

SIMPONI ARIA® (golimumab) BILLING GUIDE

SIMPONI ARIA® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX), active psoriatic arthritis (PsA), and active ankylosing spondylitis (AS).

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with SIMPONI ARIA®, 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 [pages 20 and 21](#).

Simponi ARIA®
golimumab
for infusion

Janssen Biotech, Inc., is committed to providing reimbursement information for SIMPONI ARIA® (golimumab). This Billing Guide has been developed to provide information regarding:

- Essential Coding Considerations
- Sample Claims Forms
- Important Product Information
- Reimbursement Support Resources

Information about SIMPONI ARIA® access and reimbursement support is available through Janssen CarePath. Please call 877-CarePath (877-227-3728) to speak with a Janssen Care Coordinator about any reimbursement-related questions or concerns.

Disclaimer

Third-party reimbursement is affected by many factors. This document and the information and assistance provided by Janssen CarePath are presented for informational purposes only. They do not constitute reimbursement or legal advice. Janssen CarePath does not promise or guarantee coverage, levels of reimbursement, or payment.

Similarly, all CPT* and Healthcare Common Procedure Code System (HCPCS) codes are supplied for informational purposes only and represent no statement, promise, or guarantee, expressed or implied, by Janssen or its third-party service providers that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the Medicare program.

Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Accordingly, the information may not be current or comprehensive.

Janssen and its third-party service providers strongly recommend you consult your payer for its most current coverage, reimbursement, and coding policies. Janssen and its third-party service providers make no representations or warranties, expressed or implied, as to the accuracy of the information provided. In no event shall the third-party service providers or Janssen, or their employees or agents, be liable for any damages resulting from or relating to any information provided by, or accessed to or through, Janssen CarePath. All HCPs and other users of this information agree that they accept responsibility for the use of this program.

*CPT®—Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2019.

Simponi **ARIA**®
golimumab
for infusion

TABLE OF CONTENTS

INTRODUCTION	2
SIMPONI ARIA® INDICATIONS AND USAGE	4
SIMPONI ARIA® DOSING AND ADMINISTRATION	4
CODING FOR SIMPONI ARIA®	5
ICD-10-CM Diagnosis Codes	5
National Drug Code (NDC)	5
NDC Units	6
Healthcare Common Procedure Code System (HCPCS) Level II Codes	6
CODING FOR DRUG ADMINISTRATION	7
Introduction	7
Codes for SIMPONI ARIA® Administration	7
OTHER CODING CONSIDERATIONS	8
Place of Service Codes	8
Revenue Codes	8
HCPCS and CPT® Modifiers	9
Same Day Evaluation and Management Services	10
CMS Discarded Drug Policy	10
Patient-Supplied Drugs	10
SAMPLE CLAIM FORMS	11
Introduction	11
SIMPONI ARIA® 2020 Physician Office Sample Claim Form: CMS-1500	12
SIMPONI ARIA® 2020 HOPD Sample Claim Form: CMS-1450 (UB-04)	14
COVERAGE CONSIDERATIONS	16
JANSSEN CAREPATH	17
APPENDIX: Sample Letter of Medical Necessity	19
IMPORTANT SAFETY INFORMATION	20
REFERENCES	22



SIMPONI ARIA® INDICATIONS AND USAGE

SIMPONI ARIA® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX), active psoriatic arthritis (PsA), and active ankylosing spondylitis (AS).¹

SIMPONI ARIA® DOSING AND ADMINISTRATION

SIMPONI ARIA® dosing is weight based. Induction and maintenance doses are administered by intravenous infusion over a period of 30 minutes.¹

Table 1. SIMPONI ARIA® Dosage and Intervals¹

Indication	Induction	Maintenance
Moderately to severely active rheumatoid arthritis in combination with methotrexate	2 mg/kg 0 & 4 weeks	2 mg/kg every 8 weeks thereafter
Active psoriatic arthritis	2 mg/kg 0 & 4 weeks	2 mg/kg every 8 weeks thereafter
Active ankylosing spondylitis	2 mg/kg 0 & 4 weeks	2 mg/kg every 8 weeks thereafter

Preparation and Administration of SIMPONI ARIA® for IV Infusion¹

SIMPONI ARIA® solution for intravenous infusion should be diluted by a healthcare professional using aseptic technique as follows:

1. Calculate the dosage and the number of SIMPONI ARIA® vials needed based on the recommended dosage of 2 mg/kg and the patient's weight. Each 4-mL vial of SIMPONI ARIA® contains 50 mg of golimumab.
2. Check that the solution in each vial is colorless to light yellow. The solution may develop a few fine translucent particles, as golimumab is a protein. Do not use if opaque particles, discoloration, or other foreign particles are present.
3. Dilute the total volume of the SIMPONI ARIA® solution with 0.9% Sodium Chloride Injection, USP to a final volume of 100 mL. For example, this can be accomplished by withdrawing a volume of the 0.9% Sodium Chloride Injection, USP from the 100-mL infusion bag or bottle equal to the total volume of SIMPONI ARIA®. Slowly add the total volume of SIMPONI ARIA® solution to the 100-mL infusion bag or bottle. Gently mix. Discard any unused solution remaining in the vials. Alternatively, SIMPONI ARIA® can be diluted using the same method described above with 0.45% Sodium Chloride Injection, USP.
4. Prior to infusion, visually inspect the diluted SIMPONI ARIA® solution for particulate matter or discoloration. Do not use if these exist.
5. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.22 micrometer or less).
6. Do not infuse SIMPONI ARIA® concomitantly in the same intravenous line with other agents. No physical biochemical compatibility studies have been conducted to evaluate the use of SIMPONI ARIA® with other intravenous agents in the same intravenous line.
7. Infuse the diluted solution over 30 minutes.
8. Once diluted, the infusion solution can be stored for 4 hours at room temperature.

Please refer to the Dosage and Administration section of the full [Prescribing Information](#) for complete information on how to prepare and administer SIMPONI ARIA®.

Please see accompanying full [Prescribing Information](#) and [Medication Guide](#) for SIMPONI ARIA®. Provide the [Medication Guide](#) to your patients and encourage discussion.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).



CODING FOR SIMPONI ARIA®

ICD-10-CM Diagnosis Codes

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.² Table 2 below lists possible ICD-10-CM diagnosis codes that you may consider for patients treated with SIMPONI ARIA® (golimumab).

Table 2. ICD-10-CM Codes ³ for Consideration*	
Rheumatoid Arthritis	
M06.00	Rheumatoid arthritis w/o rheumatoid factor, unspecified
M05.60	Rheumatoid arthritis of unspecified site with involvement of organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site with-out organ or systems involvement
Psoriatic Arthritis	
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.59	Other psoriatic arthropathy
Ankylosing Spondylitis	
M45.9	Ankylosing spondylitis of unspecified sites in spine

*These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not intended to be exhaustive and may require a higher level of specificity when reporting for individual patients.

National Drug Code (NDC)

The National Drug Code (NDC) is a unique number that identifies a drug's labeler, product, and trade package size. The NDC has typically been reserved for pharmacy billing, including drugs provided for home infusion. However, Medicaid fee-for-service programs, Medicare crossover claims for dual eligibles and some private payers⁴ now also require the NDC for billing instead of, or in addition to, the HCPCS code, for physician claims and those of other service providers. Although the FDA uses a 10-digit format when registering NDCs, payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires use of the 11-digit NDC in a 5-4-2 sequence. To convert the 10-digit format of SIMPONI ARIA® to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below. In some cases, you may be required to include the NDC number on a claim form.

Table 3: SIMPONI ARIA® NDC ¹		
10-digit NDC	11-digit NDC	Description
57894-350-01	57894-0350-01	50-mg vial Single-use vial containing 50 mg of golimumab per 4 mL of solution

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).



CODING FOR SIMPONI ARIA® (cont'd)

NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in vials in liquid form.⁴ NDC units dispensed are based on the packaging and numeric quantity administered to the patient. Here is an example for a 150-mg dose of SIMPONI ARIA® (golimumab):

Dose to Be Billed	NDC (11-digit)	Packaging	NDC Unit of Measure	NDC Units
150 mg	57894-0350-01	50-mg/4-mL vial (liquid)	ML	12

Reporting the NDC quantity is based on the NDC quantity dispensed. If the NDC unit of measure is milliliters (ML) then the NDC quantity reported will equal the amount of ML given to the patient.

In this example the drug is supplied as a liquid in 50-mg/4-mL vials. The NDC is specific to the packaging, thus one 50-mg/4-mL vial equals 4 NDC units. The total dose to be billed is 150 mg (50 mg/4 mL = 12 mL), or 12 NDC units. The drug is packaged in liquid form so the unit of measure is "ML." Accurate NDC coding typically requires the following components⁴:

- Reporting the NDC with 11 digits in a 5-4-2 configuration; this may require converting a 10-digit NDC to an 11-digit NDC
- Reporting the correct NDC unit of measure (ie, UN, ML)
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC

Using the same 150-mg SIMPONI ARIA® example, here is how this format would appear:

N457894035001 ML12

Healthcare Common Procedure Code System (HCPCS) Level II Codes

Drugs are typically reported using product-specific HCPCS codes (eg, J codes) assigned by the Centers for Medicare & Medicaid Services (CMS). The descriptor is not necessarily the same as the package or therapeutic dose, so the dose must be converted to billable HCPCS units to accurately complete a claim. The HCPCS code for SIMPONI ARIA® (golimumab) is:

J1602 - Injection, golimumab, 1 mg for intravenous use⁵

Each 50-mg vial of drug represents 50 units of J1602, thus each 1-mg dose of SIMPONI ARIA® equals one billing unit or 1/50th of a vial. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment. When coding for J1602, report the total number of 1 mg increments administered. Table 5 illustrates the correlation between SIMPONI ARIA® vials, milligrams, and billing units.

