

# Medical Policy: INFLIXIMAB INJECTABLE (Avsola, Inflectra®, Remicade®, Infliximab, Renflexis™)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.04 November 10, 2023		

#### Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

### **Definitions**

Infliximab is an injectable, intravenously infused, chimeric monoclonal antibody that binds to tumor necrosis factor alpha (TNF-a). It is believed to be critical to the human body's reaction to inflammation. TNF-a is a cytokine that is a key biologic response mediator found to be increased in chronic and inflammatory disorders such as Crohn's disease, rheumatoid arthritis (RA), and other autoimmune diseases.

#### Guideline

I. Initial

Members  $\geq$  6 years of age (unless otherwise indicated) are eligible for infliximab coverage if the below conditions are met **AND** use is consistent per the indications depicted in the table below (or when the criteria are met for the approval of off-label use of FDA-approved drugs).

1. Failed trial of Remicade, Unbranded Infliximab, Inflectra **OR** Avsola prior to using Renflexis.

## **Indications**

Indication	Usage guidance
Ankylosing	1. Documented active disease; AND
spondylitis,	2. Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti- inflammatory agents (NSAIDs) over 4 weeks (in total), unless use is contraindicated
Autoimmune uveitis	<ol> <li>Disease (with or without systemic condition) resulting in glaucoma, synechiae and/or diminished visual acuity</li> <li>Inadequate response, contraindication or intolerance to ≥ 1 other modality (e.g., corticosteroid eye drops, periocular or systemic corticosteroids, immunosuppressive agents, etc.)</li> </ol>
Uveitis Associated with Bechet's disease	<ol> <li>Patient's disease is refractory to immunosuppressive therapy (e.g., corticosteroids, etc.); AND</li> <li>Patient had an inadequate response to a self-administered biologic therapy (e.g., adalimumab)</li> </ol>
Crohn's disease	<ol> <li>Diagnosis of moderate to severe active Crohn's disease</li> <li>Moderate to severe Crohn's disease has remained active despite treatment (minimum 3-month) with one of the following:         <ul> <li>a. Corticosteroids</li> <li>b. 6-mercaptopurine/azathioprine</li> <li>c. 5 aminosalicylates if colonic disease or ileocolonic disease</li> </ul> </li> </ol>
Crohn's disease — fistulizing	Presence of fistulizing Crohn's disease for at least 3 months and no absolute contraindication therapy with infliximab.
Plaque Psoriasis	<ol> <li>≥ 18 years of age (or clinical diagnosis of moderate to severe chronic plaque psoriasis) and all:         <ol> <li>Presence of plaque psoriasis &gt; 6 months</li> <li>At least one of the following:</li></ol></li></ol>

Indication	Usage guidance
Psoriatic Arthritis	<ol> <li>Documented moderate to severe active disease; AND</li> <li>For patients with predominantly axial disease OR active enthesitis, a trial and failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; OR</li> <li>For patients with peripheral arthritis or dactylitis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc.</li> </ol>
Rheumatoid arthritis	<ol> <li>Documented moderate to severe active disease; AND</li> <li>Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; AND</li> <li>Used in combination with methotrexate (MTX) unless contraindicated</li> </ol>
Sarcoid	Refractory to treatment with steroids and other standard drug regimens
Severe immune- related colitis (Medicare only; eff. 11/1/2017)	Does not respond promptly (within 1 week) to therapy with high dose steroids. A single dose of infliximab is sufficient to resolve immune-related colitis in most patients
Takayasu's arteritis	No response to the standard therapies
Ulcerative colitis	Diagnosis of moderate to severe refractory to a minimum 3 month trial with ≥ 1 of the following:  1. Corticosteroids (e.g., prednisone)  2. 5-aminosalicylic acid agents (e.g., sulfasalazine, mesalamine, balsalazide)
	3. Immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

## \*\*Examples of contraindications to phototherapy (PUVA or UVB) include the following

- Xeroderma pigmentosum
- Pregnancy or lactation (PUVA only)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (UVB only)
- Photosensitizing medications (PUVA only)
- Severe liver, renal, or cardiac disease (PUVA only)
- Young age < 12 years old (PUVA only)</li>

## **Dosage/Administration**

Once a dose and frequency are approved, increasing the dose or shortening the frequency will require reapproval.

#### II. RENEWAL CRITERIA

Coverage can be renewed in up to 1-year intervals based upon the following criteria:

- 1. Clinical response or remission of disease is maintained with continued use; AND
- 2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicities include: infections, malignancies, Hepatitis B virus reactivation, hepatotoxicity, heart failure, cardiovascular and cerebrovascular reactions (i.e. cerebrovascular accidents, myocardial infarctions, arrhythmias), hypersensitivity reactions, etc.

