

STRIDEsm (HMO) MEDICARE ADVANTAGE

Effective Date: January 1, 2017

Subject: Rituxan® (rituximab)

Policy:

Harvard Pilgrim StrideSM (HMO) Medicare Advantage covers medically necessary Rituxan® (rituximab) for eligible members when standard therapies are contraindicated or have been ineffective, and condition-specific criteria (below) are met.

Covered services must be:

- Reasonable and medically necessary based on the member's condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member's medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.¹

Authorization:

Prior authorization from Harvard Pilgrim StrideSM (HMO) Medicare Advantage is required for all treatment with Rituxan® (rituximab).

- Unless otherwise noted, (below), authorizations, and reauthorizations for ongoing treatment, are limited to periods of 12 months.

Criteria:

Treatment with Rituxan® (rituximab) is authorized when medical record documentation confirms criteria (below) are met.

¹ Appropriate accrediting organizations include the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), or another Centers for Medicare and Medicaid Services (CMS) Approved Accrediting Organization.

Medical Review Criteria

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Harvard Pilgrim StrideSM (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim StrideSM (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim StrideSM (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.

Condition	Criteria
Acute Lymphoblastic or Lymphoblastic Leukemia (ALL)	Documentation confirms diagnosis of ALL. <ul style="list-style-type: none"> Documentation of prior treatment failure is not required.
Acquired Blood Factor Deficiency	Documentation confirms diagnosis of Acquired Blood Factor Deficiency.
Bullous Pemphigoid	Drug is prescribed by a board-certified or board eligible dermatologist, and documentation confirms ALL the following: <ol style="list-style-type: none"> Member age 18 years or older has refractory disease;
Castleman's Disease	Documentation confirms diagnosis of systemic multicentric disease.
Central Nervous System (CNS) Cancers <ul style="list-style-type: none"> Includes Leptomeningeal Metastases 	Documentation confirms diagnosis of CNS Cancer. <ul style="list-style-type: none"> Documentation of prior treatment failure is not required.
Chronic Lymphocytic Leukemia (CLL)	Documentation confirms diagnosis of CLL. <ul style="list-style-type: none"> Documentation of prior treatment failure is not required.
Dermatomyositis	Documentation confirms diagnosis of Dermatomyositis
Evans Syndrome	Documentation confirms diagnosis of Evans Syndrome
Graft-Versus-Host Disease (GVHD)	Documentation confirms chronic, steroid-refractory disease.
Granulomatosis with Polyangiitis (GPA) <ul style="list-style-type: none"> Formerly known as Wegener's Granulomatosis <p>NOTE: Authorization and reauthorization is limited to a maximum of 6 months.</p>	An initial course of Rituxan® (rituximab) is authorized when documentation confirms ALL the following: <ol style="list-style-type: none"> Drug is prescribed by a board-certified or board-eligible rheumatologist or nephrologist: Member aged 18 years or older has diagnosis of GPA <p>Additional courses of Rituxan® (rituximab) are authorized for members aged 18 years or older when drug is prescribed by a board-certified or board-eligible rheumatologist or nephrologist.</p>

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Condition	Criteria
Hodgkin's Disease	Documentation confirms CD20-positive expression.
Human Herpes Virus 8 (HHV-8)²	Documentation confirms diagnosis of HHV-8.
Idiopathic Thrombocytopenic Purpura (ITP)	Documentation confirms ALL the following: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board-eligible hematologist or oncologist; 2. Member aged 18 years or older has diagnosis of ITP;
Microscopic Polyangiitis (MPA) NOTE: Each authorization and reauthorization is limited to a period of 6 months.	An initial course of Rituxan® (rituximab) is authorized when documentation confirms: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board-eligible rheumatologist or nephrologist; 2. Member aged 18 years or older has diagnosis of MPA; <p>Additional courses of Rituxan® (rituximab) are authorized for members aged 18 years or older when documentation confirms ALL the following:</p> <ol style="list-style-type: none"> 1. Drug prescribed by either a board-certified or board-eligible rheumatologist or nephrologist; AND
Minimal Change Disease (MCD)³	Documentation confirms ANY of the following: <ul style="list-style-type: none"> • Refractory disease • Steroid-dependence • History of steroid-resistance
Multiple Sclerosis (MS): <ul style="list-style-type: none"> • Primary-progressive (PPMS) 	Documentation confirms ALL the following: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board-eligible neurologist; 2. Member aged 18 years or older has a diagnosis of primary-progressive MS;

² HHV-8, also known as Kaposi sarcoma-associated herpes virus (KSHV), is the etiologic agent of Kaposi sarcoma (KS) and primary effusion lymphoma (PEL), as well as many cases of Castleman disease.

