

UPLIZNA® (inebilizumab-cdon) PATIENT ENROLLMENT FORM



Once complete, submit pages 1-4 by fax 1-833-329-8477 or email UPLIZNAABYS@amgen.com

Complete all required fields, including prescriber's signature and date, to initiate patient enrollment process. For support and/or assistance obtaining patient signature, call Amgen By Your Side at 1-833-842-8477. (X Indicates a required field)

USA-335-81798

PATIENT INFORMATION

First name Last name

Gender: Male Female Date of birth: ___ / ___ / ___
(MM/DD/YYYY)

Email address Primary language

Primary Primary

Mobile phone Home phone

Address

City State ZIP code

Alternate contact name Alternate contact phone

DIAGNOSIS

Diagnosis:* G70.00 Myasthenia gravis without (acute) exacerbation
Required for processing G70.01 Myasthenia gravis with (acute) exacerbation
G36.0 - Neuromyelitis optica [Devic]

Date of diagnosis: ___ / ___ / ___ (MM/DD/YYYY)

gMG ONLY Has the patient ever tested positive for AChR antibodies? Yes No

gMG ONLY Has the patient ever tested positive for MuSK antibodies? Yes No

NMOSD ONLY Has the patient ever tested positive for AQP4 antibodies? Yes No

gMG ONLY MG-ADL score ___ MGFA clinical classification (I, II, III, IV, V) ___

Check all previous NMOSD/gMG therapies:

Azathioprine	Nipocalimab	Satralizumab
Eculizumab	Pyridostigmine	Steroid
Efgartigimod	Ravulizumab	Tocilizumab
Efgartigimod plus hyaluronidase	Riabni	Truxima
Methotrexate	Rituxan	Zilucoplan
Mycophenolate mofetil	Ruxience	None/new diagnosis
Other: _____		

INSURANCE INFORMATION (Please include front and back copies of insurance card(s) with this form)

Primary insurance Secondary insurance

Policy # Policy #

Policyholder's first and last name Policyholder's first and last name

Insurance company phone Insurance company phone

Group # Group #

Policyholder's Date of birth: ___ / ___ / ___
(MM/DD/YYYY) Policyholder's Date of birth: ___ / ___ / ___
(MM/DD/YYYY)

Patient is uninsured to my knowledge.

PRESCRIBER INFORMATION

First name Last name

Address

City State ZIP code

NPI # State license # Tax ID #

Clinic/hospital affiliation

Office contact name

Office contact phone Fax number

Office contact email address

Preferred communication: Phone Email

Prescriber specialty

PREFERRED INFUSION FACILITY

If none, Amgen By Your Side can provide options.

The infusion facility is the same as the prescribing office

Facility name

Address

City State ZIP code

Phone Fax number

Facility NPI # Tax ID #

Complete signatures and prescription information on next page



You must read the Consent to Health Data Processing on page 4 and then select one of the below responses.

Select “I consent” to proceed with enrollment. If you select “I do not consent,” you will not be able to enroll in Amgen By Your Side



I consent to the collection, processing, and disclosure of my Health Data for the purposes set forth on page 4.

I do not consent to the collection, processing, or disclosure of my Health Data for the purposes set forth on page 4.

By signing below, I am indicating that I have read and understood the Authorization for Use and Disclosure of Protected Health Information (pages 3-4), that I am legally authorized to consent, and that I am providing my consent as the patient or the patient’s legal representative for Amgen and its contractors and business partners to use and share the personal information I provide for the purposes described within the Authorization for Use and Disclosure of Protected Health Information.

X

Patient name

Name of Legal Representative (if needed)



X

Signature of Patient (or Legal Representative)

X

____ / ____ / ____
Date of signature (MM/DD/YYYY)

PRESCRIPTION (Required)

X

Patient first name

X

Patient last name

X

____ / ____ / ____
Date of Birth (MM/DD/YYYY)

Prescription Information: UPLIZNA® (inebilizumab-cdon)

X ICD-10 code:

G70.00 Myasthenia gravis without (acute) exacerbation
G70.01 Myasthenia gravis with (acute) exacerbation
G36.0 - Neuromyelitis optica [Devic]

Allergies: _____

No known drug allergies (NKDA)

