APPLICATION

This policy does not apply to the states of Kansas, Louisiana, Pennsylvania, and Washington.

- For the state of Louisiana, refer to the Medical Benefit Drug Policy titled Simponi Aria® (Golimumab) Injection for Intravenous Infusion (for Louisiana Only).

COVERAGE RATIONALE

This policy refers only to Simponi Aria (golimumab) injection for intravenous infusion for the treatment of ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis. Simponi, for self-administered subcutaneous injection, is obtained under the pharmacy benefit and is indicated in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

Simponi Aria is proven and medically necessary for the treatment of:

- **Ankylosing spondylitis when ALL of the following criteria are met:**
  - For **initial therapy**, all of the following:
    - Diagnosis of active ankylosing spondylitis (AS); and
    - Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis up to a maximum of 2 mg/kg at weeks 0 and 4 upon initiation of therapy, then 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and
    - Patient is not receiving Simponi Aria in combination with either of the following:
      - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
  - For **continuation therapy**, all of the following:
    - Documentation of positive clinical response to Simponi Aria; and
    - Simponi Aria dosing for ankylosing spondylitis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and
    - Patient is not receiving Simponi Aria in combination with either of the following:
      - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

- **Psoriatic arthritis when ALL of the following criteria are met:**
  - For **initial therapy**, all of the following:
    - Diagnosis of active psoriatic arthritis (RA); and
Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis up to a maximum of 2 mg/kg at weeks 0 and 4 upon initiation of therapy, then 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and

Patient is not receiving Simponi Aria in combination with any of the following:
- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

- For **continuation therapy**, all of the following:
  - Documentation of positive clinical response to Simponi Aria; and
  - Simponi Aria dosing for psoriatic arthritis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and
  - Patient is not receiving Simponi Aria in combination with any of the following:
    - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

- **Rheumatoid arthritis when ALL of the following criteria are met**:¹,⁸
  - For **initial therapy**, all of the following:
    - Diagnosis of moderately to severely active rheumatoid arthritis (RA); and
    - One of the following:
      - Patient is receiving concurrent therapy with methotrexate
      - History of contraindication or intolerance to methotrexate; and
    - Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for rheumatoid arthritis up to a maximum of 2 mg/kg at weeks 0 and 4 upon initiation of therapy, then 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and
    - Patient is not receiving Simponi Aria in combination with either of the following:
      - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

  - For **continuation therapy**, all of the following:
    - Documentation of positive clinical response to Simponi Aria; and
    - Simponi Aria dosing for rheumatoid arthritis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and
    - Patient is not receiving Simponi Aria in combination with either of the following:
      - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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**BACKGROUND**

Golimumab is a human anti-tumor necrosis factor (TNF) monoclonal antibody that targets both soluble and transmembrane bioactive forms of TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage and tissue.1

**CLINICAL EVIDENCE**

**Proven Ankylosing Spondylitis**

The efficacy and safety of golimumab were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 208 adult patients with active ankylosing spondylitis (AS) and inadequate response or intolerance to NSAIDs.1 Patients had a diagnosis of definite AS for at least 3 months according to modified New York criteria. Patients had symptoms of active disease [Bath AS Disease Activity Index (BASDAI) ≥ 4, VAS for total back pain of ≥ 4, on scales of 0 to 10 cm (0 to 100 mm), and a hsCRP level of ≥ 0.3 mg/dL (3 mg/L)]. Patients were randomized to receive either
golimumab 2 mg/kg (N=105) or placebo (N=103) as a 30-minute intravenous infusion at Weeks 0, 4 and 12. All patients on placebo received golimumab at Week 16, Week 20 and every 8 weeks thereafter through Week 52. Patients in the golimumab treatment group continued to receive golimumab infusions at Week 20 and every 8 weeks through Week 52. Patients were allowed to continue stable doses of concomitant methotrexate (MTX), sulfasalazine (SSZ), hydroxychloroquine (HCQ), low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day), and/or NSAIDs during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited. The primary endpoint was the percentage of patients achieving an Assessment in Ankylosing Spondylitis (ASAS) 20 response at Week 16. In this trial, golimumab, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ASAS 20 response at Week 16, where a greater percentage of patients treated with golimumab achieved a low level of disease activity (<2 [on a scale of 0 to 10 cm] CRP response at week 100, in both groups combined, 68.1% of patients had an ACR20 response, 43.8% had an ACR50, and 23.5% had an ACR70) response criteria, 28 joint count disease activity score using the C100 weeks. Efficacy assessments included the American College of Rheumatology 20%, 50%, and 70% response at either week 16 or week 24 to active therapy. In total, 486 patients (82.1%) continued golimumab therapy for 100 weeks. Patients receiving golimumab demonstrated greater improvement from baseline compared with placebo in physical component summary and mental component summary scores and in all 8 domains of the SF-36. Golimumab-treated patients showed significant improvement compared with placebo-treated patients in health related quality of life as assessed by the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL).

