Clinical Policy: Abatacept (Orencia)

Reference Number: CP.PHAR.241
Effective Date: 08.16
Last Review Date: 11.25
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

Abatacept (Orencia®) is a selective T cell costimulation modulator.

FDA Approved Indication(s)

Orencia is indicated for:

- Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA)
- Treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)
- Treatment of patients 2 years of age and older with active psoriatic arthritis (PsA)
- Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

Limitation(s) of use: Concomitant use of Orencia with other immunosuppressives [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

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 Orencia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**

1. Diagnosis of PJIA as evidenced by ≥ 5 joints with active arthritis;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 years;
4. Member meets one of the following, unless previously failed a biologic agent for pJIA (a, b, c, or d):
   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 leflunomide or sulfasalazine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
d. Documentation of high disease activity;

5. Failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. Actemra®;
   c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for adalimumab products, Actemra, and Xeljanz*
6. For members 2 to 5 years of age, prescribed route of administration is SC;
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (a or b):
   a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks (*see Appendix E for dose rounding guidelines*) (i, ii, or iii):
      i. Weight < 75 kg: 10 mg/kg per dose;
      ii. Weight 75 kg to 100 kg: 750 mg per dose;
      iii. Weight > 100 kg: 1,000 mg per dose;
   b. SC: weight-based dose once weekly (*see Appendix F for dose rounding guidelines*) (i, ii, or iii):
      i. Weight 10 to < 25 kg: 50 mg per dose;
      ii. Weight 25 to < 50 kg: 87.5 mg per dose;
      iii. Weight ≥ 50 kg: 125 mg per dose.

Approval duration: 12 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 2 years;
4. If member is ≥ 18 years, failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, d, and e, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;

b. Otezla®;
c. Taltz®;
d. One ustekinumab product (e.g., *Otulfi®, Pyzchiva® (branded), Selarsdi™, Steqeyma®, Yesintek™ are preferred*);
e. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

**Prior authorization is required for adalimumab products, Otezla, Taltz, ustekinumab products, and Xeljanz/Xeljanz XR*

5. For age 6 to 17 years, failure of a ≥ 3 consecutive month trial of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Otezla;
   b. One ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Selarsdi™, Steqeyma®, Yesintek™ are preferred*);

   **Prior authorization may be required for Otezla and ustekinumab products*
6. For members 2 to 17 years of age, prescribed route of administration is SC;
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (a or b):
   a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks (*see Appendix E for dose rounding guidelines*) (i, ii, or iii):
      i. Weight < 60 kg: 500 mg per dose;
      ii. Weight 60 kg to 100 kg: 750 mg per dose;
      iii. Weight > 100 kg: 1,000 mg per dose;
   b. SC (i or ii):
      i. Adult: 125 mg once weekly;
      ii. Age 2 to 17 years (1, 2, or 3):
         1) Weight 10 kg to < 25 kg: 50 mg once weekly;
         2) Weight 25 kg to < 50 kg: 87.5 mg once weekly;
         3) Weight ≥ 50 kg: 125 mg once weekly.

Approval duration: 12 months

C. Rheumatoid Arthritis (must meet all)**:**
1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix G*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following, unless previously failed a biologic agent for RA (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 DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated

doses, unless clinically significant adverse effects are experienced or all are contraindicated;

5. Failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. Actemra;
   c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization is required for adalimumab products, Actemra, and Xeljanz/Xeljanz XR*
6. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (*see Appendix H*);
   b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix I)*;
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (a or b):
   a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks (*see Appendix E for dose rounding guidelines*) (i, ii, or iii):
      i. Weight < 60 kg (both 1 and 2):
         1) 500 mg per dose;
         2) 2 vials per dose;
      ii. Weight 60 to 100 kg (both 1 and 2):
         1) 750 mg per dose;
         2) 3 vials per dose;
      iii. Weight > 100 kg (both 1 and 2):
         1) 1,000 mg per dose;
         2) 4 vials per dose;
   b. SC: 125 mg once weekly.

