Bristol-Myers Squibb

CONFIDENTIAL

December 4, 2017

RE: Manufacturing related supply constraint update

Dear Doctor,

This letter is being sent to update you on the manufacturing related supply constraints for NULOJIX® (belatacept).

Bristol-Myers Squibb (BMS) began limiting distribution of commercially available NULOJIX to existing patients, as of March 15, 2017, to maintain adequate supplies to existing patients during the transition to a new manufacturing process.

BMS has continued to experience delays in the transition to the new manufacturing process and therefore will continue to limit NULOJIX distribution to patients currently receiving therapy. BMS is committed to maintaining supply for patients currently treated with NULOJIX. BMS will reassess the need to continue this restriction in early third quarter 2018 when additional information about the new manufacturing process is expected, and will provide an update at that time.

Patients with an urgent medical need for NULOJIX who have exhausted all other options may be permitted to start NULOJIX as a new patient dependent on available supply. In these circumstances, prescribers can enroll their patients into the NULOJIX Distribution Program (NDP) by calling 1-855-511-6180 from 8 AM to 8 PM ET, Monday through Friday (except holidays) and completing the necessary enrollment forms. A unique patient identification number from the NDP will continue to be required to order NULOJIX for new and existing patients.

Sincerely,

Thomas Lehman, PharmD
US Medical Lead Nulojix
Bristol-Myers Squibb

Kellie Calderon, M.D.
Director, HQ Medical Immunoscience
Bristol-Myers Squibb

FORM 1

Nulojix Distribution Program

Phone: 855-511-6180 • **Fax:** 855-782-1233
Hours of Operation: Mon. – Fri. 8 am – 8 pm (Eastern Time)

Thank you for taking the time to complete this Nulojix Distribution Program Registration Form. All fields are required unless indicated with *optional*. Once the form is completed, please fax to: (855) 782-1233. If you have any questions, please contact the Nulojix Distribution Program at (855) 511-6180.

The program was developed to ensure continued access to Nulojix for existing patients. Once your patient has been admitted into the program, you will be provided a unique identification number for each patient. A unique patient identification number will be required to order Nulojix for a patient. The distributor will request this information.

PATIENT INFORMATION		
First Name:	Last Name:	
Address:		
City:	State:	Zip Code:
Phone Number: ( )	Date of Birth (mm/dd/yyyy):	

PATIENT REPRESENTATIVE INFORMATION ***(to be completed only if patient has a patient representative)***	
First Name:	Last Name:
Phone Number: ( )	Relationship to Patient:

PRESCRIBER INFORMATION		
First Name:	Last Name:	
Facility Name:	NPI Number:	
Address:		
City:	State:	Zip Code:
Phone Number: ( )	Fax Number: ( )	

INFUSING HEALTHCARE PROVIDER INFORMATION (*to be completed if different from above*)		
First Name:	Last Name:	
Facility Name:	NPI Number:	
Address:		
City:	State:	Zip Code:
Phone Number: ( )	Fax Number: ( )	

TREATMENT INFORMATION

Please indicate the therapy status: ☐ New to Therapy* ☐ Existing Patient on Therapy

When did the patient start on therapy (mm/dd/yyyy): *(optional)* ____/____/____

If you have a patient new to therapy with an urgent medical need for Nulojix, please complete Forms 1, 2, and 3. Patients new to therapy with an urgent medical need will be permitted to register into the Nulojix Distribution Program, but will be admitted as a new patient only if supply constraints allow.

I certify to the following: (1) To the best of my knowledge, the patient and healthcare provider information in this form is complete and accurate; (2) I have the authority to disclose this patient's information to Bristol-Myers Squibb and its respective agents and assignees, and I have obtained this patient's authorization for the disclosure, if required by HIPAA or other applicable privacy laws; and (3) I have determined based on my professional judgment that the Nulojix medication prescribed is medically necessary. If I am not the prescriber, I have consulted with prescriber to determine that the Nulojix medication is medically necessary. I will contact Nulojix Distribution Program at 855-511-6180 if the treatment for my patient changes in any way. I understand that the Nulojix Distribution Program may be discontinued or the rules for participation may change at any time, without notice.

Healthcare Provider Signature:	***Date:***

FORM 2

Nulojix Distribution Program

Phone: 855-511-6180 • **Fax:** 855-782-1233
Hours of Operation: Mon. – Fri. 8 am – 8 pm (Eastern Time)

Thank you for taking the time to complete this Nulojix Distribution Program Patient Authorization and Agreement form. All fields are required unless indicated as optional. Once the form is completed, please fax to: (855) 782-1233. If you have any questions, please contact the Nulojix Distribution Program at (855) 511-6180.
The Nulojix Distribution program was developed to ensure continued access to Nulojix for current patients. Your healthcare provider will be required to use a unique patient identification number to order Nulojix on your behalf.