**Psoriatic Arthritis**

The efficacy and safety of golimumab were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 480 adult patients with active psoriatic arthritis (PsA) despite NSAID or DMARD therapy. Previous treatment with a biologic was not allowed. Patients in this trial had a diagnosis of PsA for at least six months and had symptoms of active disease (≥ 5 swollen joints and ≥ 5 tender joints and a CRP level of ≥ 0.6 mg/dL). Patients were randomized to either receive golimumab 2 mg/kg (N=241) or placebo (N=239) as a 30-minute intravenous infusion at Weeks 0, 4, 12 and 20. All patients on placebo received golimumab at Week 24, Week 28 and every 8 weeks thereafter through Week 52. Patients in the golimumab treatment group continued to receive golimumab infusions at Week 28 and every 8 weeks through Week 52. Patients were allowed to continue stable doses of MTX, NSAIDs, and low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day) during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited. The primary endpoint was the percentage of patients achieving an ACR 20 response at Week 14. Patients with each subtype of PsA were enrolled, including polycharticular arthritis with absence of rheumatoid nodules (44%), asymmetric peripheral arthritis (19%), distal interphalangeal joint involvement (8.1%), spondylitis with peripheral arthritis (25%), and arthritis mutilans (4.8%). During the trial, concomitant medications used included MTX (70%), oral corticosteroids (28%), and NSAIDs (71%). Golimumab, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ACR 20 response at Week 14. Similar ACR 20 responses at Week 24 were observed in patients with different PsA subtypes. ACR 20 responses observed in the golimumab-treated groups were similar in patients who were or were not receiving concomitant MTX. Patients with enthesitis at baseline were evaluated for mean improvement using the Leeds Enthesitis Index (LEI) on a scale of 0–6. Golimumab-treated patients showed a significantly greater improvement in enthesitis, with a mean reduction of 1.8 as compared with a mean reduction in placebo-treated patients of 0.8 at Week 14. Patients with dactylitis at baseline were evaluated for mean improvement on a scale of 0–60. golimumab-treated patients showed a significantly greater improvement, with a mean reduction of 7.8 compared with a mean reduction of 2.8 in placebo-treated patients at Week 14. Golimumab inhibited the progression of structural damage compared with placebo, as assessed by total modified vdH-S score. At Week 24, a greater proportion of patients in the golimumab group (72%) had no progression of structural damage (change in the total modified vdH-S score ≤ 0), compared to 43% of patients in the placebo group. Improvement in physical function as assessed by the Health Assessment Questionnaire Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved clinically meaningful improvement of ≥ 0.3 in HAQ-DI score from baseline was greater in the golimumab-treated group compared to placebo at Week 14 (69% compared to 32%). General health status was assessed by the 36-item Short Form Health Survey (SF-36). Patients receiving golimumab demonstrated greater improvement from baseline compared with placebo in physical component summary, mental component summary scores and in all 8 domains of the SF-36.

