Medical Policy Bulletin
Title:
Golimumab (Simponi Aria®) Intravenous (IV) Injection
Policy #:
MA08.070g

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status

MEDICALLY NECESSARY
Note: This policy only addresses Simponi Aria, the intravenous (IV) form of golimumab, which is covered under the medical benefits of the Company when the medical necessity criteria listed in this medical policy are met. This policy does not address Simponi®, the subcutaneous form of golimumab, which may be available under any applicable pharmacy benefit.

INITIAL THERAPY

Ankylosing Spondylitis (AS)

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of active AS when all of the following criteria are met:

- The individual is at least 18 years old.
- Documentation of failure, contraindication, or intolerance to either of the following:
    - At least a 4-week trial of two nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum recommended or tolerated anti-inflammatory dose.
    - At least a 3-month trial of one disease-modifying antirheumatic drug (DMARD) (e.g., sulfasalazine, methotrexate, hydroxychloroquine).
- Active or latent tuberculosis (TB) has been ruled out.

Immune Checkpoint Inhibitor–Related Toxicities

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the management of moderate or severe immunotherapy-related inflammatory arthritis when all of the following criteria are met:

- If no improvement after holding immunotherapy and treating with oral corticosteroids, or if unable to taper corticosteroids, or no response to conventional synthetic DMARDs (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)
- Active or latent TB has been ruled out.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of active pJIA when all of the following criteria are met:

- The individual is at least 2 years old.
- Documentation of failure, contraindication, or intolerance to at least 2 months of one DMARD (e.g., methotrexate).
- Active or latent TB has been ruled out.

Psoriatic Arthritis (PsA)
Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of active PsA when all of the following criteria are met:

- The individual is at least 2 years old.
- Documentation of failure, contraindication, or intolerance to either of the following:
- At least a 4-week trial of any NSAIDs at maximum recommended or tolerated anti-inflammatory dose
- At least a 3-month trial of one DMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine)
- Active or latent TB has been ruled out.

Rheumatoid Arthritis (RA)
Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the treatment of moderately to severely active RA in combination with methotrexate (MTX) (or a different DMARD when MTX is contraindicated or the individual is intolerant [e.g., sulfasalazine, hydroxychloroquine and leflunomide]) when all of the following criteria are met:

- The individual is at least 18 years old.
- The individual has persistent disease despite at least 3 months of MTX
- In individuals in whom MTX is contraindicated or the individual is intolerant to MTX, a 3-month trial of a different DMARD (e.g., sulfasalazine, hydroxychloroquine, and leflunomide) is acceptable
- Active or latent TB has been ruled out.

CONTINUATION THERAPY

Golimumab (Simponi Aria) is considered medically necessary and, therefore, covered for the continuation therapy when the individual meets all of the following:

Individual has met the medical necessity criteria for Initial Therapy
There is documentation of positive clinical response or stabilization to therapy (e.g., improvement in total active [swollen and tender] joint count from baseline, or improvement in symptoms [e.g., pain, stiffness, inflammation] from baseline)

EXPERIMENTAL/INVESTIGATIONAL

All other uses for golimumab (Simponi Aria) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested

information may result in a denial for the drug.

Guidelines

There is no Medicare coverage determination addressing this drug; therefore, the Company policy is applicable.

BLACK BOX WARNINGS

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, Golimumab (Simponi Aria®) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when golimumab (Simponi Aria®) is covered under a member's medical benefit (Part B benefit). It does not address instances when golimumab (Simponi Aria®) is covered under a member's pharmacy benefit (Part D benefit).

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Golimumab (Simponi Aria®) was approved by the FDA on July 18, 2013, for the treatment of adult individuals with moderately to severely active rheumatoid arthritis, in combination with MTX. Supplemental approvals for golimumab (Simponi Aria®) have since been issued by the FDA.

The safety and effectiveness of golimumab (Simponi Aria®) have been established in pediatric individuals 2 years of age and older with active polyarticular juvenile idiopathic arthritis and psoriatic arthritis.

Description

Tumor necrosis factor (TNF) is a naturally occurring cytokine that is involved in inflammatory and immune responses. Elevated TNF levels in the blood, synovium, and joints have been implicated in the pathophysiology of ankylosing spondylitis (AS), psoriatic arthritis (PsA), and rheumatoid arthritis (RA). TNF is an important mediator of the articular inflammation that is characteristic of these diseases. Golimumab (Simponi Aria®) modulated the *in vitro* biological effects mediated by TNF in several bioassays, including the expression of adhesion proteins responsible for leukocyte infiltration (E-selectin, intercellular adhesion molecule [ICAM]-1, and vascular cell adhesion molecule [VCAM]-1) and the secretion of proinflammatory cytokines (interleukin [IL]-6, IL-8, granulocyte colony-stimulating factor [G-CSF] and granulocyte-macrophage colony-stimulating factor [GM-CSF]).

Golimumab (Simponi Aria®) is a human monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human tumor necrosis factor-alpha (TNF-α). This interaction prevents the binding of TNF-α to its receptors, thereby inhibiting the biological activity of TNF, a cytokine protein.

