

Title: UM-PT021 Infliximab	Division: Medical Management Department: Pharmacy
Approval Date: 5/25/2023	LOB: Medicaid, HIV SNP, HARP, QHP, EP, Gold, GoldCare, CHP
Effective Date: 5/25/2023	Policy Number: UM-PT021
Review Date: 1/28/2025	Cross Reference Number:
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I. POLICY DESCRIPTION:

Infliximab – Avsola (infliximab-axlxq); Inflectra (infliximab-dyyb); Ixifi (infliximab-qbtx); Remicade (infliximab); Renflexis (infliximab-abda), Zymfentra (infliximab-dyyb)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department. Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Infliximab and its biosimilars are chimeric monoclonal antibodies that bind to human tumor necrosis factor alpha (TNF α), thereby interfering with endogenous TNF α activity. Elevated TNF α levels have been found in involved tissues/fluids of patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, crohn’s disease and ulcerative colitis. Biological activities of TNF α include the induction of proinflammatory cytokines (interleukins), enhancement of leukocyte migration, activation of neutrophils and eosinophils and the induction of acute phase reactants and tissue degrading enzymes.

IV. POLICY:

Infliximab and its biosimilars will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis as prescribed by or in consultation with a gastroenterologist/rheumatologist and previous treatment(s).

Member is not using the requested medication concomitantly with any other biologic drug or targeted synthetic drug

For non-Medicaid Plan members Inflectra is the preferred product. Avsola, Ixifi, Remicade and Renflexis require trial and failure with Inflectra.

INITIAL REQUEST & RENEWAL REQUEST:

For Medicaid, SNP, HARP Plan members, follow the criteria below for the specific medications mentioned:

1. Avsola, Inflectra, Remicade, Renflexis, Zymfentra

A. Confirm diagnosis for FDA- or compendia-supported uses;

AND

B. Trial of a disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNFi) Food and Drug Administration (FDA)-approved for self-administration prior to initiation of requested medication;

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AND

C. Authorization is for no more than 12 months

INITIAL REQUEST:

For Medicaid, SNP, HARP Plan members for Ixifi, follow the criteria below:

1. Moderately to severely active crohn's disease (CD)

A. Member is 3 years of age or older;

AND

B. ONE of the following:

a. ALL of the following:

i. Member has experienced an inadequate response for at least 3 months to at least ONE systemic corticosteroids (e.g., azathioprine; mercaptopurine; methotrexate) or has an intolerance to;

AND

ii. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) a tumor necrosis factor inhibitor (TNFi) or any other biologic;

OR

b. Member has fistulizing CD;

AND

C. Authorization is for no more than 12 months

2. Moderately to severely active ulcerative colitis (UC)

A. Member is 6 years of age or older;

AND

B. ALL of the following:

a. Member has experienced an inadequate response for at least 4 weeks to ONE of the following: oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), rectal mesalamine (e.g., Canasa, Rowasa rectal hydrocortisone (e.g., Colocort, Cortifoam), balsalazide, olsalazine, prednisone, azathioprine, mercaptopurine, sulfasalazine, balsalazide, olsalazine, cyclosporine, tacrolimus;

AND

b. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) a tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

C. Authorization is for no more than 12 months

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3. Moderately to severely active rheumatoid arthritis (RA)

- A. Member is 18 years of age or older;
AND
- B. Member has a confirmed diagnosis of moderately to severely active rheumatoid arthritis (RA) as defined by ONE of the following;
 - a. ≥ 8 tender joints or painful on motion; and ≥ 6 swollen joints;
OR
 - b. high sensitivity C-reactive protein (hs-CRP) ≥ 7 mg/L;
OR
 - c. Erythrocyte sedimentation rate (ESR) ≥ 28 mm/H;
- AND**
- C. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) ALL of the following:
 - a. Methotrexate in combination with another conventional DMARD for 3 months;
AND
 - b. Tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- D. Authorization is for no more than 12 months

4. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

- A. Member is 18 years of age or older;
AND
- B. ONE of the following criteria is met:
 - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs);
OR
 - b. Member has an intolerance or contraindication to two or more NSAIDs;
- AND**
- C. ONE of the following criteria is met:
 - a. Member has tried a tumor necrosis factor inhibitor (TNFi) or any other biologic;
OR
 - b. Member has an intolerance or contraindication to a tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- D. Authorization is for no longer than 12 months

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5. Active psoriatic arthritis (PsA)

