SIMPONI ARIA™ (golimumab)

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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SIMPONI ARIA (golimumab) (cont.)

Description:
Simponi Aria is a tumor-necrosis factor (TNF) inhibitor. 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

Criteria:

Effective 02/01/17: For site of service requirements for Simponi Aria (golimumab), see BCBSAZ Medical Coverage Guideline #O1008, “Site of Service Requirements for Certain Medications”.

See Resources section for FDA-approved dosage and Arthritis Disease Activity Measurement Instruments index table.

- Simponi Aria is considered *medically necessary* with documentation of **ALL** of the following:

  1. **ONE** of the following:

     a. Prescribed by a rheumatologist
     b. Diagnosis of rheumatoid arthritis identified by **ONE** of the following:
        - Clinical Disease Activity Index (CDAI) score greater than 10
        - Disease Activity Score 28 (DAS28) of greater than 3.2
        - Patient Activity Scale (PAS) of greater than 3.7
        - Patient Activity Scale II (PASII) of greater than 3.7
        - Routine Assessment of Patient Index Data 3 (RAPID-3) score greater than 2
        - Simplified Disease Activity Index (SDAI) score greater than 11
     c. Failure, contraindication, or intolerance to methotrexate (refer to, “Small Molecules and Biologics Chart” #AP94 Administrative Procedure Guideline)
SIMPONI ARIA (golimumab) (cont.)

Criteria: (cont.)

- Simponi Aria is considered medically necessary with documentation of ALL of the following: (cont.)

1. ONE of the following: (cont.)

   - Psoriatic arthritis in adults with documentation of ALL of the following:
     
     a. Active psoriatic arthritis identified by ONE of the following:
        
        - Predominantly axial disease (i.e., sacroilitis or spondylitis) as indicated by ALL of the following:
          
          i. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
          
          ii. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration
          
          iii. Failure or intolerance of 2 or more different NSAIDs (at maximum recommended doses) over total period of at least 4 or more weeks of therapy

        - Predominantly non-axial disease, and failure of, intolerance to, or contraindication to both methotrexate and NSAIDs

     b. Prescribed by a rheumatologist
SIMPONI ARIA (golimumab) (cont.)

Criteria: (cont.)

- Simponi Aria is considered *medically necessary* with documentation of **ALL** of the following: (cont.)

1. **ONE** of the following: (cont.)

   - Ankylosing spondylitis in adults with documentation of **ALL** of the following:
     a. Clinical and diagnostic imaging evidence of ankylosing spondylitis as indicated by **ALL** of the following:
        - Back pain of 3 months or more duration and age of onset of 45 years or younger
        - Sacroiliitis on imaging
        - Spondyloarthritis signs or symptoms as indicated by **ONE** or more of the following:
           i. Arthritis
           ii. Elevated serum C-reactive protein
           iii. Enthesitis (e.g., inflammation of Achilles tendon insertion)
           iv. HLA-B27
           v. Limited chest expansion
           vi. Morning stiffness for one hour or more
     b. Disease activity and treatment scenario as indicated by **ONE** or more of the following:
        - Axial (spinal) disease
        - Failure of or intolerance to treatment with anti-tumor necrosis factor-alpha drug
        - Peripheral arthritis without axial involvement, and failure or intolerance of 4 or more months of therapy with sulfasalazine
     c. Failure or intolerance of 2 or more different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy
     d. Prescribed by a rheumatologist
SIMPONI ARIA (golimumab) (cont.)

Criteria: (cont.)

- Simponi Aria is considered **medically necessary** with documentation of **ALL** of the following: (cont.)
  1. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy
  2. 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
  3. 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
  4. Evidence of close monitoring in individuals who have a history of or develop heart failure while on Simponi Aria therapy
  5. Simponi Aria is not being used concurrently with anakinra (e.g., Kineret) or abatacept (e.g., Orencia), live vaccines or live attenuated vaccines
  6. No evidence of lupus-like syndrome while on SIMPONI ARIA therapy

- Simponi Aria for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, **but are not limited to:**

- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

1 Not applicable for current members on Simponi Aria prior to 07/09/14 or new members who are actively being treated with Simponi Aria prior to their effective date with BCBSAZ. (Excludes any changes in route of administration, such as changing intravenous delivery to subcutaneous delivery.)
SIMPONI ARIA (golimumab) (cont.)

