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
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)
- Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older

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 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

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Johnson & Johnson is committed to providing reimbursement information for SIMPONI ARIA® to you. This billing guide has been developed to provide you with information regarding:

- Essential coding considerations
- Sample claim forms
- Important product information
- Reimbursement support resources

For information and assistance about SIMPONI ARIA® access and reimbursement support resources, contact J&J withMe at 877-227-3728 or visit JNJwithMe.com.

Disclaimer

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on their clinical judgment, payer-specific guidance, and other requirements.

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SIMPONI ARIA® INDICATIONS AND USAGE

SIMPONI ARIA® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adults with moderate to severe rheumatoid arthritis (RA), used in combination with methotrexate (MTX); patients 2 years of age and older with active psoriatic arthritis (PsA); adults with active ankylosing spondylitis (AS); and patients 2 years of age and older with active polyarticular Juvenile Idiopathic Arthritis (pJIA).[1]

SIMPONI ARIA® DOSING AND ADMINISTRATION

SIMPONI ARIA® dosing is weight-based for adults. SIMPONI ARIA® dosing in pediatric patients is based on body surface area. Induction and maintenance doses are administered by intravenous infusion over a period of 30 minutes.[1]

Table 1. SIMPONI ARIA® Dosage and Intervals[1]

Indication	Induction	Maintenance
Adult patients with moderately to severely active Rheumatoid Arthritis *in combination with methotrexate*	**2 mg/kg 0 & 4 weeks**	**2 mg/kg every 8 weeks thereafter**
Pediatric patients (2-17 years of age) with Active Psoriatic Arthritis	**80 mg/m^2 0 & 4 weeks**	**80 mg/m^2 every 8 weeks thereafter**
Adult patients with Active Psoriatic Arthritis	**2 mg/kg 0 & 4 weeks**	**2 mg/kg every 8 weeks thereafter**
Adult patients with active Ankylosing Spondylitis	**2 mg/kg 0 & 4 weeks**	**2 mg/kg every 8 weeks thereafter**
Active polyarticular Juvenile Idiopathic Arthritis in patients 2 years of age and older	**80 mg/m^2 0 & 4 weeks**	**80 mg/m^2 every 8 weeks thereafter**

Preparation and Administration of SIMPONI ARIA® for IV Infusion[1]

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 adult dosage of 2 mg/kg and the patient's weight for RA, PsA and AS. Calculate the dosage and number of SIMPONI ARIA® vials needed based on the recommended pediatric dosage of 80 mg/m^2 and the patient's body surface area (BSA), for pJIA and pediatric patients with PsA. 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 are present.
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.

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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 payers 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.[4]

Table 3: SIMPONI ARIA® NDC[1]

10-digit NDC	11-digit NDC	Description
57894-350-01	57894-0350-01	50-mg vial single-dose vial containing 50 mg of golimumab per 4 mL of solution

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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):

Table 4. SIMPONI ARIA® NDC Units

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 components[4]:

- 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 use[5]

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.

Table 5: SIMPONI ARIA® 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 J&J withMe at 877-227-3728 or visit JNJwithMe.com.

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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 hour[6]

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/drug[6]

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, you may contact J&J withMe at 877-227-3728 or visit JNJwithMe.com.

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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:

Table 6. Place of Service Codes[7]

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, General[8]
- 0510 Clinic, General[8]
- 0636 Pharmacy, drugs requiring detailed coding[8]

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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.

Table 7: Summary of Code Modifiers

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]	• Patient requires distinct E/M service in addition to the infusion procedure[6] • Must be substantiated by documentation that supports the relevant criteria for the reported E/M code[6] • Append the modifier to the appropriate E/M code[6]	✓ Required by Medicare	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[5]	• Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial[9] • Append the modifier to the drug code on a line separate from that reporting the administered dose[9]	✓ Required by Medicare	✓ Required by Medicare
JZ	Zero drug amount discarded/not administered to any patient[5]	• To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)[10] • Append the modifier to the drug code line[10]	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted services provided at an off-campus, outpatient provider-based department of a hospital[5]	• 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 claim[11]	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[5]	• 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 claim[11]	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes[5]	• Must be reported by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes only[11] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[11]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities[5]	• Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes[11] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[11]	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."[11]

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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.[12]

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.[12]

CMS Discarded Drug Policy[9]

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

CMS Policy for Reporting of No Drug Wastage

Effective July 1, 2023, Medicare will require the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. This policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B. The provider or supplier must file a claim with one line for the drug.