A. Member is 18 years of age or older;

AND

B. ALL of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. A 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week) or any other conventional DMARD (e.g., leflunomide, sulfasalazine, cyclosporine);

AND

ii. NSAIDs for at least 4 weeks;

AND

iii. Corticosteroids stable on a dose of ≤ 10 mg/day prednisone or equivalent for at least 2 weeks;

AND

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

C. Authorization is for no more than 12 months

6. Moderate to severe plaque psoriasis

A. Member is 18 years of age or older;

AND

B. Body surface area affected by plaque-type psoriasis of 10% or greater;

AND

C. ALL of the following:

a. Member has tried ALL of the following for at least 3 months (unless intolerant or contraindicated):

i. Conventional DMARD therapy (see Appendix A);

AND

ii. Phototherapy (e.g. UVB, PUVA) administered 3-5 times per week;

AND

b. Member has tried a tumor necrosis factor inhibitor (TNFi) for at least 3 months (unless intolerant or contraindicated) or any other biologic;

AND

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7. Hidradenitis suppurativa

A. Member has a confirmed diagnosis of moderate to severe hidradenitis suppurativa with a total abscess and inflammatory-nodule count of three or more;

AND

B. Member has a documented trial and failure or contraindication of using at least ONE regimen from each of the following treatment options within the past 12 months:

a. Intralesional corticosteroid;

AND

b. Topical Clindamycin for 3 months;

AND

c. Oral mono antibiotics for 3 months: tetracycline, minocycline, doxycycline;

AND

d. Oral combo antibiotics for 3 months: oral clindamycin and oral Rifampin;

AND

e. Oral Hormonal therapy- Spironolactone for 3 months for female members;

AND

f. Oral retinoids- Acitretin for 6 months for members with concomitant acne;

AND

g. Biologic – Humira for 3 months;

AND

C. Authorization is for no more than 12 months

8. Juvenile Idiopathic arthritis (JIA)

A. ALL of the following:

a. Member has an inadequate response to ALL of the following:

i. 1-month trial of NSAIDs;

AND

ii. 2-week trial of corticosteroids;

AND

iii. 3-month trial of methotrexate or another non-biologic DMARD;

AND

b. Member has an inadequate response to tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

B. Authorization is for no more than 12 months

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9. Pyoderma gangrenosum

- A. ALL of the following:
 - a. Member has experienced an inadequate response to ALL of the following:
 - i. Corticosteroids;
 - AND**
 - ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);
 - AND**
 - b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- B. Authorization is for no more than 12 months

10. Sarcoidosis

- A. ALL of the following:
 - a. Member has experienced an inadequate response to ALL of the following:
 - i. Corticosteroids;
 - AND**
 - ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);
 - AND**
 - b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- B. Authorization is for no more than 12 months

11. Takayasu’s arteritis

- A. ALL of the following:
 - a. Member has experienced an inadequate response to ALL of the following:
 - i. Corticosteroids;
 - AND**
 - ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);
 - AND**
 - b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- B. Authorization is for no more than 12 months

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12. Uveitis

- A. Member has a confirmed diagnosis of non-infectious intermediate, posterior, and panuveitis with the presences of ONE of the following:
 - a. $\geq 2+$ anterior chamber cell grade (Standardization of Uveitis Nomenclature criteria);

OR

- b. Vitreous Haze grade of $\geq 2+$;

OR

- c. Active, inflammatory, chorioretinal and/or inflammatory retinal vascular lesion;

AND

- B. Recent history (within 12 months) of taking at least ONE from each of the following treatment options:

- a. Topical corticosteroid eye drops for 3 months (e.g., prednisolone, dexamethasone, fluorometholone);

AND

- b. Oral Glucocorticoids for 3 months (e.g., steroid equivalent to 40-60mg of prednisone);

AND

- c. Calcineurin Antagonist for 3 months (e.g., cyclosporine, tacrolimus);

AND

- d. Cytotoxic agents for 3 months (e.g., methotrexate, azathioprine, mycophenolate);

AND

- e. Biologic therapy for 3 months (e.g. Humira);

AND

- C. Authorization is for no more than 3 months

13. Reactive arthritis

- A. ALL of the following:

- a. Member has experienced an inadequate response to ALL of the following:
 - i. 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week);

AND

- ii. NSAIDs for at least 4 weeks;

AND

- iii. Corticosteroids stable on a dose of ≤ 10 mg/day prednisone or equivalent for at least 2 weeks;

AND

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- b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);

