Clinical Policy Title:	certolizumab pegol
Policy Number:	RxA.732
Drug(s) Applied:	Cimzia®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Cimzia ® is a tumor necrosis factor (TNF) blocker indicated for:

- Reducing signs and symptoms of Crohn's disease 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
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with active ankylosing spondylitis
- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Dosing Information

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

Dosage Forms

- For injection: 200 mg lyophilized powder in a single-dose vial
- Injection: 200 mg/mL solution in a single-dose prefilled syringe

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 400 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Crohn's Disease (must meet all)**:**

1. Diagnosis of Crohn's Disease (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. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (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. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;

   *Exception: If one biologic DMARD that is FDA-approved for crohn's disease has been previously tried, then trial of a conventional systemic agent is not required;
5. Dose does not exceed 400 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Plaque Psoriasis (must meet all):

1. Diagnosis of Plaque Psoriasis (PsO);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 18 years;

4. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for plaque psoriasis has been previously tried, then trial of a conventional systemic agent or phototherapy is not required;
5. Dose does not exceed 400 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Psoriatic Arthritis (must meet all):
1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 18 years;
4. Dose does not exceed 400 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

E. Rheumatoid Arthritis (must meet all):
1. Diagnosis of Rheumatoid Arthritis (RA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;
5. Dose does not exceed 400 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 400 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
AS: Ankylosing Spondylitis
nr-axSpA: non-radiographic axial spondyloarthritis

NSAIDs: Non-Steroidal Anti-Inflammatory Drugs
PsO: Plaque Psoriasis
PsA: Psoriatic Arthritis
RA: Rheumatoid Arthritis
CD: Crohn's Disease
TNF: Tumor necrosis factor
aPTT: activated partial thromboplastin time
LA: Lupus Anticoagulant
STA-PTT: Standard Target Activated Partial Thromboplastin time
TT: thrombin time
PT: prothrombin time
DMARDs: Disease-Modifying Antirheumatic Drugs
PUVA: Psoralen plus ultraviolet A light

