Reimbursement for NULOJIX® (belatacept)

What is the Medicare reimbursement allowable for NULOJIX?

Physicians*

- The amount paid to physicians for HCPCS code J0485 is published at the beginning of each calendar quarter in "Payment Allowance Limits for Medicare Part B Drugs," which can be downloaded at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files.
- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents one billing unit of NULOJIX, which is billed for each 1 mg.[2,12†]
- Medicare Part B will pay physicians 80% of the allowed price for J0485; the patient is responsible for 20% co-insurance, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc).[13]

Hospital outpatient clinics*

- Drugs paid separately under the hospital outpatient fee schedule are based on 106% of ASP, not including sequestration, for one billing unit for the corresponding HCPCS code. This is 1 mg for J0485.[2,11†]
- The Payment Allowance Limits are published each quarter in the addendum B updates. These are available at: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files.

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called the MS-DRGs.[14,15] This prospective rate changes on October 1 each year and does not allow for drugs to be paid separately.[16,17]

*While the statutory amount that Medicare will reimburse for a Part B Drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[18]

†**See the Centers for Medicare & Medicaid Services' (CMS) Internet-Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.**

Commercial Insurance Reimbursement for NULOJIX® (belatacept)

Physicians

- Drug reimbursement, like service reimbursement, is usually based on a fee schedule.[19]
- The fee schedules are based on the ASP or AWP, as published by a credible source,[20,21] or an average costing methodology as determined by the payer, such as usual, customary, and reasonable (UC&R).[22]

Hospital outpatient facilities

- In this setting, reimbursement is most commonly based on percentage of charges.[21]
- Alternatively, some hospitals use the same ASP or AWP methodologies typically used by physician offices.[21]
- Other methodologies include capitated model, cost minus submitted charges, or discount off submitted charges.[21]

Hospital inpatient settings

- Inpatient rates are prospective, meaning they are predetermined per discharge.[14]
- There are private payers that pay on a version of the MS-DRGs.[15]
- There are also payers that pay on a negotiated and fixed rate per day called a "per diem."[15] There are capitated rates for inpatients as well.[14]
- New drugs may be carved out of per diems or capitated rates, if the hospital negotiates to do so.[23]

Distribution

NULOJIX may be purchased through the approved distributor listed below:

Physician Offices

Wholesaler	Phone Orders	Fax/Website
Besse Medical	1-888-711-5469 Monday–Friday, 7:00AM–11:00PM ET*	www.besse.com
Cardinal Health Specialty Pharmaceutical Distribution	1-877-453-3972 Monday–Friday, 7AM–6PM CT (24-hour emergency on call)	www.specialtyonline.cardinalhealth.com
CuraScript Specialty Distribution	1-877-599-7748 Monday–Friday, 8AM–7PM ET	www.curascriptsd.com
HyGen Specialty	1-877-630-9198 Monday–Friday, 8AM–4PM PT	www.hygenpharma.com
McKesson Specialty Health	1-800-482-6700 Monday–Friday, 7AM–7PM CT	www.mscs.mckesson.com
Morris & Dickson Specialty	1-800-710-6100 Monday–Friday, 8AM–6PM CT	Fax: 1-318-524-3096 www.mdspecialtydist.com

