Statement of Medical Necessity (SMN) for Treatment With RITUXAN® (Rituximab)

Note: This form can be used to submit for prior authorization with your patient's insurance.

(866) 681-3261 PHONE
(866) 681-3288 FAX
WWW.GENENTECHACCESSSOLUTIONS.COM

Genentech Access Solutions™ Treatment made possible.™

ATTACH TO COMPLETED SMN

- Please attach a signed and dated Patient Authorization and Notice of Release of Information (PAN) form
- Genentech Access Solutions cannot work with the insurance plan on your patient's behalf without a signed and dated PAN form

INSURANCE INFORMATION

- This section should include both primary and secondary insurance to ensure that ALL potential coverage can be investigated
- Please provide a front and back copy of the patient's insurance card (enlarged and legible) and fax this information to Genentech Access Solutions with the SMN and PAN forms
- Please also provide a front and back copy of the patient's drug card (if available)

DIAGNOSIS AND OTHER PERTINENT MEDICAL INFORMATION

Diagnosis
- Check the appropriate Diagnosis Code
- If "Other" is checked, ICD-9 code is required

Previous Treatments (list both duration and frequency)
- Treatments that have failed (never worked or stopped working) and those to which patient response was inadequate (treatment provided poor control, or patient was unable to tolerate adverse events)

Medical Rationale for Prescribing RITUXAN May Include
- Lack of response to standard therapies
- Unacceptable side effects of prior treatments
- Treatments that are difficult to use and those to which adherence is an issue (eg, inability to self-inject, etc)
- Exhaustion of available therapies (if applicable)
- Symptoms and impact on daily life
- Other rationale

Treatment Information
- Please complete according to the planned (patient has not yet received RITUXAN) or administered (patient has already been infused with RITUXAN) dosing
- If you will not infuse the patient in your office and need assistance with locating an infusion site, Genentech Access Solutions will verify with your patient's insurance the infusion sites that are in network

DRUG ACQUISITION

- Please check the appropriate box to indicate the need for a specialty pharmacy to dispense RITUXAN. Genentech Access Solutions will verify with your patient's insurance whether a specialty pharmacy is in network

PRESCRIPTION

- Please complete the prescription portion only if you are planning to use a pharmacy to dispense RITUXAN for your patient
- Please fully complete the infusion and dispensing information in order to avoid therapy delays

REMINDER:
This form cannot be processed without a prescriber's signature and date, as well as a signed and dated PAN form.

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Please write legibly and complete all sections to prevent delays.

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PATIENT INFORMATION

Last Name: _____
First Name: _____
Daytime Phone: ( ) _____
Evening Phone: ( ) _____
☐ **Permission to contact patient directly for missing information**

Street: _____
City: _____ **State:** _____ **ZIP:** _____
Date of Birth (mm/dd/yy): _____
☐ **Female** ☐ **Male**
SSN: _____

INSURANCE INFORMATION

Primary Insurance: _____
Phone: ( ) _____
Subscriber: _____
Policy/Group #: _____
☐ **Copy of primary insurance card attached**

Secondary Insurance: _____
Phone: ( ) _____
Subscriber: _____
Policy/Group #: _____
☐ **Copy of secondary insurance card attached**

DIAGNOSIS AND OTHER PERTINENT MEDICAL INFORMATION

Diagnosis (Dx): ☐ Rheumatoid arthritis (714.0) ☐ Other (please specify ICD-9): _____ Date of Dx: _____
Has patient received a course of therapy in the past? ☐ Yes ☐ No **If yes, how many courses of therapy?** _____
Previous treatment(s) since Dx and duration/frequency
☐ Methotrexate _____
☐ Infliximab (Remicade) _____
☐ Abatacept (Orencia) _____
☐ Other DMARDs (list) _____
☐ Etanercept (Enbrel) _____
☐ Adalimumab (Humira) _____
☐ Anakinra (Kineret) _____
☐ Other (list) _____

Has patient started RITUXAN therapy? If so, start date: _____
Concurrent therapy prescribed with RITUXAN: _____
Medical rationale for prescribing RITUXAN: _____
Place of infusion: ☐ Prescribing physician's office ☐ Other physician's office ☐ Hospital outpatient ☐ Other _____
Facility Name (if other than prescribing MD): _____
Address: _____ **City:** _____ **State:** _____ **ZIP:** _____

DRUG ACQUISITION

Specialty pharmacy needed for RITUXAN dispensing?
☐ Yes ☐ No, MD's office will supply RITUXAN Preferred specialty pharmacy(s): _____

