Clinical Policy: Certolizumab (Cimzia)

Reference Number: ERX.SPA.167
Effective Date: 10.01.16
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

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

Description
Certolizumab (Cimzia®) is a tumor necrosis factor (TNF) blocker.

FDA Approved Indication(s)
Cimzia is indicated for:

- Reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- Treatment of adults with moderately to severely active rheumatoid arthritis (RA)
- Treatment of adult patients with active psoriatic arthritis (PsA)
- Treatment of adults with active ankylosing spondylitis (AS)
- Treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Cimzia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Axial Spondylitis (must meet all)**:**

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
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;
5. Failure of 2 of the following, each used for ≥ 3 consecutive months: etanercept (*Enbrel is preferred*), adalimumab (*Humira is preferred*), Cosentyx, infliximab (*Remicade is preferred*), golimumab (*Simponi Aria is preferred*), unless (a or b):
   **Prior authorization may be required for etanercept, adalimumab, Cosentyx, infliximab, and golimumab*
   a. Evidence supports member has nr-axSpA;
   b. Clinically significant adverse effects are experienced or all are contraindicated;
6. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

B. Crohn's Disease (must meet all)**:**
1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
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 clinically significant adverse effects are experienced or all are contraindicated;
   b. Medical justification supports inability to use immunomodulators (*see Appendix D*);
5. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: adalimumab (*Humira® is preferred*), subcutaneous Stelara®, infliximab (*Remicade® is preferred*);
   **Prior authorization may be required for adalimumab, Stelara, and infliximab*
6. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

C. Plaque Psoriasis (must meet all)**:**
1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: adalimumab (*Humira is preferred*), Cosentyx, infliximab (*Remicade is preferred*), subcutaneous Stelara, Skyrizi®, Tremfya®;
   **Prior authorization may be required for adalimumab, Cosentyx, infliximab, Stelara, Skyrizi, and Tremfya*
6. Dose does not exceed 400 mg every 2 weeks.

Approval duration: 6 months

D. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: Cosentyx®, etanercept (*Enbrel is preferred*), adalimumab (*Humira is preferred*), Otezla®, infliximab (*Remicade is preferred*), subcutaneous Stelara, golimumab (*Simponi Aria is preferred*), Xeljanz®, Xeljanz XR;
   **Prior authorization may be required for Cosentyx, etanercept, adalimumab, Otezla, infliximab, Stelara, Xeljanz, Xeljanz XR, and golimumab*
5. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

E. Rheumatoid Arthritis (must meet all)**:**
1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix E*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;

b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated;

5. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: etanercept *(Enbrel® is preferred)*, adalimumab *(Humira is preferred),* infliximab (*Remicade is preferred)*, Rinvoq®, Xeljanz®, Xeljanz XR®, golimumab (*Simponi Aria® is preferred*);
   **Prior authorization may be required for etanercept, adalimumab, infliximab, Rinvoq, Xeljanz, Xeljanz XR, and golimumab*
6. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (*see Appendix F*);
   b. Routine assessment of patient index data 3 (RAPID) score (*see Appendix G*);
7. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

F. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member meets one of the following (a or b):
   a. For RA: Member is responding positively to therapy as evidenced by one of the following (i or ii):
      i. A decrease in CDAI (*see Appendix F*) or RAPID3 (*see Appendix G*) score from baseline;
      ii. Medical justification stating ability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
   b. For all other indications: Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. For CD, RA, PsA, AS, nr-axSpA: 400 mg every 4 weeks;
   b. For PsO: 400 mg every 2 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. 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 policy – ERX.PA.01 or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia®, Enbrel®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-

23 inhibitor), Tremfya® (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz®/Xeljanz® XR, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, and Rituxan Hycela®], selective co-stimulation modulators [Orencia®], or integrin receptor antagonists [Entyvio®] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
AS: ankylosing spondylitis
CD: Crohn's disease
CDAI: clinical disease activity index
DMARD: disease-modifying anti-rheumatic drug
FDA: Food and Drug Administration
PsO: plaque psoriasis
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
NSAID: non-steroidal anti-inflammatory drug
PsA: psoriatic arthritis
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data
TNF: tumor necrosis factor

