DRUG DETERMINATION POLICY

Title: DDP-17 Rituximab (Rituxan)

Effective Date: 07/12/2019

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.

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:

Rituxan 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. Non-Oncology Indications

A. Rheumatoid Arthritis (RA)

1. Diagnosis and severity: moderate to severe RA.
2. Other therapies: contraindicated, failed or significant adverse effects with two anti-TNF agents (per packet insert indication).
3. Dosage regimen.
   a. Combination with methotrexate.
   b. Rituxan IV (rituximab): 1,000mg day one and fifteen (repeat q 24 weeks based on response).

B. Polyangiitis (PA)

1. Diagnosis and severity.
   a. Granulomatosis with Polyangiitis (GPA; Wegener Granulomatosis).
   b. Microscopic polyangiitis (MPA).

2. Dosage regimen:
    a. Combination with methylprednisolone/prednisone.
    b. Rituxan IV (rituximab): 375 mg/m^2 one time per week for four doses with methylprednisolone IV for one to three days, then prednisone by mouth one time per day.

II. Oncology

A. Non-Hodgkin's Lymphoma (NHL): CD20 positive.

1. Diffuse large B-cell NHL (untreated).
    a. Combination regimen with CHOP or other anthracycline-based regimen.
    b. Dosage regimen.
        i. Rituxan IV (rituximab): 375mg/m^2 on day one of each cycle for at least 8 infusions.
        ii. Rituxan Hycela SC (r-hyaluronidase): 1,400mg/23,400units day one cycles 2 through 8 (use Rituxan IV cycle 1).
2. Follicular B-Cell NHL (untreated).
    a. Combination regimen with first line chemotherapy.
    b. Induction dosage regimen.
        i. Rituxan IV (rituximab): 375mg/m^2 day one of each cycle for ≤8 infusions.
        ii. Rituxan Hycela SC (r-hyaluronidase): 1,400mg/23,400units day one cycles 2 through 8 (use Rituxan IV cycle 1).
    c. Maintenance dosage regimen (partial or complete response):
        i. Rituxan IV (rituximab): 375mg/m^2 every eight weeks for 12 doses
        ii. Rituxan Hycela SC (r-hyaluronidase): 1,400mg/23,400units every eight weeks for 12 doses.
3. Low grade B-cell NHL (non-progressing).
    a. Second line treatment after six to eight cycles of first line CVP.
    b. Dosage regimen:
        i. Rituxan IV (rituximab): 375mg/m^2 one time weekly times four every six months for ≤16 doses.
        ii. Rituxan Hycela SC (r-hyaluronidase): 1,400mg/23,400units one time per week for three weeks or max 16 doses (use Rituxan IV one time weekly for four doses).
4. Low-grade or follicular B-Cell NHL (relapsing or refractory).
    a. Dosage regimen:
        i. Rituxan IV (rituximab): 375 mg/m^2 one time per week for four to eight doses.
        ii. Rituxan Hycela SC (r-hyaluronidase): 1,400mg/23,400units one time per week for three weeks (use Rituxan IV week one).
    b. Retreatment following disease progression:
        i. Rituxan IV (rituximab): 375mg/m^2 every three months for two years (Canadian labeling).

B. Chronic Lymphocytic Leukemia (CLL): CD20 positive.

1. Combination regimen with fludarabine and cyclophosphamide.
2. Dosage regimen:

a. Rituxan IV (rituximab): 375mg/m^2 one-day prior to chemotherapy in cycle 1 of 28-day cycle, then 500mg/m^2 on day one of cycles 2-6.

b. Rituxan Hycela SC (r-hyaluronidase): 1,600mg/26,800units on day one of 28-day cycle in cycles 2-6 (use Rituxan IV week one).

4.0 Coding:

APPLICABLE CODING				
HCPCS Code	**Brand**	**Generic**	**HCPCS Billing (1u)**	**Prior Auth**
J9312	Rituxan	rituximab	10mg	Y
J9311	Rituxan Hycela	Rituximab hyaluronidase	10mg	Y

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Rituxan, Rituxan Hycela accessed June, 2019.

6.0 Appendices:

Appendix I: Monitoring & Patient Safety - Adverse Reactions and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Rituxan Rituxan Hycela Rituximab/ Hyaluronic-dase	• CV: peripheral edema (8-16%), HTN (6-12%) • CNS: fever (5-53%), fatigue (13-39%), chills (3-33%), HA (17-19%), insomnia (≤4%), pain (12%) • Derm: rash (8-23%), pruritus (5-17%), angioedema (11%) • GI: nausea (8-23%), diarrhea (10-17%), ab. pain (2-14%), wgt. gain (11%) • Hem: lymphopenia (48%), anemia (8-35%), leukopenia (14%), neutropenia (14%), thrombocytopenia (12%) • Hepatic: ALT ↑ • Neuro/SKLM: neuropathy (≤30%), weakness (2-26%) muscle spasm (≤17%), arthralgia (6-13%) • Resp: cough (13%), rhinitis (3-12%), epitaxis (≤11%) • Pregnancy category: C	• CV: CV monitoring • Labs: CBC w diff, plts. (Onc - wkly to monly, RA (2-4 mons); peripheral CD20 • GI: ab. pain • Neuro: PML • Renal: fx., fluid balance • Vital signs • Other: infusion rxs	None Needed

7.0 Revision History:

Original Effective Date: 12/14/2005

Last Approval Date: 07/12/2019

Next Review Date: 07/12/2020

Revision Date	Reason for Revision
4/19	Moving to new format; presented and approved by P&T Committee