



EVH Clinical Guideline 5015.CC for Infliximab Products

Guideline Number: EVH_CG_5015.CC	<u>Applicable Codes</u>	
<p>"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. © 2022 - 2026 Evolent. All rights Reserved.</p>		
Original Date: March 2022	Last Revised Date: March 2026	Implementation Date: June 2026

TABLE OF CONTENTS

STATEMENT	3
GENERAL INFORMATION.....	3
PURPOSE.....	3
SCOPE.....	3
SPECIAL NOTE.....	3
PLAN DESIGN SUMMARY.....	3
INITIAL REVIEW CRITERIA	4
GENERAL CRITERIA.....	4
ANKYLOSING SPONDYLITIS (AS) AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA) (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY).....	4
CROHN'S DISEASE	4
PLAQUE PSORIASIS (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY)	4
PSORIATIC ARTHRITIS (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY)	5
RHEUMATOID ARTHRITIS (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY)	5
ULCERATIVE COLITIS.....	6
ACUTE GRAFT VERSUS HOST DISEASE (OFF-LABEL SUPPORTED INDICATION)	6
BECHE'T'S DISEASE (OFF-LABEL SUPPORTED INDICATION)	6
HIDRADENITIS SUPPURATIVA (OFF-LABEL SUPPORTED INDICATION).....	6
IMMUNE CHECKPOINT INHIBITOR-RELATED TOXICITY (OFF-LABEL SUPPORTED INDICATION).....	7
PYRODERMA GANGRENOSUM (OFF-LABEL SUPPORTED INDICATION)	7
REACTIVE ARTERITIS (OFF-LABEL SUPPORTED INDICATION)	7
SARCOIDOSIS (OFF-LABEL SUPPORTED INDICATION)	7
TAKAYASU'S ARTERITIS (OFF-LABEL SUPPORTED INDICATION)	7
UVEITIS (OFF-LABEL SUPPORTED INDICATION)	7
REAUTHORIZATION CRITERIA	7
GENERAL CRITERIA.....	7
ANKYLOSING SPONDYLITIS (AS) AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA) (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY).....	8
CROHN'S DISEASE	8
PLAQUE PSORIASIS (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY)	8
PSORIATIC ARTHRITIS (AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY)	9



RHEUMATOID ARTHRITIS (<i>AVSOLA/INFLECTRA/INFLIXIMAB/REMICADE/RENFLEXIS ONLY</i>)	9
ULCERATIVE COLITIS	9
HIDRADENITIS SUPPURATIVA (<i>OFF-LABEL SUPPORTED INDICATION</i>).....	9
REACTIVE ARTERITIS (<i>OFF-LABEL SUPPORTED INDICATION</i>)	10
UVEITIS (<i>OFF-LABEL SUPPORTED INDICATION</i>)	10
ALL OTHER INDICATIONS	10
APPROVAL DURATIONS	10
APPENDICES	11
APPENDIX 1 - EXAMPLES OF CLINICAL REASONS TO AVOID PHARMACOLOGIC TREATMENT WITH METHOTREXATE, CYCLOSPORINE, ACITRETIN, OR LEFLUNOMIDE	11
APPENDIX 2 - 2018 ACG CLINICAL GUIDELINES CLASSIFICATION OF MODERATE-TO-SEVERE DISEASE	11
CODING AND STANDARDS	12
CODES	12
APPLICABLE LINES OF BUSINESS	12
POLICY HISTORY	12
LEGAL AND COMPLIANCE	13
GUIDELINE APPROVAL	13
<i>Committee</i>	13
DISCLAIMER	13
REFERENCES	14

STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for the following drug(s): Remicade® (infliximab), Inflectra® (infliximab-dyyb), Renflexis® (infliximab-abda), Avsola™ (infliximab-axxq), and Zymfentra™ (infliximab-dyyb, subcutaneous).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan’s medical benefit.

Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate®, Lexidrug™, Elsevier Clinical Pharmacology).

Plan Design Summary

Requests for infliximab products are subject to the preferred medical drug list program. This program applies to the products specified in this guideline. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product. The coverage review process will ascertain situations where a clinical exception can be made.