PRESCRIPTION

☐ Drug Allergies: _____ ☐ NKDA ☐ SIG: infuse _____ mg on Day 1 and Day 15 or as directed
☐ Dispense RITUXAN Quantity: _____ 100-mg vials _____ 500-mg vials Refill _____ times
Ship to address (if other than below) _____
Facility/Group Name: _____
Tax ID #: _____ **NPI #:** _____
Physician's Full Name: _____
Tax ID #: _____ **NPI #:** _____
DEA #: _____ **BCBS PIN #:** _____
Specialty ☐ Rheumatologist ☐ Oncologist/Hematologist ☐ Other: _____
Reimbursement contact: _____
Street: _____
City: _____ **State:** _____ **ZIP:** _____
Office hours: _____
Please check preferred method of contact.
☐ **Phone:** ( ) _____ ☐ **Fax:** ( ) _____

UNAPPROVED USE WARNING: Please read the FDA-approved label for RITUXAN before prescribing. If the indication for which you are prescribing RITUXAN is not listed in the label, you are prescribing RITUXAN for an "unapproved" use. The fact that the use for which you are prescribing RITUXAN is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount or safety of RITUXAN when used for such a use. Nevertheless, Genentech® Access to Care Foundation will consider providing RITUXAN for your patient with this admonition, based upon your medical order, within program requirements.

By signing below, I certify that (a) the above therapy is medically necessary, (b) I have received the necessary authorization to release the above referenced information and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech USA, Inc., Genentech Access Solutions™ and contracted dispensing pharmacy or other contractors for the purpose of seeking reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for the Genentech Access to Care Foundation related to Genentech products, as a break in treatment would negatively impact the patient's therapeutic outcome, (c) I will not attempt to seek reimbursement for free or replacement product provided directly to the patient or for the dates of service for which free or replacement product was provided, and (d) I appoint Genentech Access Solutions solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription described herein.

I agree to comply with the program guidelines as established by Genentech USA, Inc. and understand that Genentech Access to Care Foundation, at its sole and absolute discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

Prescriber Signature _____ **Date** _____
(Original signature required)

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PATIENT AUTHORIZATION AND NOTICE
OF RELEASE OF INFORMATION

www.GenentechAccessSolutions.com

Dear Patient:

Genentech Access Solutions™ is a program sponsored by Genentech USA, Inc. that provides support services such as benefits investigations, prior authorizations and appeals assistance at no charge to patients and assistance in obtaining reimbursement for RITUXAN® (Rituximab). If a patient does not have insurance or is deemed uninsured due to denial by private and public payers, and the patient meets certain financial criteria, the Genentech® Access to Care Foundation may provide RITUXAN free of charge. Additional information on these programs can be found on www.GenentechAccessSolutions.com.

In order for Genentech Access Solutions and Genentech Access to Care Foundation to provide the described services, we will need to review, use and disclose your protected health information (PHI). By law, only with your prior written authorization may your health care provider, health plan or health insurer disclose your PHI to Genentech Access Solutions and Genentech Access to Care Foundation. As soon as we obtain your prior written authorization, we will work to provide you the services.

You are not required to agree to this Authorization. However, failure to provide this Authorization may prevent you from becoming eligible for the Genentech Access Solutions coverage and reimbursement assistance or Genentech Access to Care Foundation patient assistance programs, which may result in your need to pay for certain products with your own funds. You will receive a copy of the Authorization you sign.

Please review this Authorization carefully. If you have any questions regarding this Authorization, please contact your health care provider's office. Contact information is included below.

I. Information to Be Disclosed or Used

This Authorization permits my health care providers, health plans and health insurers who provide services to me to use and disclose to Genentech Access Solutions or Genentech Access to Care Foundation and its authorized agents and assignees, all medical records and financial information with respect to my treatment, which may have bearing on the benefits payable for services or products provided through my health care provider, health plan or insurer under any plan providing benefits or services, including, without limitation, the dollar balance of benefits remaining under any applicable lifetime maximum benefits provisions, or which may have a bearing on my medical condition or compliance with therapy. All of this information may be considered PHI and may, if relevant, include information about HIV/AIDS and/or other communicable diseases, mental health information and/or information concerning genetic test results.

II. Persons Authorized to Disclose Information

The PHI identified in Paragraph I may be disclosed by my health care provider, health plan, health insurer or others who may hold my PHI.

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III. Persons to Whom Disclosure May Be Made

The PHI identified in Paragraph I may be disclosed to and/or used by Genentech Access Solutions or Genentech Access to Care Foundation, their sponsor Genentech USA, Inc., a biopharmaceutical manufacturer located at 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080, and its related entities, their agents or assignees, and certain Genentech business partners, such as Biogen Idec, Inc., as well as other companies involved in the administration of certain Genentech products.