AND

- B. Authorization is for no more than 12 months

14. Immune checkpoint inhibitor toxicity

- A. Member has diagnosis of immunotherapy-related myocarditis, pericarditis, arrhythmias, impaired ventricular function or conduction abnormalities;

AND

- B. Member is 18 years of age or older;

AND

- C. Member started pulse-dose methylprednisolone and had no improvement of toxicity within 24 hours;

AND

- D. Member has received checkpoint inhibitor therapy [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)] recently;

AND

- E. Authorization is for no more than 12 months

15. Acute graft versus host disease

- A. ONE of the following:

- a. Member has experienced an inadequate response to systemic corticosteroids;

OR

- b. Member is intolerant to systemic corticosteroids;

AND

- B. Tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

- C. Authorization is for no more than 12 months

For all other Plan members, follow the criteria below:

1. Moderately to severely active crohn's disease (CD)

- A. Member is 3 years of age or older;

AND

- B. ONE of the following:

- a. ALL of the following:

- i. Member has experienced an inadequate response for at least 3 months to at least ONE systemic corticosteroids (e.g., azathioprine; mercaptopurine; methotrexate) or has an intolerance to;

AND

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ii. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) a tumor necrosis factor inhibitor (TNFi) or any other biologic;

OR

b. Member has fistulizing CD;

AND

C. Authorization is for no more than 12 months

2. Moderately to severely active ulcerative colitis (UC)

A. Member is 6 years of age or older;

AND

B. ALL of the following:

a. Member has experienced an inadequate response for at least 4 weeks to ONE of the following: oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), rectal mesalamine (e.g., Canasa, Rowasa rectal hydrocortisone (e.g., Colocort, Cortifoam), balsalazide, olsalazine, prednisone, azathioprine, mercaptopurine, sulfasalazine, balsalazide, olsalazine, cyclosporine, tacrolimus;

AND

b. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) a tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

C. Authorization is for no more than 12 months

3. Moderately to severely active rheumatoid arthritis (RA)

A. Member is 18 years of age or older;

AND

B. Member has a confirmed diagnosis of moderately to severely active rheumatoid arthritis (RA) as defined by ONE of the following;

a. ≥ 8 tender joints or painful on motion; and ≥ 6 swollen joints;

OR

b. high sensitivity C-reactive protein (hs-CRP) ≥ 7 mg/L;

OR

c. Erythrocyte sedimentation rate (ESR) ≥ 28 mm/H;

AND

C. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) ALL of the following:

a. Methotrexate in combination with another conventional DMARD for 3 months;

AND

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- b. Tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- D. Authorization is for no more than 12 months

4. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

- A. Member is 18 years of age or older;
- AND**
- B. ONE of the following criteria is met:
 - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs);
 - OR**
 - b. Member has an intolerance or contraindication to two or more NSAIDs;
- AND**
- C. ONE of the following criteria is met:
 - a. Member has tried a tumor necrosis factor inhibitor (TNFi) or any other biologic;
 - OR**
 - b. Member has an intolerance or contraindication to a tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- D. Authorization is for no longer than 12 months

5. Active psoriatic arthritis (PsA)

- A. Member is 18 years of age or older;
- AND**
- B. ALL of the following:
 - a. Member has experienced an inadequate response to ALL of the following:
 - i. A 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week) or any other conventional DMARD (e.g., leflunomide, sulfasalazine, cyclosporine);
 - AND**
 - ii. NSAIDs for at least 4 weeks;
 - AND**
 - iii. Corticosteroids stable on a dose of ≤ 10 mg/day prednisone or equivalent for at least 2 weeks;
 - AND**
 - b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;
- AND**
- C. Authorization is for no more than 12 months

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6. Moderate to severe plaque psoriasis

- A. Member is 18 years of age or older;
AND
- B. Body surface area affected by plaque-type psoriasis of 10% or greater;
AND
- C. ALL of the following:
 - a. Member has tried ALL of the following for at least 3 months (unless intolerant or contraindicated):
 - i. Conventional DMARD therapy (see Appendix A);
AND
 - ii. Phototherapy (e.g. UVB, PUVA) administered 3-5 times per week;
AND
 - b. Member has tried a tumor necrosis factor inhibitor (TNFi) for at least 3 months (unless intolerant or contraindicated) or any other biologic;
- AND
- D. Authorization is for no more than 12 months

