

## POLICY Document for CIMZIA

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

### Section 1: Preferred Product

- Policy information specific to preferred medications

### Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

## Section 1: Preferred Product

### EXCEPTIONS CRITERIA

#### DISEASE-MODIFYING ANTIRHEUMATIC DRUGS FOR AUTOIMMUNE CONDITIONS

## I. PREFERRED PRODUCTS: ORENCIA, REMICADE, SIMPONI ARIA

This prior authorization program informs prescribers of preferred autoimmune products for treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. The prior authorization process evaluates if a clinical exception exists for use of a non-preferred autoimmune drug for these specific conditions. Coverage for a non-preferred autoimmune drug is provided when all preferred drugs have been tried, and either are not tolerated, ineffective, or contraindicated for the patient.

## II. PLAN DESIGN SUMMARY

This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for targeted products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. For plaque psoriasis indication, this program does not apply to members currently receiving therapy with a non-preferred product for which there is no preferred product in the same subclass (e.g., interleukin antagonist). For inflammatory joint or bowel disease indications, coverage for the non-preferred product will continue in situations where the patient is currently receiving treatment.

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Each PA request is reviewed based on all utilization management (UM) programs implemented.

**Table. Disease-modifying antirheumatic drugs for autoimmune conditions**

	<b>Products*</b>
<b>Preferred</b>	<ul style="list-style-type: none"><li>• <b>Orencia</b> (abatacept)</li><li>• <b>Remicade</b> (infliximab)</li><li>• <b>Simponi Aria</b> (golimumab, intravenous)</li></ul>
<b>Non-Preferred</b>	<ul style="list-style-type: none"><li>• <b>Actemra</b> (tocilizumab)</li><li>• <b>Cimzia</b> (certolizumab pegol)</li><li>• <b>Entyvio</b> (vedolizumab)</li><li>• <b>Inflectra</b> (infliximab-dyyb)</li><li>• <b>Stelara</b> (ustekinumab)</li></ul>

\*If applicable for approved indication

### **III. EXCEPTION CRITERIA**

#### **A. Coverage for a non-preferred product is provided when ANY of the following criteria are met:**

1. Member has had an inadequate response to treatment with a preferred product
2. Member has experienced an intolerable adverse event to all applicable preferred products
3. For indications where Remicade is the only preferred product option (i.e., Crohn's disease, ulcerative colitis, etc.), member has a contraindication to therapy with Remicade (i.e., moderate to severe heart failure defined as NYHA Functional Class III to IV or risk of lymphoma or serious infection) (*Note: does not apply to Inflectra*)
4. Member is currently receiving therapy with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and has received at least a 28-day supply within the past 90 days

## **Section 2: Clinical Criteria**

### **CIMZIA(certolizumab pegol)**

#### **I. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### **A. FDA-Approved Indications**

1. Moderately to severely active rheumatoid arthritis (RA)
2. Active psoriatic arthritis (PsA)
3. Active ankylosing spondylitis (AS)
4. Moderately to severely active Crohn's disease (CD)

##### **B. Compendial Uses**

1. Axial spondyloarthritis

All other indications are considered experimental/investigational and are not a covered benefit.

#### **II. CRITERIA FOR INITIAL APPROVAL**

##### **A. Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 24 months may be granted for members who have received Cimzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Cimzia.
2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
  - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
  - b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

##### **B. Active psoriatic arthritis (PsA)**

Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA).

##### **C. Active ankylosing spondylitis (AS) and axial spondyloarthritis**

1. Authorization of 24 months may be granted for members who have received Cimzia or any other biologic DMARD indicated for active ankylosing spondylitis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Cimzia.
2. Authorization of 24 months may be granted for treatment of active ankylosing

spondylitis and axial spondyloarthritis when any of the following criteria is met:

- a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over a 4-week period in total at maximum recommended or tolerated anti-inflammatory dose.
- b. Member has an intolerance and/or contraindication to two or more NSAIDs (see Appendix B).

#### **D. Moderately to severely active Crohn's disease (CD)**

1. Authorization of 24 months may be granted for members who have received Cimzia or any other biologic indicated for the treatment of Crohn's disease in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Cimzia.
2. Authorization of 24 months may be granted for treatment of moderately to severely active CD when the member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix C).

### **III. CONTINUATION OF THERAPY**

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Cimzia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

### **IV. OTHER**

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Cimzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) in a paid claim through a pharmacy or medical benefit within the previous 120 days of the continuation request are exempt from requirements related to TB screening in this Policy.

### **V. APPENDICES**

#### **Appendix A: Examples of Contraindications to Methotrexate**

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

#### **Appendix B: Examples of Contraindications to the Use of NSAIDs**

1. Allergic-type reaction following aspirin or other NSAID administration
2. Asthma
3. Gastrointestinal bleeding
4. History of intolerance or adverse event
5. Significant drug interaction
6. Urticaria

### **Appendix C: Examples of Conventional Therapy Options for CD**

1. Mild to moderate disease – induction of remission:
  - a. Oral budesonide, oral mesalamine
  - b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
  - a. Prednisone, methylprednisolone intravenously (IV)
  - b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission:
  - a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM

### **REFERENCES:**

#### **SECTION 1**

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; November 2014.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; April 2016.
3. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; May 2014.
4. Inflectra [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; April 2016.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; June 2016.
6. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2015.
7. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2016.
8. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2016.

#### **SECTION 2**

1. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; April 2016.
2. van der Heijde D, Sieper J, Maksymowych WP, 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.
3. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. *Ann Rheum Dis.* 2014;73:492-509.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1):1-26.
5. 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.
6. 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.
  7. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
  8. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(Suppl II):ii14–ii17.
  9. Peluso R, Lervolino S, Vitiello M, et al. Extra-articular manifestations in psoriatic arthritis patients. [Published online ahead of print May 8, 2014]. *Clin Rheumatol*. 2014.
  10. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896–904.
  11. Landewe R, Braun J, Deodhar A, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. *Ann Rheum Dis*. 2014;73(1):39-4.
  12. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2015: 10.1002/art.39298. [Epub ahead of print].
  13. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.