Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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, including 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. Pregnant or planning on becoming pregnant; **OR**
         c. Serious infections or concurrent sepsis; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

3. 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;
   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 – 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, including 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. Pregnant or planning on becoming pregnant; **OR**
         c. 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

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 – 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, including 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. Pregnant or planning on becoming pregnant; **OR**
      c. Serious infections or concurrent sepsis; **OR**

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

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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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.

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