Approval duration: 12 months

D. Acute Graft-versus-Host Disease (must meet all)**:**
1. Prescribed for prophylaxis of aGVHD;
2. Request is for intravenous formulation;
3. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist;
4. Age ≥ 2 years;
5. Member is undergoing HSCT from a matched or 1 allele-mismatched unrelated-donor;
6. Prescribed in combination with a calcineurin inhibitor and MTX;
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);

8. Dose does not exceed one of the following (a or b):
    a. Age ≥ 2 years and < 6 years: 15 mg/kg on day before transplantation, followed by 12 mg/kg on Days 5, 14, and 28 after transplantation;
    b. Age ≥ 6 years: 10 mg/kg (up to 1,000 mg maximum dose) on day before transplantation, followed by 10 mg/kg (up to 1,000 mg maximum dose) on Days 5, 14, and 28 after transplantation.

Approval duration: 3 months (4 doses total)

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
    a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
    b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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 H*) or RAPID3 (*see Appendix I*) score from baseline;
        ii. Medical justification stating inability 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. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed one of the following (*see Appendix E and F for dose rounding guidelines*) (a, b, c, or d):
    a. RA (i or ii):

i. IV: weight-based dose every 4 weeks (1, 2, or 3):
1) Weight < 60 kg (both a and b):
a) 500 mg per dose;
b) 2 vials per dose;
2) Weight 60 to 100 kg (both a and b):
a) 750 mg per dose;
b) 3 vials per dose;
3) Weight > 100 kg (both a and b):
a) 1,000 mg per dose;
b) 4 vials per dose;
ii. SC: 125 mg once weekly;

b. PsA (i or ii):
i. Adult (1 or 2):
1) IV: weight-based dose every 4 weeks (a, b, or c):
a) Weight < 60 kg (both i and ii):
i) 500 mg per dose;
ii) 2 vials per dose;
b) Weight 60 to 100 kg (both i and ii):
i) 750 mg per dose;
ii) 3 vials per dose;
c) Weight > 100 kg (both i and ii):
i) 1,000 mg per dose;
ii) 4 vials per dose;
2) SC: 125 mg once weekly;
ii. Age 2 to 17 years: SC (1, 2, or 3):
1) Weight 10 kg to < 25 kg: 50 mg once weekly;
2) Weight 25 kg to < 50 kg: 87.5 mg once weekly;
3) Weight ≥ 50 kg: 125 mg once weekly;

c. PJIA (i or ii):
i. IV: weight-based dose every 4 weeks (1, 2, or 3):
1) Weight < 75 kg: 10 mg/kg per dose;
2) Weight 75 kg to 100 kg: 750 mg per dose;
3) Weight > 100 kg: 1,000 mg per dose;
ii. SC: weight-based dose once weekly (1, 2, or 3):
1) Weight 10 to <25 kg: 50 mg per dose;
2) Weight 25 to <50 kg: 87.5 mg per dose;
3) Weight ≥ 50 kg: 125 mg per dose.

d. aGVHD (i or ii):
i. IV: Age ≥ 2 years and < 6 years: 15 mg/kg on day before transplantation, followed by 12 mg/kg on Days 5, 14, and 28 after transplantation;
ii. IV: Age ≥ 6 years: 10 mg/kg (up to 1,000 mg maximum dose) on day before transplantation, followed by 10 mg/kg (up to 1,000 mg maximum dose) on Days 5, 14, and 28 after transplantation.

Approval duration:
aGVHD – 3 months (4 doses total)
All other indications – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

aGVHD: acute graft versus host disease
CDAI: clinical disease activity index
cJADAS: clinical juvenile arthritis disease activity score
DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
HSCT: hematopoietic stem cell transplantation
JAKi: Janus kinase inhibitors
MTX: methotrexate
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritis
RA: rheumatoid arthritis