# **Applicable Procedure Codes**

Code	Description
J1745	Injection, infliximab, 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg (Eff. 04/01/2018)
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg (Eff. 04/01/2018)
Q5121	Injection, infliximab-axxq, biosimilar (Avsola), 10 mg (Eff. 07/01/2020)
S9359	Home infusion therapy, antitumor necrosis factor intravenous therapy; (e.g., Infliximab); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

# **Applicable NDCs**

Code	Description
57894-0030-01	Remicade 100mg Solution Reconstituted
57894-0160-01	Infliximab 100mg Solution Reconstituted
00069-0809-01	Inflectra 100mg Solution
00006-4305-02	Renflexis 100mg Solution
78206-0162-xx	Renflexis 100mg Solution
55513-0670-01	Avsola 100mg Solution

# **ICD-10 Diagnoses**

Code	Description
D86.0	Sarcoidosis of lung
D86.1	Sarcoidosis of lymph nodes
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
D86.3	Sarcoidosis of skin
D86.81	Sarcoid meningitis
D86.82	Multiple cranial nerve palsies in sarcoidosis
D86.83	Sarcoid iridocyclitis
D86.84	Sarcoid pyelonephritis;
D86.85	Sarcoid myocarditis
D86.86	Sarcoid arthropathy
D86.87	Sarcoid myositis
D86.89	Sarcoidosis of other sites
D86.9	Sarcoidosis, unspecified

H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
H20.10	Chronic iridocyclitis, unspecified eye
H20.11	Chronic iridocyclitis, right eye
H20.12	Chronic iridocyclitis, left eye
H20.13	Chronic iridocyclitis, bilateral
H30.891	Other chorioretinal inflammations, right eye
H30.892	Other chorioretinal inflammations, right eye  Other chorioretinal inflammations, left eye
	Other chorioretinal inflammations, left eye  Other chorioretinal inflammations, bilateral
H30.893	'
H30.899	Other chorioretinal inflammations, unspecified eye
H30.90	Unspecified chorioretinal inflammation, unspecified eye
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding

K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis (Effective 11/01/2017)
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis

140.50	Other provinting outbroughts.
L40.59	Other psoriatic arthropathy
M05.10	Rheumatoid lung disease with rheumatoid arthritis of unspecified site
M05.111	Rheumatoid lung disease with rheumatoid arthritis of right shoulder
M05.112	Rheumatoid lung disease with rheumatoid arthritis of left shoulder
M05.119	Rheumatoid lung disease with rheumatoid arthritis of unspecified shoulder
M05.121	Rheumatoid lung disease with rheumatoid arthritis of right elbow
M05.122	Rheumatoid lung disease with rheumatoid arthritis of left elbow
M05.129	Rheumatoid lung disease with rheumatoid arthritis of unspecified elbow
M05.131	Rheumatoid lung disease with rheumatoid arthritis of right wrist
M05.132	Rheumatoid lung disease with rheumatoid arthritis of left wrist
M05.139	Rheumatoid lung disease with rheumatoid arthritis of unspecified wrist
M05.141	Rheumatoid lung disease with rheumatoid arthritis of right hand
M05.142	Rheumatoid lung disease with rheumatoid arthritis of left hand
M05.149	Rheumatoid lung disease with rheumatoid arthritis of unspecified hand
M05.151	Rheumatoid lung disease with rheumatoid arthritis of right hip
M05.152	Rheumatoid lung disease with rheumatoid arthritis of left hip
M05.159	Rheumatoid lung disease with rheumatoid arthritis of unspecified hip
M05.161	Rheumatoid lung disease with rheumatoid arthritis of right knee
M05.162	Rheumatoid lung disease with rheumatoid arthritis of left knee
M05.169	Rheumatoid lung disease with rheumatoid arthritis of unspecified knee
M05.171	Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot
M05.172	Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot
M05.179	Rheumatoid lung disease with rheumatoid arthritis of unspecified ankle and foot
M05.19	Rheumatoid lung disease with rheumatoid arthritis of multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
L	<u> </u>

M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot

M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems

M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems
	involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot