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	**PsO** 25 or 50 mg PO QD	50 mg/day
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID **CD*** 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	**CD*** prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg PO QD	Various
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**PsA*** 2.5 – 3 mg/kg/day PO QD **RA, PsO** 2.5 – 4 mg/kg/day PO divided BID	PsA: 3 mg/kg/day RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**PsA*** 100 mg/day PO loading dose for 3 days followed by 20 mg/day PO QD	20 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	RA 100 mg PO QD for 3 days, then 20 mg PO QD	
6-mercaptopurine (Purixan®)	**CD*** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex®)	**CD*** 15 – 25 mg/week IM or SC **PsA*** 7.5 – 15 mg/week PO **RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **PsO** 10 – 25 mg/week IV,IM, or PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA** Varies	Varies
Pentasa® (mesalamine)	**CD** 1,000 mg PO QID	4 g/day
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**PsA*** 2 g/day PO QD **RA** 2 g/day PO in divided doses	PsA: 5 g/day RA: 3 g/day
tacrolimus (Prograf®)	**CD*** 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO	N/A
Cosentyx® (secukinumab)	**AS** With loading dose: 150 mg at weeks 0, 1, 2, 3, and 4, followed by 150 mg every 4 weeks thereafter Without loading dose: 150 mg every 4 weeks **PsA** With loading dose: 150 mg SC at week 0, 1, 2, 3, and 4, followed by 150 mg every 4 weeks Without loading dose: 150 mg SC every 4 weeks **PsO** 300 mg SC at weeks 0, 1, 2, 3, and 4, followed by 300 mg SC every 4 weeks. (for some patients, a dose of 150 mg may be acceptable)	AS: 150 mg every 4 weeks PsA, PsO: 300 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Enbrel® (etanercept)	**AS** 50 mg SC once weekly **PsA, RA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**AS, PsA, PsO** 40 mg SC every other week **CD** Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15 Maintenance dose: 40 mg SC every other week starting on Day 29 **RA** 40 mg SC every other week (may increase to once weekly)	AS, PsA, CD, PsO: 40 mg every other week RA: 40 mg/week
Otezla® (apremilast)	**PsA** Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID	60 mg/day
Remicade® (infliximab)	**AS** Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 6 weeks **CD** Initial dose: *Adults/Pediatrics:* 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: *Adults/Pediatrics:* 5 mg/kg IV every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response **PsA, PsO** Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 8 weeks	AS: 5 mg/kg every 6 weeks CD (adults): 10 mg/kg every 8 weeks CD (pediatrics), PsA, PsO: 5 mg/kg every 8 weeks RA: 10 mg/kg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	RA In conjunction with MTX Initial dose: 3 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg IV every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks	
Rinvoq® (upadacitnib)	**RA** 15 mg PO QD	15 mg/day
Simponi Aria® (golimumab)	**AS, PsA, RA** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg IV every 8 weeks	2 mg/kg every 8 weeks
Skyrizi® (risankizumab-rzaa)	**PsO** 150 mg (two 75 mg injections) SC at Week 0, Week 4 and every 12 weeks thereafter	150 mg every 12 weeks
Stelara® (ustekinumab)	**CD** Weight based dosing IV at initial dose, followed by 90 mg SC every 8 weeks Weight ≤ 55 kg: 260 mg Weight 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg **PsA** PsA alone: 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks PsA with co-existent PsO and weight > 100 kg: 90 mg SC at weeks 0 and 4, followed by 90 mg every 12 weeks **PsO** Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg	CD: 90 mg every 8 weeks PsA alone: 45 mg every 12 weeks PsO with or without PsA: 90 mg every 12 weeks
Tremfya® (guselkumab)	**PsO** Initial dose: 100 mg SC at weeks 0 and 4 Maintenance dose: 100 mg SC every 8 weeks	100 mg every 8 weeks
Xeljanz® (tofacitinib, immediate-release)	**RA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib, extended-release)	**RA** 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
  - There is an increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
  - Cimzia should be discontinued if a patient develops a serious infection or sepsis.
  - Perform test for latent TB; if positive, start treatment for TB prior to starting Cimzia
  - Monitor all patients for active TB during treatment, even if initial latent TB test is negative
  - Lymphoma and other malignancies have been observed.
  - Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed.

Appendix D: General Information

- Definition of failure of MTX or DMARDs:
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- The following may be considered for medical justification supporting inability to use an immunomodulator for Crohn's disease:
  - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
  - High-risk factors for intestinal complications may include:
    - Initial extensive ileal, ileocolonic, or proximal GI involvement
    - Initial extensive perianal/severe rectal disease
    - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
    - Deep ulcerations
    - Penetrating, stricturing or stenosis disease and/or phenotype
    - Intestinal obstruction or abscess
  - High risk factors for postoperative recurrence may include:
    - Less than 10 years duration between time of diagnosis and surgery
    - Disease location in the ileum and colon
    - Perianal fistula
    - Prior history of surgical resection
    - Use of corticosteroids prior to surgery
- According to the CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study (n = 17), there were no or minimal certolizumab pegol transfer from the maternal plasma to breast milk, with a relative infant dose of 0.15% of the maternal dose.

