# Medical Policy

**Healthcare Services Department**

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|---|---|---|
| Orencia (abatacept) | MP-RX-FP-68-23 | ☒ MMM MA ☐ MMM Multihealth |

**Service Category**

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other TYPE B DRUG

## Service Description

This document addresses the use of Orencia (abatacept) , a drug approved by the Food and Drug Administration (FDA) for the treatment of Rheumatoid arthritis, Psoriatic Arthritis, Juvenile Idiopathic Arthritis and Graft Versus Host Disease (GVHD).

**Background Information**
This document addresses the use of Orencia (abatacept), a selective costimulation modulator which inhibits T cell (T lymphocyte) activation. It is available in intravenous and subcutaneous injection formulations

**Approved Indications**

A. **Rheumatoid Arthritis:** The American College of Rheumatology (ACR) guidelines recommend disease-modifying antirheumatic drug (DMARD) monotherapy as first-line treatment in individuals with RA with moderate to high disease activity. Methotrexate (MTX) monotherapy, titrated to a dose of at least 15 mg, is recommended over hydroxychloroquine, sulfasalazine, and leflunomide. Methotrexate monotherapy is also recommended over monotherapy with biologics (tumor necrosis factor inhibitors [TNFi], IL-6 inhibitors, abatacept) or JAK inhibitors. For individuals taking maximally tolerated doses MTX who are not at target, the addition of a biologic or JAK inhibitor is recommended. Non-TNFi biologics or JAK inhibitors are conditionally recommended over TNFi in individuals with heart failure.
B. **Psoriatic Arthritis**: The American College of Rheumatology (ACR) guidelines recommend that initial treatment of patients with active severe PsA or concomitant psoriasis should include a TNFi biologic over an oral small molecule (OSM; including methotrexate, sulfasalazine, cyclosporine, leflunomide, and apremilast). For initial therapy, OSMs are preferred over IL-17 and ustekinumab; and may be considered over TNFi biologics in mild to moderate disease without comorbid conditions or in those who prefer oral therapy. Recommendations involving biologics over OSMs as first line therapy are conditional and based on low quality evidence. Evidence cited includes indirect comparisons of placebo-controlled trials, studies with open-label design, and extrapolation from studies in plaque psoriasis. Furthermore, most pivotal trials for TNFi biologics included a study population that were DMARD experienced. Overall, there is a lack of definitive evidence for the safety and efficacy of biologic drugs over conventional therapy for the initial treatment of most patients with psoriatic arthritis. The ACR guidelines also include recommendations for patients whose disease remains active despite treatment with an OSM. Here, TNFi biologics are recommended over other therapies including IL-17 inhibitors, ustekinumab, tofacitinib, and abatacept. When TNFi biologics are not used,

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IL-17 inhibitors are preferred over ustekinumab; both of which are preferred over tofacitinib and abatacept. For disease that remains active despite TNFi monotherapy, switching to a different TNFi is recommended over other therapies.

C. **Juvenile Idiopathic Arthritis:** The American College of Rheumatology (ACR) guidelines provide recommendations for juvenile idiopathic arthritis, including systemic disease (SJIA) and JIA with polyarthritis (PJIA). SJIA is an autoinflammatory condition marked by intermittent fever, rash, and arthritis. PJIA is marked by the presence of more than four affected joints in the first six months of illness. For SJIA, NSAIDs or glucocorticoids are conditionally recommended as initial monotherapy, depending on whether macrophage activation syndrome (MAS) is present or not. IL-1 inhibitors (anakinra or canakinumab), or tocilizumab are also conditionally recommended as initial therapy or to achieve inactive disease, with no preferred agent. For SJIA without MAS, IL-1 inhibitors (anakinra or canakinumab) and tocilizumab are strongly recommended for inadequate response to or intolerance of NSAIDs and/or glucocorticoids (ACR 2021). For children with active polyarthritis, biologic therapy including TNFi, abatacept, or tocilizumab +/- DMARD is recommended following initial DMARD therapy (preferably methotrexate) (ACR 2019).