**Rheumatoid Arthritis**

In the extension phase to the GO-FURTHER pivotal study, the long term extension study of golimumab plus methotrexate (MTX) for rheumatoid arthritis evaluated the efficacy, pharmacokinetics, immunogenicity and radiographic progression, through 100 weeks of therapy, where safety was monitored through 112 weeks. In the original trial 592 patients with active RA were randomized (2:1) to receive intravenous (IV) golimumab 2mg/kg plus MTX or placebo plus MTX at weeks 0, 4, and every 8 weeks thereafter. Patients receiving placebo were able to cross over at either week 16 or week 24 to active therapy. In total, 486 patients (82.1%) continued golimumab therapy for 100 weeks. Efficacy assessments included the American College of Rheumatology 20%, 50%, 70% (ACR 20, ACR50, ACR70) response criteria, 28 joint count disease activity score using the C-reactive protein level, physical function and quality of life (QoL) measures, and changes in the modified Sharp/van der Heijde scores (SHS). Following treatment at week 100, in both groups combined, 68.1% of patients had an ACR20 response, 43.8% had an ACR50, and 23.5% had an ACR70 response. More than 80% of all patients had a good or moderate DAS28-CRP response at week 100.
and approximately 28% achieved DAS28-CRP < 2.6. For patient reported outcomes, improvements in SF-36 PCS, MCS, FACIT-Fatigue, EQ-5D VAS scores were sustained through week 112 in both treatment groups. At week 100, the mean change from baseline in total SHS score was significantly lower in Group 1 than in Group 2 (0.74 vs. 2.10; P=0.005) and 61.8% (n=244 of 395) of patients in Group 1 and 54.8% (n=108 of 197) of patients in Group 2 had a change from baseline in total SHS of ≤ 0. When evaluated by progression beyond the smallest detectable change (3.22) in total SHS, 16.7% (n=66 of 395) of patients in Group 1 and 23.9% (n=47 of 197) in Group 2 demonstrated radiographic progression from baseline to week 100. The mean change in total SHS score from week 52 to week 100 when all patients were receiving golimumab was numerically lower in Group 1 (0.56) than in Group 2 (0.80); the median change was 0 in both groups. After 112 weeks, a total of 481 patients completed the safety follow-up with 79.1% had at least one adverse event, and 18.2% having had a serious adverse event. After 100 weeks of treatment only 6.7% (n=37 of 553) of patients developed antibodies to golimumab, with 86.5% positive for neutralizing antibodies. The authors concluded that treatment with IV golimumab plus MTX afforded a clinical response that was maintained through week 100. Radiographic progression following treatment was clinically insignificant between week 52 and week 100.

Professional Societies

Rheumatoid Arthritis

The 2015 American College of Rheumatology (ACR) RA treatment guideline addresses the use of DMARDS, biologics, tofacitinib, and glucocorticoids in early (<6 months) and established (≥ 6 months) RA and the use of various treatment approaches in frequently encountered clinical scenarios, including treat-to-target, switching between therapies, tapering of therapy, the use of biologics and DMARDS in high-risk RA patients, vaccination in patients with RA receiving DMARDS or biologics, TB screening with biologics or tofacitinib, and laboratory monitoring with DMARDS. The guideline recommendations apply to common clinical situations, since the panel considered issues common to most patients, not exceptions. Recommendations are classified as either strong or conditional. A strong recommendation means that the panel was confident that the desirable effects of following the recommendation outweigh the undesirable effects (or vice versa), so the course of action would apply to most patients, and only a small proportion would not want to follow the recommendation. A conditional recommendation means that the desirable effects of following the recommendation probably outweigh the undesirable effects, so the course of action would apply to the majority of patients, but some may not want to follow the recommendation. As a result, conditional recommendations are preference sensitive and warrant a shared decision-making approach.

Supplementary Appendix 5, of the 2015 ACR RA guideline, summarizes recommendations for patients with early RA, established RA, and high-risk comorbidities.

Recommendations for Early RA Patients

- The panel strongly recommends using a treat-to-target strategy rather than a non-targeted approach, regardless of disease activity level. The ideal target should be low disease activity or remission, as determined by the clinician and the patient. In some cases, another target may be chosen because risk tolerance by patients or comorbidities may mitigate the usual choices.
- For DMARD-naive patient with early, symptomatic RA, the panel strongly recommends DMARD monotherapy over double or triple DMARD therapy in patients with low disease activity and conditionally recommends DMARD monotherapy over double or triple DMARD therapy in patients with moderate or high disease activity. Methotrexate should be the preferred initial therapy for most patients with early RA with active disease.
- For patients with moderate or high disease activity despite DMARD therapy (with or without glucocorticoids), the panel strongly recommends treatment with a combination of DMARDS or a TNFi or a non-TNF biologic, with or without methotrexate (MTX) in no particular order of preference, rather than continuing DMARD monotherapy alone. Biologic therapy should be used in combination with MTX over biologic monotherapy, when possible, due to superior efficacy.
- For patients with moderate or high disease activity despite any of the above DMARD or biologic therapies, the panel conditionally recommends adding low-dose glucocorticoids (defined as ≤10 mg/day of prednisone or equivalent). Low-dose glucocorticoids may also be used in patients who need a bridge until realizing the benefits of DMARD therapy. The risk/benefit ratio of glucocorticoid therapy is favorable as long as the dose is low and the duration of therapy is short.
- For patients experiencing a flare of RA, the panel conditionally recommends adding short-term glucocorticoids (<3 months of treatment) at the lowest possible dose for the shortest possible duration, to provide a favorable benefit-risk ratio for the patient.