Number of 50-mg vials of SIMPONI ARIA®	Total milligrams (mg)	Number of billing units based on J1602 (1-mg SIMPONI ARIA® per unit)
1	50	50
2	100	100
3	150	150
4	200	200

Payer requirements for NDC use and format may vary. Please contact your payers for specific coding policies and more information on correct billing and claims submission. For additional support, you may contact Janssen CarePath at <https://www.JanssenCarePath.com/hcp/simoni-aria> or 877-CarePath (877-227-3728).

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).



CODING FOR DRUG ADMINISTRATION

Codes for Drug Administration Services

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form. Please note that healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements. It is advisable to contact your local payer with regard to local payment policies.

Codes for SIMPONI ARIA® Administration

Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. The CPT® code most commonly associated with the administration of SIMPONI ARIA® (golimumab) is:

- **96365** - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour⁶

This code, often referred to as a "therapeutic" infusion code, typically requires special considerations to prepare, dose, or dispose of the drug/biological and necessitates special training and competency for the administering staff. The services generally require periodic patient assessment during and/or after the procedure.⁶

Alternatively, some payers may permit the use of CPT® code:

- **96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug⁶

This code, often referred to as a "complex" infusion code, applies to the parenteral administration of chemotherapy and also anti-neoplastic agents provided for treatment of non-cancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers. Complex drug administration services also require special considerations to prepare, dose, or dispose and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.⁶

Payer policies for codes used to describe infusion services may vary. Consult your payers for guidance. For additional assistance, contact Janssen CarePath at <https://www.JanssenCarePath.com/hcp/simponi-aria> or **877-CarePath (877-227-3728)**.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).



OTHER CODING CONSIDERATIONS

Place of Service Codes

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The place of service is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on CMS-1500). Under the Physician Fee Schedule (PFS), some procedures have separate rates for professional services when provided in facility and non-facility settings, therefore it is important to accurately designate the POS to assure appropriate payment. The physician practice location is considered "nonfacility" (NF), allowing for the practice expenses to be included in the payment under the PFS. When professional services are performed in a facility (eg, hospital outpatient department) the practice does not incur the same expense (overhead, staff, equipment and supplies, etc), thus, payment under the PFS is generally lower for facility-based services than for NF.

The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus provider-based departments, CMS created a new POS code (POS 19) and revised the POS code description for outpatient hospital (POS 22). Professional services delivered in outpatient hospital settings must now specifically include the off-campus or on-campus POS on the claim form. Table 6 summarizes the potentially applicable place of service codes:

POS Code	POS Name	POS Descriptor
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus – Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
22	On Campus – Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)

Revenue Codes

Many payers require use of American Hospital Association (AHA) revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by three other digits and are used on claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. The following revenue codes may be applicable to CMS-1450 claims for drugs and their administration:

- 0260 IV Therapy, General⁸
- 0510 Clinic, General⁸
- 0636 Pharmacy, drugs requiring detailed coding⁸

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi ARIA
golimumab[®]
for infusion

OTHER CODING CONSIDERATIONS (cont'd)

HCPCS and CPT® Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing and unbundling. This could include using modifiers to designate a specific site of service, or to document an interrupted procedure, wasted product, same-day procedure, etc. Appropriately used, modifiers improve coding and reimbursement accuracy.

Table 7 summarizes modifiers that may be applicable to the provision of SIMPONI ARIA® in physician offices and hospital outpatient departments.