7. Hidradenitis suppurativa

- A. Member has a confirmed diagnosis of moderate to severe hidradenitis suppurativa with a total abscess and inflammatory-nodule count of three or more;
AND
- B. Member has a documented trial and failure or contraindication of using at least ONE regimen from each of the following treatment options within the past 12 months:
 - a. Intralesional corticosteroid;
AND
 - b. Topical Clindamycin for 3 months;
AND
 - c. Oral mono antibiotics for 3 months: tetracycline, minocycline, doxycycline;
AND
 - d. Oral combo antibiotics for 3 months: oral clindamycin and oral Rifampin;
AND
 - e. Oral Hormonal therapy- Spironolactone for 3 months for female members;
AND
 - f. Oral retinoids- Acitretin for 6 months for members with concomitant acne;
AND
 - g. Biologic – Humira for 3 months;
- AND
- C. Authorization is for no more than 12 month

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8. Juvenile Idiopathic arthritis (JIA)

A. ALL of the following:

a. Member has an inadequate response to ALL of the following:

i. 1-month trial of NSAIDs;

AND

ii. 2-week trial of corticosteroids;

AND

iii. 3-month trial of methotrexate or another non-biologic DMARD;

AND

b. Member has an inadequate response to tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

B. Authorization is for no more than 12 months

9. Pyoderma gangrenosum

A. ALL of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. Corticosteroids;

AND

ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);

AND

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

B. Authorization is for no more than 12 months

10. Sarcoidosis

A. ALL of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. Corticosteroids;

AND

ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);

AND

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

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11. Takayasu’s arteritis

A. ALL of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. Corticosteroids;

AND

ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);

AND

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi) or any other biologic;

AND

B. Authorization is for no more than 12 months

12. Uveitis

A. Member has a confirmed diagnosis of non-infectious intermediate, posterior, and panuveitis with the presences of ONE of the following:

a. $\geq 2+$ anterior chamber cell grade (Standardization of Uveitis Nomenclature criteria);

OR

b. Vitreous Haze grade of $\geq 2+$;

OR

c. Active, inflammatory, chorioretinal and/or inflammatory retinal vascular lesion;

AND

B. Recent history (within 12 months) of taking at least ONE from each of the following treatment options:

a. Topical corticosteroid eye drops for 3 months (e.g., prednisolone, dexamethasone, fluorometholone);

AND

b. Oral Glucocorticoids for 3 months (e.g., steroid equivalent to 40-60mg of prednisone);

AND

c. Calcineurin Antagonist for 3 months (e.g., cyclosporine, tacrolimus);

AND

d. Cytotoxic agents for 3 months (e.g., methotrexate, azathioprine, mycophenolate);

AND

e. Biologic therapy for 3 months (e.g. Humira);

AND

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13. Reactive arthritis

A. ALL of the following:

a. Member has experienced an inadequate response to ALL of the following:
i. 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week);

AND

ii. NSAIDs for at least 4 weeks;

AND

iii. Corticosteroids stable on a dose of ≤ 10 mg/day prednisone or equivalent for at least 2 weeks;

AND

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);

AND

B. Authorization is for no more than 12 months

14. Immune checkpoint inhibitor toxicity

A. Member has diagnosis of immunotherapy-related myocarditis, pericarditis, arrhythmias, impaired ventricular function or conduction abnormalities;

AND

B. Member is 18 years of age or older;

AND

C. Member started pulse-dose methylprednisolone and had no improvement of toxicity within 24 hours;

AND

D. Member has received checkpoint inhibitor therapy [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)] recently;

AND

E. Authorization is for no more than 12 months

15. Acute graft versus host disease

A. ONE of the following:

a. Member has experienced an inadequate response to systemic corticosteroids;

OR

b. Member is intolerant to systemic corticosteroids;

AND

B. Tumor necrosis factor inhibitor (TNFi) or any other biologic;

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RENEWAL REQUEST:

1. Moderately to severely active Crohn’s disease (CD)

A. Member has achieved or maintained remission;

OR

B. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

a. Abdominal pain or tenderness;

OR

b. Diarrhea;

OR

c. Body weight;

OR

d. Abdominal mass;

OR

e. Hematocrit;

OR

f. Endoscopic appearance of the mucosa;

OR

g. Improvement on a disease activity scoring tool (e.g., Crohn’s Disease Activity Index [CDAI] score);

AND

C. Authorization is for no more than 12 months

2. Moderately to severely active ulcerative colitis (UC)

A. Member has achieved or maintained remission;

OR

B. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

a. Stool frequency;

OR

b. Rectal bleeding;