Recommendations for Established RA Patients

- The panel strongly recommends using a treat-to-target strategy rather than a non-targeted approach, regardless of disease activity level. The ideal target should be low disease activity or remission, as determined by the clinician and the patient. In some cases, however, another target may be chosen because tolerance by patients or comorbidities may mitigate the usual choices.
For DMARD-naive patients with low disease activity, the panel strongly recommends using DMARD monotherapy over a TNFi. For DMARD-naive patients with moderate or high disease activity, the panel conditionally recommends DMARD monotherapy over double or triple DMARD therapy and DMARD monotherapy over tofacitinib. In general, MTX should be the preferred initial therapy for most patients with established RA with active disease.

For patients with moderate or high disease activity despite DMARD monotherapy including methotrexate, the panel strongly recommends using combination DMARDs or adding a TNFi or a non-TNF biologic or tofacitinib (all choices with or without methotrexate) in no particular order of preference, rather than continuing DMARD monotherapy alone. Biologic therapy should be used in combination with MTX over biologic monotherapy, when possible, due to its superior efficacy.

For all scenarios for established RA below, treatment may be with or without MTX:

- For moderate or high disease activity despite TNFi therapy in patients currently not on a DMARD, the panel strongly recommends that one or two DMARDs be added to TNFi therapy rather than continuing TNFi therapy alone.
- If disease activity is moderate or high despite single TNFi biologic therapy, the panel conditionally recommends using a non-TNF biologic.
- If disease activity is moderate or high despite non-TNF biologic therapy, the panel conditionally recommends using another non-TNF biologic. However, if a patient has failed multiple non-TNF biologics and they are TNFi-naive with moderate or high disease activity, the panel conditionally recommends treatment with a TNFi.
- For patients with moderate or high disease activity despite prior treatment with at least one TNFi and at least one non-TNF biologic (sequentially, not combined), the panel conditionally recommends first treating with another non-TNF biologic. However, when a non-TNF biologic is not an option (e.g., patient declines non-TNF biologic therapy due to inefficacy or side effects), the panel conditionally recommends treatment with tofacitinib.
- If disease activity is moderate or high despite the use of multiple (2+) TNFi therapies (in sequence, not concurrently), the panel conditionally recommends non-TNF biologic therapy and then conditionally treating with tofacitinib when a non-TNF biologic is not an option.
- If disease activity is moderate or high despite any of the above DMARD or biologic therapies, the panel conditionally recommends adding low-dose glucocorticoids.
- If patients with established RA experience an RA flare while on DMARD, TNFi, or non-TNF biologic therapy, the panel conditionally recommends adding short-term glucocorticoids (< 3 months of treatment) at the lowest possible dose and for shortest possible duration to provide the best benefit-risk ratio for the patient.
- In patients with established RA and low disease activity but not remission, the panel strongly recommends continuing DMARD therapy, TNFi, non-TNF biologic or tofacitinib rather than discontinuing respective medication.
- In patients with established RA currently in remission, the panel conditionally recommends tapering DMARD therapy, TNFi, non-TNF biologic, or tofacitinib.
- The panel strongly recommends not discontinuing all therapies in patients with established RA in disease remission.

**Recommendations for RA Patients with High-Risk Comorbidities**

- **Congestive Heart Failure:**
  - In patients with established RA with moderate or high disease activity and New York Heart Association (NYHA) class III or IV congestive heart failure (CHF), the panel conditionally recommends using combination DMARD therapy, a non-TNF biologic, or tofacitinib rather than a TNFi.
  - If patients in this population are treated with a TNFi and their CHF worsens while on the TNFi, the panel conditionally recommends switching to combination DMARD therapy, a non-TNF biologic, or tofacitinib rather than a different TNFi.
- **Hepatitis B:**
  - In patients with established RA with moderate or high disease activity and evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months), who are receiving or have received effective antiviral treatment, the panel strongly recommends treating them the same as patients without this condition.
  - For a patient with natural immunity from prior exposure to hepatitis B (i.e., HB core antibody and HBS antibody positive and normal liver function tests), the panel recommends the same therapies as those without such findings as long as the patient's viral load is monitored.
  - For patients with chronic hepatitis B who are untreated, referral for antiviral therapy is appropriate prior to immunosuppressive therapy.
- **Hepatitis C:**
  - In patients with established RA with moderate or high disease activity and evidence of chronic hepatitis C virus (HCV) infection, who are receiving or have received effective antiviral treatment, the panel conditionally recommends treating them the same as the patients without this condition.
  - The panel recommends that rheumatologists work with gastroenterologists and/or hepatologists who would monitor patients and reassess the appropriateness of antiviral therapy. This is important considering the recent availability of highly effective therapy for HCV, which may lead to a greater number of HCV patients being treated successfully.
If the same patient is not requiring or receiving antiviral treatment for their hepatitis C, the panel conditionally recommends using DMARD therapy rather than TNFi.