PATIENT AUTHORIZATION and AGREEMENT

The Nulojix Distribution Program is a registration program by Bristol-Myers Squibb (BMS) that will manage the allocation of Nulojix to new and current users.
To participate in the Nulojix Distribution Program, the Program will need to receive, use, and disclose your personal information. Please read this authorization carefully, and contact Nulojix Distribution Program at 1-855-511-6180 if you have any questions. Once you have read and agreed to this form, fax your signed copy to 1-855-782-1233.

What information will be used and disclosed?
Information on the Nulojix Distribution Program Enrollment form, which includes:
• Patient Information • Healthcare Provider Information • Treatment Information

Who will disclose, receive, and use the information?
This authorization permits my caretakers, which includes my healthcare providers who provide services to me, as well as other people that I say can help me apply, to disclose my personal information to BMS, and its authorized agents and assignees ("Administrators") and distributors of Nulojix. BMS and its Administrators may also share my information with my caretakers as well as distributors of Nulojix. Your information will not be used for marketing purposes.

What is the purpose for the use and disclosure?
My personal information will be used by and shared with the persons and organizations described in this authorization in order to: • Process my application for the Nulojix Distribution Program • Provide the Nulojix Distribution Program services to me • Contact my caretakers and me about the programs and the services that are available • Improve or develop the programs' services.

When will this authorization expire?
This authorization will be effective for 5 years unless it expires earlier by law or I cancel it in writing. I may cancel this authorization by writing to: Nulojix Distribution Program
P.O. Box 29052
Phoenix, AZ 85038-9052
If I cancel this authorization, I will no longer be able to participate in the program. The program will stop using or disclosing my information for the purposes listed in this authorization, except as necessary to end my participation or as required or allowed by law.

Notices
I understand that once my health information has been disclosed, privacy laws may no longer restrict its use or disclosure. BMS and its Administrators agree to use and disclose my information only for the purposes described in this authorization or as allowed or required by law. I further understand that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits and treatment by my healthcare providers will not change, but my healthcare provider may not be able to order product through the Nulojix Distribution Program. I have a right to receive a copy of this authorization after I have signed it.

Patient Certifications
I certify that the personal information that I provide to the Nulojix Distribution Program is true and complete. I agree that, at any time during my participation in the program, the program may request additional documentation to verify my personal information. If there is missing information or I do not respond to requests for additional documents, my participation may be delayed or I may no longer be able to participate. I understand that I have to qualify for the program in order for my healthcare provider to be eligible to order Nulojix and that acceptance is based on supply. I understand that the Nulojix Distribution Program may be discontinued or the rules for participation may change at any time, without notice.

Print Patient or Patient Representative Name:	***Date of Birth:***
Patient or Patient Representative Signature:	***Date:***

FORM 3

Nulojix Distribution Program
Phone: 855-511-6180 • **Fax:** 855-782-1233
Hours of Operation: Mon. – Fri. 8 am – 8 pm (Eastern Time)

Prescribing Physician Certification Form
NULOJIX Urgent Medical Need for New Patient in the United States

The Nulojix Distribution Program was developed to ensure continued access to Nulojix for existing patients. Bristol-Myers Squibb (BMS) recognizes that there may be exceptional circumstances where an individual patient may have an urgent medical need to start NULOJIX before resolution of the current shortage. In these cases, if a patient has an urgent medical need and has exhausted all other therapeutic options, please complete this form to enroll the patient in the NULOJIX Distribution Program. ***Patients new to therapy with an urgent medical need will be permitted to register into the Nulojix Distribution Program, but will be admitted as a new patient only if supply constraints allow.***

- I understand that there is a shortage of NULOJIX and that Bristol-Myers Squibb has limited the use of NULOJIX to existing patients.
- I certify that the patient of mine has an urgent medical need to immediately start NULOJIX despite the shortage and that all other therapeutic options have been exhausted.
- I understand that the patient is classified as new and I recognize the risks of starting new patients on NULOJIX despite the shortage which include, but are not limited to, lack of NULOJIX supply prohibiting future patients with an urgent medical need from receiving NULOJIX.

PRINT Patient Name: _____

Prescribing Physician Signature:_____

PRINT Prescribing Physicians Name:_____

PRINT Transplant Center Name (or Physician address):_____

Physician Phone Number:_____