Modifier	Description	Indication and Placement	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified health care professional on the same day of the procedure or other service ⁶	<ul style="list-style-type: none"> • Patient requires distinct E/M service in addition to the infusion procedure⁶ • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code⁶ • Append the modifier to the appropriate E/M code⁶ 	✓	✓
JW	Drug amount discarded/not administered to any patient ⁵	<ul style="list-style-type: none"> • Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial⁹ • Append the modifier to the drug code on a line separate from that reporting the administered dose⁹ 	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted services provided at an off-campus, outpatient provider-based department of a hospital ⁵	<ul style="list-style-type: none"> • To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim¹⁰ 	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital ⁵	<ul style="list-style-type: none"> • To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim¹⁰ 	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount ⁵	<ul style="list-style-type: none"> • Must be reported by providers who are NOT excepted[†] from the 340B payment policy¹⁰ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs¹⁰ 	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes ⁵	<ul style="list-style-type: none"> • Must be reported by providers who ARE excepted[†] from the 340B payment policy¹⁰ • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs¹⁰ 	N/A	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a provider-based department that is "on campus."¹⁰

[†]The following provider types are excepted from the 340B payment policy: rural sole community hospitals, childrens' hospitals, and PPS-exempt cancer hospitals.¹⁰

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi ARIA[®]
golimumab
for infusion

OTHER CODING CONSIDERATIONS (cont'd)

Same Day Evaluation and Management Services

It may be necessary to provide evaluation and management (E/M) services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate, and distinct from the drug administration procedure, and documented appropriately, are generally covered.

CMS has a specific policy regarding use of CPT® code 99211 (level 1 medical visit for an established patient) in the physician office. The policy states:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a non-chemotherapy or chemotherapy drug administration code.¹¹

This means that CPT® code 99211 cannot be paid on the same day as an office-based infusion of SIMPONI ARIA®. If a therapeutic or complex drug administration service and a significantly identifiable, distinct evaluation and management service are provided on the same day, a different diagnosis is not required.¹¹

CMS Discarded Drug Policy⁹

When a physician, hospital or other provider or supplier must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

Medicare contractors require the modifier JW to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate claim line, supports payment for the amount of discarded drug or biological.

For example, a single-use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units is billed on another line accompanied by the JW modifier. Both line items will be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

JW Modifier Summary:

- Payment for discarded amounts of drug/biological applies only to single-use vials or packages
- Multi-use vials are not subject to payment for discarded amounts
- Discarded amounts of drugs/biologicals must be recorded in the patient's medical record
- Medicare contractors require the JW modifier; other payer policies may vary

Drugs Supplied at No Cost to the Provider

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider ("white bagging"). When the drug is supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "0.01" charges.¹² Payer policies may vary.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi ARIA®
golimumab
for infusion

SAMPLE CLAIM FORMS

Physician Office Claims (CMS-1500)

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and noninstitutional providers who qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>

The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

Hospital Outpatient Claims (CMS-1450)

The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

The 837I (Institutional) is the standard format used by institutional providers to transmit health care claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at:

<https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html>

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi **ARIA**[®]
golimumab
for infusion

SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab) 2020 Physician Office Sample Claim Form: CMS-1500

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION



HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input checked="" type="checkbox"/> (Medicare#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1) 000-00-1234	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John B.		4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B.	
3. PATIENT'S BIRTH DATE MM DD YY 07 01 50		5. PATIENT'S ADDRESS (No., Street) 3914 Spruce Street	
6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street) 3914 Spruce Street	
8. RESERVED FOR NUCC USE		11. INSURED'S POLICY GROUP OR FECA NUMBER	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO PLACE (State)	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO	
d. INSURANCE PLAN NAME OR PROGRAM NAME Medicare		10d. CLAIM CODES (Designated by NUCC)	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim, I also request payment of government benefits either to myself or to the party who accepts assignment below.		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
SIGNED _____ DATE _____		SIGNED _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY		15. OTHER DATE QUAL. MM DD YY	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE Dr. Jones		17a. NPI 123 456 7890	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)		20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO \$ CHARGES	
A. M06.00		22. RESUBMISSION CODE ORIGINAL REF. NO.	
B. _____ C. _____		23. PRIORITY MEMBER	
D. _____ E. _____		24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURE(S), SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. ICD-9-CM I. ID. QUAL. J. RENDERING PROVIDER ID. #	
1 01 01 20 01 01 20 11 J1602 A 180 NPI 123 456 7890		2 01 01 20 01 01 20 11 J1602 JW A 20 NPI 123 456 7890	
3 01 01 20 01 01 20 11 96365 A 1 NPI 123 456 7890		4 _____ NPI _____	
5 _____ NPI _____		6 _____ NPI _____	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (If certify that the statements on the reverse apply to this bill and are made a part thereof.)		27. ACCEPT ASSIGNMENT? (For govt. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> NO	
SIGNED _____ DATE _____		28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rvld for NUCC Use	
32. SERVICE FACILITY LOCATION INFORMATION		33. BILLING PROVIDER INFO & PH # (203) 555-6543	
a. 123 456 7890 b.		Dr. Jones 4231 Center Road Anytown, AS 01010	

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Please see Important Safety Information on [pages 20 and 21](#).
Back to [Table of Contents](#).



SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab) 2020 Physician Office Sample Claim Form: CMS-1500

- 1 **Item 21**—Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.
- 2 **Item 24D**—Indicate appropriate CPT® and HCPCS codes and modifiers, if required.

SIMPONI ARIA®

J1602 - Injection, golimumab, 1 mg, for intravenous use

If line item NDC information is required, it will be entered in the shaded portion of Item 24A.⁷ For example:

24. A.	DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)			E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OF UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	OR SUPPLIER INFORMATION	
	MM	DD	YY	MM	DD	YY			CPT/HCPCS	MODIFIER									
1	N457894035001 ML12								J1602			A		150			NPI	123 456 7890	
2																	NPI		
3																	NPI		
4																	NPI		

Payer requirements for NDC entries may vary.*

Infusion Services

96365 - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour, or

96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour

Payer requirements for infusion codes may vary.*

- 3 When it is necessary to discard the remainder of a single-use vial after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.⁹ Other payer policies may vary.*
- 4 **Item 24E**—Refer to the diagnosis for this service (see Item 21). Enter only one diagnosis pointer per line.
- 5 **Item 24F**—Indicate charges. In the event of drug wastage charges should be prorated to reflect drug administered and drug discarded.
- 6 **Item 24G**—Enter the number of HCPCS units based on dose: 1 mg = 1 unit (50-mg vial = 50 units).

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements. For additional resources, visit Janssen CarePath for healthcare professionals at: <https://www.JanssenCarePath.com/hcp/simponi-aria>.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi ARIA®
golimumab
for infusion

SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab) 2020 HOPD Sample Claim Form: CMS-1450 (UB-04)

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT. CNTY. # b. MED. REC. # c. STATEMENT COVERS PERIOD FROM THROUGH	4 TYPE OF BILL
8 PATIENT NAME a John B. Doe (ID)		9 PATIENT ADDRESS a 3914 Spruce St. b John B. Doe b Anytown, c AS d 01010 e US			
10 BIRTHDATE 07-01-50	11 SEX M	12 DATE	13 PR.	14 TYPE	15 SRC
16 DHR	17 STAT	18	19	20	21
31 OCCURRENCE DATE		32 CODE	33 OCCURRENCE DATE	34 CODE	35 OCCURRENCE DATE
36 OCCURRENCE DATE		37 CODE	38 OCCURRENCE SPAN FROM THROUGH		39 CODE
39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
42 REV. CD	43 DESCRIPTION	44 HCPCS / RATE / HPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES
0260	IV therapy	96365	01-01-20	1	
0636	SIMPONI ARIA®	J1602	01-01-20	180	
0636	SIMPONI ARIA®	J1602JW	01-01-20	20	
50 PAYER NAME Medicare		51 HEALTH PLAN ID	52 REL. INFO	53 ARG. BEN.	54 PRIOR PAYMENTS
55 EST. AMOUNT DUE		56 NPI	246 890 1234		
57 OTHER PRV ID					
58 INSURED'S NAME		59 P.REL.	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66 SIA 0 M06.00		68			
69 ADM. DX	70 PATIENT REASON DX	71 FPS CODE	72 ECI	73	
74 PRINCIPAL PROCEDURE CODE	75 OTHER PROCEDURE CODE	76 ATTENDING NPI	123 456 7890	QUAL.	
77 OPERATING NPI		LAST Jones		FIRST John	
78 OTHER NPI		LAST		FIRST	
79 OTHER NPI		LAST		FIRST	
80 REMARKS		BICC a	b	c	d

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).



SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab) 2020 HOPD Sample Claim Form: CMS-1450 (UB-04)

- 1 **Locator Box 42**—List revenue codes in ascending order.
- 2 **Locator Box 43**—Enter narrative description for corresponding revenue code (eg, IV therapy, drug). If line item NDC information is required it will be entered in the unshaded portions of Locator Box 43.¹³ Payer requirements for NDC entries may vary.
- 3 **Locator Box 44**—Indicate appropriate CPT® and HCPCS codes and modifiers as required by the payer.

