STRIDE[sm] (HMO) MEDICARE ADVANTAGE

Effective Date: January 1, 2017

Subject: Remicade® (infliximab)

Policy:
Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage covers on- and off-label use of Remicade® (infliximab) for eligible members who meet specific criteria when services are:

1. Reasonable and medically necessary based on the member's condition, complexity of requested service(s), and accepted standards of clinical practice;
2. 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
3. Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.[1]

Authorization:
Prior authorization from Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage is required for all injections of Remicade® (infliximab).

- Initial authorization is limited to a period of 12 months.
- Reauthorization of on-going treatment may be approved for a period up to 12 months.

Criteria:

Condition	Criteria
Ankylosing Spondylitis (AS) **Recommended Dosage:** 5 mg/kg IV given at 0, 2 and 6 weeks, followed by a maintenance regimen of 5 mg/kg every 6 weeks thereafter.	Authorized when drug is prescribed by a board-certified or board eligible rheumatologist, and medical record documentation confirms ALL the following: 1. Active disease in a member 18 years or older; 2. History of treatment failure with one prescription NSAID;

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

Condition	Criteria
Behçet's Disease (BD)/Behçet's Syndrome	Authorized when drug is prescribed by a board-certified or board eligible rheumatologist, and medical record documentation confirms: 1. Clinical manifestations including severe ocular involvement, major organ involvement, severe gastrointestinal or neurological involvement, and resistant cases of joint or mucocutaneous involvement (i.e., painful oral and genital ulcers); and 2. Inadequate response to initial therapy.
Crohn's Disease (CD)- Adult **Recommended Dosage:** 5 mg/kg IV given at 0, 2 and 6 weeks, followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter. • For adult patients who respond then lose their response, consideration may be given to treatment with 10 mg/kg.)[2]	Authorized when drug is prescribed by a board-certified or board eligible gastroenterologist, and medical record documentation confirms ALL the following: 1. Member 18 and older has diagnosis of moderately to severely active CD;
Crohn's Disease- Pediatric	Authorized when drug is prescribed by a board-certified or board eligible gastroenterologist, and medical record documentation confirms ALL the following: 1. Member age 6 years or older has diagnosis of moderately to severely active CD;
Fistulizing Crohn's Disease **Recommended Dosage:** • 5 mg/kg IV given at 0, 2 and 6 weeks, followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter.	Authorized when drug is prescribed by a board-certified or board eligible gastroenterologist, and medical record documentation confirms ALL the following: 1. Member age 18 years and older has diagnosis of fistulizing CD;

[2] Patients who do not respond by Week 14 are unlikely to respond with continued dosing and consideration should be given to discontinue Remicade® in these patients.

Condition	Criteria
• For adult patients who respond and then lose their response, consideration may be given to treatment with 10 mg/kg.[3]	
Hidradenitis Suppurativa	Authorized when medical record documentation confirms severe, refractory disease.
Plaque Psoriasis **Recommended Dosage:** • 5 mg/kg IV given at 0, 2 and 6 weeks, followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter.	Authorized when drug is prescribed by a board-certified or board eligible dermatologist, and medical record documentation confirms ALL the following: 1. Severe disease in a member age 18 years or older;
Psoriatic Arthritis (PA) **Recommended Dosage:** 5 mg/kg IV given at 0, 2 and 6 weeks, and followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter. • May be used with or without methotrexate.	Authorized when medical record documentation confirms drug is prescribed by a board-certified or board eligible rheumatologist, and ALL the following: 1. Member age 18 years or older has diagnosis of active PA;
Pyoderma Gangrenosum	Authorized when: 1. Drug is prescribed by a board-certified or board eligible gastroenterologist; and 2. Medical record documentation confirms member age 18 years or older has diagnosis of Pyoderma Gangrenosum with coexisting inflammatory bowel disease.
Rheumatoid Arthritis (RA) **Recommended Dosage:** 3 mg/kg given as an intravenous (IV) induction regimen (given in combination with methotrexate) at 0, 2 and 6 weeks followed by a maintenance regimen of 3 mg/kg every 8 weeks thereafter.	Authorized when medical record documentation confirms drug is prescribed by a board-certified or board eligible rheumatologist, and ALL the following: 1. Member age 18 years or older has diagnosis of moderately to severely active RA;

[3] Patients who do not respond by Week 14 are unlikely to respond with continued dosing and consideration should be given to discontinue Remicade® in these patients.

