

# IgG4-RD Patient Enrollment Form Guide

The Patient Enrollment Form (PEF) must be completely filled out in order to get your patients started on UPLIZNA and initiate their enrollment in Amgen By Your Side, a patient support program. This guide is designed to help you understand the different fields on the form and how to complete the form accurately for submission.

## Three easy steps to initiate the patient enrollment process for UPLIZNA:



Fill out all required fields on pages 1 and 2 as indicated by the **X**, including the prescriber signature and date within the Prescriber section



Obtain the patient consent (“I Consent” check box), patient signature and date within the Patient Consent and Authorization section at the top of page 2, if possible



Send both the front and back of the patient’s insurance card(s) along with all 4 pages of the PEF

### Three ways to submit the Patient Enrollment Form:

Via DocuSign® at [UPLIZNARx.com/ig](https://UPLIZNARx.com/ig)  
Email: [UPLIZNAABYS@amgen.com](mailto:UPLIZNAABYS@amgen.com)  
Fax: 1-833-329-8477

## INDICATION

UPLIZNA® is indicated for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

**Please see additional Important Safety Information throughout.**

**If you have any questions while completing the form, please contact Amgen By Your Side at 1-833-842-8477.**

**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-335-80294

**1 PATIENT INFORMATION**

X Jane First name X Brown Last name  
 X Gender:  Male  Female X Date of birth: 01 / 01 / 1978 (MM/DD/YYYY)  
 X janebrown@email.com English Primary language  
 X 555-123-1234 Mobile phone  Primary  Home phone  
 X 123 Main Street Address  
 X Lake Forest City X IL State X 60045 Zip code  
 John Brown Alternate contact name 555-123-2345 Alternate contact phone

**2 DIAGNOSIS (required for benefits investigation.)**

X Diagnosis:  D89B4 - IgG4-RD  
 X Date of diagnosis: 01 / 01 / 2021 (MM/DD/YYYY)  
 Check all previous IgG4-RD therapies:  
 None/new diagnosis/treatment naive  
 Steroid  Rituxan  Ruxience  Truxima  
 Ritabri  Immunosuppressant therapies (e.g., azathioprine, mycophenolate, etc.)  
 Other: \_\_\_\_\_

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

X Insurance Provider One Primary insurance Insurance Provider Two Secondary insurance  
 X 000-000000-01 Policy # 000-000000-02 Policy #  
 X Jane Brown Policyholder's first and last name Jane Brown Policyholder's first and last name  
 X 555-123-5555 Insurance company phone 555-123-1111 Insurance company phone  
 X 000001 Group # 000002 Group #  
 Policyholder's Date of birth: X 01 / 01 / 1978 (MM/DD/YYYY) Policyholder's Date of birth: 01 / 01 / 1978 (MM/DD/YYYY)  
 Patient is uninsured to my knowledge.

**4 PRESCRIBER INFORMATION**

X Sarah First name X Williams Last name  
 X 123 Medical Way Address  
 X Lake Forest City X IL State X 60045 Zip code  
 X 0000000000 NPI # X 00-0000000 State license # X 000000 Tax ID #  
 Memorial Hospital Clinic/hospital affiliation  
 X Sam Davis Office contact name  
 X 555-123-2222 Office contact phone X 555-123-9999 Fax number  
 X dsarahwilliams@memorialhospital.com Office contact email address  
 Preferred communication:  Phone  Email  
 Rheumatology Prescriber specialty

**5 PREFERRED INFUSION FACILITY** (Phone, Amgen By Your Side can provide options.)  
 The infusion facility is the same as the prescribing office

Infusion Center Facility name  
 123 Facility Drive Address  
 Chicago City IL State 60601 Zip code  
 555-123-1112 Phone 555-123-1113 Fax number  
 0000000009 Facility NPI # 00-0000000807 Tax ID #

Complete signatures and prescription information on next page >>

Page 1 of 4 USA-335-80294

## 1 Patient Information

Provide the patient demographic and contact information; only one patient phone number required, mobile OR home

- Required fields are needed to conduct a benefits investigation, contact the patient for any follow-up, and provide support from Amgen By Your Side
- Alternate contact information is optional
  - It may help to include a caregiver's contact information

## 2 Diagnosis

Confirm the diagnosis code by filling in the circle next to "Diagnosis" (required to conduct a benefits investigation)

- Include date of diagnosis
- Fill in the circles next to any previous IgG4-RD therapies that the patient has received

## 3 Insurance Information

Provide the patient's primary insurance information (required to conduct a benefits investigation). Results will be delivered after the patient authorization is received

(Continued)

- Include secondary insurance plan information, if applicable, to improve the accuracy of the benefits investigation
- If the patient does not have any insurance, fill in the circle next to "Patient is uninsured to my knowledge"
  - Please include the front and back of your patient's insurance card(s), if available, along with the completed Patient Enrollment Form

## 4 Prescriber Information

Provide the prescriber name, contact information, NPI, Tax ID, and state license numbers, which are required for processing

- Include the office contact name to ensure proper follow-up, as well as contact information to streamline communication

## 5 Preferred infusion facility

If you have a preference for the infusion facility where your patient will receive UPLIZNA, complete this section

- If you do not have a preference, Amgen By Your Side will provide options based on the patient's insurance and proximity to the patient

**Disclaimer:** The information provided on this form is for demonstration purposes only and does not represent any real person.

### IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS

**Infusion Reactions:** Can cause infusion reactions, including anaphylaxis. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions of UPLIZNA were observed in 7.4% of IgG4-RD patients during the RCP. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions.