Preferred Product Table	
Preferred	<ul style="list-style-type: none"> • Inflectra® (infliximab-dyyb) – Q5103 • Renflexis® (infliximab-abda) – Q5104
Non-Preferred	<ul style="list-style-type: none"> • Avsola™ (infliximab-axxq) – Q5121 • Remicade® (infliximab) – J1745 • Zymfentra™ (infliximab-dyyb) – J1748

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

General Criteria

- **Requests for non-preferred products:** Must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Must have a negative tuberculosis skin test collected within the last 6 months
 - Example acceptable testing includes the Tuberculin PPD (purified protein derivative test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with the Infliximab product
- Must have no evidence of infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA-approved labeling (*if being used for an FDA-approved indication*)

Ankylosing Spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of ankylosing spondylitis
- Must have an adequate trial (of at least 4 weeks) with at least **TWO** NSAIDs at anti-inflammatory dose, with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies

Crohn's Disease

- Must be prescribed by a gastroenterologist
- Must be age:
 - 6 years or older (Avsola/Inflectra/infliximab/Remicade/Renflexis only)
 - 18 years or older (Zymfentra only)
- Must have a diagnosis of moderate to severely active Crohn's disease or fistulizing Crohn's disease, as described in the 2018 ACG guidelines ([Appendix 2](#))

Plaque Psoriasis *(Avsola/Inflectra/infliximab/Remicade/Renflexis*

only)

- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate-to-severe chronic plaque psoriasis
- Must have documentation of ONE of the following:
 - Affected area(s) include hands, feet, face, neck, scalp, genitals/groin, intertriginous areas
 - Minimum body surface area (BSA) involvement of >10%
 - At least 3% of BSA affected AND the member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) OR pharmacologic treatment with methotrexate, cyclosporine, or acitretin (unless there is a clinical reason to not take pharmacologic treatment – see [Appendix 1](#))

Psoriatic Arthritis

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- Must be prescribed by a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis, with the severity of disease documented
- For mild-to-moderate disease only, must have ONE of the following:
 - Must have had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) or have a contraindication or intolerance to all drugs (see [Appendix 1](#))
 - Must have enthesitis or predominantly axial disease

Rheumatoid Arthritis

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have documentation of testing of the following:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) – not required if RF & anti-CCP are positive

- Must be prescribed in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see **Appendix 1**)
- Must have documentation showing ONE of the following:
 - Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week)
 - Member has an intolerance or contraindication to methotrexate (see **Appendix 1**)

Ulcerative Colitis

- Must be prescribed by a gastroenterologist
- Must be age:
 - 6 years or older (Avsola/Inflectra/infliximab/Remicade/Renflexis only)
 - 18 years or older (Zymfentra only)
- Must have a diagnosis of moderate to severely active Ulcerative Colitis, as evidenced by ONE of the following:
 - Dependency on or refractory to corticosteroids
 - Severe endoscopic disease activity (e.g., presence of ulcers)
 - High risk of colectomy
 - Mayo Clinic scores of 6-12, with an endoscopic subscore of 2 or 3
 - Hospitalized with ≥ 6 bloody bowel movements per day with at least 1 marker of systemic toxicity (e.g., heart rate >90 beats/min, temperature $>37.8^{\circ}\text{C}$, hemoglobin <10.5 g/dL, and/or erythrocyte sedimentation rate >30 mm/h)

Acute Graft Versus Host Disease (*off-label supported indication*)

- Must have had an inadequate response to systemic corticosteroids

Behcet's Disease (*off-label supported indication*)

- Must have an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids)

Hidradenitis Suppurativa (*off-label supported indication*)

- Must have a diagnosis of severe, refractory hidradenitis suppurativa
- Must have had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines) for at least 90 days

Immune Checkpoint Inhibitor-related Toxicity (*off-label supported indication*)

- Must have had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)

Pyroderma Gangrenosum (*off-label supported indication*)

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)

Reactive arteritis (*off-label supported indication*)

- Must have had an inadequate response to methotrexate or sulfasalazine

Sarcoidosis (*off-label supported indication*)

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy

Takayasu's arteritis (*off-label supported indication*)

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)

Uveitis (*off-label supported indication*)

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, methotrexate, azathioprine, mycophenolate mofetil)

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

EXCEPTION: Reauthorization requests for immune checkpoint inhibitor related toxicity and acute graft versus host disease must meet initial criteria.

General Criteria

- Requests for non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)

Ankylosing Spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Functional status
 - Total spinal pain
 - Inflammation (e.g., morning stiffness)
 - Swollen joints
 - Tender joints
 - C-reactive protein (CRP)

Crohn's Disease

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Abdominal pain or tenderness
 - Diarrhea
 - Body weight
 - Abdominal mass
 - Hematocrit
 - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Plaque Psoriasis (*Avsola/Inflectra/infliximab/Remicade/Renflexis only*)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Body surface area (BSA)
 - Signs and Symptoms (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Psoriatic Arthritis

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Number of swollen joints
 - Number of tender joints
 - Dactylitis
 - Enthesitis
 - Skin and/or nail involvement
 - Functional status
 - C-reactive protein (CRP)

Rheumatoid Arthritis

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by disease activity or improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Ulcerative Colitis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Stool frequency
 - Rectal bleeding
 - Urgency of defecation
 - C-reactive protein (CRP)
 - Fecal calprotectin (FC)
 - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Hidradenitis Suppurativa *(off-label supported indication)*

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

Reactive arteritis (*off-label supported indication*)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, pain).

