Clinical Policy: Abatacept (Orencia®)

Reference Number: QCP.PHAR.004
Date of Last Revision:

Coding Implications
Revision Log

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

Description
Abatacept (Orencia®) is a biologic drug.

Policy/Criteria
I. Initial Approval Criteria

A. Acute Graft-versus-Host Disease (must meet all):
1. Prescribed for prophylaxis of aGVHD;
2. Request is for intravenous formulation of Orencia;
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 of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
8. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 3 months (4 doses total)

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all):
1. Diagnosis of PJIA as evidenced by ≥ 5 joints with active arthritis;
2. Request is for Orencia
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years
5. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) (see Appendix I);
6. Member meets one of the following (a, b, c, or d):
    a. Failure of a ≥ 3 consecutive months trial of MTX at up to maximally indicated doses;
    b. Member has intolerance or contraindication to MTX (see Appendix D), failure of a ≥ 3 consecutive months trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
    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 I);

7. For Orencia: Member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. One of the following (i, ii, or iii, see Appendix D):
      i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
         1) Humira,
         2) Enbrel;
      ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira
      iii. History of failure of two TNF blockers and request is not for another TNF blocker;
   b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz, used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
9. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all):
1. Diagnosis of PsA;
2. Request is for Orencia
3. Age ≥ 18 years;
4. For Orencia: Member meets ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
   a. One of the following (i, ii, or iii, see Appendix D):
      i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
         1) Humira
         2) Enbrel;
      ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira
      iii. History of failure of two TNF blockers and request is not for another TNF blocker;
   b. Failure of a trial of ALL of the following, each used for ≥ 3 consecutive months: Otezla, Cosentyx, Skyrizi, Stelara, Tremfya;
   c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR and Rinvoq, each used for ≥ 3 consecutive months, unless

member has cardiovascular risk and benefits do not outweigh the risk of treatment;

5. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
6. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

D. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per ACR criteria (see Appendix F);
2. Request is for Orencia
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
    a. Failure of a ≥ 3 consecutive months 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 months 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;
6. Member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
    a. One of the following (i, ii, or iii, see Appendix D):
        i. Failure of both of the following, each used for ≥ 3 consecutive months (1 and 2):
            1) Humira
            2) Enbrel;
        ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira
        iii. History of failure of two TNF blockers and request is not for another TNF blocker;
    b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR and Rinvoq, each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
7. Documentation of one of the following baseline assessment scores (a or b):
    a. Clinical disease activity index (CDAI) score (see Appendix G);
    b. Routine assessment of patient index data 3 (RAPID3) score (see Appendix H);
8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);

9. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

II. Continued Therapy

All Indications in Section I (must meet all):

1. Member currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 G) or RAPID3 (see Appendix H) score from baseline;3. member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors
        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 I);
    c. For all other indications: Member is responding positively to therapy;
3. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK 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 maximum dose indicated in Section V.

aGVHD – 3 months (4 doses total)

For all other indications – 12 months

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 – HIM.PA.154 for health insurance marketplace or evidence of coverage documents;

B. Combination use of 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, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] 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

ACR: American College of Rheumatology
aGVHD: acute graft-versus-host disease
CDAI: clinical disease activity index
DMARDs: disease-modifying antirheumatic drugs
EULAR: European Union League Against Rheumatism
JAK: Janus kinase
MTX: methotrexate
NSAIDs: non-steroidal anti inflammatory drugs
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritiss
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 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	3 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	RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**PJIA*** • Weight < 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	20 mg/day

	Maintenance dose: 20 mg PO QD	
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**CD*** 15 – 25 mg/week IM or SC **PsO** 10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week **RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**PJIA***: Varies	Varies
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**PJIA*** 30-50 mg/kg/day PO divided BID **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	PJIA, ERA: 2 g/day RA: 3 g/day
biologic DMARDs (e.g., Humira, Enbrel, Cosentyx, Remicade, Simponi Aria, Otezla, Xeljanz/Xeljanz XR, Kevzara)	See Section V. Dosing and Administration	See Section V. Dosing and Administration

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
Contraindications: None
BBW: None

Appendix D: General Information
- Definition of failure of MTX or DMARDs
    - Failure of a trial of conventional 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.
- 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:** Immunomodulator Medical Justification

Appendix E: Dose Rounding Guidelines for Weight-Based Doses

Orencia for Intravenous Use PJIA and SJIA

Weight-based Dose Range	Vial Quantity Recommendation
≤ 262.49 mg	1 vial of 250 mg
262.50 mg to524.99 mg	2 vial of 250 mg
525 to 787.49 mg	3 vial of 250 mg
787.50 mg to 1,049.99 mg	4 vial of 250 mg

Appendix F: 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)	Score
	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)	Score
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1

D	Duration of symptoms	Score
	< 6 weeks	0
	≥ 6 weeks	1

Appendix G: 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 H: 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 I: Clinical Juvenile Arthritis Disease Activity Score based on 10 joints (cJADAS10)

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

Drug Name	Indication	Dosing Regimen	Maximum Dose
Abatacept (Orencia)* *Also see Appendix E: Dose Rounding Guidelines for Weight-Based Doses	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
	aGVHD	• 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 • 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	1,000 mg/dose

VI. Product Availability

Abatacept (Orencia):
Single-use vial: 250 mg
Single-dose prefilled syringe: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL
Single-dose prefilled ClickJect™ autoinjector: 125 mg/mL

References

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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

Revision Log

Reviews, Revisions, and Approvals	Revision Date	Approval Date

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed healthcare 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.

Clinical Policy: Abatacept (Orencia®)

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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