For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the Units field.[10]

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.[13] Payer policies may vary.

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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

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SAMPLE CLAIM FORMS (cont'd)

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

HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [ ] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (ID#)	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.	3. PATIENT'S BIRTH DATE MM DD YY: 07 01 50 SEX M [X] F [ ]
4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B.	
5. PATIENT'S ADDRESS (No., Street): 3914 Spruce Street	6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]
7. INSURED'S ADDRESS (No., Street): 3914 Spruce Street	
CITY: Anytown STATE: AS	8. RESERVED FOR NUCC USE
CITY: Anytown STATE: AS	
ZIP CODE: 01010 TELEPHONE (Include Area Code): (203) 555-1234	
ZIP CODE: 01010 TELEPHONE (Include Area Code): (203) 555-1234	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:
11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) YES [ ] NO [ ]
a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]	
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES [ ] NO [ ] PLACE (State)
b. OTHER CLAIM ID (Designated by NUCC)	
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES [ ] NO [ ]
c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare	10d. CLAIM CODES (Designated by NUCC)
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] *If yes*, complete items 9, 9a, and 9d.	
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM. 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. SIGNED _____ DATE _____	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 _____
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.	15. OTHER DATE QUAL. MM DD YY
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones	17a. 17b. NPI 123 456 7890
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. A. M06.00 B. C. D. E. F. G. H. I. J. K.	22. RESUBMISSION CODE ORIGINAL REF. NO.
	23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		J1602		A		180		NPI	123 456 7890
2 MM DD YY	MM DD YY	11		J1602	JW	A		20		NPI	123 456 7890
3 MM DD YY	MM DD YY	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.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ]	28. TOTAL CHARGE $	29. AMOUNT PAID $	30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED DATE	32. SERVICE FACILITY LOCATION INFORMATION a. b.		33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010 a. 123 456 7890 b.		

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

1 2 3 4 5 6

SAMPLE

Please see Important Safety Information on pages 20 and 21.
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Simponi ARIA® golimumab for infusion

SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab)
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 From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N457894035001 ML14.4											
MM DD YY	MM DD YY			J1602		A		180		NPI	123 456 7890
2											
										NPI	

ER INFORMATION

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.*

If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the same line as the drug code.[10]

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N457894035001 ML16											
MM DD YY	MM DD YY			J1602	JZ	A		200		NPI	123 456 7890
2											
										NPI	

ER INFORMATION

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 J&J withMe to confirm payer requirements. For additional resources, contact J&J withMe at 877-227-3728 or visit JNJwithMe.com.

