PERMANENT J CODE

SIMPONI ARIA® (golimumab) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate (MTX). It is available in individual single-use vials of 50 mg of golimumab per 4 mL of solution. SIMPONI ARIA® is given as a 2-mg/kg intravenous (IV) infusion over 30 minutes at Weeks 0 and 4, then every 8 weeks thereafter.[1]

HCPCS CODE[2] FOR SIMPONI ARIA®	
J1602	Injection, golimumab, 1 mg, for intravenous use* (one 50-mg vial equals 50 units)

NDC FOR SIMPONI ARIA® (11-DIGIT)[1]	
57894-0350-01	SIMPONI ARIA® (50-mg/4-mL vial)

DIAGNOSIS CODES: ICD-9[3]	
714.0	Rheumatoid arthritis
714.2	Other rheumatoid arthritis with visceral or systemic involvement

CPT® CODES FOR DRUG ADMINISTRATION AND E/M SERVICES[4]	
96413† OR 96365†	Chemotherapy, IV infusion, up to 1 hour Intravenous infusion, up to 1 hour
99211‡ – 99215§‖	Evaluation and Management (E/M) Services

* Please consult individual payer policy if unclassified biologics code (J3590) is required, or contact AccessOne®.

† Individual payer policies may vary regarding the use of drug administration codes 96413 and 96365. Please consult payer policy or contact AccessOne®.

‡ CPT 99211 is not billable, or payable, on Medicare claims when used in conjunction with codes for infusion services in physician offices.

§ Medicare requires use of CPT modifier 25 to indicate a significant, separately identifiable E/M service by the same physician on the same day of the procedure. Private payers may also require use of a modifier.

‖ Use of E/M codes requires documentation of medically appropriate services performed on the same day as the infusion.

For information on comprehensive support services, call 1-888-ACCESS-1 (1-888-222-3771) Monday – Friday, 8:00 AM – 8:00 PM ET or visit www.janssenaccessone.com.

The information in this guide is provided to assist you in understanding the reimbursement process. It is intended to help providers in accurately obtaining reimbursement for healthcare services. It is not intended to increase or maximize reimbursement by any payer. We strongly suggest that you consult your payer organization with regard to local reimbursement policies. This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and updated frequently. While Janssen Biotech, Inc., has made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Please consult with your counselor reimbursement specialist for any reimbursement or billing questions. Similarly, all Current Procedural Terminology (CPT®) & Healthcare Common Procedural Coding System (HCPCS) billing codes are supplied for informational purposes only and represent no statement, promise or guarantee by Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made.

Please see full Prescribing Information and Medication Guide for SIMPONI ARIA®. Provide the Medication Guide to your patients and encourage discussion.

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA® (golimumab), including infections due to tuberculosis, invasive fungal infections (eg, histoplasmosis), bacterial, viral, or other opportunistic pathogens. Prior to initiating SIMPONI ARIA® and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection. Lymphoma, including a rare and fatal cancer called hepatosplenic T-cell lymphoma, and other malignancies can occur in adults and children, and can be fatal. Other serious risks include melanoma and Merkel cell carcinoma, heart failure, demyelinating disorders, lupus-like syndrome, hypersensitivity reactions, and hepatitis B reactivation. Prior to initiating SIMPONI ARIA®, test patients for hepatitis B viral infection. Please see related and other Important Safety Information on following pages.

Simponi ARIA® golimumab for infusion

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with SIMPONI ARIA® (golimumab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue SIMPONI ARIA® if a patient develops a serious infection.

Reported infections with TNF blockers, of which SIMPONI ARIA® is a member, include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before SIMPONI ARIA® use and during therapy. Initiate treatment for latent infection prior to SIMPONI ARIA® use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Consider the risks and benefits of treatment with SIMPONI ARIA® prior to initiating therapy in patients with chronic or recurrent infection. Do not start SIMPONI ARIA® in patients with clinically important active infections, including localized infections. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with SIMPONI ARIA®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who are on treatment for latent TB, or who were previously treated for TB infection.

Risk of infection may be higher in patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. Other serious infections observed in patients treated with SIMPONI ARIA® included sepsis, pneumonia, cellulitis, and abscess.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which SIMPONI ARIA® is a member. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies usually associated with immunosuppression and malignancies not usually observed in children or adolescents. Malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

In the controlled portions of clinical trials of TNF blockers including the subcutaneous formulation of golimumab, more cases of lymphoma have been observed among patients receiving anti-TNF treatment compared with patients in the control groups. In clinical trials, the incidence of malignancies other than lymphoma and non-melanoma skin cancer per 100 patient-years of follow-up was 0.56 (95% CI: 0.01, 3.11) in the SIMPONI ARIA® group compared with an incidence of 0 (95% CI: 0.00, 3.79) in the placebo group. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including SIMPONI ARIA®. The risks and benefits of TNF-blocker therapy should be considered prior to initiating therapy in patients with a known malignancy or who develop a malignancy.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers. These cases have had a very aggressive disease course and have been fatal. Nearly all reported cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. A risk for the development for HSTCL in patients treated with TNF blockers cannot be excluded.

