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Drug Policy

Policy:	**201725**	**Initial Effective Date: 06/22/2017**
Code(s):	**HCPCS J0129**	**Annual Review Date: 05/18/2023**
SUBJECT:	**Abatacept (Orencia®) SC**	**Last Revised Date: 05/18/2023**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

Overview

Orencia subcutaneous (SC) is a recombinant fully human fusion protein that selectively inhibits T lymphocyte activation by competitively binding to CD80 and CD86, thereby blocking interaction with CD28.[1] This provides a co-stimulation signal that is necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of rheumatoid arthritis (RA). The SC injection is available in prefilled syringes containing three different doses (50 mg, 87.5 mg, and 125 mg per syringe) to allow for weight-based dosing in adults and pediatric patients.

POLICY STATEMENT

This policy involves the use of Orencia SC. Prior authorization is recommended for medical benefit coverage of Orencia SC. Coverage is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria and **Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** are listed following the Recommended Authorization Criteria and Waste Management section.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Orenica SC as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Orenica SC to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is required, a response to therapy is required for continuation of therapy. **Orenica SC is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

Recommended Authorization Criteria

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FDA-Approved Indications

1. **Rheumatoid Arthritis (RA).** Approve for the duration noted if the patient meets ONE of the following (A or B):

   i. **Initial therapy.** *Approve if the patient meets the following criteria (A, B, C, D, and E):*
      - **A.** Age ≥ 18 years; and
      - **B.** Moderately to severe rheumatoid arthritis; and
      - **C.** The patient meets one of the following: (1 or 2)
        1. The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months or patient has an intolerance to or unable to receive methotrexate or other non-biologic DMARD (e.g., hydroxychloroquine, leflunomide, sulfasalazine, minocycline); OR
        2. The patient has tried ONE biologic disease-modifying antirheumatic drug (DMARD) for 3 months [Refer to Appendix A for examples]; OR
      - **D.** Orencia is prescribed by or in consultation with a rheumatologist.
      - **E.** Site of care medical necessity is met*

   ii. Patient is Currently Receiving Orencia (Intravenous or Subcutaneous). Approve for 1 year if the patient meets BOTH of the following (i and ii):
      - **i.** Patient has been established on therapy for at least 6 months; AND
        Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
      - **ii.** Patient meets at least one of the following (a or b):
        - **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
          Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
        - **b)** Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Dosing in RA: Orencia SC is indicated for moderate or severe active RA in adults and can be used alone or in combination with DMARDs other than TNF antagonists.[1] Patients may initiate therapy with or without a loading dose of Orenica IV. If administered with a loading dose, the loading dose is followed by 125 mg of Orencia SC within 1 day, then Orencia 125 mg SC weekly. If no loading dose is administered, Orencia SC is administered as a weekly SC dose. Patients are evaluated for response after the third month of therapy.

Initial Approval/Extended Approval.
A) *Initial Approval*: 6 months (180 days)
B) *Extended Approval*: 1 year (365 days)

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2. **Juvenile Idiopathic Arthritis (JIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **i. Initial Therapy:** *Approve if the patient meets the following criteria (A, B, C, D, E and F):*
     - A. Age ≥ 2 years; AND
     - B. Moderately to severe polyarticular juvenile idiopathic arthritis; AND
     - C. Abatacept will not be used in combination with another biologic agent (e.g., adalimumab, anakinra, certolizumab pegol, etanercept, infliximab, golimumab, rituximab, tocilizumab), Otezla or Xeljanz; AND
     - D. Orencia is prescribed by or in consultation with a rheumatologist; AND
     - E. The patient meets one of the following conditions (a, b, c or d):
       - **a)** The patient has tried one other agent for this condition (e.g., methotrexate [MTX], sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug [NSAID]).
       - **b)** The patient has tried a biologic DMARD [See Appendix A for examples]; OR
       - **c)** The patient will be starting on Orencia SC concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR
       - **d)** The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR
       - **e)** Patient has aggressive disease, as determined by the prescriber; AND
     - F. Site of Care medical necessity is met*

   - **ii.** Patients Currently Receiving Orencia (IV or SC). Approve if the patient has had a response (e.g., has improvement in limitation of motion; less joint pain or tenderness; improved function or activities of daily living; decreased duration of morning stiffness or fatigue; reduced dosage of corticosteroids; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Orencia IV or SC. And Site of care medical necessity is met*

Dosing in JIA:
SubQ: Children ≥2 years, and Adolescents: **Note:** Administer without an IV loading dose and use weight-based dosing.
10 to <25 kg: 50 mg once weekly
≥25 to <50 kg: 87.5 mg once weekly
≥50 kg: 125 mg once weekly

Initial Approval/Extended Approval.
A) *Initial Approval*: 6 months (180 days)
B) *Extended Approval*: 1 year (365 days)

3. **Psoriatic Arthritis (PsA)** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if prescribed by or in consultation with a rheumatologist or a dermatologist. And Site of care medical necessity is met*
   - **B)** Extended Approval: Approve if the patient has responded (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths;

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improvements in acute phase reactants [for example, C-reactive protein]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Orencia. And Site of care medical necessity is met*

Dosing in PsA: SubQ: 125 mg once weekly. **Note:** Administer without an IV loading dose.
If transitioning from IV therapy to SubQ therapy, administer the first SubQ dose instead of the next scheduled IV dose.