NDC: 75987-150-03: One carton containing three 100 mg/10 mL vials

Dose: 300 mg per IV infusion

Target infusion date: ____ / ____ / ____
(MM/DD/YYYY)

Initial Rx: 300 mg IV infusion over 90 minutes at Day 1 and 2 weeks later

Maintenance Rx: 300 mg IV infusion over 90 minutes every 6 months

Refill: _____ times

NMOSD-ONLY Patient is Medically Urgent: A Medically Urgent patient is a patient who (1) is at immediate risk of permanent disability from either an NMOSD medical crisis or potential attack; (2) is not on an NMOSD maintenance therapy OR has experienced new NMOSD-related disease activity while on current maintenance therapy OR is unable to tolerate current maintenance therapy and (3) requires treatment with UPLIZNA while insurance coverage for UPLIZNA is actively being pursued. I certify that the patient meets the definition of Medically Urgent above.

Administration instructions: Dilute 300 mg (30 mL) in 250 mL 0.9% Sodium Chloride Injection and administer diluted infusion over approximately 90 minutes at an increasing rate: 42 mL/hour for first 30 minutes, followed by 125 mL/hour for the next 30 minutes, then 333 mL/hour until completion.

State requirements: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to the prescriber.

Signature below indicates prescription authorization and prescriber certification.



X

Prescriber signature/Dispense as written

Written or e-signature only; stamps not acceptable.

Prescriber signature (substitutions allowed)

X

____ / ____ / ____
Date (MM/DD/YYYY)

Prescriber Certification: I certify that the above therapy is medically necessary, that the information provided is accurate to the best of my knowledge and that my patient is being administered UPLIZNA® (inebilizumab-cdon) injection, 300 mg, for intravenous infusion in accordance with the labeled use of the product. I represent that my patient has requested and authorized the disclosure of their personal information to Amgen Inc. and its affiliates and their respective employees or agents (collectively, “Amgen”) for Amgen to administer the Amgen By Your Side program (the “Program”), which provides patient-focused support, including providing logistical and non-medical treatment support for UPLIZNA, as prescribed, and educating about the insurance process. I further represent that I have explained to the patient, and the patient indicated they understand and have consented to, the following: 1) Amgen will use the patient’s name, date of birth, contact information, prescriptions, and other necessary health information to administer the Program; 2) Amgen will then disclose the patient’s personal information to the patient’s insurer(s) for the same purposes; 3) the patient can withdraw their consent by contacting Amgen at 1-844-469-4297 or visiting www.amgen.com/DataSubjectRights, but if the patient does not agree to, or withdraws consent for, these uses and disclosures, the patient cannot receive these patient support services for this medication which necessarily requires Amgen to process the patient’s personal information; and 4) the patient can view more details about Amgen’s privacy practice at www.amgen.com/privacy. I authorize Amgen to transmit this prescription on my behalf to the appropriate pharmacy designated by the patient utilizing their benefit plan by any means allowed under applicable law. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use UPLIZNA or any other Amgen product or service, for any other person; (b) my decision to prescribe UPLIZNA was based solely on my professional determination of medical necessity; and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Amgen may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Amgen makes no representation or guarantee concerning coverage or reimbursement for any item or service. On behalf of the patient, Amgen expects the prescriber to coordinate with Amgen By Your Side to provide, to the best of the prescriber’s ability, in-network infusion services and work with Amgen By Your Side to effectively communicate both in-network and out-of-network choices and the corresponding financial obligations of the patient connected to each choice. Should the prescriber knowingly perform out-of-network services without the knowledge and consent of the patient, the prescriber cannot balance bill the patient for the out-of-network services. State requirements: I certify that the prescription I am submitting as part of this Patient Enrollment Form complies with my state’s prescription requirements (e.g., e-prescribing, state-specific prescription form, fax language). I understand that noncompliance with my state’s specific prescription requirements will result in outreach to me to obtain a compliant prescription.

By filling out and signing this form, the enrollment process in Amgen By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Amgen By Your Side. Please note that your patient will not benefit from the services and support offered by the Program unless your patient signs a Patient Authorization, consenting to receiving such services. If your patient does not sign the Patient Authorization contained within this form, Amgen will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

Medically Urgent Attestation

If I have checked the “Patient is Medically Urgent” box, I understand and agree that (a) my determination that the patient is Medically Urgent is based solely on my professional medical judgment; (b) Amgen will provide UPLIZNA at no cost to the patient, up to limits as set by Amgen; (c) I am actively pursuing insurance coverage for UPLIZNA for the patient, which is a requirement for the patient to be eligible to receive UPLIZNA at no cost; (d) I will not seek reimbursement, including from any government program, insurer, or the patient, for UPLIZNA provided by Amgen at no cost to the patient; and (e) Amgen may modify or terminate Medically Urgent supply at any time without notice.