M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites			
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified			
M06.00	Rheumatoid arthritis with rheumatoid factor, unspecified site			
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder			
M06.012				
M06.019	Rheumatoid arthritis without rheumatoid factor, left shoulder			
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder			
	Rheumatoid arthritis without rheumatoid factor, right elbow			
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow			
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow			
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist			
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist			
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist			
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand			
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand			
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand			
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip			
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip			
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip			
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee			
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee			
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee			
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot			
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot			
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot			
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae			
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites			
M06.80	Other specified rheumatoid arthritis, unspecified site			
M06.811	Other specified rheumatoid arthritis, right shoulder			
M06.812	Other specified rheumatoid arthritis, left shoulder			
M06.819	Other specified rheumatoid arthritis, unspecified shoulder			
M06.821	Other specified rheumatoid arthritis, right elbow			
M06.822	Other specified rheumatoid arthritis, left elbow			
M06.829	Other specified rheumatoid arthritis, unspecified elbow			
M06.831	Other specified rheumatoid arthritis, right wrist			
M06.832	Other specified rheumatoid arthritis, left wrist			
M06.839	Other specified rheumatoid arthritis, unspecified wrist			
M06.841	Other specified rheumatoid arthritis, right hand			
M06.842	Other specified rheumatoid arthritis, left hand			
M06.849	Other specified rheumatoid arthritis, unspecified hand			
M06.851	Other specified rheumatoid arthritis, right hip			
M06.852	Other specified rheumatoid arthritis, left hip			
M06.859	Other specified rheumatoid arthritis, unspecified hip			
M06.861	Other specified rheumatoid arthritis, right knee			
M06.862	Other specified rheumatoid arthritis, left knee			
M06.869	Other specified rheumatoid arthritis, unspecified knee			
M06.871	Other specified rheumatoid arthritis, right ankle and foot			
	other specified incumation districts, right direct and root			

M06.872	Other specified rheumatoid arthritis, left ankle and foot			
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot			
M06.88	Other specified rheumatoid arthritis, vertebrae			
M06.89	Other specified rheumatoid arthritis, multiple sites			
M06.9	Rheumatoid arthritis, unspecified			
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site			
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder			
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder			
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder			
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow			
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow			
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow			
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist			
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist			
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist			
M08.041	Unspecified juvenile rheumatoid arthritis, right hand			
M08.042	Unspecified juvenile rheumatoid arthritis, left hand			
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand			
M08.051	Unspecified juvenile rheumatoid arthritis, right hip			
M08.052	Unspecified juvenile rheumatoid arthritis, left hip			
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip			
M08.061	Unspecified juvenile rheumatoid arthritis, right knee			
M08.062	Unspecified juvenile rheumatoid arthritis, left knee			
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee			
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot			
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot			
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot			
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae			
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites			
M08.1	Juvenile ankylosing spondylitis			
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site			
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder			
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder			
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder			
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow			
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow			
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow			
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist			
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist			
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist			
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand			
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand			
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand			
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip			
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip			
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip			

1100 001				
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee			
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee			
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee			
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot			
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot			
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot			
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae			
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites			
M08.3	Juvenile rheumatoid polyarthritis (seronegative)			
M08.40	Pauciarticular juvenile rheumatoid arthritis, unspecified site			
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder			
M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder			
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder			
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow			
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow			
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow			
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist			
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist			
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist			
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand			
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand			
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand			
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip			
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip			
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip			
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee			
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee			
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee			
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot			
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot			
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot			
M08.48	Pauciarticular juvenile rheumatoid arthritis, vertebrae			
M08.80	Other juvenile arthritis, unspecified site			
M08.811	Other juvenile arthritis, right shoulder			
M08.812	Other juvenile arthritis, left shoulder			
M08.819	Other juvenile arthritis, unspecified shoulder			
M08.821	Other juvenile arthritis, right elbow			
M08.822	Other juvenile arthritis, left elbow			
M08.829	Other juvenile arthritis, unspecified elbow			
M08.831	Other juvenile arthritis, right wrist			
M08.832	Other juvenile arthritis, left wrist			
M08.839	Other juvenile arthritis, unspecified wrist			
M08.841	Other juvenile arthritis, right hand			
M08.842	Other juvenile arthritis, left hand			
M08.849	Other juvenile arthritis, unspecified hand			
M08.851	Other juvenile arthritis, right hip			
l	- and Janama distribution			

