curative

TITLE:	TUMOR NECROSIS FACTOR (TNF) INHIBITORS POLICY
POLICY #:	MM-PNP-024
VERSION #:	02
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	10/01/2023
CURRENT REVISION DATE:	3/25/2024

1. PURPOSE

Brand Selection for Medically Necessary Indications

Health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Remicade (infliximab), and Renflexis (infliximab-abda) are more costly to Curative than other targeted immune modulators for certain indications. There is a lack of reliable evidence that Remicade (infliximab), and Renflexis (infliximab-abda) are superior to the lower cost targeted immune modulators, Avsola and Inflectra, for Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis/axial spondyloarthritis, psoriatic arthritis, plaque psoriasis, hidradenitis suppurative, juvenile idiopathic arthritis, and uveitis.

Note: For plaque psoriasis, this policy applies to all members (new starts and continuation of therapy) requesting treatment with a targeted immune modulator. For Avsola and Inflectra, this policy applies to all members (new starts and continuation of therapy) requesting treatment with the targeted infliximab product for all indications. For targeted immune modulators other than infliximab for all other indications (other than plaque psoriasis), this policy applies only to members who are new to treatment with a targeted immune modulator for the first time.

There are currently 3 FDA-approved biosimilars to Remicade in the United States: Inflectra, Reneflexis, and Avsola. Biosimilars are medications that are similar to a brand-name drug.

Curative considers Avsola and Inflectra to be preferred immune modulators.

All other medications are considered non-preferred

2. SCOPE

Medical and Pharmacy UM Departments

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Note: Requires Prior Approval:

Prior Approval of Avsola and Inflectra is required of all Curative participating providers and members in applicable plan designs.

Prescriber Specialties

This medication must be prescribed by or in consultation with *one* of the following:

- Crohn's disease and ulcerative colitis: gastroenterologist.
- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Behcet's disease: rheumatologist.
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist.
- Plaque psoriasis: dermatologist.
- Uveitis: ophthalmologist or rheumatologist.

Criteria for Initial Approval

Curative considers Avsola and Inflectra medically necessary for members with any of the following indications, where the member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB:

Crohn's disease (CD)

For treatment of moderately to severely active CD in members 6 years of age or older.

Ulcerative colitis (UC)

For treatment of moderately to severely active UC in members 6 years of age or older.

Rheumatoid arthritis (RA)

For adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis (RA). The requested medication must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide *or*

For adult members for treatment of moderately to severely active RA when *all* the following criteria are met:

Member meets *either* of the following criteria:

Member has been tested for *either* of the following biomarkers and the test was positive:

- Rheumatoid factor (RF); *or*
- Anti-cyclic citrullinated peptide (anti-CCP); *or*
- Member has been tested for *all* the following biomarkers:
    - RF; *and*
    - Anti-CCP; *and*
    - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); *and*
    - Member is prescribed the requested medication in combination with methotrexate or leflunomide, or has a clinical reason not to use methotrexate or leflunomide; *and*

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

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

- For adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis; or
- For adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:
- Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs); *or*
- Member has an intolerance or contraindication to two or more NSAIDs.

Psoriatic arthritis (PsA)

- For adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis; or
- For adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
    - Member has mild to moderate disease and meets *one* of the following criteria:
        - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration; *or*
        - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine); or
        - Member has enthesitis or predominantly axial disease; or
        - Member has severe disease.

Plaque psoriasis (PsO)

- For adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis; or
- For adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:
    - Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; *or*
    - At least 10% of the body surface area (BSA) is affected; *or*
    - At least 3% of body surface area (BSA) is affected and the member meets *any* of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin; *or*

- Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin

Hidradenitis suppurativa

For members who have previously received a biologic indicated for the treatment of severe, refractory hidradenitis suppurativa; or

For treatment of severe, refractory hidradenitis suppurativa when either of the following is met:

- Member has experienced an inadequate response to an oral antibiotic for at least 90 days; or
- Member has an intolerance or contraindication to oral antibiotics.

Uveitis

For members who have previously received a biologic indicated for uveitis; or

For treatment of uveitis when any of the follow criteria is met:

- Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, or mycophenolate mofetil); or
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, or mycophenolate mofetil);

Curative considers all other indications as experimental and investigational

Continuation of Therapy

Crohn's disease (CD)

For all members 6 years of age and older (including new members) who are using the requested medication for moderately to severely active Crohn's disease (CD) and who achieve or maintain remission; or

For all members 6 years of age and older (including new members) who are using the requested medication for moderately to severely active CD and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Abdominal pain or tenderness; or
- Diarrhea; or
- Body weight; or
- Abdominal mass; or
- Hematocrit; or
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound; or
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score).

Ulcerative colitis (UC)

For all members 6 years of age and older (including new members) who are using the requested medication for moderately to severely active ulcerative colitis (UC) and who achieve or maintain remission; or

For all members 6 years of age and older (including new members) who are using the requested medication for moderately to severely active UC and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency; or
- Rectal bleeding; or
- Urgency of defecation; or
- C-reactive protein (CRP); or
- Fecal calprotectin (FS); or
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound; or
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score);

Rheumatoid arthritis (RA)

For all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain 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.

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

For all adult members (including new members) who are using the requested medication for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status; or
- Total spinal pain; or
- Inflammation (e.g., morning stiffness).

Psoriatic arthritis (PsA)

For all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints; or
- Number of tender joints; or
- Dactylitis; or
- Enthesitis; or

- Axial disease; or
- Skin and/or nail involvement.

Plaque psoriasis (PsO)

For all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

- Reduction in body surface area (BSA) affected from baseline; or
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain).

Hidradenitis suppurativa

For all members (including new members) who are using the requested medication for severe, refractory hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

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

Uveitis

For all members (including new members) who are using the requested medication for uveitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when the patient meets *any* of the following:

- Reduced frequency of recurrence compared to baseline; or
- Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline: or
- Decreased reliance on topical corticosteroids.

If the screening test for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

a. All Curative Medical and Pharmacy UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

a. Medical and Pharmacy

12. DOCUMENT CONTROL

APPROVED BY:		
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(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

N/A