Melanoma has been reported in patients treated with TNF-blocking agents, including SIMPONI ARIA®. Merkel cell carcinoma has been reported in patients treated with TNF-blocking agents. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

HEPATITIS B REACTIVATION

The use of TNF blockers, of which SIMPONI ARIA® (golimumab) is a member, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immunosuppressants.

All patients should be tested for HBV infection before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consult a physician with expertise in the treatment of hepatitis B before initiating TNF-blocker therapy. Exercise caution when prescribing SIMPONI ARIA® for patients identified as carriers of HBV and closely monitor for active HBV infection during and following termination of therapy with SIMPONI ARIA®. Discontinue SIMPONI ARIA® in patients who develop HBV reactivation, and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of SIMPONI ARIA®, and monitor patients closely.

HEART FAILURE

Cases of worsening congestive heart failure (CHF) and new-onset CHF have been reported with TNF blockers, including SIMPONI ARIA®. Some cases had a fatal outcome. Exercise caution in CHF patients receiving SIMPONI ARIA® and monitor them closely during therapy. Discontinue SIMPONI ARIA® if new or worsening symptoms of heart failure appear.

DEMYELINATING DISORDERS

Use of TNF blockers, of which SIMPONI ARIA® is a member, has been associated with rare cases of new-onset or exacerbation of demyelinating disorders, including multiple sclerosis (MS) and Guillain-Barré syndrome. Cases of central demyelination, MS, optic neuritis, and peripheral demyelinating polyneuropathy have rarely been reported in patients treated with the subcutaneous formulation of golimumab. Exercise caution in considering the use of SIMPONI ARIA® in patients with these disorders. Consider discontinuation if these disorders develop.

AUTOIMMUNITY

Treatment with TNF blockers, including SIMPONI ARIA®, may result in the formation of antinuclear antibodies. Rarely, treatment with TNF blockers may result in a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

USE WITH OTHER DRUGS

The concomitant use of a TNF blocker and abatacept or anakinra was associated with a higher risk of serious infections, therefore the use of SIMPONI ARIA® in combination with these products is not recommended. Care should be taken when switching from one biologic to another since overlapping biological activity may further increase the risk of infection. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. The concomitant use of SIMPONI ARIA® with biologics approved to treat RA is not recommended because of the possibility of an increased risk of infection.

HEMATOLOGIC CYTOPENIAS

There have been reports of pancytopenia, leukopenia, neutropenia, and thrombocytopenia in patients receiving SIMPONI ARIA® in clinical trials. Additionally, aplastic anemia has been reported in patients receiving TNF blockers. Exercise caution when using SIMPONI ARIA® in patients who have or had significant cytopenias.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

VACCINATIONS/THERAPEUTIC INFECTIOUS AGENTS

People receiving SIMPONI ARIA® (golimumab) can receive vaccinations, except for live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections. Administration of live vaccines to infants exposed to SIMPONI ARIA® *in utero* is not recommended for 6 months following the mother's last SIMPONI ARIA® infusion during pregnancy due to an increased risk of infection. It is recommended that therapeutic infectious agents not be given concurrently with SIMPONI ARIA® due to the possibility of clinical infections, including disseminated infections.

HYPERSENSITIVITY REACTIONS

Serious systemic hypersensitivity reactions (including anaphylactic reaction) have been reported following administration of the subcutaneous formulation of golimumab, some occurring after the first dose. If an anaphylactic or other serious allergic reaction occurs, discontinue SIMPONI ARIA® immediately and institute appropriate therapy.

ADVERSE REACTIONS

The most serious adverse reactions were serious infections and malignancies.

Upper respiratory tract infection was the most common adverse reaction reported in the Phase 3 trial through Week 24, occurring in 6.5% of patients treated with SIMPONI ARIA® as compared with 7.6% of patients in the control group. The rate of infusions associated with an infusion reaction was reported in 1.1% of SIMPONI ARIA® infusions compared with 0.2% of infusions in the control group.

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Please see full Prescribing Information and Medication Guide for SIMPONI ARIA®. Provide the Medication Guide to your patients and encourage discussion.

References: 1. SIMPONI ARIA® (golimumab) Prescribing Information. Janssen Biotech, Inc. **2.** 2014 Alpha-numeric HCPCS File. http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2014-Alpha-Numeric-HCPCS.html?DLPage=1&DLSort=0&DLSortDir=descending. Accessed December 5, 2013. **3.** Buck, CJ. *2014 ICD-9-CM for Hospitals, Volumes 1, 2 & 3, Professional Edition.* St. Louis, MO: Elsevier Saunders; 2014. **4.** American Medical Association. *CPT® 2014 Professional Edition.* Chicago, IL: American Medical Association; 2013.

Simponi ARIA® golimumab for infusion

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