M08.852	Other juvenile arthritis, left hip			
M08.859	Other juvenile arthritis, unspecified hip			
M08.861	Other juvenile arthritis, right knee			
M08.862	Other juvenile arthritis, left knee			
M08.869	Other juvenile arthritis, unspecified knee			
M08.871	Other juvenile arthritis, right ankle and foot			
M08.872	Other juvenile arthritis, left ankle and foot			
M08.879	Other juvenile arthritis, unspecified ankle and foot			
M08.88	Other juvenile arthritis, other specified site			
M08.89	Other juvenile arthritis, multiple sites			
M08.90	Juvenile arthritis, unspecified, unspecified site			
M08.911	Juvenile arthritis, unspecified, right shoulder			
M08.912	Juvenile arthritis, unspecified, left shoulder			
M08.919	Juvenile arthritis, unspecified, unspecified shoulder			
M08.921	Juvenile arthritis, unspecified, right elbow			
M08.922	Juvenile arthritis, unspecified, left elbow			
M08.929	Juvenile arthritis, unspecified, unspecified elbow			
M08.931	Juvenile arthritis, unspecified, right wrist			
M08.932	Juvenile arthritis, unspecified, left wrist			
M08.939	Juvenile arthritis, unspecified, unspecified wrist			
M08.941	Juvenile arthritis, unspecified, right hand			
M08.942	Juvenile arthritis, unspecified, left hand			
M08.949	Juvenile arthritis, unspecified, unspecified hand			
M08.951	Juvenile arthritis, unspecified, right hip			
M08.952	Juvenile arthritis, unspecified, left hip			
M08.959	Juvenile arthritis, unspecified, unspecified hip			
M08.961	Juvenile arthritis, unspecified, right knee			
M08.962	Juvenile arthritis, unspecified, left knee			
M08.969	Juvenile arthritis, unspecified, unspecified knee			
M08.971	Juvenile arthritis, unspecified, right ankle and foot			
M08.972	Juvenile arthritis, unspecified, left ankle and foot			
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot			
M08.98	Juvenile arthritis, unspecified, vertebrae			
M08.99	Juvenile arthritis, unspecified, multiple sites			
M35.2	Behcet's disease			
M45.0	Ankylosing spondylitis of multiple sites in spine			
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region			
M45.2	Ankylosing spondylitis of cervical region			
M45.3	Ankylosing spondylitis of cervicothoracic region			
M45.4	Ankylosing spondylitis of thoracic region			
M45.5	Ankylosing spondylitis of thoracolumbar region			
M45.6	Ankylosing spondylitis lumbar region			
M45.7	Ankylosing spondylitis of lumbosacral region			
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region			
M45.9	Ankylosing spondylitis of unspecified sites in spine			
M46.90	Unspecified inflammatory spondylopathy, site unspecified			

M46.91	Unspecified inflammatory spondylopathy, occipito-atlanto-axial region			
M46.92	Unspecified inflammatory spondylopathy, cervical region			
M46.93	Unspecified inflammatory spondylopathy, cervicothoracic region			
M46.94	Unspecified inflammatory spondylopathy, thoracic region			
M46.95	Unspecified inflammatory spondylopathy, thoracolumbar region			
M46.96	Unspecified inflammatory spondylopathy, lumbar region			
M46.97	Unspecified inflammatory spondylopathy, lumbosacral region			
M46.98	Unspecified inflammatory spondylopathy, sacral and sacrococcygeal region			
M46.99	Unspecified inflammatory spondylopathy, multiple sites in spine			
M48.8X1	Other specified spondylopathies, occipito-atlanto-axial region			
M48.8X2	Other specified spondylopathies, cervical region			
M48.8X3	Other specified spondylopathies, cervicothoracic region			
M48.8X4	Other specified spondylopathies, thoracic region			
M48.8X5	Other specified spondylopathies, thoracolumbar region			
M48.8X6	Other specified spondylopathies, lumbar region			
M48.8X7	Other specified spondylopathies, lumbosacral region			
M48.8X8	Other specified spondylopathies, sacral and sacrococcygeal region			
M48.8X9	Other specified spondylopathies, site unspecified			

# **Revision History**

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	11/10/2023	Add Avsola as preferred agent, effective 1/1/2024
EmblemHealth & ConnectiCare	9/25/2023	Annual Review: Initial Criteria:

Ankylosing spondylitis,- Removed: "psoriatic arthritis and other Spondyloarthropathies" and placed in separate column	Removed: "Both:  1. Evidence of inflammatory disease with an inadequate response contraindication, or intolerance to, ≥ 2 nonsteroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen, naproxen, indomethacin, diclofenac, sulindac, etc.
	<ul> <li>≥ 1 disease modifying antirheumatic drugs (DMARDs), separately or in combination, for 3 months (with a minimum of 2 months at a standard dose), e.g. sulfasalazine, methotrexate, azathioprine, cyclosporine, etc.*</li> <li>* Not required if axial skeletal involvement is present; applies only to peripheral arthritis caused by psoriatic arthritis and other spondyloarthropathies."</li> <li>Added:</li> </ul>
	"1. Documented active disease; AND
	2. Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs) over 4 weeks (in total), unless use is contraindicated"
Updated name to include "Uveitis Associated with" Bechet's disease	Removed: "Severe, refractory organ- threatening disease manifestations"  Added:
	<ol> <li>"Patient's disease is refractory to immunosuppressive therapy (e.g., corticosteroids, etc.); AND</li> </ol>
	<ol> <li>Patient had an inadequate     response to a self-administered     biologic therapy (e.g.,     adalimumab)"</li> </ol>

Crohn's disease	<ol> <li>Removed "with manifestation of ≥         1 of the following signs or symptoms:     </li> </ol>
	a. Abdominal pain b. Bleeding c. Diarrhea d. Extraintestinal manifestations (arthritis or spondylitis) e. Internal fistulae f. Intestinal obstruction caused by active disease and not fixed fibrotic structure. g. Megacolon (in conjunction with other standard treatment for this condition— hospitalization, bowel decompression, IV fluids, etc.) h. Perianal disease i. Weight loss"
	<ol> <li>Moderate to severe Crohn's disease has remained active despite treatment Added " (minimum 3-month) " with one of the following:</li> </ol>
Removed Hidradenitis suppurativa	Removed " Moderate to severe disease after failure of oral antibiotics and intralesional steroid injections "
Removed "Juvenile idiopathic arthritis "	Removed "Severe, refractory and has failed to adequately respond to etanercept (Enbrel) and adalimumab (Humira), unless contraindicated. "

Updated name to include "Plaque" Psoriasis	<ol> <li>Presence of plaque psoriasis updated time frame from &gt; "1 year" to "6 months"</li> </ol>
	At least one of the following:
	<ul><li>d. Updated BSA from ≥ "10%" to</li><li>"3 % "of body surface area</li><li>affected</li></ul>
	e. Added "Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
	f. Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; AND"
	<ol> <li>Removed "Inadequate response or intolerance to 3–4-month trial of 1 of the following phototherapies (unless contraindicated):</li> </ol>
	<ul><li>a. Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA)</li><li>b. UVB</li></ul>
	c. 3–4 month adjacent trial of an oral/systemic medication for psoriasis, including but not limited to Methotrexate, Acitretin, Cyclosporine, Azathioprine and other medications"
	4. Added "Patient did not respond adequately (or is not a candidate) to a 4 week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues); AND
	<ol> <li>Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least one non- biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND</li> </ol>
	<ol> <li>Patient did not respond adequately (or is not a candidate**) to a 3 month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal</li> </ol>

			tar or dithranol) " added contraindication chart
		Psoriatic Arthritis	Added all criteria "Documented moderate to severe active disease;  AND
			<ol> <li>For patients with predominantly axial disease OR active enthesitis, a trial and failure of at least a 4-week trial of ONE non-steroidal anti- inflammatory agent (NSAID), unless use is contraindicated; OR</li> </ol>
			3. For patients with peripheral arthritis or dactylitis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying antirheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc."
		Rheumatoid arthritis	Removed "Inadequate response or intolerance to methotrexate monotherapy
			Recommend to be given in combination with MTX"
			Added "Documented moderate to severe active disease; AND
			2. Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; AND
			Used in combination with methotrexate (MTX) unless contraindicated"
		Removed "Still's disease (adult onset)"	Removed criteria "Severe, refractory disease that has failed corticosteroid treatment"
		Ulcerative colitis	Diagnosis of moderate to severe refractory added "to a minimum 3 month trial with" ≥ 1 of the following:
		Removed "Wegener's granulomatosis"	<ol> <li>Removed Criteria "Refractory to conventional treatments</li> <li>In combination with corticosteroids"</li> </ol>
EmblemHealth & ConnectiCare	1/1/2023	Added Inflectra as a preferre	ed agent. <b>EFFECTIVE 1/1/23</b>
EmblemHealth & ConnectiCare	11/10/2022	Added Unbranded Inflixima	ab as a preferred agent