Please see Important Safety Information on pages 20 and 21.
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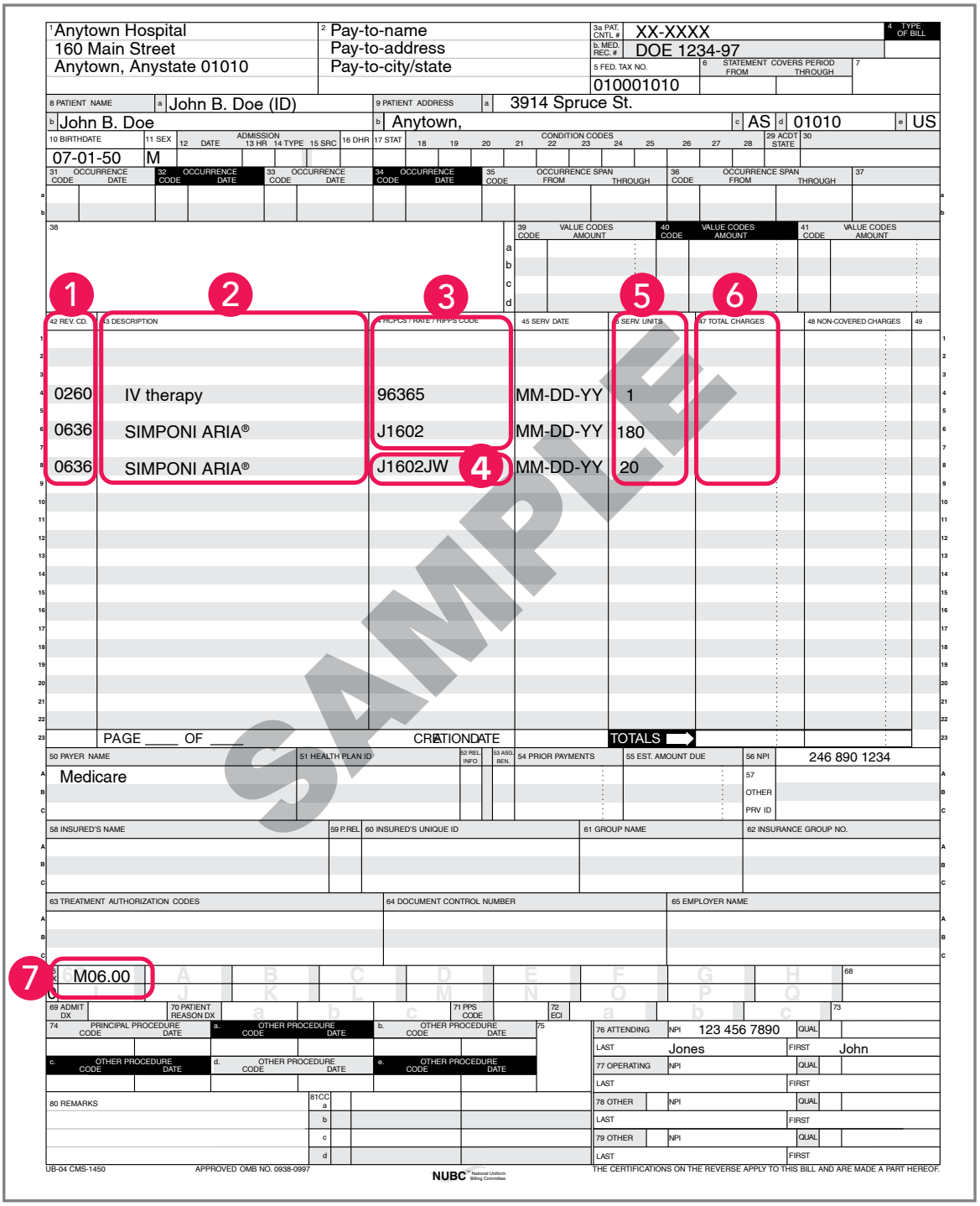
Simponi ARIA® golimumab for infusion

SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab)
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. CNTL # XX-XXXX b. MED. REC. # DOE 1234-97	4 TYPE OF BILL								
		5 FED. TAX NO. 010001010	6 STATEMENT COVERS PERIOD FROM THROUGH								
8 PATIENT NAME a John B. Doe (ID) b John B. Doe		9 PATIENT ADDRESS a 3914 Spruce St. b Anytown, c AS d 01010 e US									
10 BIRTHDATE 07-01-50	11 SEX M	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28		29 ACDT STATE	30
31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE	35 OCCURRENCE SPAN CODE FROM THROUGH		36 OCCURRENCE SPAN CODE FROM THROUGH		37			
38		39 VALUE CODES CODE AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT							

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0260	IV therapy	96365	MM-DD-YY	1			
0636	SIMPONI ARIA®	J1602	MM-DD-YY	180			
0636	SIMPONI ARIA®	J1602JW	MM-DD-YY	20			
	PAGE ____ OF ____	CREATION DATE		TOTALS			

50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	
Medicare						57 OTHER PRV ID	246 890 1234

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

67 M06.00 A B C D E F G H 68
I J K L M N O P Q

69 ADMIT DX	70 PATIENT REASON DX a b c	71 PPS CODE	72 ECI a b c	73

74 PRINCIPAL PROCEDURE CODE DATE	a. OTHER PROCEDURE CODE DATE	b. OTHER PROCEDURE CODE DATE	75
c. OTHER PROCEDURE CODE DATE	d. OTHER PROCEDURE CODE DATE	e. OTHER PROCEDURE CODE DATE	

76 ATTENDING	NPI 123 456 7890	QUAL	
LAST Jones		FIRST John	
77 OPERATING	NPI	QUAL	
LAST		FIRST	
78 OTHER	NPI	QUAL	
LAST		FIRST	
79 OTHER	NPI	QUAL	
LAST		FIRST	

80 REMARKS	81CC a b c d

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Please see Important Safety Information on pages 20 and 21.
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Simponi ARIA® golimumab for infusion

SAMPLE CLAIM FORMS (cont'd)

