BRITISH COLUMBIA | Ministry of Health

SPECIAL AUTHORITY REQUEST

RITUXIMAB FOR RHEUMATOID ARTHRITIS INITIAL / RENEWAL

HLTH 5373 Rev. 2023/01/18

◯ **INITIAL**
Complete sections 1-4, 6.
Also complete section 8 if applicable.

◯ **RENEWAL**
Complete sections 1-5.

For up-to-date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1-800-609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

If you have received this fax in error, please write MISDIRECTED across the front of the form and fax toll-free to 1-800-609-4884, then destroy the pages received in error.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

SECTION 1 – PRESCRIBING RHEUMATOLOGIST'S INFO.

Name and Mailing Address	
College ID (use ONLY College ID number)	Phone Number (include area code)
CRITICAL FOR A TIMELY RESPONSE →	Prescriber's Fax Number

SECTION 2 – PATIENT INFORMATION

Patient (Family) Name	
Patient (Given) Name(s)	
Date of Birth (YYYY / MM / DD)	Date of Application (YYYY / MM / DD)
CRITICAL FOR PROCESSING →	Personal Health Number (PHN)

SECTION 3 – INITIAL OR RENEWAL COVERAGE

BIOSIMILAR RITUXIMAB: 9901-0348

◯ BIOSIMILAR RITUXIMAB INITIAL COVERAGE

◯ **Riximyo®** ◯ **Ruxience®** ◯ **Truxima®**

TWO COURSES, IN COMBINATION WITH CONCURRENT DMARD

1 year dispensing window

Year of Diagnosis of Rheumatoid Arthritis (YYYY): _____

Patient Weight: _____

Each course is 1000 mg at 0 & 2 weeks, mininum 24 weeks between courses. A minimum ACR20 response is required after the initial course for retreatment.

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate, in patients who have failed to respond to an adequate trial of at least one anti-TNF agent OR have contraindication(s) to anti-TNF agents. Rituximab should not be used concomitantly with anti-TNF agents.

◯ BIOSIMILAR RITUXIMAB – RENEWAL / DOSING ADJUSTMENT

◯ **Riximyo®** ◯ **Ruxience®** ◯ **Truxima®**

Dosing up to 1000 mg at 0 and 2 weeks per course.
One course up to every 24 weeks.

◯ **INDEFINITE COVERAGE**
◯ **3 YEARS**
◯ **1 YEAR**

ACR20 response compared to pre-rituximab status is required for treatment.

Date of last Rituximab Infusion (YYYY / MM / DD): _____

Patient Weight (if significantly changed): _____

Planned Dosing Regimen:

◯ 1000 mg at 0 and 2 weeks, 24 weeks between courses
◯ Other (give details):

_____

Please complete additional information on page 2 >>

PHARMACARE USE ONLY

STATUS	EFFECTIVE DATE (YYYY / MM / DD)	DURATION OF APPROVAL

PATIENT NAME	PHN

SECTION 4 – CURRENT CLINICAL ASSESSMENT (REQUIRED FOR ALL APPLICATIONS)

68 JOINT COUNT: NO. OF SWOLLEN JOINTS	NO. OF TENDER JOINTS	ESR OR CRP	DURATION OF MORNING STIFFNESS	DOSE OF PREDNISONE

PHYSICIAN OVERALL ASSESSMENT OF ***INFLAMMATION*** (ON A SCALE OF 0 - 10) 0 = REMISSION, 10 = SEVERE ACTIVE DISEASE	☐ **ATTACHED:** HEALTH ASSESSMENT QUESTIONNAIRE (HAQ) COMPLETED BY PATIENT

CONCURRENT DMARD THERAPY:	DRUG	DOSE ROUTE	FREQUENCY
OR	DRUG	DOSE ROUTE	FREQUENCY
SPECIFY REASONS FOR MONOTHERAPY IN SECTION 7.	DRUG	DOSE ROUTE	FREQUENCY

SECTION 5 – ASSESSMENT 4 MONTHS POST MOST RECENT RITUXIMAB COURSE (REQUIRED FOR RENEWALS)

☐ AFTER MOST RECENT RITUXIMAB COURSE, AT LEAST 20% IMPROVEMENT (ACR20) WAS ACHIEVED COMPARED TO STATUS JUST PRIOR TO INITIAL RITUXIMAB THERAPY.