OR

c. Urgency of defecation;

OR

d. C-reactive protein (CRP);

OR

e. Fecal calprotectin (FC);

OR

f. Endoscopic appearance of the mucosa;

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OR

- g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score);

AND

- C. Authorization is for no more than 12 months

3. Moderately to severely active rheumatoid arthritis (RA)

- A. Member achieved or maintained a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability;

AND

- B. Authorization is for no more than 12 months

4. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

- A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

- a. Functional status;

OR

- b. Total spinal pain;

OR

- c. Inflammation (e.g., morning stiffness)

AND

- B. Authorization is for no more than 12 months

5. Active psoriatic arthritis (PsA)

- A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

- a. Number of swollen joints;

OR

- b. Number of tender joints;

OR

- c. Dactylitis;

OR

- d. Enthesitis;

OR

- e. Skin and/or nail involvement

AND

- B. Authorization is for no more than 12 months

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6. Moderate to severe plaque psoriasis

- A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
 - a. Reduction in body surface area (BSA) affected from baseline;
 - OR**
 - b. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain);

AND

- B. Authorization is for no more than 12 months

7. Hidradenitis suppurativa

- A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when ONE of the following is met:
 - a. Reduction in abscess and inflammatory nodule count from baseline;
 - OR**
 - b. Reduced formation of new sinus tracts and scarring;
 - OR**
 - c. Decrease in frequency of inflammatory lesions from baseline;
 - OR**
 - d. Reduction in pain from baseline;
 - OR**
 - e. Reduction in suppuration from baseline;
 - OR**
 - f. Improvement in frequency of relapses from baseline;
 - OR**
 - g. Improvement in quality of life from baseline;
 - OR**
 - h. Improvement on a disease severity assessment tool from baseline;

AND

- B. Authorization is for no more than 12 months

8. Juvenile idiopathic arthritis (JIA)

- A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
 - a. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion);
 - OR**
 - b. Number of joints with limitation of movement;

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OR

c. Functional ability;

AND

B. Authorization is for no more than 12 months

9. Uveitis

A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

a. Reduced frequency of recurrence compared to baseline;

OR

b. Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline;

OR

c. Decreased reliance on topical corticosteroids

AND

B. Authorization is for no more than 12 months

10. Reactive arthritis

A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

a. tender joint count;

OR

b. swollen joint count;

OR

c. pain

AND

B. Authorization is for no more than 12 months

11. Immune checkpoint inhibitor toxicity and acute graft versus host disease

A. Member must meet all initial authorization criteria;

AND

B. Authorization is for no more than 4 doses

12. All other indications

A. Member has achieved or maintained a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition;

AND

B. Authorization is for no more than 12 months

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V. LIMITATIONS/ EXCLUSIONS:

The use of Infliximab and its biosimilars is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J1745	Injection, infliximab, excludes biosimilar, (remicade)
J1748	Injection, infliximab-dyyb (zymfentra), 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra)
Q5104	Injection, infliximab-abda, biosimilar, (renflexis)
Q5109	Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola)

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
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

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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

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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
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, 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

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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

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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

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M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site 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
M05.8A	Other Rheumatoid Arthritis With Rheumatoid Factor Of Other Specified Site
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	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

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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
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site
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
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
M06.8A	Other specified rheumatoid arthritis, other specified site
M06.9	Rheumatoid arthritis, unspecified
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region

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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

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Policy and Procedure

Title: UM-PT021 Infiximab	Division: Medical Management Department: Pharmacy
Approval Date: 5/25/2023	LOB: Medicaid, HIV SNP, HARP, QHP, EP, Gold, GoldCare, CHP
Effective Date: 5/25/2023	Policy Number: UM-PT021
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43. Medicaid Update. March 2023 Volume 39 Number 6

44. Drug Utilization Review (DUR) Meeting July 2022

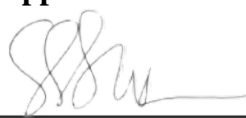


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REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	SC	5/25/2023
Update	AKC	11/28/2023
Annual review	AKC	1/28/2025

Approved:	Date:	Approved:	Date:
<i>Suzana Patel</i>	1/28/2025		04.03.26
Suzana Patel, PharmD Senior Director of Pharmacy		Sanjiv Shah, MD Chief Medical Officer	



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Medical Guideline Disclaimer:

Property of MetroPlus HealthPlan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan 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). MetroPlus Health Plan 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 MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. 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 website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.