Uses and Disclosure of Protected Health Information

I authorize Amgen and its data processors (collectively, “Amgen”) to collect, use, and disclose my protected health information for the following purposes:

- To operate, administer, enroll me in, and/or continue my participation in the Amgen By Your Side program or any other Amgen-affiliated patient support services and activities related to my condition or treatment (for example, co-pay card programs, reimbursement assistance programs, drug coverage verification, patient access liaison services, adherence program and disease management support);
- To contact, with my permission, my doctor and the rest of my health care team and share with them my health information that may be useful for my care;
- To improve, develop, and evaluate Amgen’s products, services, materials and programs related to my condition or treatment.

In order for Amgen to provide me with the services and/or programs described above, Amgen needs to collect and use my personal information, including my protected health information. I understand that my protected health information may include any information, in electronic or physical form, in the possession of or derived from a health care provider, health care plan, pharmacy, pharmaceutical company, laboratory and/or their contractor (each, a “Health Care Provider”). This may include select information from or about my medical history and general health, my health care plan benefits, payment limits or restrictions covered by my health care plan policy, and/or my adherence to my treatment.

I authorize my Health Care Providers to disclose my protected health information to Amgen, and between themselves, as necessary, but only for the purposes stated above in this Authorization. I understand that certain of my Health Care Providers (such as pharmacies and specialty pharmacies) may receive remuneration from Amgen in exchange for disclosing my protected health information and/or for using my information to contact me with communications about Amgen products which have been prescribed to me (for example, medication reminder programs and other patient support services).

Expiration, Right to Obtain a Copy, and Right to Cancel

I understand that by signing this form, I authorize my Health Care Providers or others who might hold my health information to disclose it to Amgen. I also understand I am authorizing my personal information, including my protected health information, to be used for the purposes described above. I understand and agree that by signing below, I am authorizing those who rely on this Authorization to disclose my protected health information for the earlier of five (5) years or until my participation in the Amgen By Your Side program ends through my cancellation, unless a shorter time period is required by state law.

I understand that I can obtain a copy of this Authorization or cancel this Authorization at any time by calling Amgen at 1-844-469-4297 or by writing to Amgen By Your Side, 1 Horizon Way, Deerfield, IL 60015. If I cancel this Authorization, I will no longer qualify for the services described. I also understand that if a Health Care Provider is disclosing my protected health information to Amgen in reliance on this Authorization on an on-going basis, my cancellation with Amgen will be effective with respect to any such Health Care Providers as soon as they receive notice of my cancellation.

No Effect on Treatment

I understand I do not have to sign this Authorization and that my enrollment in any of the services

AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION, CONTINUED

Please read and provide signature in Patient Consent and Authorization section on page 2

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and/or programs described above is entirely voluntary. I understand that Amgen, as well as Health Care Providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment or other care, to sign this Authorization. Federal Law (including HIPAA) requires a signed authorization in order for Amgen to collect my protected health information from my Health Care Providers. I understand I cannot participate in the listed services and/or programs without signing this Authorization or an equivalent authorization with my Health Care Providers.

Information Received from Health Care Providers

I understand that once my protected health information has been disclosed to Amgen, federal privacy laws may no longer apply and may no longer protect it from further disclosure, and that Amgen may disclose my protected health information to its data processors, contractors, and business partners for its business purposes. Amgen agrees, however, to protect my protected health information by only using and disclosing it as stated in the Authorization or as otherwise allowed or required by law.

U.S. STATE LAW CONSENT TO PROCESS HEALTH DATA FOR AMGEN BY YOUR SIDE

Please read and provide response in Patient Consent and Authorization section on page 2

I consent to Amgen processing my Health Data for the following purposes:

- To enroll me and manage my participation in the Amgen By Your Side program, which includes activities related to my condition or treatment (for example, co-pay card programs, payer medication coverage verification, patient access liaison support, disease management support), and to manage Amgen's products, services, and programs related to my condition or treatment.

