Clinical Policy: Immunomodulator Agents for Systemic Inflammatory Disease

Reference Number: OH.PHAR.PPA.64
Effective Date: 01.01.2020
Last Review Date: 11/2021
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ENBREL® kit, SureClik, syringe (etanercept) HUMIRA® pen, starter packs, syringe (adalimumab)	CIMZIA® syringe (certolizumab pegol) ORENCIA® syringe (abatacept) SIMPONI™ pen, syringe (golimumab)

ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
TALTZ™ **(pa and step therapy medication)** KINERET	ACTEMRA® syringe (tocilizumab) COSENTYX™ (secukinumab) ILUMYA™ (tildrakizumab-asmn) KEVZARA® (sarilumab) SILIQ™ (brodalumab) STELARA (ustekinumab) SKYRIZI™ (risankizumab-rzza) TREMFYA™ (guselkumab)

JANUS KINASE INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
XELJANZ® IR tablets (tofacitinib citrate)	OLUMIANT® (baricitinib) RINVOQ XELJANZ® solution (tofacitinib citrate) XELJANZ® XR (tofacitinib tablet, extended release)

PHOSPHODIESTERASE-4 INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OTEZLA® tablet (apremilast)	

FDA Approved Indication(s)
• Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved Indications

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that the medications listed in the above tables are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of Rheumatoid arthritis;
2. Requested medication is FDA approved for rheumatoid arthritis;
3. Member does not have a current infection;
4. Member meets one of the following (a or b):
    a. Failure of a ≥ 90 consecutive day trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
    b. If intolerance or contraindication to MTX, failure of a ≥ 90 day trial of at least ONE conventional disease-modifying anti-rheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. If the requested medication is Simponi prescribed concomitantly with MTX, or another DMARD if intolerance or contraindication to MTX;
6. Member has had therapeutic failure to no less than a 90 day trial of at least two preferred medications unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
7. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
8. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

B. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of plaque psoriasis;
2. Requested medication is FDA approved for plaque psoriasis;
3. Member does not have a current infection;
4. Member meets one of the following (a or b):
    a. Failure of a trial of ≥ 90 days of methotrexate (MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
    b. If intolerance or contraindication to MTX, failure of a trial of ≥ 90 days of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. If the medication is non-preferred member has had therapeutic failure to no less than a 90 day trial of at least two preferred medications unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
6. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
7. If requested medication is Enbrel or Humira member has had an inadequate clinical response to at least 90 days of phototherapy
8. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

C. Psoriatic arthritis (must meet all):

1. Diagnosis of psoriatic arthritis;
2. Requested medication is FDA approved for psoriatic arthritis;
3. Member does not have a current infection;
4. If the medication is non-preferred member has had therapeutic failure to no less than a 90 day trial of at least two preferred medications unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications

5. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

D. Crohn's disease (must meet all):
1. Diagnosis of Crohn's disease;
2. Requested medication is FDA approved for Crohn's disease;
3. Member does not have a current infection;
4. Member meets one of the following (a or b):
    a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
    b. Medical justification supports inability to use immunomodulators;
5. Member has had therapeutic failure to no less than a 90 day trial of two preferred medications unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
6. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
7. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

E. Ankylosing Spondylitis (must meet all):
1. Diagnosis of ankylosing spondylitis;
2. Requested medication is FDA approved for ankylosing spondylitis;
3. Member does not have a current infection;

4. If the medication is Cimzia, Cosentyx, Taltz, Humira or Enbrel member has had failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. If the medication is non-preferred member has had therapeutic failure to no less than a 90 day trial of at least two preferred medications unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
6. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to or drug interaction with preferred medications
    c. History of unacceptable/toxic side effects to preferred medications
7. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

F. Ulcerative colitis (must meet all):
1. Diagnosis of moderate to severe ulcerative colitis;
2. Requested medication is Humira, Simponi or Xeljanz;
3. Member does not have a current infection;
4. Humira may be approved if there is an inadequate clinical response to at least 90 days of therapy with both 5-ASA (e.g., sulfasalazine) AND immunosuppressants (e.g., oral corticosteroids, azathioprine). **Initial approval** for Humira will be **for 56 days.** If clinical response is not seen in 56 days further therapy with TNF inhibitors will NOT be approved. If there is an initial clinical response to Humira after 56 days of therapy, but no improvement in the progression of ulcerative colitis symptoms after 180 days, Simponi or Xeljanz may be approved.
5. Quantity limits for Ulcerative Colitis diagnosis:
    a. Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
    b. Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month
    c. Xeljanz – 60 tablets per month
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration:
Initial: 56 days
Subsequent: 12 months

G. Polyarticular juvenile idiopathic arthritis (must meet all):

1. Diagnosis of polyarticular juvenile idiopathic arthritis;
2. Requested medication is FDA approved for polyarticular juvenile idiopathic arthritis;
3. Member does not have a current infection;
4. Member meets one of the following (a or b):
a. Failure of a ≥ 90 day trial of methotrexate (MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
b. If intolerance or contraindication to MTX, failure of a ≥ 90 day trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Member has had therapeutic failure to no less than a 90 day trial of at least two preferred medications unless one of the following:
a. Allergy to preferred medications
b. Contraindication to or drug interaction with preferred medications
c. History of unacceptable/toxic side effects to preferred medications
6. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
a. Allergy to preferred medications
b. Contraindication to or drug interaction with preferred medications
c. History of unacceptable/toxic side effects to preferred medications
7. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

H. Hidradenitis suppurativa (must meet all):

1. Diagnosis of hidradenitis suppurativa
2. Requested medication is FDA approved for hidradenitis suppurativa;
3. Member does not have a current infection;
4. Documentation of Hurley stage II or stage III;
5. Failure of a ≥ 90 day trial of systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

I. Uveitis (must meet all):

1. Diagnosis of uveitis
2. Requested medication is FDA approved for uveitis;
3. Member does not have a current infection;
4. Failure of a ≥ 2 week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a trial of a non-biologic immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

J. Giant Cell Arteritis

1. Diagnosis of giant cell arteritis;
2. Requested medication is FDA approved for Giant Cell Arteritis;
3. Member does not have a current infection;
4. Request is for SC formulation;
5. Failure of a ≥ 3 consecutive month trial of a systemic corticosteroid at up to maximally tolerated doses in conjunction with MTX or azathioprine, unless contraindicated or clinically significant adverse effects are experienced
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

K. Cryopyrin-Associated Periodic Syndromes

1. Diagnosis of neonatal onset multisystem inflammatory disease (NOMID)
2. Requested medication is FDA approved for neonatal onset multisystem inflammatory disease
3. Member does not have a current infection
4. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

L. Non-Radiographic Axial Spondyloarthritis

1. Diagnosis of non-radiographic axial spondyloarthritis;
2. Requested medication is FDA approved for non-radiographic axial spondyloarthritis;
3. Member does not have a current infection;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
4. Member has had therapeutic failure to no less than a 90 day trial of at least two preferred medications unless one of the following:
   a. Allergy to preferred medications
   b. Contraindication to or drug interaction with preferred medications
   c. History of unacceptable/toxic side effects to preferred medications
5. If the medication is step therapy member has had therapeutic failure to no less than a 30 day trial of at least one preferred TNF inhibitor medication unless one of the following:
   a. Allergy to preferred medications
   b. Contraindication to or drug interaction with preferred medications
   c. History of unacceptable/toxic side effects to preferred medications
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
• Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications/Boxed Warnings
• Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	
Annual review – added step therapy criteria. Changed pa requirement from trial of one preferred to two preferreds. Updated preferred/non-preferred chart	11.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.