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

Simponi (golimumab)

Override(s)	Medications	Line of business
Prior Authorization Quantity Limit	Simponi (golimumab)	All MCD
	Simponi Aria (golimumab)	AGP, VA MCD ONLY

Medication	Quantity Limit
Simponi (golimumab) 50mg/0.5 mL SmartJect autoinjector/prefilled syringe	1 autoinjector/syringe per 28 days
Simponi (golimumab) 100mg/1 mL SmartJect autoinjector*/prefilled syringe*	1 autoinjector/syringe per 28 days
Simponi Aria (golimumab) 50 mg vial	2 mg/kg as frequently as every 8 weeks

*Initiation of therapy for Ulcerative Colitis (UC): May approve up to 2 (two) additional syringes or autoinjectors (100mg/1 mL) in the first month (28 days) of treatment.

Dosing Override Criteria (Simponi Aria):

For initiation of therapy, may approve up to 2 mg/kg at weeks 0 and 4.

APPROVAL CRITERIA

Requests for Simponi (golimumab) may be approved for the following:

I. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe UC; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants);
   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 ONE (1) preferred biologic agent [Current preferred biologic include Humira (adalimumab), Inflectra (infliximab-dyyb), or Renflexis (infliximab-abda)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **OR**
      2. The preferred agents are not acceptable due to concomitant clinical conditions, including but not limited to any of the following:

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

a. Known hypersensitivity to any active or inactive component which is not also associated with Simponi (golimumab); **OR**
b. Pregnant or planning on becoming pregnant; **OR**
c. Serious infections or concurrent sepsis

OR

II. Ankylosing spondylitis (AS) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe AS; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)];
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), Humira (adalimumab)] unless the following criteria is met:
1. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **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 Simponi (golimumab); **OR**
b. Pregnant or planning on becoming pregnant; **OR**
c. Serious infections or concurrent sepsis.

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 (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)];
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 [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
1. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **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 Simponi (golimumab); **OR**
b. Pregnant or planning on becoming pregnant; **OR**

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

c. Serious infections or concurrent sepsis; **OR**

3. The preferred agent(s) do not have activity against a concomitant clinical condition and Simponi (golimumab) 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) or Stelara are preferred;

OR

IV. 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, or hydroxychloroquine)] (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), Humira (adalimumab)] unless the following criteria is met:
    1. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **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 the prescribed non-preferred; **OR**
        b. Pregnant or planning on becoming pregnant; **OR**
        c. Serious infections or concurrent sepsis; **OR**
    3. The preferred agent(s) do not have activity against a concomitant clinical condition and Simponi (golimumab) 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**
        b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

Requests for Simponi Aria (golimumab) may be approved for the following:

I. Ankylosing spondylitis (AS) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe AS; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease

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

modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)];

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), Humira (adalimumab)] unless the following criteria is met:
    3. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **OR**
    4. 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 Simponi (golimumab); **OR**
        b. Pregnant or planning on becoming pregnant; **OR**
        c. Serious infections or concurrent sepsis.

OR

II. 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 (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)];

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 [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
    1. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **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 Simponi (golimumab); **OR**
        b. Pregnant or planning on becoming pregnant; **OR**
        c. Serious infections or concurrent sepsis; **OR**

OR

III. 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, or hydroxychloroquine)] (ACR 2015);

AND

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

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), Humira (adalimumab)] unless the following criteria is met:
    1. Individual has been receiving and is maintained on a stable dose Simponi (golimumab); **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 the prescribed non-preferred; **OR**
        b. Pregnant or planning on becoming pregnant; **OR**
        c. Serious infections or concurrent sepsis; **OR**

Requests for Simponi (golimumab) and Simponi Aria (golimumab) may **not** be approved for the following:

I. All other indications not included above; **OR**
II. In combination with TNF antagonists, apremilast, or JAK inhibitors, or other biologic drugs (such as, abatacept, anakinra, or vedolizumab); **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Preventions -recommended equivalent to evaluate for latent tuberculosis prior to initiating golimumab.

Note:
TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

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

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

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