D. **Graft Versus Host Disease (GVHD):** Acute GVHD is a common complication of hematopoietic stem cell transplantation (HSCT) that frequently occurs soon after transplantation. This occurs when immune cells from the donor recognize and attack the transplant recipient, manifesting in an immune reaction present in the skin, gastrointestinal tract, and/or liver. While transplant recipients receive intensive immunosuppressive regimens, GVHD is associated with a significant decrease in survival and may not respond to treatment. There is no standard GVHD prophylaxis regimen, and clinical practice varies by institution. Agents for pharmacologic prophylaxis include methotrexate, calcineurin inhibitors (cyclosporine or tacrolimus), and mycophenolate mofetil. Orencia is FDA approved for the prophylaxis of acute GVHD in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing HSCT from a matched or 1 allele-mismatched unrelated-donor. It is administered via intravenous infusion starting the day before transplantation (Day -1), followed by administration on days 5, 14, and 28 after transplantation. Orencia is not indicated for the treatment of acute or chronic GVHD.

**Other Uses**

The National Comprehensive Cancer Network® (NCCN) provides recommendations for off-label use of Orencia with a category 2A level of evidence. These include as treatment of steroid-refractory chronic GVHD and immune checkpoint Inhibitor-related myocarditis. High-quality evidence supporting its safety and efficacy in these conditions has not been reported

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## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| HCPC | J0129 Injection, abatacept, 10 mg [Orencia] |

| ICD-10 | Description |
|---|---|
| ICD-10 | L40.50-L40.59 Arthropathic psoriasis<br>M05.00-M05.9 Rheumatoid arthritis with rheumatoid factor<br>M06.00-M06.09 Rheumatoid arthritis without rheumatoid factor<br>M06.4 Inflammatory polyarthropathy<br>M06.80-M06.9 Other specified and unspecified rheumatoid arthritis<br>M08.00-M08.09 Unspecified juvenile rheumatoid arthritis<br>M08.20-M08.29 Juvenile rheumatoid arthritis with systemic onset<br>M08.3 Juvenile rheumatoid polyarthritis (seronegative)<br>M08.40-M08.48 Pauciarticular juvenile rheumatoid arthritis |

## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

**Orencia (abatacept)**
Initial requests for Orencia (abatacept) may be approved if the following criteria are met:
I. *Rheumatoid arthritis (RA)* when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe RA; **AND**
B. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
C. If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a
contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine);

**OR**
II. *Polyarticular juvenile idiopathic arthritis (PJIA)* when each of the following criteria are met:
A. Individual has moderate to severe PJIA; **AND**
B. Individual is 6 years of age and older for administration of intravenous infusion, or 2 years of age and older for administration of subcutaneous injection; **AND**
C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs, such as methotrexate)] (ACR 2019);

**OR**
III. *Psoriatic arthritis (PsA)* when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] (ACR 2019);
**OR**

IV. *Graft Versus Host Disease (GVHD), prophylaxis*, when each of the following criteria are met:
A. Individual is 2 years of age or older using for prophylaxis of acute GVHD; **AND**
B. Individual will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor; **AND**
C. Individual is using Orencia (abatacept) in combination with a calcineurin inhibitor and methotrexate.

Continuation requests for Orencia (abatacept) may be approved if the following criterion is met:
I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

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Requests for Orencia (abatacept) may not be approved if the following criteria are met:
I. In combination with topical or oral JAK inhibitors, ozanimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
II. ; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

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## Limits or Restrictions

A. Therapeutic Alternatives

*The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.*

**Orencia Step Therapy**

This medical policy may be subject to Step Therapy. Please refer to the document published on the MMM Website: https://www.mmm-pr.com/planes-medicos/formulario-medicamentos

1Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness

B. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

| Drug | Limit |
|---|---|
| Orencia 250 mg/vial (for IV use) | 4 vials per 28 days |
| Orencia 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL prefilled syringe/ClickJect™ autoinjector (for S.C. use) | 4 syringes/autoinjectors per 28 days |
| **Exceptions** | |
| Initiation of intravenous therapy: For RA, PJIA, or PsA, May approve 4 (four) additional vials (250 mg/vial) in the first 28 days (4 weeks) of treatment. For GVHD, May approve up to 4 vials (250 mg/vial) per infusion for a total of 4 (four) infusions starting the day before transplantation (day -1), followed by administration on days 5, 14, and 28 after transplantation. | |

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## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |

Revised: 11/18/2022