IV. Description of Each Purpose

My PHI may be used for the purposes of reimbursement and/or participation in a coverage and reimbursement assistance or patient assistance program administered by Genentech Access Solutions and Genentech Access to Care Foundation, respectively. My PHI may also be used for purposes of tracking the general use of a Genentech product, assessing and improving Genentech's coverage and reimbursement and patient assistance services, and proper management and administration of Genentech's business.

V. Expiration Date or Event

California residents only: This Authorization will be effective, unless revoked by me in writing, until December 31, 2015.

All other residents: This Authorization will be effective, unless revoked by me in writing, for up to one year from the date of this Authorization.

VI. Notices

I understand that once my health information is disclosed pursuant to this Authorization, there is no guarantee under federal law that the recipient will not redisclose my health information to a third party. Any such third party may not be required to abide by this Authorization or applicable federal law governing the use and disclosure of my health information.

I understand that I may refuse to sign or may revoke (at any time) this Authorization for any reason and that such refusal or revocation will not affect the commencement, continuation or quality of my health care provider's treatment of me. If I refuse to sign or revoke this Authorization, however, I may be responsible for costs that may have otherwise been covered by Genentech Access Solutions and Genentech Access to Care Foundation.

I understand that this Authorization will remain in effect until it expires as described above or I provide a written notice of revocation via mail to Genentech Access Solutions, 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080 or via fax to (866) 681-3338. The revocation will be effective immediately upon my health care provider's receipt of my written notice, except that the revocation will not have any effect on any action taken by my health care provider or others referenced in this Authorization, including without limitation, Genentech Access Solutions or Genentech Access to Care Foundation, in reliance on this Authorization before my health care provider received my written notice of revocation.

VII. Distribution Acknowledgment

I hereby state (or my parent/guardian hereby states) that if I should receive free product from Genentech Access to Care Foundation, I will utilize RITUXAN for the reason that my physician has prescribed it to me. I will not sell or distribute RITUXAN, as I acknowledge it is unlawful to do so. I will be responsible to ensure that RITUXAN will be delivered to a secure address for purposes of receipt of shipment, and I understand it is my duty to control RITUXAN while it remains in my possession.

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VIII. Signature

Signature Required

I have read and understand the terms of this Authorization and I have had an opportunity to ask questions about the use and disclosure of my health information. By my signature below, I hereby, knowingly and voluntarily, authorize the use and/or disclosure of my health information in the manner described above.

Print Patient's Name

Signature of Patient or Guardian* | Description of Authority | Date

Patient's/Guardian's Address

* If the patient is an unemancipated minor or otherwise incapacitated (physically or mentally)

IX. Financial Information

- Only uninsured patients (and patients whose insurance has denied treatment) who wish to apply to Genentech Access to Care Foundation for assistance need to fill out this section.
- There is no need to complete this section if the patient has insurance coverage for RITUXAN.

Complete If Necessary

Household Adjusted Gross Income: ❑ $0-25K/yr ❑ $25,001-50K/yr ❑ $50,001-75K/yr ❑ $75,001-100K/yr

I understand that in order to qualify, my adjusted gross income may not exceed $100K/yr. I certify that the above statement of my previous year's income is true and that I have no medical insurance coverage for RITUXAN, including Medicare, Medicaid or other public programs, and that I have insufficient financial resources to pay for the prescribed therapy. I also agree to furnish my IRS 1040 (or if none, then my Social Security Benefit Statement or W-2) within 45 days of the submission of this form. I understand that failure to provide this documentation may result in an interruption in therapy.

Signature of Patient (complete if necessary)

Date Signed (complete if necessary)

RISE™ (RA Information, Service, and Education)

Optional

I authorize Genentech USA, Inc. to enroll me in RISE™. I understand that my name, address, e-mail address, phone number and the name of my pharmacy, once identified, will be sent by Genentech Access Solutions to RISE to complete my enrollment. I agree that Genentech and its agents may contact me in the future by mail, e-mail and/or telephone concerning RISE. I understand that all my personally identifiable information will be kept strictly confidential and will not be distributed outside of Genentech or its agents, as Genentech USA, Inc. privacy policy provides (available at RITUXAN.com). I also understand that I do not have to sign this Authorization in order to receive RITUXAN for RA or participate in the Genentech Access Solutions/Genentech Access to Care Foundation programs and that I may cancel this Authorization at any time by giving written notice to Genentech, Inc., through its agent, at 5901B Peachtree Dunwoody Rd., Suite 380, Atlanta, GA 30328.

Signature of Patient | Patient's E-mail Address | Date

Patient's Phone Number | Patient's Address

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Attn: Genentech® Access to Care Foundation	**Date:**
To:	**Fax #:** (866) 681-3338
From:	**Phone:**
	# Pages:

RITUXAN® (Rituximab)

Patient's Name: Date of Birth:

Comments:

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