Initial Approval/Extended Approval.
A) *Initial Approval*: 6 months (180 days)
B) *Extended Approval*: 1 year (365 days)

4. Graft Versus Host Disease (GVHD)

A) Initial Therapy. *Approve for patients who meet the following criteria:*
Treatment of Chronic Graft Versus Host Disease (cGVHD)
a. Patient has received a hematopoietic stem cell transplant (HSCT); **AND**
i. Used for steroid-refractory chronic GVHD; **AND**
ii. Used in combination with systemic corticosteroids as additional therapy following no response to first line therapies

B) Patients currently receiving Orencia (IV or SC):
a. **Treatment of Chronic Graft Versus Host Disease (cGVHD)**
i. Patient has had an absence of unacceptable toxicity from the drug; **AND**
ii. Patient has had a response to therapy with an improvement in clinical assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.) or patient- reported symptoms (e.g., Lee Symptom Scale, etc.)

Dosing in Treatment of Chronic Graft Versus Host Disease:
Intravenous/Subcutaneous Dosing
- Up to 10 mg/kg (with a maximum dose of 1,000mg) at weeks 0, 2, & 4, then every 4 weeks thereafter until disease progression or unacceptable toxicity

Initial Approval/Extended Approval.
A) *Initial Approval*: 6 months (180 days)
B) *Extended Approval*: 6 months (180 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Orencia SC has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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1. **Ankylosing Spondylitis (AS).** In an open-label Phase II trial, Orencia was administered by intravenous infusion on Days 1, 15, 29, and every 28 days thereafter to patients with active AS.[6] Patients received a fixed dosage of Orencia of approximately 10 mg/kg based on body weight. The primary endpoint was a 40% improvement in disease activity at Week 24 in the Assessment of SpondyloArthritis international Society criteria (ASAS 40). At Week 24, the ASAS 40 was 13.3% (n = 2/15) in TNF blocker-naïve patients compared with no responses in patients who had previously failed TNF blockers (n = 15). ASAS 20 response was 26.7% (n = 4/15) in TNF blocker-naïve patients compared with 20% (n = 3/15) in those who had previously failed TNF blockers. A major response was not shown with treatment to Orencia.

2. **Concurrent Use with a Biologic or with a Targeted Synthetic DMARD.** Orencia SC should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see APPENDIX for examples). Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[7] Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Orencia (IV or SC).

3. **Inflammatory Bowel Disease (i.e., Crohn's Disease [CD], Ulcerative Colitis [UC]).** In placebo-controlled trials evaluating the efficacy of Orencia IV for induction and maintenance in adults with active, moderate to severe CD (n = 451) and UC (n = 490), Orencia was no more effective than placebo.[9] Patients were randomized to Orencia 30, 10, or 3 mg/kg IV (according to body weight) or placebo and dosed at Weeks 0, 2, 4, and 8. A total of 90 patients with CD and 131 patients with UC who responded to Orencia IV induction were then randomized to Orencia 10 mg/kg IV or placebo every 4 weeks through Week 52. When used for induction of CD, 17.2%, 10.2%, and 15.5% of patients receiving Orencia 30 mg, 10 mg, and 3 mg/kg IV achieved a clinical response at Weeks 8 and 12 compared with 14.4% of patients receiving placebo (P = not significant [NS] for all comparisons). In patients with CD, response and remission at Week 52 was not significantly different between the Orencia IV and placebo treatment groups. When used as induction therapy in UC, 21.4%, 19.0%, and 20.3% of patients receiving Orencia 30 mg, 10 mg, and 3 mg/kg IV achieved a clinical response at Week 12 compared with 29.5% of patients receiving placebo (P = 0.043 for 10 mg/kg vs. placebo; other comparisons NS). At Week 52, 12.5% (n = 8/64) and 14.1% (n = 9/64) of patients with UC were in remission (P = NS) and 17.2% of patients in each treatment group (n = 11/64 for each group) had achieved a response.

4. **Psoriasis**. In a multicenter, Phase I, 26-week, open-label dose-escalation study, 43 patients with stable plaque psoriasis (10% to 49% body surface area involvement) received four doses of Orencia given as a 1-hour IV infusion on Days 1, 3, 16 and 29.[10] The starting dose was 0.5 mg/kg. Four to six patients were accrued to each of eight dose levels: 0.5, 1, 2, 4, 8, 16, 25 and 50 mg/kg. A parallel control group was matched for age and overall disease severity. In all, 46% of patients on Orencia for IV infusion achieved a 50% or greater sustained improvement in clinical disease activity (Physician's Global Assessment of disease activity) compared with baseline psoriasis evaluation. Progressively greater effects were observed with the highest doses. Further studies are needed to establish safety and efficacy in plaque psoriasis. Note: Patients with concomitant plaque psoriasis and psoriatic arthritis may be reviewed under the psoriatic arthritis criteria above.

5. **Concurrent use with Otezla.** No evidence to suggest Orencia in combination with Otezla is superior to monotherapy.

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6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Code J0129.

References

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4. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res (Hoboken).* 2011;63(4):465-482.
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6. Song IH, Heldmann F, Rudwaleit M, et al. Treatment of active ankylosing spondylitis with abatacept: an open-label, 24-week pilot study. *Ann Rheum Dis*. 2011;70(6):1108-1110.
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12. 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 Rheumatol*. 2019 Apr 25. [Epub ahead of print].
13. Bristol-Myers Squibb. Safety and efficacy of abatacept versus placebo in participants with psoriatic arthritis. In ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 June 27]. Available from: https://clinicaltrials.gov/ct2/show?term=abatacept&rank=23. NLM Identifier: NCT00534313.

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Drug Policy

Prior approval: Prior approval is required for abatacept SC **(HCPCS Code J0129)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within the Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J0129** will edit with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J0129	Injection, abatacept, 10 mg

Appendix A

	Mechanism of Action	**Examples of Inflammatory Indications***
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD

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Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.

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