

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Orencia (abatacept)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Comments	Quantity Limit
Orencia (abatacept) - Intravenous	AGP, VA MCD only	4 vials per 28 days*
Orencia (abatacept) - Subcutaneous	ALL MCD	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

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 – Enbrel (etanercept) and 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 preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Orencia (abatacept); **OR**

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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.

CRX-ALL-0345-19

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- b. Individual's age; **OR**
- c. Pregnant or planning on becoming pregnant; **OR**
- d. Serious infections or concurrent sepsis; **OR**
- 3. The individual has either concomitant clinical condition:
 - a. Demyelinating disease; **OR**
 - b. Heart failure with documented left ventricular dysfunction; **OR**
- 4. The preferred agent(s) do not have activity against a concomitant clinical condition and Orenzia (abatacept) does. An example includes but may not be limited to the following:
 - a. Concomitant Crohn's disease: TNFi (agents FDA-approved for both indications) are preferred;

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 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 2011);

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 – Enbrel (etanercept) and Humira (adalimumab)] unless the following criteria is met;

- 1. Individual has been receiving and is maintained on a stable dose of Orenzia (abatacept); **OR**
- 2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Orenzia (abatacept) does; **OR**
- 3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Orenzia (abatacept); **OR**

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- b. Individual's age; **OR**
- c. Pregnant or planning on becoming pregnant; **OR**
- d. Serious infections or concurrent sepsis; **OR**
- 4. 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 (AAD 2011);

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 – Enbrel (etanercept) and 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 preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Orencia (abatacept) does; **OR**
 - 3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Orencia (abatacept); **OR**
 - b. Individual's age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis; **OR**
 - 4. The preferred agent(s) do not have activity against a concomitant clinical condition and the requested non-preferred agent does. Examples include but may not be limited to the following:
 - a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
 - b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

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

- I. In combination with other biologic drugs (such as, TNF antagonists or anakinra); **OR**
- II. Tuberculosis or other active serious infections or a history of recurrent infections;
- III. 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 prior to initiating abatacept.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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: September 14, 2018.
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. 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.
8. 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):465-482.

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