EmblemHealth & ConnectiCare	7/21/2022	Transferred policy to new template	
EmblemHealth & ConnectiCare	4/7/2022	Removed Site of Service language. Refer to Site of Service Policy effective 7/1/2022	
EmblemHealth & ConnectiCare	12/30/2020	Renewal criteria added	
EmblemHealth & ConnectiCare	06/17/2020	Added Avsola (Injection, infliximab-axxq, biosimilar)	
EmblemHealth & ConnectiCare	02/06/2020	Added under Dosage/Administration - Once a dose and frequency are approved, increasing the dose or shortening the frequency will require reapproval.	
EmblemHealth & ConnectiCare	01/24/2020	Added criteria for Dosage/Administration	
EmblemHealth & ConnectiCare	09/11/2019	Added Mandatory Site of Service, effective on 04/01/2020, (Effected lines of business: Commercial and Healthcare Exchange).	
EmblemHealth & ConnectiCare	11/01/2017	<ul> <li>Added Renflexis coverage with prerequisite of failed trial of Remicade prior to using Renflexis (Commercial and Healthcare Exchange members only)</li> <li>Added Severe immune-related colitis (Medicare only)</li> </ul>	
EmblemHealth & ConnectiCare	4/1/2017	Added Inflectra coverage with prerequisite of failed trial of Remicade prior to using Inflectra (Commercial and Healthcare Exchange members only)	
EmblemHealth & ConnectiCare	10/14/2016	<ul> <li>Fistulizing Crohn's disease — added prerequisite that the disease must be present for at least 3 months</li> <li>Severe Juvenile arthritis — added prerequisite of failure to adequately respond to etanercept (Enbrel) and adalimumab (Humira) unless contraindicated</li> </ul>	

## References

- 1. Antoni C, Dechant C, Hanns-Martin Lorenz PD, et al. Open-label study of infliximab treatment for psoriatic arthritis: clinical and magnetic resonance imaging measurements of reduction of inflammation. *Arthritis Rheum*. 2002;47:506-512.
- 2. Antoni C, Kalden JR. Combination therapy of the chimeric monoclonal anti-tumor necrosis factor alpha antibody (infliximab) with methotrexate in patients with rheumatoid arthritis. *Clin Exp Rheumatol.* 1999;17(6 Suppl 18):S73-S77.
- 3. Baeten D, Kruithof E, Van den Bosch F, et al. Immunomodulatory effects of anti-tumor necrosis factor alpha therapy on synovium in spondyloarthropathy: histologic findings in eight patients from an open-label pilot study. *Arthritis Rheum*. 2001; 44:186-195.
- 4. Blam ME, Stein RB, Lichtenstein GR. Integrating anti-tumor necrosis factor therapy in inflammatory bowel disease: current and future perspectives. *Am J Gastroenterol*. 2001;96:1977-1997.