Amgen uses the following when it administers the Amgen By Your Side program:

- Health Data – my name (and the name of my caregiver if applicable), gender, date of birth, contact information and information relating to my health condition or treatment.

I understand that my consent to processing is required for me to participate in the Amgen By Your Side program. I also understand that Amgen will not sell my Health Data to third parties, but Amgen may disclose my Health Data to Amgen's data processors, contractors, and business partners for Amgen's business purposes related to the Amgen By Your Side program. I understand that Amgen may use my Health Data to contact me by mail, email, telephone, or text for the above purposes. Mobile Terms & Conditions can be found at AmgenByYourSide.com/mobile-terms-and-conditions. I also understand that if I do not consent to the use of my Health Data for the above purposes, I will not be able to participate in the Amgen By Your Side program. Finally, I understand that I may withdraw my consent to processing my Health Data for the above purposes at any time using one of the methods listed in the Additional Disclosures section below and that if I withdraw my consent, I will no longer be able to participate in the Amgen By Your Side program.

Additional Disclosures

I understand that participation in the Amgen By Your Side program is an optional service at no cost to me. The consent above in no way affects my right to obtain any medications and I do not have to provide consent to be able to receive any medications. To obtain a copy of the consent above or to withdraw my consent to collection, processing, and/or disclosure of my Health Data for any of the above purposes to which I have consented, I can contact Amgen by visiting www.amgen.com/DataSubjectRights or calling 1-844-469-4297. For more information about Amgen's privacy practices, Amgen's Privacy Statement can be found at <http://www.amgen.com/privacy>



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PATIENT INFORMATION

Patient Name: _____ Sex: _____ DOB: _____
Address: _____ City: _____ State: _____ Zip: _____
Phone: _____ Alt. Phone: _____ Height: _____ Weight: _____ kg
Allergies: _____ No Known Drug Allergies
Emergency Contact: _____ Emergency Contact Phone: _____
Alternate Contact: _____ Alternate Contact Phone: _____
Patient Status: New to therapy Continuing therapy Therapy change Last Infusion Date (if applicable): _____
Is the patient pregnant, nursing or planning a pregnancy? Yes No Does the patient need interpreter services? Yes No

PRESCRIBER INFORMATION

Referral Co. Name: _____ Referral Co. Phone: _____
Referral Co. Email: _____ Practice Name: _____
Prescriber's Name: _____ Address: _____
NPI: _____ Tax ID: _____ Phone: _____ Fax: _____

PREFERRED PURE INFUSION LOCATION

City, State: _____

REQUIRED DOCUMENTATION (submit copies of the following with this order form)

Insurance card (front & back) Current Medications History/Progress Notes to Support Diagnosis

LAB ORDERS

Required pre-treatment labs to be completed prior to infusion/injection. If lab results are unavailable or outside required timeframes, Pure may obtain required labs.

Other: _____

If patient has port, please complete port order form.

DIAGNOSIS (ICD-10 Codes)

D89.84 IgG4-related disease G70.00 Myasthenia gravis without (acute) exacerbation
 G36.0 Neuromyelitis Optica Spectrum Disorder G70.01 Myasthenia gravis with (acute) exacerbation
 Other: _____

MEDICATION ORDER**DOSE/DIRECTIONS FOR USE**

Uplizna® (inebilizumab-cdon) 300mg IV day 1 and day 15 then every 6 months
 300mg IV every 6 months

Duration: 1 year of treatment unless indicated otherwise

PRE-MEDICATIONS

acetaminophen (Tylenol) 500 mg PO 650 mg PO 1000 mg PO
 diphenhydramine (Benadryl) 25 mg 50 mg PO IV
 cetirizine (Zyrtec) 10 mg PO OR loratadine (Claritin) 10 mg PO
 methylprednisolone (Solu-Medrol) 40 mg IV 125 mg IV OR hydrocortisone (Solu-Cortef) 100 mg IV
 Other: _____ No pre-medications

PATIENT INFORMATION

Patient Name: _____ DOB: _____

INFUSION REACTION PROTOCOL

 [Pure Infusion Reaction Protocol](#) Other Reaction Protocol (please send with order)_____
Prescriber's Signature_____
Date_____
Time