Rituxan, Ruxience, Truxima, Riabni

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical* ❑ *Home* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

PANDAS Criteria

1. Is the requested drug being used to treat either of the following conditions:
   A. pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, or B) pediatric acute onset neuropsychiatric syndrome? *If Yes, no further questions* ❑ Yes ❑ No

Exception Criteria Questions:

A. What drug is being prescribed?
   ❑ Rituxan
   ❑ Ruxience, *Skip to Clinical Criteria Questions*
   ❑ Truxima, *Skip to Clinical Criteria Questions*
   ❑ Riabni, *Skip to Clinical Criteria Questions*

B. The preferred products for your patient's health plan are Riabni, Ruxience, and Truxima. Can the patient's treatment be switched to a preferred product?

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

 Rituxan, Ruxience, Truxima, Riabni MR Biosimilar PANDAS SGM – 04/2022.

❑ Yes – Riabni, *Skip to Clinical Criteria Questions*
❑ Yes – Ruxience, *Skip to Clinical Criteria Questions*
❑ Yes – Truxima, *Skip to Clinical Criteria Questions*
❑ No

C. Does the patient have a documented intolerable adverse event to all of the preferred products (Riabni, Ruxience, and Truxima)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

D. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)? ***ACTION REQUIRED: If 'No', attach supporting chart note(s).*** ❑ Yes ❑ No

Clinical Criteria Questions:

1. What is the prescribed product? ❑ Rituxan ❑ Ruxience ❑ Truxima ❑ Riabni

2. What is the diagnosis?

Non-Oncology

❑ Moderately to severely active rheumatoid arthritis
❑ Relapsing-remitting multiple sclerosis (RRMS)
❑ Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis)
❑ Microscopic polyangiitis (MPA)
❑ Churg-Strauss syndrome
❑ Pauci-imune glomerulonephritis
❑ Sjögren's syndrome
❑ Immune or idiopathic thrombocytopenic purpura (ITP), refractory
❑ Autoimmune hemolytic anemia
❑ Thrombotic thrombocytopenic purpura (TTP)
❑ Myasthenia gravis, refractory
❑ Chronic graft versus host disease
❑ Prevention of Epstein-Barr virus (EBV) related post-transplant lymphoproliferative disorder (PTLD)
❑ Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic disease)
❑ Autoimmune blistering disease (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus)
❑ Cryoglobulinemia
❑ Solid organ transplant and prevention of antibody mediated rejection in solid organ transplant
❑ Opsoclonus-myoclonus ataxia
❑ Systemic lupus erythematosus
❑ Immune Checkpoint Inhibitor-related toxicities

Oncology

❑ Diffuse large B-cell lymphoma (DLBCL), CD20 positive
❑ High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), CD20 positive
❑ High-grade B-cell lymphoma, not otherwise specified, CD20 positive
❑ Follicular lymphoma, CD20 positive
❑ Mantle cell lymphoma, CD20 positive
❑ Marginal zone lymphomas (nodal marginal zone lymphoma, gastric mucosa associated lymphoid tissue [MALT] lymphoma, Nongastric MALT lymphoma, splenic marginal zone lymphoma), CD20 positive
❑ Burkitt lymphoma, CD20 positive
❑ Castleman's disease, CD20 positive
❑ Acquired immunodeficiency syndrome (AIDS-)-related B-cell lymphoma, CD20 positive
❑ Post-transplant lymphoproliferative disorder (PTLD), CD20 positive
❑ B-cell lymphoblastic lymphoma, CD20 positive
❑ Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma, CD20 positive

- ❑ Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma, CD20 positive
- ❑ Primary cutaneous B-cell lymphoma, CD20 positive
- ❑ Hairy cell leukemia, CD20 positive
- ❑ Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL), CD20 positive
- ❑ Hodgkin's lymphoma, nodular lymphocyte-predominant, CD20 positive
- ❑ Primary central nervous system (CNS) lymphoma, CD20 positive
- ❑ Leptomeningeal metastases from lymphomas, CD20 positive q B-cell acute lymphoblastic leukemia (ALL), CD20 positive
- ❑Chronic lymphocytic leukemia (CLL), CD20 positive
- ❑ Small lymphocytic lymphoma (SLL), CD20 positive
- ❑ Pediatric aggressive mature B-cell lymphomas, CD20 positive
- ❑ Rosai-Dorfman disease, CD20 positive
- ❑ Other _____

3. What is the ICD-10 code? _____
If diagnosis is RA, MS or any oncologic indications, skip to diagnosis section.

4. Is this a request for continuation of therapy with the requested drug?
❑ Yes ❑ No *If No, skip to diagnosis section.*

5. Is the patient experiencing benefit from therapy? ❑ Yes ❑ No

Complete the following section(s) based on the patient's diagnosis, if applicable.