- 5. Brandt J, Haibel H, Reddig J, et al. Successful short-term treatment of severe undifferentiated spondyloarthropathy with the anti-tumor necrosis factor-alpha monoclonal antibody infliximab. *J Rheumatol*. 2002;29:118-122.
- 6. Brandt J, Haibel H, Sieper J, et al. Infliximab treatment of severe ankylosing spondylitis: one-year follow-up. *Arthritis Rheum*. 2001;44:2936-2937.
- 7. Braun J, Brandt J, Listing J, et al. Treatment of active ankylosing spondylitis with infliximab: a randomized controlled multicentre trial. *Lancet*. 2002;359:1187-1193.
- 8. Cauza E, Spak M, Cauza K, et al. Treatment of psoriatic arthritis and psoriasis vulgaris with the tumor necrosis factor inhibitor infliximab. *Rheumatol Int*. 2002;22:227-232.
- 9. Chaudhari U, Romano P, Mulcahy LD, et al. Efficacy and safety of infliximab monotherapy for plaque-type psoriasis: a randomized trial. *Lancet*. 2001; 357:1842-1847.
- 10. Chey WY. Infliximab for patients with refractory ulcerative colitis. Inflamm Bowel Dis. 2001;7(Suppl 1):S30-S33.
- 11. Chey WY, Hussain A, Ryan C, et al. Infliximab for refractory ulcerative colitis. Am J Gastroenterol. 2001;96:2373-2381.
- 12. D'haens G, Van Deventer S, Van Hogezand R, et al. Endoscopic and histological healing with infliximab anti-tumor necrosis factor antibodies in Crohn's disease: a European multicenter trial. *Gastroenterology*. 1999;116:1029-1034.
- 13. Emery P. Infliximab: a new treatment for rheumatoid arthritis. Hosp Med. 2001;62(3):150-152.
- 14. Furst DE, Keystone E, Maini RN, Smolen JS. Recapitulation of the round-table discussion assessing the role of anti-tumor necrosis factor therapy in the treatment of rheumatoid arthritis. *Rheumatology (Oxford)*. 1999;38(Suppl 2):50-53.
- 15. Garnett WR, Yunker N. Treatment of Crohn's disease with infliximab. Am J Health Syst Pharm. 2001;58:307-316.
- 16. Gottlieb AB, Chaudhari U, Mulcahy LD, et al. Infliximab monotherapy provides rapid and sustained benefit for plaque-type psoriasis. *J Am Acad Dermatol*. 2003;48:829-835.
- 17. Gottlieb AB, Masud S, Ramamurthi R, et al. Pharmacodynamic and pharmacokinetic response to anti-tumor necrosis factor-alpha monoclonal antibody (infliximab) treatment of moderate to severe psoriasis vulgaris. *J Am Acad Dermatol*. 2003;48:68-75.
- 18. Hanauer SB. Review article: safety of infliximab in clinical trials. Aliment Pharmacol Ther. 1999;13(Suppl 4):16-22, 38.
- 19. Harriman G, Harper LK, Schaible LF. Summary of clinical trials in rheumatoid arthritis using infliximab, an anti-TNF alpha treatment. *Ann Rheum Dis.* 1999;58(Suppl 1):161-164.
- 20. Heller T, James SP, Drachenberg C, Hernandez C, Darwin PE. Treatment of severe esophageal Crohn's disease with infliximab. *Inflamm Bowel Dis.* 1999;5:279-282.
- 21. Infliximab (Remicade) for Crohn's disease. Med Lett Drugs Ther. 1999;41(1047):19-20.
- 22. Jones RE, Moreland LW. Tumor necrosis factor inhibitors for rheumatoid arthritis. Bull Rheum Dis. 1999;48(3):1-4.
- 23. Kaiser MJ, Sany J. Efficacy of infliximab (Remicade) in the treatment of spondyloarthropathies. Two case reports. *Joint Bone Spine*. 2001;68:525-527.
- 24. Kremer JM. Rational use of new and existing disease-modifying agents in rheumatoid arthritis. *Ann Intern Med.* 2001;134:695-706.
- 25. Kruithof E, Van den Bosch F, Baeten D, et al. Repeated infusions of infliximab, a chimeric anti-TNF alpha monoclonal antibody, in patients with active spondyloarthropathy: one year follow up. *Ann Rheum Dis.* 2002; 61:207-212.
- 26. Lebwohl M. Psoriasis. Lancet. 2003;361:1197-1204.
- 27. Lofberg R. Treatment of fistulas in Crohn's disease with infliximab. Gut. 1999;45:642-643.
- 28. Maini RN, St Clair EW, Breedveld F, et al. For the ATTRACT Study Group. Infliximab (chimeric anti-tumor necrosis factor alpha monoclonal antibody) versus placebo in rheumatoid arthritis patients receiving concomitant methotrexate: a randomized Phase III trial. *Lancet*. 1999;354:1932-1939.

