

Clinical Policy: Abatacept (Orencia)

Reference Number: CP.PHAR.241

Effective Date: 08.16

Last Review Date: 05.19

Line of Business: HIM*, 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.

**For Health Insurance Marketplace (HIM), if request is through pharmacy benefit, Orencia ClickJect[™] autoinjector is non-formulary and cannot be approved using these criteria; it can be covered under the medical benefit using this policy or under the pharmacy benefit via HIM.PA.103.*

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)

Limitation(s) of use: 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;
2. Prescribed by or in consultation with a rheumatologist;
3. Age \geq 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 etanercept (*Enbrel[®] is preferred*) and adalimumab (*Humira[®] is preferred*), each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for etanercept and adalimumab*
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:

Medicaid – 6 months

HIM – 6 months for IV or prefilled syringe (*medical benefit or HIM.PA.103 for autoinjector*)

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all):

1. Diagnosis of PJIA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 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 sulfasalazine or leflunomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept (*Enbrel is preferred*) AND adalimumab (*Humira is preferred*), each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for etanercept and adalimumab*
6. For members 2 to 5 years of age, prescribed route of administration is SC;
7. 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 \geq 50 kg: 125 mg per dose.

Approval duration:

Medicaid – 6 months

HIM – 6 months for IV or prefilled syringe (*medical benefit or HIM.PA.103 for autoinjector*)

C. Psoriatic Arthritis (must meet all):

- 1. Diagnosis of PsA;
- 2. Prescribed by or in consultation with a dermatologist or rheumatologist;
- 3. Age \geq 18 years;
- 4. Failure of etanercept (*Enbrel is preferred*) and adalimumab (*Humira is preferred*), each used for \geq 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for etanercept and adalimumab*
- 5. 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:

Medicaid – 6 months

HIM – 6 months for IV or prefilled syringe (*medical benefit or HIM.PA.103 for autoinjector*)

D. Other diagnoses/indications

- 1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

II. Continued Therapy

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

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. 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) Weight < 60 kg: 500 mg per dose;
 - 2) Weight 60 to 100 kg: 750 mg per dose;
 - 3) Weight > 100 kg: 1,000 mg per dose;
 - ii. SC: 125 mg once weekly;
 - b. PJIA (i or ii):

- i. IV: weight-based dose every 4 weeks;
 - 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) 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.

Approval duration:

Medicaid – 12 months

HIM – 6 months for IV or prefilled syringe (*medical benefit or HIM.PA.103 for autoinjector*)

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

- 1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

- 2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 – HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DMARD: disease-modifying antirheumatic drug

FDA: Food and Drug Administration

MTX: methotrexate

PJIA: polyarticular juvenile idiopathic arthritis

PsA: psoriatic arthritis

RA: rheumatoid arthritis

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* <u>Initial dose:</u>	1,500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	125 or 250 mg PO QD <u>Maintenance dose:</u> 500 – 750 mg/day PO QD	
cyclosporine (Sandimmune [®] , Neoral [®])	RA 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil [®])	RA* <u>Initial dose:</u> 400 – 600 mg/day PO <u>Maintenance dose:</u> 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 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (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)
sulfasalazine (Azulfidine [®])	RA 2 g/day PO in divided doses	RA: 3 g/day
Enbrel [®] (etanercept)	PsA, RA 25 mg SC twice weekly or 50 mg SC once weekly PJIA Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 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	PJIA, PsA: 40 mg every other week RA: 40 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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)	

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
- 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.

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	IV: 1,000 mg every 4 weeks SC: 125 mg/week
PsA	SC: 125 mg once weekly (For RA: if single IV loading dose is given, start first SC injection within one day of IV dose)	
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

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. Orenzia Prescribing Information. Princeton, NJ: Bristol-Meyers Squibb Company; June 2017. Available at: <http://www.orenciahcp.com/>. Accessed February 26, 2019.
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/annrhumdis-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

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 split from CP.PHAR.86 Arthritis Treatments and converted to new template.RA: updated age requirement to ≥ 18 years per PI; removed questions related to HBV, active malignancy, concomitant use with other biologics, and concurrent administration of live vaccines; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine as an alternative to MTX if MTX is contraindicated; added preferencing for Enbrel & Humira; PJIA: removed question related to number of affected; clarified required age to include only children and adolescents ≥ 6 years; removed questions related to HBV, active malignancy, concomitant use with other biologics, and concurrent administration of live vaccinesI; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine as an alternative to MTX if MTX is contraindicated; added preferencing for Enbrel & Humira. Added weight range-based dosing for each indication. Re-auth: combined into All Indications; added criteria related to weight range-based dosing and reasons to discontinue. Shortened background section. References updated.	06.16	08.16
Added new indication for PsA Revised criteria for confirmation of RA diagnosis per 2010 ACR Criteria. Removed safety requirements per updated CPAC Safety Precaution in PA Policies approach.	07.17	11.17
2Q 2018 annual review: added HIM; added rheumatologist specialist requirement for RA; removed TB testing from RA and PJIA; revised dosing in initial and continuation approval criteria for PJIA per package insert; references reviewed and updated.	02.27.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.	08.28.18	11.18
2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for PsA per ACR/NPF 2018 guidelines; references reviewed and updated.	03.05.19	05.19

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.

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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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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