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin	**PsO:** 25 or 50 mg orally once daily	50 mg/day
azathioprine (Azasan®, Imuran®)	**RA:** 1 mg/kg/day orally once daily or divided twice daily **CD (off-label)** 1.5 – 2 mg/kg/day orally	2.5 mg/kg/day
Corticosteroids	**CD*:** prednisone 40 mg orally once daily for 2 weeks or intravenous 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg orally once daily	Various
d-penicillamine (Cuprimine®)	**RA (off-label)** Initial dose: 125 or 250 mg orally once daily Maintenance dose: 500 – 750 mg/day orally once daily	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**PsO:** 1 – 4 mg/kg/day orally divided twice daily **RA:** 2.5 – 4 mg/kg/day orally divided twice daily	PsO, RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA (off-label)** Initial dose: 400 – 600 mg/day orally once daily Maintenance dose: 200 – 400 mg/day orally once daily	600 mg/day
leflunomide (Arava®)	**RA:** 100 mg orally once daily for 3 days, then 20 mg orally once daily	20 mg/day
mercaptopurine (Purixan®)	**CD*:**50 mg orally once daily or 1 – 2 mg/kg/day orally	2 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methotrexate	**CD (off-label):** 15 – 25 mg/week intramuscular or subcutaneous **PsO:** 10 – 25 mg/week orally or 2.5 mg orally every 12 hr for 3 doses/week **RA:** 7.5 mg/week orally, subcutaneous, or intramuscular or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA:** Varies	Varies
Mesalamine (Pentasa®)	**CD :** 1,000 mg orally four times daily	4 g/day
Ridaura®	**RA:** 6 mg orally once daily or 3 mg orally twice daily	9 mg/day (3 mg Three times daily)
tacrolimus (Prograf®)	**CD (off-label):** 0.27 mg/kg/day orally in divided doses or 0.15 – 0.29 mg/kg/day orally	N/A
sulfasalazine (Azulfidine®)	**RA:** 2 g/day orally in divided doses	RA: 3 g/day
Biologic DMARDs		
Humira®	**RA:** Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every Week or 80 mg every other week **PsO**: Initial dose: 80 mg Maintenance dose: 40 mg subcutaneous every other week starting one week after initial dose **AS, PsA:** 40 mg subcutaneously every other week **CD: Initial dose:** Adults: 160 mg subcutaneous on Day 1, then 80 mg subcutaneously on Day 15 Pediatrics: Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg subcutaneously on Day 1, then 40 mg subcutaneously on Day 15 Weight ≥ 40 kg (88 lbs)160 mg subcutaneously on Day 1, then 80 mg subcutaneously on Day 15 **Maintenance dose:** Adults: 40 mg subcutaneously every other week starting on Day 29 Pediatrics: Weight 17 kg (37 lbs) to < 40 kg (88 lbs):	RA: 40 mg/week All other indications: 40 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	20 mg subcutaneously every other week starting on Day 29 Weight ≥ 40 kg (88 lbs): 40 mg subcutaneously every other week starting on Day 29	
Cosentyx®	**PsA:** With loading dose: 150 mg subcutaneous at week 0, 1, 2, 3, and 4, followed by 150 mg subcutaneous every 4 weeks Without loading dose: 150 mg subcutaneous every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks. Pediatric Patients 2 years and older: Recommended dosage is administered by subcutaneous injection at weeks 0,1 ,2,3, and 4 and every 4 weeks after: For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg. **AS, nr-axSpA:** nr-axSpA: With loading dose: 150 mg subcutaneous at weeks 0, 1, 2, 3, and 4, followed by 150 mg subcutaneous every 4 weeks thereafter Without loading dose: 150 mg subcutaneous every 4 weeks If the patient continues to have active ankylosing spondylitis: 300 mg every 4 weeks can be considered **PsO:** Adults: Recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable. Children and Adolescents 6 to 17 years weighing 50 kg or more: 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4. Then give 150 mg subcutaneously every 4 weeks. Children and Adolescents 6 to 17 years weighing less than 50 kg: 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4. Then give 75 mg subcutaneously every 4 weeks	PsA: 300 mg every 4 weeks AS: 300mg every 4 weeks nr-axSpA: 150 mg every 4 weeks PsO Adults: 300 mg/dose subcutaneously Adolescents weighing 50 kg or more: 150 mg/dose subcutaneously. weighing less than 50 kg: 75 mg/dose subcutaneously.
infliximab (Remicade®), Renflexis®, Inflectra®, Avsola®	**CD: Initial dose:** 5 mg/kg intravenously at weeks 0, 2 and 6 **Maintenance dose:** 5 mg/kg intravenously every 8 weeks. Pediatric CD: ≥ 6 years old For CD: 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:	PsA, PsO: 5 mg/kg every 8 weeks RA:10 mg/kg every 4 weeks AS: 5 mg/kg every 6 weeks CD: Adults: 10 mg/kg every 8 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks **RA:** In conjunction with MTX Initial dose: 3 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 3 mg/kg intravenously every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks **AS:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 6 weeks	
Simponi Aria®	**AS** **PsA, RA:** Initial dose: 2 mg/kg intravenously at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks	AS PsA, RA: 2 mg/kg every 8 weeks
Otezla®	**PsO** **PsA:** Initial dose: Day 1: 10 mg orally in morning Day 2: 10 mg orally in morning and 10 mg orally in evening Day 3: 10 mg orally in morning and 20 mg orally in evening Day 4: 20 mg orally in morning and 20 mg orally in evening Day 5: 20 mg orall in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	60 mg/day
Xeljanz® / Xeljanz® oral Solution, Xeljanz® XR	Xeljanz®: **PsA, RA, AS**: 5 mg orally twice daily PsA: use in combination with nonbiologic disease-modifying antirheumatic drugs RA: monotherapy or use in combination with nonbiologic disease-modifying antirheumatic drugs Xeljanz® XR: **PsA, RA, AS**: 11 mg orally once daily	Xeljanz®: PsA RA AS: 10 mg/day Xeljanz® / Xeljanz® oral Solution: 5 mg or 5 ml twice daily Xeljanz® XR: 11 mg/day
Kevzara®	**RA:** 200 mg subcutaneous once every two weeks	200 mg/2 Weeks
Enbrel®	**RA:** 25 mg subcutaneous twice weekly or 50 mg subcutaneous once Weekly	**RA, PsA:** Adults 50 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	PsA: Adult: 50 mg once weekly with or without methotrexate (MTX) **AS:** 50 mg once weekly **PsO:** Adult PsO: 50 mg twice weekly for 3 months, followed by 50 mg once weekly Pediatric PsO: Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly Weight ≥ 63 kg: 50 mg subcutaneously once weekly	subcutaneously. Induction therapy for psoriatic arthritis should not exceed 100 mg/week with no more than 50 mg/dose subcutaneously. **AS, PsO:** 50 mg/week
Ilumya®	**PsO:** Initial dose: 100 mg subcutaneous at weeks 0 and 4 Maintenance dose: 100 mg subcutaneous every 12 weeks Tildrakizumab should only be administered by a healthcare professional.	100 mg every 12 weeks
Orencia®	**RA, PsA:** Intravenously: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose Subcutaneous: 125 mg once weekly RA and PsA: Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose. (For RA: Prior to the first subcutaneous dose, may administer an optional loading dose as a single intravenous infusion as per body weight categories above.) For PsA: Intravenous loading dose is not recommended	**RA, PsA:** Intravenous: 1,000 mg every 4 weeks Subcutaneous: 125 mg/week
Rinvoq®	**RA, PsA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non-biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	15 mg/day
Siliq®	**PsO:** Initial dose: 210 mg subcutaneous at weeks 0, 1, and 2 Maintenance dose: 210 mg subcutaneous every 2 weeks	210 mg every 2 weeks
Simponi®	**RA, AS, PsA:** 50 mg subcutaneously once monthly	50 mg/month