SIMPONI ARIA®
J1602 - Injection, golimumab, 1 mg, for intravenous use

Infusion Services
96365 - Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour, or
96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour

Payer requirements for infusion codes may vary.*

Modifiers
 *PO or PN modifiers must be reported by all off-campus HOPDs. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus, PBD of a hospital. The PN modifier is to be reported on each claim line for all items and services furnished in a *nonexcepted*, off-campus, PBD of a hospital.¹⁰

*JG and TB modifiers must be reported for all 340B-acquired drugs. Providers who are not excepted from the 340B payment policy will report modifier JG. Providers who are excepted from the 340B payment policy will report informational modifier TB.¹⁰
- 4 When it is necessary to discard the remainder of a single-use vial after administering a dose of drug/biological to a Medicare patient, the program provides payment for the amount discarded as well as the dose administered. Medicare requires the modifier JW be appended to the discarded amount, billed on a separate line from the administered dose.⁹ Other payer policies may vary.*
- 5 **Locator Box 46**—Enter the number of HCPCS units based on dose: 1 mg = 1 unit (50-mg vial = 50 units).
- 6 **Locator Box 47**—Indicate total charges. In the event of drug wastage charges should be prorated to reflect drug administered and drug discarded.
- 7 **Locator Box 67**—Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

*Contact your local payer or Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements. For additional resources, visit Janssen CarePath for healthcare professionals at: <https://www.JanssenCarePath.com/hcp/simponi-aria>.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi ARIA®
golimumab
for infusion

COVERAGE CONSIDERATIONS

Factors That Influence Coverage

Third-party payers (eg, commercial insurers, Medicare, Medicaid) will generally cover parenteral drugs for their approved U.S. Food and Drug Administration (FDA) indications, and the associated professional administration services. However, benefits may vary depending upon the payer and the specific plan (“insurance product”) in which a patient is enrolled.

Medical Necessity

When third-party payers review infusible drug claims, they will first determine if the type of service provided is covered under their policies. Next, payers will look for evidence supporting the medical necessity of the therapy. This evidence may include:

- Information about the patient’s medical condition and history
- A physician’s statement or Letter of Medical Necessity
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Full Prescribing Information
- Availability of other treatment alternatives

Medical necessity refers to a decision by a health plan that a treatment, test, or procedure is necessary for health or to treat a diagnosed medical problem. Health insurance companies provide coverage only for health-related services that they define or determine to be medically necessary. Medicare National Coverage Determinations (NCDs) and Medicare Administrative Contractors (MACs) Local Coverage Determinations (LCDs) define medical necessity requirements for Medicare coverage. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific services in accordance with medical necessity.

Administrative Considerations

Other considerations may be involved in a payer’s decision to cover a product or service:

- **Does the payer’s contract specifically indicate the sites of care that may bill for infusion services or infused drugs?**

A small portion of payers have exclusive contracts with designated preferred providers for infusion services. This may include certain clinics or specialty pharmacies that deliver drugs to healthcare providers or other infusion centers.

- **Does the payer cover the therapy only when provided through a specific treatment site?**

Payers may have site-specific coverage rules that restrict provision of infused therapies. For example, currently Medicare does not cover infusions when they are billed by Medicare-certified ambulatory surgery centers. Payers also may restrict coverage for certain infused drugs in the home or hospital outpatient setting.

- **Is the billing provider a “participating” member of, or “in-network” provider for, that particular plan?**

Payers contract with providers to deliver services to the plan’s members. Providers are thus “participating” or within that plan’s network, requiring them to abide by the contract charge structure when providing care for that plan’s members.

- **Is the plan willing to grant in-network status when a service is otherwise out of network?**

In some cases, (eg, when there are no available in-network providers), health plans may grant in-network status for a provider and related services. In such cases, the provider accepts the in-network rate and the patient will be able to access in-network cost-sharing. It may be helpful to contact a payer to ask for a service to be converted to in-network status.

- **If required by the plan, has the appropriate referral or prior authorization been obtained?**

Many plans require that non-emergency services be pre-approved or that a primary care physician make the referral for specialty care. Failing to obtain appropriate referrals or pre-authorization can result in non-payment by the plan.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi **ARIA**[®]
golimumab
for infusion

Janssen CarePath is your one source for access, affordability, and treatment support for your patients



Access support to help navigate payer processes

Janssen CarePath helps verify insurance coverage for your patients taking SIMPONI ARIA® (golimumab) and provides reimbursement information.

Our digital resources available at [JanssenCarePathPortal.com](https://www.janssencarepath.com) include:

- eBenefits investigations
- ePrior authorization support and status monitoring
 - Payer-specific Prior Authorization (PA) forms delivered in Portal
- eCreation of medical necessity and exceptions letters
- eRequest for exceptions and appeals information
- Online coding and billing information
- Online Secure Messaging to ask a question, request a status update, or send missing information related to an existing case
- Triage to specialty pharmacy providers, if needed

[Learn more](#)



Affordability support to help your patients start and stay on the Janssen treatment you prescribe

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking SIMPONI ARIA®:

Support for patients using commercial or private insurance:

- **Janssen CarePath Savings Program** allows eligible patients to save on their out-of-pocket medication costs. Depending on the health insurance plan, savings may apply toward co-pay, co-insurance or deductible.
 - Eligible patients pay \$5 for each infusion, with a \$20,000 maximum program benefit per calendar year.
 - Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. There is no income requirement. For medication costs only; program does not cover cost to give patients their infusion. The Savings Program for SIMPONI ARIA® provides a rebate when used with medical/primary insurance and provides instant savings when used with pharmacy/prescription insurance. See full eligibility requirements at [SimoniAria.JanssenCarePathSavings.com](https://www.SimoniAria.JanssenCarePathSavings.com).
- Online enrollment and tracking of patient Savings Program benefits by you, the pharmacy, or the patient.
 - Comprehensive Provider Portal at [JanssenCarePathPortal.com](https://www.JanssenCarePathPortal.com) allows you to enroll eligible patients in Savings Programs, view patients' available benefit and transactions as requested by the patient, and receive timely alerts and program updates.
 - Patients can manage Savings Program benefits and more on their Janssen CarePath Account at [MyJanssenCarePath.com](https://www.MyJanssenCarePath.com)

Support for patients using government-funded healthcare programs or patients without insurance coverage:

- Janssen CarePath can provide information about other resources that may be able to help your patients with their out-of-pocket medication costs, including:
 - State Pharmaceutical Assistance Programs (SPAPs)
 - State Health Insurance Programs (SHIPs)
 - Medicare Savings Program
 - Medicare Part D Extra Help—Low-Income Subsidy
 - Independent Foundations*
- Call a Janssen CarePath Care Coordinator at **877-CarePath (877-227-3728)** or visit [JanssenPrescriptionAssistance.com/SimoniAria](https://www.JanssenPrescriptionAssistance.com/SimoniAria) for more information on affordability programs that may be available.

[Learn more](#)

*Independent co-pay assistance foundations have their own rules for eligibility. We have no control over these independent foundations and can only refer your patients to a foundation that supports their disease state. We do not endorse any particular foundation.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).





Treatment support to help your patients get informed and stay on prescribed treatment

Janssen CarePath provides additional support to your patients taking SIMPONI ARIA® (golimumab), including:

- Care coordination with treatment provider or pharmacy
- Personalized treatment reminders
- Treatment demonstration videos
- Patient education and tools
- Nurse Support to answer patients' questions*
- Infusion site locator at **2infuse.com**

[Learn more](#)



Call a Janssen CarePath Care Coordinator at

877-CarePath (877-227-3728),

Monday-Friday, 8:00 AM to 8:00 PM ET.

Multilingual phone support available.



Sign Up or Log In to the Provider Portal at

JanssenCarePathPortal.com



Visit JanssenCarePath.com/hcp/Simponi-Aria

Patient insurance benefits investigation and other Janssen CarePath program offerings are provided by third-party service providers for Janssen CarePath, under contract with Johnson & Johnson Health Care Systems Inc. on behalf of Janssen Biotech, Inc. (Janssen). Janssen CarePath is not available to patients participating in the Patient Assistance Program offered by Johnson & Johnson Patient Assistance Foundation. The availability of information and assistance may vary based on the Janssen medication, geography, and other program differences. Janssen CarePath assists healthcare providers (HCPs) in the determination of whether treatment could be covered by the applicable third-party payer based on coverage guidelines provided by the payer, and patient information provided by the HCP under appropriate authorization following the provider's exclusive determination of medical necessity. This information and assistance are made available as a convenience to patients, and there is no requirement that patients or HCPs use any Janssen product in exchange for this information or assistance. Janssen assumes no responsibility for and does not guarantee the quality, scope, or availability of the information and assistance provided. The third-party service providers, not Janssen, are responsible for the information and assistance provided under this program. Each HCP and patient is responsible for verifying or confirming any information provided. All claims and other submissions to payers should be in compliance with all applicable requirements.

*Nurse Support is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).



APPENDIX: SAMPLE LETTER OF MEDICAL NECESSITY

Some payers and other formulary decision makers may require that treating physicians complete a Letter of Medical Necessity before patients can receive a specific therapy. We have provided a sample for your convenience. Create a Letter of Medical Necessity on JanssenCarePathPortal.com or download a **sample letter** at JanssenCarePath.com/hcp/Simponi-Aria

[Insert Physician Letterhead]

[Insert Name of Medical Director] RE: Member Name: [Insert Member Name]
 [Insert Payer Name] Member Number: [Insert Member Number]
 [Insert Address] Group Number: [Insert Group Number]
 [Insert City, State Zip]

REQUEST: Authorization for treatment with SIMPONI ARIA® (golimumab)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: Standard EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive intravenous treatment with SIMPONI ARIA® for [Insert Indication]. My request is supported by the following:

Summary of Patient's Diagnosis
 [Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History
 [Insert previous therapies/procedures, response to those interventions, description of patient's recent symptoms/condition, summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with SIMPONI ARIA®. Note: Exercise your medical judgement and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
 [Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of SIMPONI ARIA®, I believe treatment with SIMPONI ARIA® at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. Include the full Prescribing Information for SIMPONI ARIA® and any peer reviewed journal articles or supporting clinical guidelines that provide additional clinical information to support the recommendation for SIMPONI ARIA® for this patient.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
 [Insert Physician Name and Participating Provider Number]

If this request is denied, I am requesting an expedited Exception review by a professional in my specialty.