³ Minimal change nephropathy or disease (MCD) accounts for 10–15% of cases of the nephrotic syndrome in adults with frequent relapses occurring in up to 25% of cases.

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	3. ANY of the following: <ul style="list-style-type: none"> • Member is \leq 50 years of age; OR • Evidence of enhancing lesions on MRI
Multiple Sclerosis (MS): <ul style="list-style-type: none"> • Relapsing-remitting (RRMS) 	Documentation confirms ALL the following: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board-eligible neurologist; 2. Member aged 18 years or older has a diagnosis of relapsing-remitting MS; AND 3. ANY of the following: <ul style="list-style-type: none"> • Positive serology to JC virus; OR
Multiple Sclerosis (MS) <ul style="list-style-type: none"> • Secondary-progressive 	Documentation confirms ALL the following: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board-eligible neurologist; 2. Member aged 18 years or older has a diagnosis of primary secondary-progressive MS; AND 3. ANY of the following: <ul style="list-style-type: none"> • Positive serology to JC virus; OR
Neuromyelitis Optica	Documentation confirms diagnosis of Neuromyelitis Optica. <ul style="list-style-type: none"> • Documentation of prior treatment failure is not required.
Non-Hodgkin's Lymphoma (NHL)/ B Cell Lymphoma	Documentation confirms diagnosis of Non-Hodgkin's Lymphoma (NHL)/ B Cell Lymphoma. <ul style="list-style-type: none"> • Documentation of prior treatment failure is not required.
Pemphigous Vulgaris	Documentation confirms ALL the following: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board-eligible dermatologist; 2. Member aged 18 years or older has refractory disease in a; 3. History of failed first-line therapy;
Polymyositis	Documentation confirms diagnosis of Polymyositis

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Condition	Criteria
Post-Transplant Lymphoproliferative Disorder	Documentation confirms diagnosis of Post-Transplant Lymphoproliferative Disorder. <ul style="list-style-type: none"> • Documentation of prior treatment failure is not required.
Rheumatoid Arthritis (RA) Recommended dosage: Two (2) 1000 mg IV infusions (in combination with methotrexate) separated by 2 weeks (one course) every 24 weeks, or sooner based on clinical evaluation (but not sooner than every 16 weeks).	Documentation confirms ALL the following: <ol style="list-style-type: none"> 1. Drug is prescribed by a board-certified or board eligible rheumatologist; 2. Member aged 18 years or older has moderate to severely active disease; <p>Ongoing treatment is authorized when drug is prescribed by a board-certified or board eligible rheumatologist, and documentation confirms ALL the following:</p> <ol style="list-style-type: none"> 1. Adult patient with moderate to severely active RA; 2. Evidence of improvement of symptoms with prior Rituxan® (rituximab) treatment.
Sjögren’s Syndrome	Documentation confirms diagnosis of primary Sjögren’s Syndrome. ⁴
Systemic Lupus Erythematosus (SLE)	Documentation confirms SLE is refractory to immunosuppressive therapy.
Thrombocytopenic Purpura	Documentation confirms idiopathic/ immune disease.

Exclusions:

Harvard Pilgrim StrideSM (HMO) Medicare Advantage does not cover Rituxan® (rituximab) when criteria above are not met.

Coding: Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

⁴ Primary Sjögren’s syndrome causes early and gradually progressive decreased function in the lacrimal and salivary glands, and can include a variety of extraglandular conditions. The secondary form occurs in people who already have another autoimmune connective tissue disease (e.g., RA or systemic lupus erythematosus) who then develop dry eyes or dry mouth.

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CPT® Code	Description
J9310	Injection, rituximab, 100 mg (Rituxan®)

Summary of Changes

Date	Change
12/15	Add covered conditions. Updated references.
9/16	Annual review/update. Minor language and formatting changes.

Approved by UMCPD: 9/28/16

- Revised: 2/16
- Initial Approval: 8/12/15 (effective 1/1/16)

References:

1. Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals at: <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>
2. Rituxan injection [package insert]. South San Francisco, CA: Genentech, Inc. (Revised 8/14) http://www.gene.com/download/pdf/rituxan_prescribing.pdf
3. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). Available at: http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=68
4. Medicare Coverage Database: Local Coverage Article: Rituximab (RITUXAN®) - Related to LCD L33394 (A52452); Original Effective Date 10/01/2015; Revision Effective Date 02/04/2016

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