Uveitis (*off-label supported indication*)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Reduced frequency of flare recurrence compared to baseline
 - Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
 - Decreased reliance on topical corticosteroids

All Other Indications

- Must have recent chart documentation showing achievement or maintenance of a clinical response and/or remission, as evidenced by low disease activity or improvement in signs and symptoms of the condition.

APPROVAL DURATIONS

Initial Authorization	Up to 1 year
Reauthorization	Same as initial

APPENDICES

Appendix 1 - Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix 2 - 2018 ACG Clinical Guidelines Classification of Moderate-to-Severe Disease

Moderate-to-Severe Disease	Severe-Fulminant Disease
<p><i>One of the following:</i></p> <ul style="list-style-type: none"> ● CDAI 220-450 ● Have failed treatment for mild to moderate disease ● Prominent symptoms such as fever, weight loss, abdominal pain and tenderness, intermittent nausea or vomiting, or anemia ● Moderate to severely active endoscopic mucosal disease 	<p><i>One of the following:</i></p> <ul style="list-style-type: none"> ● CDAI >450 ● Persistent symptoms despite glucocorticoids or biologic agents ● Individuals presenting with high fever, persistent vomiting, intestinal obstruction, peritoneal signs, cachexia, or evidence of an abscess

CODING AND STANDARDS

Codes

Code	Brand	Description
J1745	Remicade	Injection, infliximab, excludes biosimilar, 10 mg
J1748	Zymfentra	Injection, infliximab-dyyb (zymfentra), 10 mg
Q5103	Inflectra	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Renflexis	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q5121	Avsola	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg

Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

POLICY HISTORY

Date	Summary
June 2026	<ul style="list-style-type: none"> Removed Ixifi Updated preferred/non-preferred agents; brand Remicade moved to non-preferred status
June 2025	<ul style="list-style-type: none"> Added Ixifi Updated reauthorization criteria for all indications
July 2024	<ul style="list-style-type: none"> Added Zymfentra Updated criteria for RA, psoriasis, psoriatic arthritis, and ankylosing spondylitis

Date	Summary
	<ul style="list-style-type: none"> ● Removed prerequisite trials for Crohn’s and Ulcerative Colitis; Added diagnostic criteria for Crohn’s and Ulcerative Colitis ● Added 9 indications: Bechet’s disease, Hidradenitis suppurativa, Pyroderma gangrenosum, Sarcoidosis, Takayasu’s arteritis, Uveitis, Reactive arteritis, Immune checkpoint inhibitor-related, Acute Graft Versus Host
March 2022	<ul style="list-style-type: none"> ● New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members’ health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Remicade [package insert]. Horsham, PA: Jansen Biotech, Inc.; October 2021.
2. American College of Rheumatology. Guidelines for the Management of Rheumatoid Arthritis 2002 Update. *Arthritis & Rheumatism*. 2002; 46(2) :328-346.
3. Andonopoulos AP, Meimaris N, Daoussis D, et al. Experience with infliximab (anti-TNF alpha monoclonal antibody) as monotherapy for giant cell arteritis. *Ann Rheum Dis*. 2003;62:1116.
4. 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.
5. Antoni C, Kavanaugh A, Kirkham B, et al. The one year results of the infliximab multinational psoriatic arthritis controlled trial (IMPACT) [abstract]. Presented at: American College of Rheumatology 67th Annual Scientific Meeting; October 23-28, 2003; Orlando, FL. Arthritis foundation. www.arthritis.org. Accessed June 2005.
6. Baldassano R, Braegger CP, Escher JC, et al. Infliximab (REMICADE) therapy in the treatment of pediatric Crohn's disease. *Am J Gastroenterol*. 2003;98:833-838.
7. Bartolucci P, Ramanoelina J, Cohen P, et al. Efficacy of the anti-TNF-alpha antibody infliximab against refractory systemic vasculitides: an open pilot study on 10 patients. *Rheumatology (Oxford)*. 2002;41:1126-1132.
8. Benitez-Del-Castillo JM, Martinez-De-La-Casa JM, Pato-Cour E, et al. Long-term treatment of refractory posterior uveitis with anti-TNFalpha (infliximab). *Eye*. 2004 Sep 24; [Epub ahead of print]
9. Billiau AD, Cornillie F, Wouters C. Infliximab for systemic onset juvenile idiopathic arthritis: experience in 3 children [letter]. *J Rheumatol*. 2002;29:1111-1114.
10. Booth A, Harper L, Hammad T, et al. Prospective study of TNFalpha blockade with infliximab in anti-neutrophil cytoplasmic antibody-associated systemic vasculitis. *J Am Soc Nephrol*. 2004;15:717-721.
11. Booth AD, Jefferson HJ, Ayliffe W, et al. Safety and efficacy of TNF alpha blockade in relapsing vasculitis [letter]. *Ann Rheum Dis*. 2002;61:559.
12. Brandt J, Haibel H, Reddig J, et al. Successful short term treatment of severe undifferentiated spondyloarthritis with the anti-tumor necrosis factor-alpha monoclonal antibody infliximab. *J Rheumatol*. 2002;29:118-122.
13. Bran J, Pham T, Sieper J, et. Al. International ASAS consensus statement for the use of tumour necrosis factor agents in patients with ankylosing spondylitis. *Ann Rheum Dis* 2003;62:817.
14. Bran J, Davis J, Dougados M, et. Al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. *Ann Rheum Dis* 2006;65:316.
15. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008;58:826-850.
16. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol*. 2008;1-17.
17. Pariser DM, Bagel J, Gelfand JM, et al; National Psoriasis Foundation clinical consensus on disease severity. *Arch Dermatol*. 2007;143:239-242.
18. Tzu J, Kerdel F. From conventional to cutting edge: the new era of biologics in treatment of psoriasis. *Dermatologic Therapy*. 2008;21:131-141.

