Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
abatacept (Orencia®)	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
☒ Part B Drugs

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 acute Graft Versus Host Disease (aGVHD). It is available in intravenous and subcutaneous injection formulations.

Background Information

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.

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, 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.

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

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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).

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.

Approved Indications

Orencia is approved by the FDA for the treatment of moderately to severely active rheumatoid arthritis (RA), moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA), active psoriatic arthritis (PsA), and prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

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
J0129	Injection, abatacept, 10 mg [Orencia]

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

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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.

Abatacept (Orencia®)

A. Criteria For Initial Approval

I. Initial requests for Orencia (abatacept) may be approved if the following criteria are met:

i. Individual is 18 years of age or older with moderate to severe rheumatoid arthritis (RA); **AND**

ii. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**

iii. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to, or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**

iv. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

v. Individual has moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); **AND**

vi. 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**

vii. 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**

viii. Individual has a contraindication to methotrexate;

OR

ix. Individual is 2 years of age or older with moderate to severe Psoriatic arthritis (PsA) ; **AND**

x. 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**

xi. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

xii. Individual is 2 years of age or older using for prophylaxis of acute Graft Versus Host Disease (aGVHD); **AND**

xiii. Individual will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor; **AND**

xiv. Individual is using Orencia (abatacept) in combination with a calcineurin inhibitor and methotrexate.

OR

xv. Individual has a diagnosis of steroid-refractory chronic graft-versus-host disease (GVHD), (NCCN 2A); **AND**

xvi. Individual is initiating abatacept in combination with systemic corticosteroids;

OR

xvii. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis (NCCN 2A); **AND**

xviii. Individual is experiencing immunotherapy-related myocarditis; **AND**

xix. Myocarditis is unresponsive to high-dose systemic corticosteroids.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of abatacept (Orencia®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following criteria are met:
   A. Individual has been receiving and is maintained on a stable dose of Orencia; **AND**
   B. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months

ii. Reauthorization Approval Duration: Up to 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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Requests for Orencia (abatacept) may not be approved for the following criteria:

i. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, 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. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
iii. 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**
iv. When the above criteria are not met and for all other indications.

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.

i. 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

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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.	

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 11, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939.
6. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol. 2011; 65: 137-174.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
8. Ringold S, Weiss PF, Beukelman T, et al. 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 Rheum. 2013; 65(10):2499-2512.

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9. 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 Rheum. 2019; 71(6):846-863.
10. 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 & Research. 2011; 63(4):465.
11. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2021 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: October 11, 2021.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Annual Review	Add immunotherapy-related toxicities and chronic graft-versus-host disease per NCCN; add new pediatric indication for psoriatic arthritis; update contraindication to prior therapy language for clarity; clarify repeat TB testing requirements; include etrasimod in combination exclusion; add continuation of use language; wording and formatting updates. Coding Reviewed: No changes.	11/18/2024	12/17/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 10/28/2024.