ANTICIPATED RETREATMENT DATE (APPROXIMATE IF EXACT DATE UNKNOWN): _____

SECTION 6 – MOST RECENT TARGETED DMARD AND REASON FOR DISCONTINUATION

Additional information regarding prior targeted DMARD trial(s) will be requested if required.

NAME, DOSE & FREQUENCY	APPROX. DURATION OF USE	FAILURE		SIDE EFFECT(S) OR OTHER DETAILS - SPECIFY
		TYPE I*	TYPE II**	
		◯	◯	

* Never achieving a 20% improvement

** At least 20% improvement in first 12 weeks of a TNF inhibitor (24 weeks for abatacept and rituximab) but loss of benefit

Report all adverse events to the post-market surveillance program, Canada Vigilance, toll-free 1-866-234-2345 (health professionals only).

SECTION 7 – ADDITIONAL COMMENTS

ADDITIONAL COMMENTS REGARDING PATIENT'S CURRENT MEDICAL STATUS AND/OR CONTRAINDICATIONS TO CONCURRENT DMARD THERAPY

Personal information on this form is collected under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* 22(1) and *Freedom of Information and Protection of Privacy Act* 26 (a),(c),(e). The information is being collected for the purposes of (a) administering the PharmaCare program, (b) analyzing, planning and evaluating the Special Authority and other Ministry programs and (c) to manage and plan for the health system generally. If you have any questions about the collection of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

_____

Prescribing Rheumatologist's Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request.
Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PATIENT NAME	PHN

SECTION 8 – SUPPLEMENTAL PAGE - CRITERIA FOR INITIAL COVERAGE

Complete if biologic coverage has not previously been approved by PharmaCare for this patient; this page does not need to be completed or submitted if PharmaCare has previously approved coverage of a biologic for the treatment of rheumatoid arthritis for this patient.

Expectation for adequate dose/duration of DMARD trials; If a medication must be discontinued due to intolerance(s) prior to the expected duration of trial an alternate DMARD trial is required. Exceptions considered when additional DMARD trials cannot be attempted (supporting information must be provided for consideration).

DMARD UTILIZATION	Duration of use	Reason for discontinuation	Reason for discontinuation if not due to inadequate response
☐ **methotrexate (parenteral)** 25 mg (15 mg for over 65 years), minimum 8 weeks required		◯ Inadequate Response ◯ AE ◯ Other	
PLUS at least one or more of the following (not including hydroxychloroquine)			
☐ a) **leflunomide** 20 mg daily for 10 weeks		◯ Inadequate Response ◯ AE ◯ Other	
☐ b) **sulfasalazine** ≥ 2 gm daily for 3 months		◯ Inadequate Response ◯ AE ◯ Other	
☐ c) **azathioprine** 2-3 mg/kg/day for 3 months		◯ Inadequate Response ◯ AE ◯ Other	
☐ d) **other** – specify drug and dose (e.g. tacrolimus, cyclosporine, gold, doxycycline):		◯ Inadequate Response ◯ AE ◯ Other	
PLUS at least one DMARD combination (NOTE: antimalarial in combination with one other DMARD is not acceptable)			
☐ a) methotrexate with hydroxychloroquine and sulfasalazine (O'Dell protocol), minimum 4 month trial		◯ Inadequate Response ◯ AE ◯ Other	
☐ b) methotrexate with leflunomide, minimum 10 week trial		◯ Inadequate Response ◯ AE ◯ Other	
☐ c) other – (specify drugs, duration):		◯ Inadequate Response ◯ AE ◯ Other	

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