Hospitals and Infusion Centers

Wholesaler	Phone Orders	Fax/Website
ASD Healthcare	1-800-746-6273 Monday–Thursday, 7AM–6:30PM CT; Friday, 7AM–6PM CT	Fax: 1-800-547-9413 www.asdhealthcare.com
Besse Medical	1-888-711-5469 Monday-Friday, 7:00AM-11:00PM ET*	www.besse.com
BioCare SD	1-800-304-3064 24/7/365	www.store.biocaresd.com/biocare/en/USD/login
Cardinal Health Specialty Pharmaceutical Distribution	1-866-677-4844 Monday–Friday, 7AM–6PM CT (24-hour emergency)	Fax: 1-614-553-6301 www.orderexpress.cardinalhealth.com
DMS Pharmaceutical Group, Inc.	1-877-788-1100 Monday–Friday, 8:30AM–5PM CT	Fax: 1-847-518-1105 www.dmspharma.com
HyGen Specialty	1-877-630-9198 Monday–Friday, 8AM–4PM PT	www.hygenpharma.com
McKesson Plasma and Biologics	1-877-625-2566 Monday–Friday, 8AM–6:30PM CT	Fax: 1-888-752-7626 www.connect.mckesson.com
Morris & Dickson Specialty	1-800-710-6100 Monday–Friday, 8AM–6PM CT	Fax: 1-318-524-3096 www.mdspecialtydist.com

Optum Specialty Pharmacy

Wholesaler	Phone Orders	Website
Optum Specialty Distribution	1-855-427-4682 24/7/365	

Above information is accurate as of 07/24.

The NULOJIX distribution program includes extended payment terms to Bristol Myers Squibb authorized NULOJIX distributor. Healthcare providers and institutions should contact the NULOJIX distributor to understand specific payment terms that may be available to them.

Important Safety Information

Post-Transplant Lymphoproliferative Disorder (PTLD)

- **NULOJIX patients are at increased risk for developing PTLD, predominantly involving the central nervous system (CNS).**
- **Recipients without immunity to EBV (ie, seronegative) are at particularly increased risk; therefore, NULOJIX is contraindicated in transplant recipients who are EBV seronegative or with unknown serostatus.**
- Monitor for new or worsening neurological, cognitive, or behavioral signs and symptoms.
- As the total burden of immunosuppression is a risk factor for PTLD, higher than recommended doses or more frequent dosing of NULOJIX or concomitant immunosuppressive agents are not recommended.
- Other known risk factors for PTLD include cytomegalovirus (CMV) infection and T cell-depleting therapy.
  - CMV prophylaxis is recommended for at least 3 months after transplantation.
  - Use T cell-depleting therapy to treat acute rejection cautiously.
- Patients who are EBV seropositive and CMV seronegative may be at increased risk of PTLD.
  - Since CMV seronegative patients are at increased risk for CMV disease (a known risk factor for PTLD), the clinical significance of CMV serology for PTLD remains to be determined; however, these findings should be considered when prescribing NULOJIX.

Management of Immunosuppression

- **Only physicians experienced in immunosuppressive therapy and management of kidney transplant patients should prescribe NULOJIX.**
  - **Patients should be managed in facilities with adequate laboratory and supportive medical resources.**
  - **The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.**

Progressive Multifocal Leukoencephalopathy (PML)

- NULOJIX patients are at increased risk for PML, often a rapidly progressive and fatal opportunistic infection.
  - In clinical trials, two cases were reported in patients receiving NULOJIX at higher cumulative doses and more frequently than the recommended regimen, along with MMF and corticosteroids; one occurred in a kidney transplant recipient and one occurred in a liver transplant recipient.
- As PML has been associated with high levels of immunosuppression, higher than recommended doses or more frequent dosing of NULOJIX and concomitant immunosuppressive agents, including MMF, are not recommended.
- Monitor for new or worsening neurological, cognitive, or behavioral signs and symptoms.
  - PML is usually diagnosed by brain imaging, cerebrospinal fluid testing for JC viral DNA by polymerase chain reaction, and/or brain biopsy.
  - Consultation with a specialist should be considered.
  - If PML is diagnosed, consider reduction or withdrawal of immunosuppression, weighing risk to the allograft.

Other Malignancies and Serious Infections

- **Increased susceptibility to infection and possible development of malignancies may result from immunosuppression.**
- Patients should avoid prolonged exposure to ultraviolet light and sunlight.
- Patients receiving immunosuppressants, including NULOJIX, are at increased risk for bacterial, viral, fungal, and protozoal infections, including opportunistic infections and tuberculosis. Some infections were fatal.
  - Polyoma virus-associated nephropathy can lead to deteriorating renal function and graft loss; consider reduction in immunosuppression, weighing risk to the graft.