RAPID3: routine assessment of patient index data 3

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
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
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®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO Maintenance dose: 200 – 400 mg/day PO	600 mg/day
leflunomide (Arava®)	**PJIA*** Weight 10 mg/1.73 m^2/day Or < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day **RA** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**PJIA*** 10 – 20 mg/m^2/week PO, SC, or IM **RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sulfasalazine (Azulfidine®)	**RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose: 2 g/day PO in divided doses	RA: 3 g/day
Actemra® (tocilizumab)	**PJIA** • Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks • Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks **RA** IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response Weight ≥ 100 kg: 162 mg SC every week	PJIA: • IV: 10 mg/kg every 4 weeks • SC: 162 mg every 2 weeks RA: • IV: 800 mg every 4 weeks • SC: 162 mg every week
Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk),Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	**pJIA** **Cyltezo, Hadlima, Hyrimoz:** Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week **Cyltezo, Hadlima, Hulio, Yuflyma:** Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week **Cyltezo, Hadlima, Hulio, Hyrimoz, Simlandi, Yuflyma, Yusimry:** Weight ≥ 30 kg (66 lbs): 40 mg SC every other week **RA, PsA** 40 mg SC every other week	40 mg every other week
Otezla® (apremilast)	**PsA** **Adults:** Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM	Adults: 60 mg/day Pediatric: *Weight ≥ 50 kg:*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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 **Pediatric:** *Weight ≥ 50 kg:* 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 *Weight 20 kg to < 50 kg:* 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 20 mg PO QPM Maintenance dose: Day 6 and thereafter: 20 mg PO BID	60 mg/day *Weight 20 kg to < 50 kg:* 40 mg/day
Otulfi® (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Selarsdi™ (ustekinumab-aekn), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce)	**PsA** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks *Pediatrics (age 6 years to 17 years):* Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter	PsA: 45 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Otulfi, Pyzchiva, Yesintek: Weight < 60 kg: 0.75 mg/kg **Otulfi, Pyzchiva, Selarsdi, Steqeyma, Yesintek:** Weight ≥ 60 kg: 45 mg	
Taltz	**PsA** Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks
Xeljanz® (tofacitinib)	**PsA, RA** 5 mg PO BID **pJIA** • 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID • 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID • Body weight ≥ 40 kg: 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**PsA, 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
None reported

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

- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: IV Dose Rounding Guidelines for PJIA, PsA, and RA

Weight-based Dose Range	Vial Quantity Recommendation
≤ 262.49 mg	1 vial of 250 mg
262.50 mg to 524.99 mg	2 vials of 250 mg
525 to 787.49 mg	3 vials of 250 mg
787.50 mg to 1,049.99 mg	4 vials of 250 mg

Appendix F: SC Dose Rounding Guidelines for PJIA, PsA, and RA

Weight-based Dose Range	Prefilled Syringe Quantity Recommendation
10 to 24.99 kg	1 syringe of 50 mg/0.4 mL
25 to 49.99 kg	1 syringe of 87.5 mg/0.7 mL
> 50 kg	1 syringe of 125 mg/mL

Appendix G: 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 H: 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 I: 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

Appendix J: Polyarticular Juvenile Idiopathic Arthritis Disease Activity
According to 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis, disease activity (moderate/high and low) as defined by the clinical Juvenile Disease Activity score based on 10 joints (cJADAS-10) is provided as a general parameter and should be interpreted within the clinical context.
The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;
- Count of joints with active disease to a maximum count of 10 active joints*

**ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both*

cJADAS-10	Disease state interpretation
≤ 1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA	IV: 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 SC: 125 mg once weekly (For RA: if single IV loading dose is given, start first SC injection within one day of IV dose)	IV: 1,000 mg every 4 weeks SC: 125 mg/week
PsA	*Adult:* IV: 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 SC: 125 mg once weekly (For RA: if single IV loading dose is given, start first SC injection within one day of IV dose) *Pediatric:* SC: • Weight 10 kg to < 25 kg: 50 mg once weekly • Weight 25 to < 50 kg: 87.5 mg once weekly • Weight ≥ 50 kg: 125 mg once weekly	IV: 1,000 mg every 4 weeks SC: 125 mg/week
PJIA	IV: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks • Weight < 75 kg: 10 mg/kg per dose • Weight 75 to 100 kg: 750 mg per dose • Weight >100 kg: 1,000 mg per dose SC: weight-based dose once weekly • Weight 10 to < 25 kg: 50 mg per dose • Weight 25 to < 50 kg: 87.5 mg per dose • Weight ≥ 50 kg: 125 mg per dose	IV: 1,000 mg every 4 weeks SC: 125 mg/week
aGVHD	• Age ≥ 6 years: 10 mg/kg (up to 1,000 mg maximum dose) on day before transplantation, followed by Days 5, 14, and 28 after transplantation • Age ≥ 2 years and < 6 years: 15 mg/kg on day before transplantation, followed by 12 mg/kg on Days 5, 15, and 28 after transplantation	1,000 mg/dose

