| Market Applicability | | | | | |
|---|---|---|---|---|---|
| **Market** | **GA** | **KY** | **MD** | **NJ** | **NY** |
| **Applicable** | X | NA | X | X | X |

# Orencia (abatacept)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| Orencia (abatacept) - Intravenous | 4 vials per 28 days* |
| Orencia (abatacept) - Subcutaneous | 4 syringes/autojectors per 28 days |

*Initiation of intravenous therapy: May approve 4 (four) additional vials (250 mg/vial) in the first 28 days (4 weeks) of treatment.

## APPROVAL CRITERIA

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, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)] or a tumor necrosis factor (TNF) antagonist (ACR 2015);
   **AND**
   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Avsola (infliximab-axxq), Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Orencia (abatacept); **OR**
      2. The individual has either concomitant clinical condition:
         a. Demyelinating disease; **OR**
         b. Heart failure with documented left ventricular dysfunction;

**OR**

II. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual has moderate to severe PJIA;

| Market Applicability | | | | | |
|---|---|---|---|---|---|
| **Market** | **GA** | **KY** | **MD** | **NJ** | **NY** |
| **Applicable** | X | NA | X | X | X |

**AND**

B. Individual is 6 years of age or older for administration of intravenous infusion; **OR**

C. Individual is 2 years of age and older for administration of subcutaneous injection;

**AND**

D. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as, methotrexate)] or a tumor necrosis factor (TNF) antagonist (ACR 2019);

**AND**

E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Avsola (infliximab-axxq), Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met;

1. Individual has been receiving and is maintained on a stable dose of Orencia (abatacept); **OR**
2. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction.

**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 disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)] or a tumor necrosis factor (TNF) antagonist (ACR 2019);

**AND**

C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Avsola (infliximab-axxq), Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:

1. Individual has been receiving and is maintained on a stable dose of Orencia (abatacept); **OR**
2. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction.

Continuation requests for Orencia (abatacept) may be approved if the following criterion is met:

| Market Applicability | | | | | |
|---|---|---|---|---|---|
| **Market** | **GA** | **KY** | **MD** | **NJ** | **NY** |
| **Applicable** | X | NA | X | X | X |

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

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

I. All other indications not included above; **OR**
II. In combination with JAK inhibitors, apremilast, or other biologic drugs (such as, TNF antagonists or anakinra); **OR**
III. Tuberculosis or other active serious infections or a history of recurrent infections;
IV. Prior to initiating therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention - recommended equivalent test to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no risk factors).

**Key References**:


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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Singh JA, Saag KG, Bridges SL et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheum*. 2016;68:1-26.
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.
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.

| Market Applicability | | | | | |
|---|---|---|---|---|---|
| **Market** | **GA** | **KY** | **MD** | **NJ** | **NY** |
| **Applicable** | X | NA | X | X | X |





This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.