(continued on next page)

Important Safety Information (cont.)

Other Malignancies and Serious Infections (cont.)

– Tuberculosis was more frequently observed in patients receiving NULOJIX. Evaluate for tuberculosis and initiate treatment for latent infection prior to NULOJIX use.

– CMV and Pneumocystis jiroveci prophylaxis is recommended after transplantation.

Liver Transplant: use in liver transplant patients is not recommended due to increased risk of graft loss and death in a clinical trial with more frequent administration of NULOJIX than studied in kidney transplant, along with MMF and corticosteroids.

Acute Rejection and Graft Loss with Corticosteroid Minimization

- In NULOJIX postmarketing experience, corticosteroid minimization to 5 mg/day between Day 3 and Week 6 post-transplant was associated with an increased rate and grade of acute rejection, particularly Grade III.
  – These Grade III rejections occurred in patients with 4-6 human leukocyte antigen (HLA) mismatches.
  – Graft loss was a consequence of Grade III rejection in some patients.
- Corticosteroid utilization should be consistent with the NULOJIX clinical trial experience.
  – Median (25th-75th percentile) corticosteroid doses were tapered to about 15 mg (10-20 mg)/day by the first 6 weeks and remained at about 10 mg (5-10 mg)/day for the first 6 months post-transplant.

Immunizations: avoid use of live vaccines during NULOJIX treatment.

Coadministration with Anti-Thymocyte Globulin: in de novo kidney transplant recipients, especially those with other predisposing risk factors for venous thrombosis of the renal allograft, coadministration (at the same or nearly the same time) with anti-thymocyte globulin may pose a risk for venous thrombosis of the renal allograft. If anti-thymocyte globulin (or any other cell-depleting induction treatment) and NULOJIX will be administered concomitantly, a 12-hour interval between the two administrations is suggested.

Risk of Rejection with Conversion From a Calcineurin Inhibitor (CNI) Based Maintenance Regimen: conversion of patients from a CNI based maintenance regimen increases the risk of acute rejection. Conversion of stable kidney transplant recipients from a CNI based maintenance regimen to a NULOJIX based maintenance regimen is not recommended unless the patient is CNI intolerant.

Pregnancy: the data with NULOJIX use in pregnant women are insufficient to inform on drug-associated risk. NULOJIX is known to cross the placenta of animals. To monitor maternal-fetal outcomes of pregnant women who have received NULOJIX, or whose partners have received NULOJIX, healthcare providers are strongly encouraged to register pregnant patients in the Transplant Pregnancy Registry International (TPR) by calling 1-877-955-6877.

Lactation: there are no data on the presence of NULOJIX in human milk or the effects on breastfed infants or human milk production to inform risk of NULOJIX to an infant during lactation. NULOJIX is excreted in rat milk and it is possible that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NULOJIX, and any potential adverse effects on the breast fed child from NULOJIX or from the underlying maternal conditions.

Most Common Adverse Reactions (≥20%) through 3 years: anemia (45%), diarrhea (39%), urinary tract infection (37%), peripheral edema (34%), constipation (33%), hypertension (32%), pyrexia (28%), graft dysfunction (25%), cough (24%), nausea (24%), vomiting (22%), headache (21%), hypokalemia (21%), hyperkalemia (20%), and leukopenia (20%). No new adverse reactions were observed in the long-term extension (years 4-7) studies.

Looking for support? We're here for you.

Patient access support, reimbursement resources, and financial support options may be available through **BMS Access Support®**

Call a Patient Access Specialist at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday

Visit **www.BMSAccessSupport.com**

Schedule a meeting with a BMS Access and Reimbursement Manager on the BMS Access Support website

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