Appendix E: The 2010 ACR Classification Criteria for RA

Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA ** Low: < 3 x upper limit of normal*	2
	High positive RF *or* high positive ACPA ** High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix F: Clinical Disease Activity Index (CDAI) Score
The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix G: Routine Assessment of Patient Index Data 3 (RAPID3) Score
The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 400 mg every 4 weeks	400 mg every 4 weeks
RA, PsA, AS, nr-axSpA	Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
PsO	400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at weeks 0, 2 and 4, followed by 200 mg SC every other week may be considered.	400 mg every other week

VI. Product Availability

- Single-use vial: 200 mg
- Single-use prefilled syringe: 200 mg/mL

VII. References

1. Cimzia Prescribing Information. Smyrna, GA: UCB, Inc.; September 2019. Available at https://www.cimzia.com/ . Accessed January 11, 2021.
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines for the management of psoriasis and psoriatic arthritis. Section 1: Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2008;58(5):826-850.
3. Braun J, van den berg R, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Am Rheu Dis*. 2011: 70; 896-904.
4. 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.
5. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2012; 64(5): 625-639.
6. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. *Gastroenterology*. 2014; 147: 702-705.
7. 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.
8. Singh JA. Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care and Research*. 2015; 1-25. doi 10.1002/acr.22783.
9. Ward MM, 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 & Rheumatology.* 2015. DOI 10.1002/ART.39298.
10. Clowse MEB, Forger F, Hwang C, et al. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study. *Ann Rheum Dis.* 2017;76:1980-1896. doi:10.1136/annrheumdis-2017-211384.
11. van der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;76:978-991. doi:10.1136/annrheumdis-2016-210770.
12. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018; 113:481-517.
13. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80:1029-72. doi:10.1016/j.aad.201811.057.
14. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *American College of Rheumatology*. 2019; 71(1):5-32. doi: 10.1002/art.40726

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q17 Annual Review Converted to new template. Aligned diagnostic criteria per 3Q17 TCRs: All indications: removed requirement of additional biologic; Specified trial of conventional and biologic DMARDs for 3 months or greater; CD: modified diagnostic criteria from requirement of poor prognostic factors to appropriate diagnosis only from specialist, removed active verbiage;	10.02.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
PsA: listed alternatives for those not a candidate for MTX (leflunomide, sulfasalazine, or cyclosporine); RA: added age requirement; removed requirement for submission of diagnostic lab since a specialist is required to prescribe or be consulted Removed UpToDate references		
2Q 2018 annual review: removed disease qualifiers (i.e., active); modified specialist requirement to any GI specialist for CD; modified trial and failure for RA to at least one conventional DMARD; modified trial and failure of preferred agents for all indications; references reviewed and updated.	02.27.18	05.18
4Q 2018 annual review: criteria added for new FDA indication: plaque psoriasis; modified prescriber specialist from GI specialist to gastroenterologist for CD; added trial and failure of immunosuppressants, or medical necessity for use of biologics in CD; allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.	09.04.18	11.18
2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for biologic DMARDs for PsA per ACR/NPF 2018 guidelines; revised requirement of trial and failure of biologics to preferred TNF inhibitors and Otezla for PsA per ACR/NPF 2018 guidelines; added Xeljanz/Xeljanz XR to list of trial options for RA; references reviewed and updated.	03.05.19	05.19
Criteria added for new FDA indication: non-radiographic axial spondyloarthritis; references reviewed and updated.	05.21.19	08.19
2Q 2020 annual review: for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy, and added Rinvoq as a preferred option for redirection per formulary status; for PsA, added Cosentyx and SC Stelara as preferred options for redirection per formulary status; for PsO, added Tremfya as a preferred option for redirection per formulary status; references reviewed and updated.	04.28.20	05.20
Revised typo in Appendix E from “normal ESR” to “abnormal ESR” for a point gained for ACR Classification Criteria.	11.22.20	
Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.	11.24.20	02.21
Per CVS, removed redirection to Kevzara for RA despite preferred status on Formulary 500/550 files in order to maximize rebates	02.01.21	
2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function; added Skyrizi as a preferred option for PsO per formulary status; added combination of bDMARDs under Section III; updated CDAI table with “>” to prevent overlap in classification of severity; references reviewed and updated.	02.23.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.