VI. Product Availability

- Single-use vial for IV infusion: 250 mg
- Single-dose prefilled syringes for SC injection: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL
- Single-dose prefilled ClickJect™ autoinjector for SC injection: 125 mg/mL

VII. References

1. Orencia Prescribing Information. Princeton, NJ: Bristol-Meyers Squibb Company; May 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125118s255lbl.pdf. Accessed February 27, 2025.
2. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Care and Research. 2019:71(6):717-734. DOI 10.1002/acr.23870.
3. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79:700–712. doi:10.1136/annrheumdis-2020-217159.
4. 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.
5. Fraenkel L, Bathon JM, Engglland BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021; 73(7):924-939. DOI 10.1002/acr.24596.
6. Smolen JS, Landewe RB, Dergstra SA, et al. 2022 update of the EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. Arthritis Rheumatology. 2023 January; 32:3-18. DOI:10.1136/ard-2022-223356.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0129	Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: 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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Per August SDC and prior clinical guidance, for RA added Actemra to redirect options and modified to require a trial of all; for PsA removed Simponi as a redirect option and modified to require a trial of all; for Xeljanz redirection requirements added bypass for members with cardiovascular risk and qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers.	08.25.21	11.21
2Q 2022 annual review: for PJIA, added redirection to Actemra per February SDC; for RA, added redirection to Olumiant per February SDC; RT4: added newly FDA approved indicatoin for aGVHD; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	02.20.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
2Q 2023 annual review: for pJIA, PsA, and RA, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; references reviewed and updated.	02.13.23	05.23
Per July SDC: for pJIA, PsA, RA, removed criteria requiring use of Enbrel and replaced with requirement for use of one adalimumab product and stating Yusimry, Hadlima, unbranded adalimumab-fkjp, and unbranded adalimumab-adaz as preferred; updated Appendix B with relevant therapeutic alternatives.	07.25.23	
Per December SDC, added adalimumab-adbm to listed examples of preferred adalimumab products; for RA removed redirection to Kevzara and Olumiant. RT4: for PsA, updated criteria with pediatric extension to include ages 2 years and older; added Wezlana to section III.B.	12.06.23	02.24
2Q 2024 annual review: updated Appendix D with removal of PsA guideline supplemental information; added Bimzelx, Zymfentra, Omvoh, Tofidence, Sotyktu, and Velsipity to section III.B; references reviewed and updated.	01.19.24	05.24
Per June SDC: for pJIA, PsA, RA, added Simlandi to listed examples of preferred adalimumab products. Per SDC: for pJIA, PsA, RA, added unbranded adalimumab-aaty to listed examples of preferred adalimumab products.	07.23.24	08.24
2Q 2025 annual review: for pJIA: removed criteria for minimum cJADAS-10 score $\geq$ 8.5 for documentation of high disease activity and "baseline 10-joint clinical juvenile arthritis disease activity score" in initial criteria to align with competitor analysis; removed criteria for "member is responding positively to therapy as evidence by decrease in cJADAS-10 from baseline" in continued therapy; for Appendix J, added pJIA disease activity information per 2019 ACR guidelines;	01.23.25	05.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
updated section III.B with Spevigo and biosimilar verbiage; references reviewed and updated.		
Per April SDC: for PsA, added criteria requiring use of one preferred Stelara biosimilar (Otulfi, Pyzchiva (branded), Selarsdi, Yesintek, and Steqeyma are preferred).	04.23.25	06.25
For PsA, applied step therapy to Otezla for pediatric age redirection as Otezla has a newly approved pediatric extension for 6 years and older; for pJIA and RA, added bypass of conventional therapies if a member has failed a biologic agent to clarify intention of not stepping back from biologic agent to conventional therapy. Extended initial approval durations to 12 months for chronic conditions.	08.05.25	11.25

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.