BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

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SIMPONI® (golimumab) AND SIMPONI ARIA™ (golimumab)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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.

Definitions:

Adult: Age 18 years and older

Preferred TNF Medications:
- Enbrel®
- Humira®
- Remicade®

SIMPONI (golimumab) AND SIMPONI ARIA (golimumab) (cont.)

Description: (cont.)

Significant Adverse Drug Event:
A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Criteria:

See Resources section for FDA-approved dosage.

- FDA-approved dosage of Simponi is considered ***medically necessary*** for adults with documentation of **ALL** of the following:

  1. **ONE** of the following:

     - Moderately to severely active rheumatoid arthritis in combination with methotrexate
     - Active psoriatic arthritis alone or in combination with methotrexate
     - Active ankylosing spondylitis

  2. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - 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
  8. Dosage is not greater that the FDA approved dosing for the labeled indication (refer to dosing table)

SIMPONI (golimumab) AND SIMPONI ARIA (golimumab) (cont.)

Criteria: (cont.)

- FDA-approved dosage of Simponi is considered ***medically necessary*** for adults with moderate to severely active ulcerative colitis (UC) who have had an inadequate response or intolerant 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. **ONE** of the following:

     - Induce and maintain clinical response
     - Induce clinical remission
     - Achieve and sustain clinical remission in induction responders
     - Improve endoscopic appearance of mucosa during induction

  2. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - 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. 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. 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
  9. Dosage is not greater that the FDA approved dosing for the labeled indication (refer to dosing table)

SIMPONI (golimumab) AND SIMPONI ARIA (golimumab) (cont.)

Criteria: (cont.)

- FDA-approved dosage of Simponi Aria, in combination with methotrexate, is considered ***medically necessary*** for adults with moderately to severely active rheumatoid arthritis with documentation of **ALL** of the following:

    1. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

        - 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

    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
    7. Dosage is not greater that the FDA approved dosing for the labeled indication (refer to dosing table)

- Simponi and Simponi Aria for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

    1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
    2. Insufficient evidence to support improvement of the net health outcome, and
    3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

SIMPONI (golimumab) AND SIMPONI ARIA (golimumab) (cont.)

Resources:

1. Biologics & Non-TNF Agents Potentially Winners in the New ACR Guidelines for Early & Experienced Rheumatoid Arthritis (RA) Patients. Specialty Pharma Journal. Received 06/11/2012.

Simponi Package Insert.

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate Adult active ankylosing spondylitis (AS) Adult active psoriatic arthritis (PsA), alone or in combination with methotrexate Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy ▪ Inducing and maintaining clinical response ▪ Improving endoscopic appearance of the mucosa during induction ▪ Inducing clinical remission ▪ Achieving and sustaining clinical remission in induction responders	Simponi is administered by subcutaneous injection: - 50 mg once a month for RA, AS and PsA - 200 mg initially at week 0 followed by 100 mg at week 2 and then 100 mg every 4 weeks for UC

SIMPONI (golimumab) AND SIMPONI ARIA (golimumab) (cont.)

Resources: (cont.)

Simponi Aria Package Insert.

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate	Simponi Aria is administered by intravenous infusion. - 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks - Dilution of supplied Simponi Aria solution with 0.9% w/v sodium chloride is required prior to administration