Resources:

Literature reviewed 08/08/18. We do not include marketing materials, poster boards and non-published literature in our review.


Simponi Aria Package Insert:

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
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<tbody>
<tr>
<td>Adult moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate</td>
<td>Simponi Aria is administered by intravenous infusion.</td>
</tr>
<tr>
<td>Active Psoriatic Arthritis (PsA)</td>
<td>- 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks</td>
</tr>
<tr>
<td>Active Ankylosing Spondylitis (AS)</td>
<td>- Dilution of supplied Simponi Aria solution with 0.9% w/v sodium chloride is required prior to administration.</td>
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## SIMPONI ARIA (golimumab) (cont.)

**Resources:** (cont.)

Rheumatoid Arthritis Disease Activity Measurement Instruments:

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Threshold of Disease Activity</th>
</tr>
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</table>
| Clinical Disease Activity Index (CDAI) | Range: 0 to 76  
Remission: \( \leq 2.8 \)  
Low activity: \( >2.8 \) to \( \leq 10 \)  
Moderate activity: \( >10 \) to \( <22 \)  
High activity: \( >22 \) |
| Disease Activity Score 28 (DAS28) | Range: 0.5 to 9  
Remission: \( <2.6 \)  
Low activity: \( >2.6 \) to \( \leq 3.2 \)  
Moderate activity: \( >3.2 \) to \( <5.1 \)  
High activity: \( >5.1 \) |
| Patient Activity Scale (PAS)  
Patient Activity Scale II (PASII) | Range 0 to 10  
Remission: 0 to 0.25  
Low activity: \( >0.25 \) to 3.7  
Moderate activity: \( >3.7 \) to \( <8.0 \)  
High activity: \( >8.0 \) |
| Routine Assessment of Patient Index Data 3  
(RAPID-3) | Range 0 to 10  
Remission: 0 to 1.0  
Low activity: \( >1.0 \) to 2.0  
Moderate activity: \( >2.0 \) to 4.0  
High activity: \( >4.0 \) to 10 |
| Simplified Disease Activity Index (SDAI) | Range 0 to 90  
Remission: \( \leq 3.3 \)  
Low activity: \( >3.3 \) to \( <11.0 \)  
Moderate activity: \( >11.0 \) to \( \leq 26 \)  
High activity: \( >26 \) |
SIMPONI ARIA (golimumab) (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah nilinígíí Blue Cross Blue Shield of Arizona haada yít’éego biná’ídilkidgo éí doodago Háida biibí aníllee déégíi t’àadoo le’é yina’ídilkidgo beehaz’óóhii hóó díí t’aá hazaadk’ehjí háká a’dooowolgo bee haz’á doo baah ilinígóó. Ata’ halné’égíi kojí ‘bhich’y’ hodilinhíí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。請洽一位翻譯員，撥打電話 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدك أسئلة مصورة بخصوص Blue Cross Blue Shield of Arizona السرورية باللغة من دون أي تكلفة. للتحدث مع متجم جملة [877-475-4799].
SIMPONI ARIA (golimumab) (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuanan, ay mga mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan na makakahila ng tulong at impormasyon sa iyong wika ng walang gastos. Upang maeuskap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하로서 피드백을 받아질 때 귀하로서 비용 부담없이 참여할 수 있는 권리가 있습니다. 그렇게 돕거나 필요한 경우에 877-475-4799로 전화해주시기 바랍니다.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

انگلیسی: با کمک که شما به آن کمک می‌کنید، سوالات مربوط به Blue Cross Blue Shield of Arizona اطلاعات به زبان خود را به طور رایگان دریافت نمایید. 877-475-4799.

Assyrian:

Assyrian: Blue Cross Blue Shield of Arizona, گویش خود را به طور رایگان دریافت نمایید. 877-475-4799.

Serbo-Croatian: Ukoiko Vi ili neko kome Vi pomazeete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ ต้องการความช่วยเหลือและข้อมูลเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถติดต่อเราได้ที่ 877-475-4799