PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**REMICADE, INFLECTRA, RENFLEXIS**
(generic)	**(infliximab)** **(infliximab-dyyb)** **(infliximab-abda)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref #187-A***

FDA-APPROVED INDICATIONS[1-3]

Crohn's Disease

Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Infliximab is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Pediatric Crohn's Disease

Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis

Infliximab is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis

Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis

Infliximab, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.

Ankylosing Spondylitis

Infliximab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Psoriatic Arthritis

Infliximab is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

Plaque Psoriasis

Infliximab is indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Compendial Uses

- Axial spondyloarthritis[4]
- Behcet's syndrome[5,6]
- Granulomatosis with polyangiitis (Wegener's granulomatosis)[5]

- Hidradenitis suppurativa, severe, refractory[5,7]
- Juvenile idiopathic arthritis[5,8]
- Pyoderma gangrenosum[5,9]
- Sarcoidosis[5,10]
- Takayasu's arteritis[5,11]
- Uveitis[5,12,25]

CRITERIA FOR APPROVAL

1	Has the patient previously received the requested medication for one of the following conditions: A) Crohn's disease, B) Ulcerative colitis, C) Rheumatoid arthritis, D) Ankylosing spondylitis, E) Psoriatic arthritis, F) Plaque psoriasis, G) Axial spondyloarthritis, H) Behcet's syndrome, I) Granulomatosis with polyangiitis (Wegener's granulomatosis), J) Hidradenitis suppurativa, K) Juvenile idiopathic arthritis, L) Pyoderma gangrenosum, M) Sarcoidosis, N) Takayasu's arteritis, O) Uveitis? [If yes, no further questions.]	Yes	No
2	Is the requested medication prescribed for a patient with moderately to severely active Crohn's disease? [If no, skip to question 5.]	Yes	No
3	Does the patient have fistulizing Crohn's disease? [If yes, no further questions.]	Yes	No
4	Has the patient had an inadequate response or intolerance to a self-injectable tumor necrosis factor (TNF) inhibitor (e.g., adalimumab)? [No further questions.]	Yes	No
5	Is the requested medication prescribed for a patient with moderately to severely active ulcerative colitis? [If no, skip to question 7.]	Yes	No
6	Does the patient meet one of the following criteria: A) Patient has had an inadequate response to at least one conventional therapy (e.g., corticosteroids, sulfasalazine, azathioprine, mesalamine), or B) Patient has a contraindication or intolerance to conventional therapy? [No further questions.]	Yes	No
7	Is the requested medication prescribed for a patient with moderately to severely active rheumatoid arthritis? [If no, skip to question 10.]	Yes	No
8	Does the patient meet one of the following criteria: A) the requested medication will be used in combination with methotrexate or leflunomide, or B) Patient has a contraindication or intolerance to methotrexate or leflunomide? [If no, no further questions.]	Yes	No
9	Has the patient had an inadequate response or intolerance to a self-injectable tumor necrosis factor (TNF) inhibitor (e.g., adalimumab) or a targeted synthetic disease-modifying antirheumatic drug (DMARD) (e.g., tofacitinib)? [No further questions.]	Yes	No
10	Is the requested medication prescribed for a patient with active ankylosing spondylitis or	Yes	No

	axial spondyloarthritis? [If no, skip to question 12.]		
11	Has the patient had an inadequate response to a non-steroidal anti-inflammatory drug (NSAID) trial at maximum recommended or tolerated dose OR has intolerance or contraindication to NSAIDs? [No further questions.]	Yes	No
12	Is the requested medication prescribed for a patient with active psoriatic arthritis? [If yes, no further questions.]	Yes	No
13	Is the requested medication prescribed for a patient with chronic moderate to severe plaque psoriasis? [If no, skip to question 16.]	Yes	No
14	Does the patient meet one of the following criteria: A) At least 5 percent of body surface area was affected by plaque psoriasis at the time of diagnosis, or B) Crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis? [If no, no further questions.]	Yes	No
15	Has the patient had an inadequate response or intolerance to a self-injectable tumor necrosis factor (TNF) inhibitor (e.g., adalimumab)? [No further questions.]	Yes	No
16	Is the requested medication prescribed for a patient with juvenile idiopathic arthritis? [If no, skip to question 18.]	Yes	No
17	Has the patient had an inadequate response or intolerance to a self-injectable tumor necrosis factor (TNF) inhibitor (e.g., adalimumab)? [No further questions.]	Yes	No
18	Is the requested medication prescribed for a patient with hidradenitis suppurativa? [If no, skip to question 20.]	Yes	No
19	Does the patient have severe, refractory disease? [No further questions.]	Yes	No
20	Is the requested medication prescribed for a patient with uveitis? [If no, skip to question 22.]	Yes	No
21	Has the patient experienced an inadequate response or intolerance or has a contraindication to a trial of immunosuppressive therapy for uveitis (e.g., methotrexate, azathioprine, or mycophenolate mofetil)? [No further questions.]	Yes	No
22	Is the requested medication prescribed for a patient with one of the following conditions: A) Behcet's syndrome, B) Granulomatosis with polyangiitis (Wegener's granulomatosis), C) Pyoderma gangrenosum, D) Sarcoidosis, E) Takayasu's arteritis?	Yes	No