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Tremfya®	**PsO, PsA:** Initial dose: 100 mg subcutaneously at weeks 0 and 4 Maintenance dose: 100 mg subcutaneously every 8 weeks Can be used alone or in combination with conventional DMARD e.g. methotrexate	100 mg every 8 weeks
Taltz®	**PsO:** Adult Plaque Psoriasis: Recommended dose is 160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks Pediatric Plaque Psoriasis (age 6 years or older): For patients weighing greater than 50 kg:160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. For patients weighing 25-50 kg: 80 mg subcutaneously at Week 0, followed by 40 mg every 4 weeks. For patients weighing less than 25 kg:40 mg subcutaneously at Week 0, followed by 20 mg every 4 weeks **PsA, AS,:** Initial dose: 160 mg (two 80 mg injections) subcutaneously Maintenance dose: 80 mg subcutaneous every 4 weeks. **nraxSpA:** 80 mg subcutaneous every 4 weeks	**PsO:** 80 mg every 4 weeks **nraxSpA, PsA, AS:** 80 mg every 4 weeks
Skyrizi®	**PsO:** 150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 Weeks
Stelara®	**PsO:** Weight based dosing subcutaneously at weeks 0 and 4, followed by maintenance dose every 12 weeks Adult: Weight ≤ 100 kg: 45 mg (some patients may require doses of 90 mg or maintenance dosing of every 8 weeks) Weight > 100 kg: 90 mg (some patients may require maintenance dosing of every 8 weeks) Pediatrics (Age 6 years and older): Weight < 60 kg: 0.75 mg/kg Weight ≥ 60 to ≤100 kg: 45 mg Weight > 100kg: 90 mg **PsA:** 45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12 weeks	**PsO, CD:** 90 mg every 8 weeks **PsA:** 45 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	CD: Weight based dosing intravenous at initial dose, followed by 90 mg subcutaneous every 8 weeks Weight ≤ 55 kg: 260 mg Weight 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	
Entyvio®	**CD:** Initial dose: 300 mg intravenously at weeks 0, 2, and 6 Maintenance dose: 300 mg intravenously every 8 weeks	300 mg per dose
Tysabri®	CD: 300 mg intravenously every 4 weeks	300 mg every 4 Weeks
Actemra®	Intravenously: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Subcutaneously: Weight < 100 kg: 162 mg every other week, followed by an increase to every week based on clinical response. Weight ≥ 100 kg: 162 mg every week.	Intravenously: 800 mg every 4 weeks Subcutaneously: 162 mg every week
Kineret®	**RA:**100 mg subcutaneously once daily	100 mg/day
Olumiant®	**RA:** 2 mg orally once daily	2 mg/day

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Serious hypersensitivity reaction to certolizumab pegol or to any of the excipients

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- 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.
  - Lymphoma and other malignancies some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which Cimzia® is a member. Cimzia® is not indicated for use in pediatric patients.

APPENDIX D: General Information

- Ankylosing Spondylitis: Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti-TNF agent. A two-year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- Cimzia®:According to the CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study (n = 17), there were no or minimal certolizumab pegoltransfer from the maternal plasma to breast milk, with a relative infant dose of 0.15% of the maternal dose.
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.
- Interference with certain coagulation assays has been detected in patients treated with Cimzia®. Certolizumab pegol may cause erroneously elevated activated partial thromboplastin time (aPTT) assay results in patients without coagulation abnormalities. This effect has been observed with the PTT-Lupus Anticoagulant (LA) test and Standard Target Activated Partial Thromboplastin time (STA-PTT) Automate tests from Diagnostica Stago, and the HemosIL APTT-SP liquid and HemosIL lyophilized silica tests from Instrumentation Laboratories. Other aPTT assays may be affected as well. Interference with thrombin time (TT) and prothrombin time (PT) assays has not been observed. There is no evidence that Cimzia® therapy has an effect on in vivo coagulation.

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Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs	01/05/2022	04/18/2022
Drug specific policy for Otezla was created based on RxA.592.Biologic_DMARDs 1. Initial Approval Criteria, I.B.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 2. Initial Approval Criteria, I.C.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 3. Appendix A: Updated to include abbreviation PUVA. 4. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 5. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 6. Appendix C, Contraindications: Updated to include new contraindication, Serious hypersensitivity reaction to certolizumab pegol or to any of the excipients. 7. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 8. Appendix D, General Information: Updated to remove information regarding: (a and b): a. Medical justification supporting inability to use an immunomodulator for Crohn's disease; b. Definition of failure of MTX or DMARDs in RA; 9. References were reviewed and updated.	02/10/2022	04/18/2022