GPI CODING:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>GPI</th>
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<tbody>
<tr>
<td>Simponi (golimumab)</td>
<td>6627004000D5**; 6627004000E5**</td>
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<tr>
<td>Simponi Aria (golimumab)</td>
<td>662700400020**</td>
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DESCRIPTION:

Simponi® and Simponi Aria™ are tumor-necrosis factor (TNF) inhibitors. TNF inhibitors are naturally occurring proteins involved in the body's normal immune responses. Overproduction of TNF can cause inflammation and tissue damage. TNF inhibition may ease certain inflammatory disease symptoms and prevent disease progression.

APPROVAL DURATION:

12 months

CRITERIA FOR SIMPONI & SIMPONI ARIA

FDA-approved dosage of Simponi (golimumab) is considered medicinally necessary for adults (18 years of age or older) with documentation of ALL of the following:

1. One of the following:
   - Moderately to severely active rheumatoid arthritis and Simponi (golimumab) will be used in combination with methotrexate
   - Active psoriatic arthritis and Simponi (golimumab) will be used alone or in combination with methotrexate
   - Active ankylosing spondylitis

2. Failed response to at least TWO of the preferred TNF medications: Enbrel, Humira and Remicade (unless otherwise contraindicated) with documentation of any of the following:*  
   - Individual’s condition has not improved or has worsened
   - Individual experienced a significant adverse drug event to the preferred TNF medications
   - Individual is intolerant to the preferred TNF medications
   - Individual is non-adherent to the preferred TNF medications

3. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy

4. Evidence of testing for latent tuberculosis before Simponi use and during therapy and any treatment for latent infection has been initiated prior to Simponi therapy

5. Evidence of testing for hepatitis B infection before Simponi use and ongoing monitoring in individuals who are known hepatitis B carriers for reactivation of this viral infection during Simponi therapy

6. Evidence of close monitoring in individuals who have a history of or develop heart failure while on Simponi therapy
7. Simponi is not being used concurrently with anakinra (e.g., Kineret) or abatacept (e.g., Orencia), live vaccines, or live attenuated vaccines

FDA-approved dosage of Simponi (golimumab) is considered *medically necessary* for adults (18 years of age or older) with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to prior conventional treatment (i.e., oral aminosalicylates, oral corticosteroids, azathioprine or 6-mercaptopurine) or requiring continuous steroid therapy with documentation of ALL of the following:

1. Simponi is being used for ONE of the following purposes:
   A. To induce and maintain clinical response
   B. To induce clinical remission
   C. To achieve and sustain clinical remission in induction responders
   D. To improving endoscopic appearance of the mucosa during induction

2. Failed response to both of the preferred TNF medications: Humira and Remicade (unless otherwise contraindicated) with documentation of ANY of the following:*  
   o Individual's condition has not improved or has worsened  
   o Individual experienced a significant adverse drug event to the preferred TNF medications  
   o Individual is intolerant to the preferred TNF medications  
   o Individual is non-adherent to the preferred TNF medications

3. Failed response to conventional therapy (unless otherwise contraindicated)  

4. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy

5. Evidence of testing for latent tuberculosis before Simponi use and during therapy and any treatment for latent infection has been initiated prior to Simponi therapy

6. Evidence of testing for hepatitis B infection before Simponi use and ongoing monitoring in individuals who are known hepatitis B carriers for reactivation of this viral infection during Simponi therapy

7. Evidence of close monitoring in individuals who have a history of or develop heart failure while on Simponi therapy

8. Simponi is not being used concurrently with anakinra (e.g., Kineret) or abatacept (e.g., Orencia), live vaccines or live attenuated vaccines

FDA-approved dosage of Simponi Aria (golimumab), in combination with methotrexate, is considered *medically necessary* for adults (≥ 18 years of age or older) with moderately to severely active rheumatoid arthritis with documentation of ALL of the following:

1. Failed response to at least TWO of the preferred TNF medications: Enbrel, Humira and Remicade (unless otherwise contraindicated) with documentation of any of the following:*  
   o Individual’s condition has not improved or has worsened  
   o Individual experienced a significant adverse drug event to the preferred TNF medications  
   o Individual is intolerant to the preferred TNF medications  
   o Individual is non-adherent to the preferred TNF medications

2. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy

3. Evidence of testing for latent tuberculosis before Simponi Aria use and during therapy and any treatment for latent infection has been initiated prior to Simponi Aria therapy

4. Evidence of testing for hepatitis B infection before Simponi Aria use and ongoing monitoring in individuals who are known hepatitis B carriers for reactivation of this viral infection during Simponi Aria therapy

5. Evidence of close monitoring in individuals who have a history of or develop heart failure while on Simponi Aria therapy
6. Simponi Aria is not being used concurrently with anakinra (e.g., Kineret) or abatacept (e.g., Orencia), live vaccines or live attenuated vaccines

*Not applicable in patients currently stable on treatment with Simponi/Simponi Aria

Simponi and Simponi Aria for all other indications not previously listed or if above criteria not met is considered experimental or investigational.