Section A: Rheumatoid Arthritis

6. Has the patient previously received a biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) that is indicated for moderately to severely active rheumatoid arthritis? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #11.*** ❑ Yes ❑ No

7. Has the patient received at least two full doses of the requested medication, with the most recent dose being within 6 months before this request? *If Yes, skip to #11* ❑ Yes ❑ No

8. Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and the anti-CCP biomarker test was positive? ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #12.***
❑ Yes ❑ No

9. Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

10. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 mg per week? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

11. Is the requested drug being prescribed in combination with methotrexate or leflunomide?
If Yes, skip to #15 ❑ Yes ❑ No

12. Has the patient experienced an intolerance to methotrexate or leflunomide? *If Yes, skip to #15* ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

13. Does the patient have a contraindication to methotrexate or leflunomide? ***ACTION REQUIRED: If***

Yes, please attach documentation of clinical reason to avoid therapy. ❑ Yes ❑ No
If Yes, indicate contraindication: _____

14. Has the patient experienced an inadequate response with another conventional DMARD (e.g., hydroxychloroquine, leflunomide, sulfasalazine)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

15. Will the requested drug be used with another biologic for the treatment of rheumatoid arthritis? ❑ Yes ❑ No

16. Is the planned date of administration at least 16 weeks after the date of the last dose received? ❑ Yes ❑ No ❑ Not applicable - Patient has not received any previous dose

17. Is this request for continuation of therapy? ❑ Yes ❑ No *If No, no further questions.*

18. How many doses in total has the patient received since starting treatment with the requested medication? _____doses *If one dose, no further questions.*

19. Has the patient achieved or maintained positive clinical response since starting treatment with the requested medication? ❑ Yes ❑ No

20. What is the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***_____%

Section B: Multiple Sclerosis

21. Is the patient taking the requested medication with any other medication used for the treatment of multiple sclerosis other than Ampyra? ❑ Yes ❑ No

22. Is this a request for continuation of therapy? ❑ Yes ❑ No *If No, no further questions.*

23. Is the patient experiencing disease stability or improvement while receiving the requested medication? ❑ Yes ❑ No

Section C: Oncologic Indications

24. Is this a request for continuation of therapy with the requested drug? ❑ Yes ❑ No

25. Does the patient have CD20 positive disease that was confirmed by testing or analysis? ***ACTION REQUIRED: If Yes, attach results of testing or analysis confirming CD20 protein on the surface of the B-cell.*** ❑ Yes ❑ No ❑ Unknown *No further questions*

26. Is there evidence of unacceptable toxicity on the current regimen? ❑ Yes ❑ No

Section D: Systemic Lupus Erythematosus

27. Is the disease refractory to immunosuppressive therapy? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

Section E: Sjogren's Syndrome or Cryoglobulinemia

28. Have corticosteroids and other immunosuppressive agents been ineffective? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

Section F: Neuromyelitis Optica (i.e., Neuromyelitis Optica Spectrum Disorder; NMOSD, Devic Sisease)

29. Has at least one other immunotherapy agent been ineffective? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

30. Will the patient receive the requested drug concomitantly with other biologics for the treatment of neuromyelitis optica spectrum disorder (NMOSD)? ❑ Yes ❑ No

Section G: Autoimmune Blistering Disease (e.g., Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Cicatricial Pemphigoid, Epidermolysis Bullosa Acquisita and Paraneoplastic Pemphigus)

31. Is the disease corticosteroid refractory? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

Section H: Solid Organ Transplant

32. Is the requested drug being used for the prevention of antibody mediated rejection in solid organ transplant? ❑ Yes ❑ No

Section I: Opsoclonus-Myoclonus-Ataxia

33. Is the requested drug being used for opsoclonus-myoclonus ataxia associated with neuroblastoma? ❑ Yes ❑ No

34. Is the patient refractory to steroids and chemotherapy? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720