SIMPONI ARIA® (golimumab)
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.[14] 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.[11]

   *For informational purposes, JG and TB modifiers must be reported for all 340B-acquired drugs. Hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) report TB. All others report JG.[11]

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.*

   If there is no discarded drug or wastage, use the JZ modifier to attest that no amount of drug was discarded and eligible for payment. The modifier should only be used for claims that bill for drugs from single-dose containers. The modifier would be placed on the drug code line, immediately after the drug code with no spaces.[10]

4	0260	IV therapy	96365	MM-DD-YY	1			
5								
6	0636	SIMPONI ARIA®	J1602JZ	MM-DD-YY	200			

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 J&J withMe to confirm payer requirements. For additional resources, contact J&J withMe at 877-227-3728 or visit JNJwithMe.com.

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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.
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Once the clinical decision has been made to prescribe a J&J medicine, Johnson & Johnson has resources to help you support your patients.

J&J withMe Is Your Single Source for Access, Affordability, and Treatment Support for Your Patients

Access support to help navigate payer processes

J&J withMe helps verify insurance coverage for your patients taking SIMPONI ARIA® and provides reimbursement information.

Online benefits investigation and prior authorization support at **Portal.JNJwithMe.com**

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

J&J withMe can help you find out what affordability assistance may be available for your patients taking SIMPONI ARIA®.

Comprehensive Provider Portal to enroll eligible patients in the J&J withMe Savings Program and more at **Portal.JNJwithMe.com**

Treatment support to help your patients get informed and stay on SIMPONI ARIA®

J&J withMe provides additional support to your patients, including patient education, web-based resources, and personalized reminders.

Call your Case Manager team at 877-227-3728, Monday-Friday, 8:00 AM to 8:00 PM ET

Sign Up or Log In to the Provider Portal at Portal.JNJwithMe.com

Visit JNJwithMe.com

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe a J&J medicine.

Please see Important Safety Information on pages 20 and 21.
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Simponi ARIA® golimumab for infusion

Once the clinical decision has been made to prescribe a J&J medicine, Johnson & Johnson has resources to help you support your patients.

J&J withMe Savings Program

Eligible commercially insured patients can save on out-of-pocket medicine costs.

Add SIMPONI ARIA® to the patient account from your patient dashboard on the Provider Portal.

Request a benefits investigation for SIMPONI ARIA® to initiate the enrollment process.

Visit **Portal.JNJwithMe.com**

Support for patients using commercial or private insurance to pay for medicine:

- Eligible patients using commercial insurance pay as little as $5 per infusion for their SIMPONI ARIA® medicine
- Maximum program benefit per calendar year shall apply
- Savings may apply to co-pay, co-insurance, or deductible
- Offer subject to change or end without notice
- Program does not cover the cost to give patients their infusion
- Patients may participate without sharing their income information
- See program requirements at **SimponiAria.JNJwithMeSavings.com**

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe a J&J medicine.

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Simponi ARIA® golimumab for infusion

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 or download a sample letter template for SIMPONI ARIA® from JNJwithMe.com.

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

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 or name of individual responsible for prior authorization],

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, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with SIMPONI ARIA®

Note: Exercise your medical judgment 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 medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for SIMPONI ARIA® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[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 Healthcare Provider's Name and Participating Provider Number]

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

Please see Important Safety Information on pages 20 and 21.
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Simponi ARIA® golimumab for infusion

Johnson&Johnson

IMPORTANT SAFETY INFORMATION

Indications

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**
- **Active Psoriatic Arthritis (PsA) in patients 2 years of age and older**
- **Adult patients with active Ankylosing Spondylitis (AS)**
- **Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older**

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

Malignancies, some fatal, have been reported in children, adolescents, and young adult patients treated with golimumab. 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.

CONGESTIVE 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

Live vaccines or therapeutic infectious agents should not be given with SIMPONI ARIA® due to the possibility of clinical infections, including disseminated infections.

Update vaccinations prior to initiation of treatment in accordance with current vaccination guidelines. Advise patients to discuss with the physician before seeking any immunizations. At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants exposed *in utero* to SIMPONI ARIA®.

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 ≥ 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.

The adverse reactions observed in pediatric patients with polyarticular Juvenile Idiopathic Arthritis (pJIA) were consistent with the established safety profile of SIMPONI ARIA® in adult patients with RA and PsA.

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

cp-51207v3

Simponi ARIA® golimumab for infusion

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