19. Menter A, Griffiths CEM. Current and future management of psoriasis. *Lancet*. 2007; 370:272-284.
20. Saag KG, Teng GG, Patkar NM et al. American college of rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum* 2008;59(6):762-784
21. American Gastroenterological Association Institute Technical Review on Corticosteroids, Immunomodulators, and Infliximab in Inflammatory Bowel Disease. *Gastroenterology* 2006; 130:940-987.
22. Lichtenstein GR, Hanauer SB et al. American College of Gastroenterology Practice Guidelines on the Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2009; 1-19.
23. Kornbluth A, Sachar DB et al. Ulcerative Colitis Practice Guidelines in Adults (Update): American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol* 2004; 1371-1385.25. Lamireau T, Cezard JP, Dbadie A, et al. Efficacy and tolerance of infliximab in children and adolescents with Crohn's disease. *Inflammatory Bowel Disease* 2004; 10(6):745-50.
24. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis infection – United States 2010. Department of Health and Human Services Centers for Disease Control and Prevention [U.S.]. vol 59, RR-5. 2010 June 25.
25. Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm>. Accessed 10/29/2012
26. Van der Heijde D, Sieper J, Maksymowych W, et al. 2010 Update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. *Ann Rheum Dis* 2011;70:905-908.
27. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 2. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol*. 2008;58(5):851-864.
28. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009b;61(3):451-485.
29. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. *J Am Acad Dermatol*. 2010;62(1):114-135.
30. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
31. Lichenstein GR, Loftus EV, Isaacs KL. ACS Clinical Guideline Management of Crohn's Disease in Adults. *AM J Gastroenterol*. 2018;113(4): 418. Epub 2018 Mar 27.
32. Feurstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology* 2020; 158: 1450-1461.
33. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. *J Am Acad Dermatol*. 2019; 81(1): 76-90.
34. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. *J Am Acad Dermatol*. 2019; 81(1): 91- 101.

35. Zymfentra [package insert]. Jersey City, NJ: Celltrion USA, Inc.; October 2023.
36. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.
37. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. *Ann Rheum Dis.* 2018;77:808-818.
38. Agarwal A, Andrews JM. Systematic review: IBD-associated pyoderma gangrenosum in the biologic era, the response to therapy. *Aliment Pharmacol Ther.* 2013;38(6):563-572.
39. Arguelles-Arias F, Castro-Laria L, Lobaton T, et al. Characteristics and treatment of pyoderma gangrenosum in inflammatory bowel disease. *Dig Dis Sci.* 2013;58(10):2949-2954
40. Marzano AV, Ishak RS, Saibeni S, et al. Autoinflammatory skin disorders in inflammatory bowel diseases, pyoderma gangrenosum and Sweet's syndrome: A comprehensive review and disease classification criteria. *Clin Rev Allergy Immunol.* 2013;45(2):202-10.
41. George, C, Deroide, F, Rustin, M. Pyoderma gangrenosum – a guide to diagnosis and management. *Clin Med.* 2019;19(3):224-8
42. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; May 2023
43. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; May 2023
44. Avsola (infliximab-axxq) [prescribing information]. Thousand Oaks, CA: Amgen Inc; September 2021.