**Malignancy:**
- Previous Melanoma and Non-Melanoma Skin Cancer:
  - In patients with established RA and moderate or high disease activity and a history of previously treated or untreated skin cancer (melanoma or non-melanoma), the panel conditionally recommends the use of DMARD therapy over biologics or tofacitinib.
- Previous Lymphoproliferative Disorders:
  - In patients with established RA with moderate or high disease activity and a history of a previously treated lymphoproliferative disorder, the panel strongly recommends using rituximab rather than a TNFi and conditionally recommends using combination DMARD therapy, abatacept or tocilizumab rather than TNFi.
- Previous Solid Organ Cancer:
  - In patients with established RA with moderate or high disease activity and previously treated solid organ cancer, the panel conditionally recommends that they be treated for RA just as one would treat an RA patient without a history of solid organ cancer.

**Serious Infections:**
- In patients with established RA or moderate or high disease activity and previous serious infection(s), the panel conditionally recommends using combination DMARD therapy or abatacept rather than TNFi.

**Psoriatic Arthritis**
The American Academy of Dermatology (AAD) defines psoriatic arthritis (PsA) as mild, moderate, or severe. Where mild disease responds to NSAIDs, moderate disease requires DMARDs or TNF blockers. Appropriate treatment of severe PsA requires DMARDs plus TNF blockers or other biologic therapies. If PsA is diagnosed, treatment should be initiated to alleviate signs and symptoms of PsA, inhibit structural damage, and maximize quality of life (QOL). According to the AAD Practice Guidelines for the management of psoriatic arthritis, the potential importance of TNF-α in the pathophysiology of PsA is underscored by the observation that there are elevated levels of TNF-α in the synovium, joint fluid, and skin of patients with PsA. The guidelines support the use of infliximab for PsA based on evidence ranked as consistent, good quality, and patient-oriented. (Strength of Recommendation: A).\(^9\)

**Ankylosing Spondylitis**
Evidence based recommendations for the management of ankylosing spondylitis (AS) were created as a combined effort of the ‘ASsessment in AS’ international working group and the European League Against Rheumatism (EULAR). According to these comprehensive guidelines, anti-TNF treatment (infliximab, etanercept, adalimumab, and golimumab) should be given to patients with persistently high disease activity despite conventional treatments. There is no evidence to support the obligatory use of DMARDs before, or concomitant with, anti-TNF treatment in patients with axial disease. There is no evidence to support a difference in efficacy of the various TNF inhibitors on the axial and articular/entheseal disease manifestations; but in the presence of IBD a difference in gastrointestinal efficacy needs to be taken into account. Switching to a second TNF blocker might be beneficial especially in patients with loss of response.\(^10\)

American College of Rheumatology, Spondylitis Association of America and Spondyloarthritis Research developed provide evidence-based recommendations for the treatment of patients with ankylosing spondylitis (AS). In patients with active AS, the strong recommendations from the committee regarding pharmacologic treatment include: use of nonsteroidal antiinflammatory drugs (NSAIDs), use of tumor necrosis factor inhibitors (TNFi) when persistent disease activity while on NSAID treatment, not to use systemic glucocorticoids. In addition, no specific TNFi was preferred with the exception of patients who have concomitant inflammatory bowel disease or recurrent iritis. In these patients, the committee recommends TNFi monoclonal antibodies.\(^12\)

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**
This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Simponi Aria, for intravenous infusion, is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active RA in combination with methotrexate (MTX), active PsA and AS.\(^1\)

Simponi, for subcutaneous injection, is indicated in adult patients for the following: treatment of moderately to severely active RA in combination with MTX; treatment of active psoriatic arthritis (PsA) alone, or in combination with MTX; treatment of active ankylosing spondylitis (AS); and the treatment of moderately to severely active ulcerative colitis (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for: inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.\(^7\)
Medicare does not have a National Coverage Determination (NCD) that specifically addresses SIMPONI ARIA® (golimumab). Local Coverage Determinations (LCDs) do not exist at this time.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, Section 50 - Drugs and Biologicals. (Accessed January 10, 2019)

REFERENCES

6. Olumiant [prescribing information]. Indianapolis, IN: Lilly USA. LLC; May 2018.

POLICY HISTORY/REVISION INFORMATION

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INSTRUCTIONS FOR USE

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.