Enclosures [Include full Prescribing Information and the additional support noted above]

© Janssen Biotech, Inc. 2018 8/18 cp-19553v2

Please see Important Safety Information on [pages 20 and 21](#).

Back to [Table of Contents](#).

Simponi ARIA®
 golimumab
 for infusion

IMPORTANT SAFETY INFORMATION

Indications

SIMPONI ARIA® is indicated for the treatment of adults with:

- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)
- Active psoriatic arthritis (PsA)
- Active ankylosing spondylitis (AS)

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

HEPATITIS B REACTIVATION

The use of TNF blockers, of which SIMPONI ARIA® 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.

Simponi ARIA®
golimumab
for infusion

IMPORTANT SAFETY INFORMATION (cont'd)

HEPATITIS B REACTIVATION (cont'd)

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, including SIMPONI ARIA®, 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 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, agranulocytosis, aplastic anemia, and thrombocytopenia in patients receiving SIMPONI ARIA®. Exercise caution when using SIMPONI ARIA® in patients who have or had significant cytopenias.

VACCINATIONS/THERAPEUTIC INFECTIOUS AGENTS

People receiving SIMPONI ARIA® 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 anaphylaxis) have been reported following administration of the subcutaneous formulation of golimumab and SIMPONI ARIA®, some occurring after the first dose. Hypersensitivity reactions including hives, pruritus, dyspnea, and nausea, were reported in association with infusions of SIMPONI ARIA®. 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.

The most common adverse reactions (incidence $\geq 3\%$) reported in clinical trials were: upper respiratory tract infection, alanine aminotransferase increase, viral infection, aspartate aminotransferase increase, neutrophil count decrease, bronchitis, hypertension, and rash. In the controlled phase of Trial RA, 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.

Please see accompanying full [Prescribing Information](#) and [Medication Guide](#) for SIMPONI ARIA®.

Provide the [Medication Guide](#) to your patients and encourage discussion.

Simponi ARIA®
golimumab
for infusion

REFERENCES

1. SIMPONI ARIA® (golimumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. September 2019.
2. Centers for Medicare & Medicaid Services. ICD-10-CM official guidelines for coding and reporting FY 2020 (October 1, 2019 - September 30, 2020). <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-Coding-Guidelines.pdf>. Revised November 5, 2019. Accessed March 4, 2020.
3. American Medical Association. *ICD-10-CM 2020: The Complete Official Code Book*. Chicago, IL: Optum 360 LLC; 2019.
4. UnitedHealthcare. National Drug Code requirements UnitedHealthcare commercial and UnitedHealthcare Medicare Advantage professional and hospital outpatient claims frequently asked questions. <https://www.uhcprovider.com/content/dam/provider/docs/public/claims/NDC-Requirement-FAQ.pdf>. Published February 26, 2019. Accessed March 2, 2020.
5. American Medical Association. *HCPCS Level II Professional 2020*. Chicago, IL: Elsevier Inc.; 2020.
6. American Medical Association. *Current Procedural Terminology: CPT® 2020: Professional Edition*. Chicago, IL: AMA Press; 2019.
7. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26: Completing and Processing the Form CMS-1500 Data Set. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>. Accessed March 2, 2020.
8. Noridian Healthcare Solutions. Revenue Codes. (September 26, 2018). <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>. Accessed March 5, 2020.
9. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>. Accessed March 2, 2020.
10. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 4: Part B Hospital. <https://www.cms.gov/files/document/chapter-4-part-b-hospital-including-inpatient-hospital-part-b-and-opps-0>. Accessed March 5, 2020.
11. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 12: Physicians/Non-Physician Practitioners. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>. Accessed March 2, 2020.
12. Noridian Healthcare Solutions. Local Coverage Article: Patients Supplied Donated or Free-of-Charge Drug (A55044). Last revised October 2019. <https://med.noridianmedicare.com/documents/10546/12461373/Patients+Supplied+Donated+or+Free-of-Charge+Drug+Coverage+Article>. Accessed March 5, 2020.
13. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>. Accessed March 2, 2020.

Please see Important Safety Information on [pages 20 and 21](#).
Back to [Table of Contents](#).

Simponi ARIA®
golimumab
for infusion