| 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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# Simponi (golimumab)

CG-DRUG-65

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

| Medication | Quantity Limit |
|---|---|
| Simponi 50mg/0.5 mL SmartJect autoinjector | 1 autoinjector per 28 days |
| Simponi 50mg/0.5 mL prefilled syringe | 1 syringe per 28 days |
| Simponi 100mg/1 mL SmartJect autoinjector | 1 autoinjector* per 28 days |
| Simponi 100mg/1 mL prefilled syringe | 1 syringe* per 28 days |

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

## APPROVAL CRITERIA

Requests for Simponi (golimumab) may be approved when the following criteria are met:

I. Diagnosis of Ulcerative Colitis:
   A. Individual is 18 years of age or older; **AND**
   B. Individual has a diagnosis of moderately to severely active ulcerative colitis; **AND**
   C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as 6-mercaptopurine, azathioprine, oral aminosalicylates, or oral corticosteroids), or has demonstrated dependence on corticosteroids, and Simponi (golimumab) is used for one of the following:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical remission and mucosal healing; **AND**
   D. 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

| 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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(golimumab); **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 Simponi (golimumab) 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 Simponi (golimumab); **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 Simponi (golimumab) does. Examples include but may not be limited to the following:
    a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
    b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred.

Requests for Simponi (golimumab) and Simponi Aria (golimumab) may be approved when following criteria are met:

I. Diagnosis of Ankylosing Spondylitis:
- A. Individual is 18 years of age or older; **AND**
- B. Individual has a diagnosis of active ankylosing spondylitis; **AND**
- C. Is being used to reduce signs or symptoms of the disease; **AND**
- D. Individual failed to respond to, is intolerant of, or has a medical contraindication to, conventional therapy (such as NSAIDs or non-biologic DMARDs); **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), 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 FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Simponi (golimumab) does; **OR**
    3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:

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

II. Diagnosis of 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; **OR**
3. To improve physical function; **AND**
D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as non-biologic DMARDs); **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 [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 FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Simponi (golimumab) 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 Simponi (golimumab); **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 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) are preferred.

| 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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III. Diagnosis of Rheumatoid Arthritis:
   A. Individual is 18 years of age or older with moderately to severely active rheumatoid arthritis; **AND**
   B. Agent is used for **any** of the following reasons:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical response; **OR**
      3. To improve physical function; **AND**
   C. Golimumab is given in combination with methotrexate or with another immunosuppressive agent if the individual is intolerant to methotrexate; **AND**
   D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more nonbiologic DMARDs. **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), 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, 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 the prescribed non-preferred; **OR**
         b. Individual's age; **OR**
         c. Pregnant or planning on becoming pregnant; **OR**
         d. 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.

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

I. In combination with TNF antagonists; **OR**
II. In combination with tofacitinib citrate; **OR**
III. In combination with the following non-TNF immunomodulatory drugs: abatacept, anakinra, or vedolizumab; **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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IV. Tuberculosis, invasive fungal infections, other active serious infections, or a history of recurrent infections; **OR**

V. Individual has not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating golimumab; **OR**

VI. When the above approval criteria are not met and for all other indications.

**Note**: Simponi/Simponi Aria (golimumab) has black box warnings related to serious infection and malignancy. The increased risk of developing serious infections can result in hospitalization or death. Most individuals that developed serious infections were taking concomitant immunosuppressants. Individuals should be closely monitored for the development of an infection during and after treatment with discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Simponi/Simponi Aria should be considered prior to initiating in individuals with chronic or recurrent infection. Simponi/Simponi Aria is not indicated for the use in pediatric individuals due to reports of lymphoma and other malignancies developing in children and adolescents treated with tumor necrosis factor (TNF) blockers.

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

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| 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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