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

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Orencia (abatacept)

CG-DRUG-105

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

I. Rheumatoid Arthritis:
   A. Individual is 18 years of age or older; **AND**
   B. Individual has a diagnosis of moderately to severely active rheumatoid arthritis; **AND**
   C. Agent is being used to reduce signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function; **AND**
   D. Individual has had an inadequate response to a trial of one or more non-biologic or biologic disease-modifying anti-rheumatic drugs (DMARDs), such as, methotrexate or a tumor necrosis factor (TNF) antagonist; **AND**
   E. Individual is not using in combination with a biologic DMARD (for example, TNF antagonist); **AND**
   F. 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

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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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**

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 Orencia (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:
A. Individual is 6 years of age or older;
AND
B. Request is for intravenous infusion;

OR
C. Individual is 2 years of age and older;
AND
D. Request is for subcutaneous injection;

AND
E. Agent is being used to reduce signs and symptoms of the disease; **AND**
F. Individual has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis; **AND**
G. Individual has had an inadequate response to a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one or more non-biologic or biologic disease-modifying antirheumatic drugs (DMARDs), such as, methotrexate or a tumor necrosis factor (TNF) antagonist;
AND
H. Individual is not using in combination with a biologic DMARD (for example, TNF antagonist); **AND**
I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to

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

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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 individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction.

OR

III. Psoriatic Arthritis:

A. Individual is 18 years of age or older; **AND**

B. Individual has a diagnosis of active psoriatic arthritis; **AND**

C. Agent is used for any of the following reasons:
    1. To reduce signs or symptoms; **OR**
    2. To induce or maintain clinical response; **AND**

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional drug therapy including disease-modifying anti-rheumatic drugs or a tumor necrosis factor antagonist; **AND**

E. Is not used in combination with a biologic DMARD (for example, TNF antagonist) or other biologic rheumatoid arthritis therapy, such as anakinra (Kineret);

AND

F. 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**

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

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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.

Note: May be used as monotherapy or concomitantly with methotrexate

Orencia (abatacept) may **not** be approved for an individual with any of the following:

A. Use in combination with TNF antagonists or other biologic rheumatoid arthritis therapy, such as anakinra; **OR**
B. Tuberculosis or other active serious infections or a history of recurrent infections;
C. Individual has not had a tuberculin skin test or Centers for Disease Control - recommended equivalent test to evaluate for latent tuberculosis; **OR**
D. All other indications, including, but not limited to the treatment of: ankylosing spondylitis, Crohn's disease, giant cell arteritis and Takayasu's arteritis, graft versus host disease (GVHD), lupus nephritis, multiple sclerosis, psoriasis vulgaris, scleroderma, systemic lupus erythematosus, type 1 diabetes, ulcerative colitis, and uveitis.

State Specific Mandates

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

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

Key References:

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3. Ringold S, Weiss PF, Beukelman T, et al; American College of Rheumatology. 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.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016; 68(1):1-26. Available at: http://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf. Accessed on May 14, 2018.
5. United States FDA. Clinical review of Orencia (Abatacept). Reviewed May 2, 2016. Available at: https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM552559.pdf. Accessed on May 14, 2018.