Guidelines for Approval							
Duration of Approval				**12 months**			
Set 1: Renewal		**Set 2:** CD option 1		**Set 3:** CD option 2		**Set 4:** UC	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	2	1	2	1	5	1
		3		4	3	6	2
Set 5: RA		**Set 6:** AS, Axial SpA		**Set 7:** PsA		**Set 8:** PsO	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
7	1	10	1	12	1	13	1
8	2	11	2		2	14	2
9	5		5		5	15	5
			7		7		7
					10		10
							12
Set 9: JIA		**Set 10:** HS		**Set 11:** Uveitis		**Set 12:** Other	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
16	1	18	1	20	1	22	1
17	2	19	2	21	2		2
	5		5		5		5
	7		7		7		7
	10		10		10		10
	12		12		12		12
	13		13		13		13
			16		16		16
					18		18
							20

Mapping Instructions		
	Yes	**No**
1	Approve, 12 months	Go to 2
2	Go to 3	Go to 5
3	Approve, 12 months	Go to 4
4	Approve, 12 months	Deny
5	Go to 6	Go to 7
6	Approve, 12 months	Deny
7	Go to 8	Go to 10
8	Go to 9	Deny
9	Approve, 12 months	Deny
10	Go to 11	Go to 12
11	Approve, 12 months	Deny
12	Approve, 12 months	Go to 13
13	Go to 14	Go to 16
14	Go to 15	Deny
15	Approve, 12 months	Deny
16	Go to 17	Go to 18
17	Approve, 12 months	Deny
18	Go to 19	Go to 20
19	Approve, 12 months	Deny
20	Go to 21	Go to 22

Mapping Instructions		
	Yes	**No**
21	Approve, 12 months	Deny
22	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

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2. Inflectra [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; April 2016.
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DOCUMENT HISTORY

Written:	UM Development (GP) 06/1999
Revised:	LS 01/2000, 03/2001, JG 10/2001; 07/2002 (new indication); 04/2003, MG 06/2004; NB 12/2004 (new indication and warnings), 05/2005 (new indication), 09/2005 (new indication); MG 06/2006. 09/2006 (New indication), 10/2006 (2) (expanded indication), 05/2007, 07/2008; TG 06/2009, 01/2010; AC 09/2010, 04/2011 (removed trial/failure of Enbrel), GY 08/2011, 10/2011 (CMS), 02/2012 (added Enbrel/Humira step), KR 09/2012 (CMS), KW 09/2013 (CMS), DK 09/2014 (CMS), JP 08/2015 (CMS), IP 09/2015, HY 10/2015 (CMS – TNF examples), IP 07/2016 (CMS), KF 08/2016 (annual), 01/2017 (added Inflectra), 02/2017 (trade, simplification), KF 07/2017 (CMS), KF 08/2017 (added Renflexis)
Reviewed:	CRC 6/1999, 02/2000, 03/2001; 12/2001; 07/2002; 04/2003; CDPR 06/2004, 12/2004, 05/2005, 09/2005, 07/2006, 05/2007, 07/2008, 07/2009; KP 09/2010, 04/2011, 09/2011, 02/2012, 11/2012, 04/2013, 09/2013; SES 09/2014; MM 09/2015, 10//2015, DNC 02/2016; MES 04/2016; ME 09/2016; JG 02/2017, AN 07/2017
External Review:	Dermatology 12/2001, 06/2003, 10/2004, 08/2005, 06/2006, 09/2007, 09/2008, 08/2009, 02/2010, 11/2010, 09/2011, 12/2012, 10/2013, 11/2014, 11/2015, 11/2016, 07/2017 Rheumatology 09/2006, 11/2007, 11/2008, 10/2009, 03/2010, 10/2010, 11/2011, 12/2012, 01/2014, 11/2014, 10/2015, 10/2016, 07/2017 Gastroenterology 10/2006, 11/2007, 10/2008, 11/2009, 01/2010, 12/2010, 12/2011, 02/2013, 11/2013, 11/2014, 10/2016, 11/2016, 07/2017