GCHP Medi-Cal Clinical Guidelines
Abatacept (Orencia IV ™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Prophylaxis of acute graft-versus-host disease (in combination with calcineurin inhibitor and methotrexate) in adults and pediatric patients ≥2 years of age undergoing hematopoietic stem cell transplantation from a matched or one allele-mismatched unrelated donor. • Treatment of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ≥2 years of age. • Treatment of active psoriatic arthritis (PsA)in patients ≥2 years of age. • Treatment of moderately to severely active rheumatoid arthritis (RA) in adults. *Non-FDA approved indication or off-label use will be reviewed if there is sufficient documentation of efficacy and safety in published literature.*
Exclusion Criteria	• Active infection. • Concurrent treatment with Janus kinase inhibitors or other biologic drug (e.g., Tumor necrosis factor inhibitor, anakinra). • Concurrent use of live vaccine during treatment or within three months of discontinuing treatment. • Untreated latent or active tuberculosis.
Required Medical Information	**Prophylaxis of acute graft-versus-host disease** • Administered in combination with calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate and • Receiving concurrent antiviral prophylaxis for Epstein-Barr virus reactivation and • Underdoing hematopoietic stem cell transplant from a matched or one allele-mismatched unrelated donor. **Juvenile idiopathic arthritis (JIA)** • Intolerance of or inadequate response to either (1) tumor necrosis factor inhibitor (e.g., adalimumab, etanercept) or (2) methotrexate or leflunomide and • Joint involvement of five joints or more. **Psoriatic arthritis (PsA)** • Active disease with one or more tender and swollen joints and • Inadequate response, intolerance or contraindication to at least one (1) of the following: i. Apremilast. ii. Conventional synthetic DMARD (e.g., methotrexate, sulfasalazine, hydroxychloroquine, leflunomide)

	iii. NSAIDs. iv. Non-tumor necrosis factor inhibitor biologic medication (e.g., abatacept, guselkumab, ixekizumab, risankizumab, secukinumab, ustekinumab). v. Tumor necrosis factor (TNF) inhibitor (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab). **Rheumatoid arthritis (RA)** • Inadequate response to three or more months of treatment with at least one DMARD medication, i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine v. TNF inhibitor and • Moderate to severe active RA demonstrated by at least one of the following: i. Clinical Disease Activity Index score greater than 10 ii. Disease Activity Score of 3.2 or greater iii. Patient Activity Scale of 3.71 or greater iv. Patient Activity Scale-I of 3.71 or greater v. Routine Assessment of Patient Index Data 3 score greater than two vi. Simplified Disease Activity Index score greater than 11 **Renewal for JIA, PsA, RA** Favorable clinical response to abatacept. **Off-label indications:** 1) The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic & professional specialists. 2) In addition, one of the following is required: a. Documentation of trial & failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.
Age Restriction	Prophylaxis of acute graft-versus-host disease: 2 years of age and older JIA: 6 years of age and older (IV formulation is not FDA approved for 2 – 6 years of age) PsA, RA: 18 years and older (IV formulation is not FDA approved for PsA in children) 2 – 21 years of age: check for CCS
Prescriber Restrictions	Prescribed or recommended by a rheumatologist for PsA, JIA, RA. Prescribed by a transplant specialist for prophylaxis of acute graft-versus-host disease.
Coverage Duration	Six months.

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<tr><td>Other Criteria/Information</td><td>Orencia™ Prefilled Syringe is FDA approved as a self-administered injection and should be provided to the member by a pharmacy through pharmacy benefit.
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<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J0129</td><td>Injection, abatacept, 10mg (Orencia™)</td><td><u>Adults (RA, PsA)</u>
< 60 kg: 500mg (50 units)
60 – 100 kg: 750mg (75 units)
>100 kg: 1,000mg (100 units)
<u>JIA and Age >6 years</u>
<75 kg: 10mg/kg
75 – 100kg: 750mg (75 units)
>100kg: 1,000mg (100 units)
<u>Acute graft-versus-host disease prophylaxis</u>
Adults: 10mg/kg on the day prior to transplant (day-1), followed by 10mg/kg on days five, 14, and 28 post-transplant.
2 to <6 years of age: 15mg/kg day-1 followed by 12 mg/kg on days five, 14, and 28 post-transplant.
>6 years of age and adolescents: 10mg/kg day-1 followed by 10mg/kg on days five, 14, and 28 post-transplant.
Max dose 1g/dose.</td></tr>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	8/5/2024	8/5/2024	Yoonhee Kim, Interim Director of Pharmacy Services	N/A
Approved	N/A	8/14/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025