- 29. Maini RN, Taylor PC, Paleolog E. Anti-tumor necrosis factor specific antibody (infliximab) treatment provides insights into the pathophysiology of rheumatoid arthritis. *Ann Rheum Dis.* 1999;58(Suppl 1):156-160.
- 30. Maksymowych WP, Jhangri GS, Lambert RG, et al. Infliximab in ankylosing spondylitis: a prospective observational inception cohort analysis of efficacy and safety. *J Rheumatol*. 2002;29:959-965.
- 31. Marteau P. Inflammatory bowel disease. *Endoscopy*. 2000;32:131-137.
- 32. Mease PJ. Cytokine blockers in psoriatic arthritis. Ann Rheum Dis. 2001;60(Suppl 3):iii37-40.
- 33. Mouser JF, Hyams JS. Infliximab: a novel chimeric monoclonal antibody for the treatment of Crohn's disease. *Clin Ther.* 1999;21:932-942.
- 34. National Government Services. Local Coverage Article: Infliximab, Infliximab-dyyb (e.g., Remicade™, Inflectra™) Related to LCD L25820 (A46764). January 2017. <a href="https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52423&ver=31&Contrld=300&ContrVer=1&CntrctrSelected=300\*1&Cntrctr=300&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13202%2c+A+and+B+and+HHH+MAC%2c+Jr-+K))&LCntrctr=300\*1&bc=AgABAAEAAAAA%3d%3d&. Accessed March 24, 2017.
- 35. Ogilvie AL, Antoni C, Dechant C, et al. Treatment of psoriatic arthritis with antitumor necrosis factor-alpha antibody clears skin lesions of psoriasis resistant to treatment with methotrexate. *Br J Dermatol*. 2001;144:587-589.
- 36. Pincus T, O'Dell JR, Kremer JM. Combination therapy with multiple disease-modifying antirheumatic drugs in rheumatoid arthritis: a preventive strategy. *Ann Intern Med.* 1999;131:768-774.
- 37. Present DH. Infliximab therapy for ulcerative colitis: many unanswered questions. *Am J Gastroenterol*. 2001;96:2294-2296.
- 38. Present DH. Review article: the efficacy of infliximab in Crohn's disease healing of fistulae. *Aliment Pharmacol Ther*. 1999;13(Suppl 4):23-28, 38.
- 39. Present DH, Rutgeerts P, Targan S, et al. Infliximab for the treatment of fistulas in patients with Crohn's disease. *N Engl J Med*. 1999:340:1398-1405.
- 40. Remicade [package insert]. Janssen Biotech, Inc., Horsham, PA; 2013. <a href="http://www.remicade.com/hcp/remicade/assets/hcp-ppi.pdf">http://www.remicade.com/hcp/remicade/assets/hcp-ppi.pdf</a>. Accessed October 18, 2016.
- 41. Renflexis [package insert]. Merck, Whitehouse Station, NJ. https://www.merck.com/product/usa/pi\_circulars/r/renflexis/renflexis pi.pdf. Accessed November 28, 2017.
- 42. Ricart E, Panaccione R, Loftus EV, Tremaine WJ, Sanborn WJ. Successful management of Crohn's disease of the ileoanal pouch with infliximab. *Gastroenterology*. 1999;117:429-432.
- 43. Ricart E, Sanborn WJ. Infliximab for the treatment of fistulas in patients with Crohn's disease. *Gastroenterology*. 1999;117:1247-1248.
- 44. Rutgeerts PJ. Review article: efficacy of infliximab in Crohn's disease induction and maintenance of remission. *Aliment Pharmacol Ther*. 1999;13(Suppl 4):9-15, 38.
- 45. Rutgeerts P, Baert F. New strategies in the management of inflammatory bowel disease. *Acta Clin Belg.* 1999;54:274-280.
- 46. Rutgeerts P, D'haens G, Targan S, et al. Efficacy and safety of retreatment with anti-tumor necrosis factor antibody (infliximab) to maintain remission in Crohn's disease. *Gastroenterology*. 1999;117:761-769.
- 47. Rutgeerts PJ, Targan SR. Introduction: anti-TNF strategies in the treatment of Crohn's disease. *Aliment Pharmacol Ther.* 1999;13(Suppl 4):1.
- 48. Sandborn WJ, Hanauer SB. Antitumor necrosis factor therapy for inflammatory bowel disease: a review of agents, pharmacology, clinical results, and safety. *Inflamm Bowel Dis.* 1999;5:119-133.
- 49. Schopf RE, Aust H, Knop J. Treatment of psoriasis with the chimeric monoclonal antibody against tumor necrosis factor alpha, infliximab. *J Am Acad Dermatol*. 2002;46:886-891.

- 50. Specialty-matched clinical peer review.
- 51. Stein RB, Hanauer SB. Medical therapy for inflammatory bowel disease. Gastroenterol Clin North Am. 1999;28:297-321.
- 52. Stone M, Salonen D, Lax M, et al. Clinical and imaging correlates of response to treatment with infliximab in patients with ankylosing spondylitis. *J Rheumatol*. 2001;28:1605-1614.
- 53. Van Assche G, Rutgeerts P. Anti-TNF agents in Crohn's disease. Expert Opin Investig Drugs. 2000;9:103-111.
- 54. Van den Bosch F, Kruithof E, Baeten D, et al. Effects of a loading dose regimen of three infusions of chimeric monoclonal antibody to tumor necrosis factor alpha (infliximab) in spondyloarthropathy: an open pilot study. *Ann Rheum Dis.* 2000;59:428-433.
- 55. Van den Bosch F, Kruithof E, Baeten D, et al. Randomized double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (infliximab) versus placebo in active spondyloarthropathy. *Arthritis Rheum*. 2002;46:755-765.
- 56. Van den Bosch F, Kruithof E, De Vos M, et al. Crohn's disease associated with spondyloarthropathy: effect of TNF-alpha blockade with infliximab on articular symptoms. *Lancet*. 2000;356:1821-1822.
- 57. Van Deventer SJ. Review article: targeting TNF alpha as a key cytokine in the inflammatory processes of Crohn's disease the mechanisms of action of infliximab. *Aliment Pharmacol Ther*. 1999;13(Suppl 4):3-8, 38.