Condition	Criteria
• For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks bearing in mind that risk of serious infections is increased at higher doses.	
Sarcoidosis	Authorized when medical record documentation confirms a diagnosis of sarcoidosis.
Still's Disease (Adult Onset)	Authorized when medical record documentation confirms drug is prescribed by a board-certified or board eligible rheumatologist, and ALL the following: 1. Member age 18 years or older has diagnosis of Adult Onset Still's Disease (AOSD);
Takayasu's disease	Authorized when medical record documentation confirms drug is prescribed by a board-certified or board eligible rheumatologist, and ALL the following: 1. Member age 18 years or older has diagnosis of refractory disease;
Ulcerative Colitis (UC)- Adult **Recommended Dosage:** 5 mg/kg IV given at 0, 2 and 6 weeks, followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter.	Authorized when drug is prescribed by a board-certified or board eligible gastroenterologist, and medical record documentation confirms ALL the following: 1. Member age 18 years or older has diagnosis of moderately to severely active disease;
Ulcerative Colitis- Pediatric (Age 6 years or older) **Recommended Dosage:** 5 mg/kg IV given at 0, 2 and 6 weeks, followed by a maintenance regimen of 5 mg/kg every 8 weeks.	Authorized when drug is prescribed by a board-certified or board eligible gastroenterologist, and medical record documentation confirms ALL the following: 1. Member age 6 years or older has diagnosis of moderately to severely active disease;
Uveitis	Authorized when drug is prescribed by a board-certified or board eligible ophthalmologist or rheumatologist, and medical record documentation

Condition	Criteria
	confirms ALL the following: 1. Member has chronic, recurrent, refractory, OR vision-threatening non-infectious disease;
Wegener's Granulomatosis	Authorized in combination with corticosteroids when medical record documentation confirms refractory disease.

For reauthorization for ongoing treatment, medical record documentation must confirm ALL the following:

1. Remicade® is prescribed by the appropriate specialist (described above) for a member with a diagnosis listed above;
2. There is evidence of symptom improvement with on-going Remicade® treatment.

Exclusions:

Harvard Pilgrim Stride^{SM} (HMO) Medicare Advantage does not cover Remicade® (infliximab) 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.

CPT® Code	Description
J1745	Injection, infliximab, 10 mg (Remicade®)

Approved by UMCPC: 8/24/16

- **Revised 2/16**
- **Initial Approval 8/12/15 (for effective date 1/1/16)**

Summary of Changes

Date	Change
8/16	Annual review/update. Minor language and formatting changes. Add back step for Humira failure in Adult Crohn's disease criteria.
2/16	Add conditions covered per CMS Coverage Article Infliximab (e.g., REMICADE™). **Minor formatting changes. Updated references.**

References:

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2. Remicade for intravenous infusion [package insert]. Malvern, PA 19335. Janssen Biotech, Inc. (Revised 10/15) http://www.remicade.com/shared/product/remicade/prescribing-information.pdf
3. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 64, No. 5, May 2012, pp 625–639.
4. 2015 American College of Rheumatology Clinical Practice Guideline for the Treatment of Rheumatoid Arthritis; Arthritis Care & Research, DOI 10.1002/acr.22783: http://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf (accessed 2/11/16)
5. Medicare Coverage Database: Local Coverage Article: Infliximab (e.g., REMICADE™) – Related to LCD L33394 (A52423); Original Effective Date 10/01/2015; Revision Effective Date 02/04/2016
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14. Rosenbaum, JT. Uveitis: Treatment. In: UpToDate, Post, TW (ed), Waltham, MA, 2016.
15. Peppercorn, MA., Farrell, RJ. Management of severe ulcerative colitis in adults. In: UpToDate, Post, TW (ed), Waltham, MA, 2016.