Administer pre-medication with a corticosteroid, an antihistamine, and an antipyretic. For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Please see additional Important Safety Information throughout.

**6 PATIENT CONSENT AND AUTHORIZATION** (required—please see language on pages 3-4) USA-335-80294

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 understand 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 Jane Brown Patient name Name of Legal Representative (if needed)  
X Jane Brown Signature of Patient (or Legal Representative) 01 / 07 / 2025 Date (MM/DD/YYYY)

**7 PRESCRIPTION** (required)

X Jane Patient first name X Brown Patient last name 01 / 01 / 1978 Date of Birth (MM/DD/YYYY)

Prescription information: UPLIZNA® (nabixumab-cdon) ICD-10 code: D09.84  
 Allergies: Sulfu  No known drug allergies (NDA)

NDC: 75987-80-03 One carton containing three 100 mg/10 mL vials Dose: 300 mg per IV infusion Target infusion date: 02 / 01 / 2025 (MM/DD/YYYY)  
 Initial Rx:  300 mg IV infusion over 90 minutes at Day 1 and 5 weeks later Refill: 2 times  
 Maintenance Rx:  300 mg IV infusion over 90 minutes every 6 months Refill: 2 times

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. 45 mL/hour for first 15 minutes, followed by 125 mL/hour for the next 15 minutes, then 325 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 Sarah Williams Prescriber signature (dispense as written) 01 / 07 / 2025 Date (MM/DD/YYYY)  
 Written or e-signature only; stamps not acceptable

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 (nabixumab-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") that Amgen will 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-ADL-8337 or visiting www.amgen.com/Data-Subject-IRB, 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 the medication which necessarily requires Amgen to process the patient's personal information; (4) the patient can view most details about Amgen's privacy practices 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 benefits plan by any means allowed under applicable law. I further understand and agree that all my medication or service provided through the Program as a result of this form for the named patient only and is 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; (5) my decision to prescribe UPLIZNA was based solely on my professional determination of medical necessity, and (6) 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 use 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, the coverage or reimbursement services and seek with Amgen By Your Side the appropriate communication in-network and out-of-network. Once the patient, the prescriber cannot balance bill the patient for the out-of-network services. State requirements: I certify that the patient form complies with my state's specific 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 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.

Page 2 of 4 USA-335-80294

## 6 Patient Consent and Authorization

- Patient must sign and date form
- Patient must check "I consent" circle in order to be enrolled in Amgen By Your Side
- If the patient can't sign the form at your office, Amgen By Your Side can follow up to obtain consent

## 7 Prescription and Prescriber Signature

This section should be completed, as it can be used as a prescription by the specialty pharmacy or the infusion center

- If known, provide the target infusion date
- Include patient name and date of birth within prescription section along with prescription information
- Fill in the circle next to "Initial Rx" and/or "Maintenance Rx." Please also include the number of refills
- Prescriber signature is required for processing the Patient Enrollment Form

Pages 3-4 of the PEF will include the patient authorization and consent language. Once the PEF is submitted, you can provide these 2 pages to the patient for their reference.

### IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS

**Infections:** An increased risk of infections has been observed with other B-cell depleting therapies. In the IgG4-RD RCP and open-label period, the most common infections reported by UPLIZNA-treated patients were upper respiratory tract infection (11%), nasopharyngitis (10%), urinary tract infection (9%), and influenza (6%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

**Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants:** UPLIZNA has not been studied in combination with other immunosuppressants. If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

**Hepatitis B Virus (HBV) Reactivation:** Risk of HBV reactivation has been observed with other B-cell depleting antibodies. There have been no cases of HBV reactivation in patients treated with UPLIZNA, but patients with chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active hepatitis. For patients who are chronic carriers of HBV [HBsAg+], consult liver disease experts before starting and during treatment.

**Progressive Multifocal Leukoencephalopathy (PML):** Although no confirmed cases of PML were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell depleting antibodies and other therapies that affect immune competence. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms.

Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

#### Tuberculosis

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA. Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

#### Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

#### Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy

In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B-cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

Please see additional Important Safety Information throughout.

## Connecting Patients with their Amgen By Your Side PAL

The Patient Access Liaison (PAL) is a dedicated support partner who helps investigate, explain, and educate on the steps in your patient's treatment experience. They are your patient's point of contact and champion while your patient is accomplishing their treatment goals.

- Make sure the patient is aware their PAL will be calling them in the next few days to provide information on next steps, the infusion process, and getting started on UPLIZNA
  
- Have the patient save their PAL's contact in their phone
  - **It is important that a patient answers the PAL's call**

**PAL Name:** \_\_\_\_\_ **Phone Number:** \_\_\_\_\_

**Please ensure that all four pages of the enrollment forms are submitted by fax to 1-833-329-8477 or emailed to [UPLIZNAABYS@amgen.com](mailto:UPLIZNAABYS@amgen.com). Incomplete forms may delay enrollment.**

### IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (CONT'D)

- **Reduction in Immunoglobulins:** There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the levels of quantitative serum immunoglobulins during treatment with UPLIZNA, especially in patients with opportunistic or recurrent infections, and until B-cell repletion after discontinuation of therapy. Consider discontinuing UPLIZNA therapy if a patient with low immunoglobulin G or M develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.
  
- **Fetal Risk:** Based on animal data, UPLIZNA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to UPLIZNA even after B-cell repletion. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose.

### ADVERSE REACTIONS

- The most common adverse reactions in IgG4-RD (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infections and lymphopenia.

**Please see UPLIZNA® [full Prescribing Information](#).**