YouthCare
HealthChoice Illinois

Clinical Policy: Abatacept (Orencia)

Reference Number: IL.PHAR.241
Effective Date: 1.13.2020
Last Review Date: 5.7.24
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:

- Reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). Orencia may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.
- Reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Orencia may be used as monotherapy or concomitantly with methotrexate (MTX).
- Treatment of adult patients 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. Orencia should not be administered concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

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. 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 (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX (*see Appendix D*), 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 contraindicated or clinically significant adverse effects are experienced;
5. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d):
   a. Cimzia®; unless the member has had a history of failure of two TNF blockers
   b. Enbrel®; unless the member has had a history of failure of two TNF blockers
   c. Adalimumab-adbm or adalimumab-ryvk (Simlandi®); unless the member has had a history of failure of two TNF blockers
   d. Xeljanz®/Xeljanz XR®;

   **Prior authorization is required for Cimzia, Enbrel, adalimumab products, and Xeljanz/Xeljanz XR*
   **Prior authorization is required for Enbrel, , Adalimumab-adbm , adalimumab-ryvk (Simlandi®,)Cimzia, 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;
      i. Weight < 60 kg: 500 mg per dose, 2 vials per dose;
      ii. Weight 60 to 100 kg: 750 mg per dose, 3 vials per dose ;
      iii. Weight > 100 kg: 1,000 mg per dose, 4 vials per dose;
   b. SC: 125 mg once weekly.

Approval duration: 6 months

B. 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. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) (*see Appendix J*);
5. Member meets one of the following (a, b, c, or d):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;

b. If intolerance or contraindication to MTX (*see Appendix D*), 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. Documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 (*see Appendix J*);

6. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
   a. Enbrel®; unless the member has had a history of failure of two TNF blockers;
   b. Adalimumab-adbm or adalimumab-ryvk (Simlandi®) unless the member has had a history of failure of two TNF blockers;
   c. Xeljanz®/Xeljanz XR®;

   **Prior authorization may be required for Enbrel. adalimumab, and Xeljanz/Xeljanz XR*

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. For members 2 to 5 years of age, prescribed route of administration is SC;
9. 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;
      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;
      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: 6 months

C. 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 TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d):
   a. Cimzia®; unless the member has had a history of failure of two TNF blockers;
   b. Enbrel®; unless the member has had a history of failure of two TNF blockers;
   c. Adalimumab-adbm or adalimumab-ryvk (Simlandi®); unless the member has had a history of failure of two TNF blockers;
   d. Xeljanz®/Xeljanz XR®

**Prior authorization is required for Cimzia, Enbrel, adalimumab, and Xeljanz/Xeljanz XR*

5. 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*);
6. 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;
      i. Weight < 60 kg: 500 mg per dose;
      ii. Weight 60 to 100 kg: 750 mg per dose;
      iii. Weight > 100 kg: 1,000 mg per dose;
   b. SC: 125 mg once weekly.

Approval duration: 6 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

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, b, or c):
   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 pJIA, member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline (*see Appendix J*);
   c. For all other indications: member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. RA and PsA (i or ii):
      i. IV: weight-based dose every 4 weeks (1, 2, or 3);
         1) Weight < 60 kg: 500 mg per dose, 2 vials per dose;
         2) Weight 60 to 100 kg: 750 mg per dose, 3 vials per dose;
         3) Weight > 100 kg: 1,000 mg per dose, 4 vials per dose;
      ii. SC: 125 mg once weekly;
   b. 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.
   c. c. 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. 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 (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), 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), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], 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

CDAI: clinical disease activity index
cJADAS: clinical juvenile arthritis disease activity score
DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
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
Enbrel® (etanercept)	**PJIA** Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly **PsA, RA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**PJIA** Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week Weight ≥ 30 kg (66 lbs): 40 mg every other week **PsA** 40 mg SC every other week **RA** 40 mg SC every other week (may increase to once weekly)	PJIA, PsA: 40 mg every other week RA: 40 mg/week
Xeljanz® (tofacitinib)	**PsA, RA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**PsA, RA** 11 mg PO QD	11 mg/day
Cimzia® (certolizumab)	**PsA, RA** Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks

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®), adalimumab-atto (Amjevita™), infliximab (Remicade®) and infliximab 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 to524.99 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: Clinical Juvenile Arthritis Disease Activity Score based on 10 joints (cJADAS-10)
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

Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA PsA	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
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

V. 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

VI. References

1. Orencia Prescribing Information. Princeton, NJ: Bristol-Meyers Squibb Company; October 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125118s250lbl.pdf. Accessed January 18, 2024.

2. Ringold, S., Weiss, P. F., Beukelman, T., DeWitt, E. M., Ilowite, N. T., Kimura, Y., Laxer, R. M., Lovell, D. J., Nigrovic, P. A., Robinson, A. B. and Vehe, R. K. (2013), 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 65: 2499–2512.
3. 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 Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337.
4. Gottlieb, Alice et al.Guidelines of care for the management of psoriasis and psoriatic arthritis: Journal of the American Academy of Dermatology, Volume 58, Issue 5, 851 – 864.
5. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Rheumatology*. 2016; 68(1):1-26.
6. 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
7. 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
Policy created, adapted from CP.PHAR.241 Abatacept (Orencia) for migration to HFS PDL	1.13.2020	
1Q 2021 annual review added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; added rounding guidelines for weight-based dosing for all indications; updated criteria to allow tiered redirection or bypass of MTX in the event of sacroiliitis or high disease activity; Updated pJIA criteria to require diagnosis as evidenced by ≥ 5 joints, cJADAS assessment; Added criteria for	3.11.2021	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.		
1Q 2022 Annual review: For PJIA, added redirection to Xeljanz; Redirected criteria for sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID or documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 from indication RA to PJIA; Revised criteria for Diagnoses/Indications for which coverage is NOT authorized; updated limitation of use; reference reviewed and updated	4.15.22	
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; template changes applied to other diagnoses/indications and continued therapy section; 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.	4.18.23	
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.	5.6.24	
2Q 2025 Annual review: updated preferred adalimumab products; references reviewed and updated.	4.10.25	

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.