DRUG DETERMINATION POLICY

Title: DDP-17 Rituximab (Rituxan Biosimilars), Non-Oncologic Indications

Effective Date: 4/24/24

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Rituximab (originator: Rituxan/Hycela, biosimilars: Ruxience,Truxima, Riabni) is an immunosuppressant specialty drug indicated for a number of diagnoses and is associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. General Considerations for use:

   A. Appropriate Medication Use [must meet all listed below]:

      1. Diagnosis: meets standard diagnostic criteria that designates signs, symptoms, and test results to support specific diagnosis

      2. Food and Drug Administration (FDA) approval Status [must meet one listed below]:

         a. FDA approved: product, indication, and/or dosage regimen.

         b. Non-FDA approved use: Compendium support (Lexicomp®) for use of a drug for a non-FDA approved indication or dosage regimen.

      3. Place in therapy: sequence of therapy supported by national or internationally accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

   B. Approval.

1. Initial: six months.
2. Re-approval: decreased or sustained reduction in disease activity.
    a. Rheumatoid arthritis: one year.
    b. All other indications: six months.

II. Non-Oncology Indications [must meet one listed below]:

A. Rheumatoid Arthritis [must meet all listed below]:

1. Diagnosis and severity: moderate to severe rheumatoid arthritis.
2. Other therapies: contraindicated, failed, or significant adverse effects with two anti-tumor necrosis factor inhibitors.
3. Dosage regimen: Rituxan, Ruxience, and Truxima only [must meet both listed below]:
    a. Rituximab intravenous: 1,000mg on days one and fifteen of a six-month cycle.
    b. Combination with methotrexate (if contraindicated, use leflunomide or other standard disease modifying antirheumatic drugs).

B. Polyangiitis [must meet all listed below]:

1. Age: at least two years.
2. Diagnosis and severity [must meet one listed below]:
    a. Granulomatosis with Polyangiitis (Wegener Granulomatosis).
    b. Microscopic polyangiitis
3. Dosage regimen:
    a. Combination with methylprednisolone or prednisone.
    b. Induction: rituximab 375 mg per m^2 one time per week for four doses with methylprednisolone intravenous for one to three days, and then oral prednisone one time per day.
    c. Maintenance:
        i. Adult: rituximab intravenous 500 mg week zero and two, then 500 mg every 6 months.
        ii. Pediatric: rituximab 250 mg per m^2 week zero and two, then 250 mg per m^2 every six months

C. Pemphigus Vulgaris.

1. Diagnosis and severity [must meet both listed below below]:
    a. Treatment of moderate to severe pemphigus vulgaris in adults.
    b. Refractory disease.
2. Other therapies: contraindication, inadequate response after four months, or significant adverse effects to one in each category listed below:
    a. Steroids: initial treatment, then taper or increase as needed.

b. Disease modifying rheumatoid agents: azathioprine, mycophenolate, dapsone.

3. Dosage regimen: Rituxan intravenous only.

   a. Initial: 1,000 mg at weeks zero and two.

   b. Maintenance: 500 mg at months twelve and then every six months thereafter or based on clinical evaluation.

   c. Relapse: 1,000 mg for one dose, no sooner than 16 weeks following the previous dose.

   d. Concurrent therapy:

      i. Combination with tapering glucocorticoids and with relapse, consider resuming or increasing steroid dose.

      ii. Pre-medicate with methylprednisolone intravenous 30 minutes prior to each rituximab dose.

4.0 Coding:

COVERED CODES - MEDICAL BENEFIT				
HCPCS Code	**Brand Name**	**Generic Name**	**Billing (1 Unit)**	**Prior Approval**
J9312	Rituxan	rituximab	10 mg	Y
Q5119	Ruxience	Rituximab-pvvr	10 mg	Y
Q5115	Truxima	Rituximab-abbs	10 mg	Y
Q5123	Riabni	Rituximab-arrx	10 mg	Y

COVERED PRODUCTS - PHARMACY BENEFIT		
Brand Name	**Generic Name**	**Prior Approval**
Rituxan Hycela	rituximab r-hyaluronidase	Y

EXCLUDED CODES AND PRODUCTS			
HCPCS Code	**Brand Name**	**Generic Name**	**Benefit Plan Reference/Reason**
J9311	Rituxan Hycela	rituximab r-hyaluronidase	Covered on the pharmacy benefit with prior approval

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Rituxan, Rituxan Hycela accessed March, 2022.
2. Package insert rituximab Genetech/Biogen https://www.gene.com/download/pdf/rituxan_prescribing.pdf accessed April 2020.

3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939. doi:https://doi.org/10.1002/acr.24596
4. Hellmich B, Sanchez-Alamo B, Schirmer JH, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Annals of the Rheumatic Diseases*. Published online March 16, 2023. doi:https://doi.org/10.1136/ard-2022-223764
5. Joly P, Horvath B, Patsatsi A, et al. Updated S2K guidelines on the management of pemphigus vulgaris and foliaceus initiated by the european academy of dermatology and venereology (EADV). *Journal of the European Academy of Dermatology and Venereology*. 2020;34(9):1900-1913. doi:https://doi.org/10.1111/jdv.16752

6.0 Appendices:

None

7.0 Revision History:

Original Effective Date: 12/14/2005

Next Review Date: 05/01/2025

Revision Date	Reason for Revision
4/19	Moving to new format; presented and approved by P&T Committee
3/20	Annual review; added indication Pemphigus Vulgaris, added drugs Ruxience, Truxima, replaced abbreviations RA – clarified combo with MTX, PA – added pediatric indication
2/21	Annual review; replaced abbreviations, added Riabni, added appropriate use section; approved at 4/28/21 P&T
9/21	Changed code for Riabni
2/22	Annual review
2/23	Annual review; added general considerations for use section with defined approval and re-approval time frames and moved appropriate use section, updated Riabni billing units, fixed formatting/numbering scheme
2/24	Annual review; remove oncology section after discussion of new legislature MCL 500.3406e, renamed policy adding “Non-Oncologic Indications”, removed monitoring and patient safety appendix, updated coding section