Clinical Policy: Abatacept (Orencia)

Reference Number: CP.PHAR.241
Effective Date: 08.16
Last Review Date 11.17
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 the treatment of:

- Moderately to severely active rheumatoid arthritis (RA) in adults.
- Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate.
- Active psoriatic arthritis (PsA) in adults

Limitation(s) of use: Orencia should not be given concomitantly with tumor necrosis factor (TNF) antagonists.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) 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 (refer to *Appendix B*);
2. Member meets one of the following (a or b):
   a. Failure of methotrexate (MTX) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
3. 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*

4. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
5. Dose does not exceed the following:
   a. Intravenous (IV):
      i. < 60kg: 500mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      ii. 60-100 kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      iii. > 100kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
   b. Subcutaneous (SC): 125mg once weekly.

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of arthritis 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 MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine or leflunomide for ≥ 3 consecutive months 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. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Prescribed route of administration is IV infusion;
8. Dose does not exceed the following:
   i. ≤ 100kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
   ii. > 100 kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter.

Approval duration: 6 months

A. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of active PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;

   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or cyclosporine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect 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 the following (a or b):
   a. IV (weight based)
      i. < 60kg: 500mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      ii. 60-100 kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      iii. > 100kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
   b. Subcutaneous (SC): 125mg once weekly.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (ex. reduced inflammation/tenderness in joints, reduction in number of joints affected, reduced morning stiffness, improvement with activities of daily living);
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. For RA and PsA (i or ii):
      i. IV (weight based):
         1) < 60 kg: 500mg every 4 weeks;
         2) 60-100 kg: 750mg every 4 weeks;
         3) > 100kg: 1000mg every 4 weeks;
      ii. For RA and PsA (SC): 125mg once weekly;
   b. For PJIA (IV):
      i. ≤ 100kg: 750mg every 4 weeks;
      ii. > 100kg: 1000mg every 4 weeks.

Approval duration: 12 months

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 12 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

I. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CRP: C-reactive protein
DMARDs: disease-modifying antirheumatic drugs
ESR: erythrocyte sedimentation rate
FDA: Food and Drug Administration
IV: intravenous
MTX: methotrexate
PJIA: polyarticular juvenile idiopathic arthritis
RA: rheumatoid arthritis
SC: subcutaneous
TB: tuberculosis
TNF: tumor necrosis factor

Appendix B: The 2010 ACR Classification Criteria for RA

Classification criteria for RA (score-based algorithm: 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)		
		Score
A	**Joint involvement**	
	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	2
	High positive RF *or* high positive ACPA	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 normal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or DMARD Failure

In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count,

≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

II. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Rheumatoid Arthritis	IV: • < 60kg: 500mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; • 60-100 kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; • >100kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; SC: 125mg once weekly;	IV: • < 60kg: 500mg every 4 weeks • 60-100 kg: 750mg every 4 weeks • >100kg: 1000mg every 4 weeks SC: 125mg once weekly
Polyarticular Juvenile Idiopathic Arthrtis	IV: • ≤ 100kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; • > 100 kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;	IV: • ≤ 100kg: 750mg every 4 weeks • > 100 kg: 1000mg every 4 weeks
Psoriatic Arthritis	IV: • < 60kg: 500mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; • 60-100 kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; • >100kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter; SC: 125mg once weekly;	IV: • < 60kg: 500mg every 4 weeks • 60-100 kg: 750mg every 4 weeks • >100kg: 1000mg every 4 weeks SC: 125mg once weekly

III. Product Availability

- Intravenous Infusion
  - For Injection: 250 mg lyophilized powder in a single-use vial
- Subcutaneous Injection
  - Injection: 125 mg/mL of a clear, colorless to pale-yellow solution in a single-dose prefilled glass syringe
  - Injection: 125 mg/mL of a clear, colorless to pale-yellow solution in a single-dose prefilled ClickJect autoinjector

IV. References

1. Orencia Prescribing Information. Princeton, NJ: Bristol-Meyers Squibb Company; June 2016. Available at: http://www.orenciahcp.com/. Accessed July 19, 2016.
2. Enbrel Prescribing Information. Thousand Oaks, CA: Amgen Inc.; March 2015. Available at: https://www.enbrel.com/. Accessed June 16, 2016.
3. Humira Prescribing Information. North Chicago, IL: AbbVie Inc.; March 2016. Available at: https://www.humira.com/. Accessed June 16, 2016.
4. 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.
5. 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
6. 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.

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	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	06.16	08.16

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.		
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

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.