Note: Golimumab (Simponi Aria®) is an intravenous formulation that was approved by the US Food and Drug Administration (FDA) on July 18, 2013. There is also a subcutaneous formulation that was approved by the FDA on April 24, 2009.

ANKYLOSING SPONDYLITIS (AS)

The spondyloarthritis (SpA) category of conditions are broken down into two major subtypes: ankylosing spondylitis (AS) and nonradiographic axial SpA (nr-axSpA). AS is a chronic inflammatory disease manifested by back pain and progressive spinal stiffness. AS characteristically affects young adults with a peak age of onset between 20 and 30 years. Although classically thought of as a spinal disease, transient acute arthritis of peripheral joints occurs in up to 50% of affected individuals. In addition, other organs such as the eyes, lungs, heart, and kidneys can be affected.

The US Food and Drug Administration (FDA) approved the intravenous (IV) form of golimumab (Simponi Aria®) on October 20, 2017, for the treatment of adults with active AS.

The safety and efficacy of golimumab (Simponi Aria®) was studied in a phase III, randomized, double-blind, placebo-controlled trial in 208 adults with active AS who had an inadequate response or intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs) (Deodhar et al., 2018). Participants were randomly assigned (1:1) to receive IV infusions of golimumab (Simponi Aria®) at weeks 0, 4, 12, and every 8 weeks, or placebo at weeks 0, 4, and 12, with crossover to golimumab (Simponi Aria®) at week 16. The primary outcome was the clinical response, measured using the American College of Rheumatology (ACR) response criteria. The results are reported as a percentage of study participants who achieve ACR20 (20% improvement in swollen joints) at week 16. The results showed a statistically significant improvement in the golimumab (Simponi Aria®) group (73% of participants) when compared with the placebo group (26% of participants) (P<0.001).

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA)

Polyarticular juvenile idiopathic arthritis (pJIA) is a subset of JIA and comprises 20% to 30% of all individuals with JIA. The diagnosis of pJIA is made when five or more joints are affected in the first 6 months after disease onset. Management of pJIA may include medications such as corticosteroids, NSAIDs, or disease-modifying antirheumatic drugs (DMARDs), including immunomodulators or biologic agents.

The FDA approved the IV form of golimumab (Simponi Aria®), on September 29, 2020, for the treatment of pediatric individuals 2 years of age and older for the treatment of active pJIA.

The efficacy of golimumab (Simponi Aria®) in pediatric individuals with pJIA was based on the pharmacokinetic exposure and extrapolation of the established efficacy of golimumab (Simponi Aria®) in individuals with RA. The efficacy was also assessed in a multicenter, open-label, single-arm study in 127 children (2 to <18 years of age) with JIA with active polyarthritis despite treatment with MTX for at least 2 months (Trial pJIA, NCT02277444). The pJIA subtypes included in the study were as follows: rheumatoid factor negative (43%), rheumatoid factor positive (35%), enthesitis-related arthritis (9%), oligoarticular extended (6%), juvenile psoriatic arthritis (4%), and systemic JIA without systemic manifestations (3%). All individuals received golimumab (Simponi Aria®) 80 mg/m^2 as an intravenous infusion at week 0, 4, and every 8 weeks through week 52. Participants continued stable doses of MTX weekly through week 28; after week 28, changes in MTX dose were permitted. Efficacy was assessed as supportive endpoints through Week 52. The efficacy was generally consistent with responses in individuals with RA.

PSORIATIC ARTHRITIS (PsA)

Psoriatic arthritis (PsA) is an inflammatory arthritis associated with psoriasis. Similarly to rheumatoid arthritis, those with PsA present with pain and stiffness in the affected joints. Morning stiffness lasting more than 30 minutes occurs in one-half of patients. The stiffness is accentuated with prolonged immobility and is alleviated by physical activity. A history of psoriasis is present in about 70% of patients presenting with arthritis.

The FDA approved the IV form of golimumab (Simponi Aria®), on October 20, 2017, for the treatment of adults with active PsA.

The safety and efficacy of golimumab (Simponi Aria®) was studied in a phase III, randomized, double-blind, placebo-controlled trial in 480 adults with active PsA (Kavanaugh et al., 2017). Participants had previously received DMARD therapy (≥3 months) and/or NSAID therapy (≥4 weeks) or demonstrated intolerance to these agents. Participants were randomly assigned (1:1) to receive golimumab (Simponi Aria®) or placebo at weeks 0, 4, 12, and 20. The primary outcome of the study was the percentage of participants who met the ACR 20% improvement criteria (achieving an ACR20 response) at week 14. The results showed a statistically significant improvement in the golimumab (Simponi Aria®) group (75% of participants) when compared with the placebo group (22% of participants) (P<0.001).

The efficacy of golimumab (Simponi Aria®) in pediatric individuals with PsA was based on the pharmacokinetic exposure and extrapolation of the established efficacy of golimumab (Simponi Aria®) in adults with PsA.

RHEUMATOID ARTHRITIS (RA)

Rheumatoid arthritis (RA) is an autoimmune disease that results in a chronic and systemic inflammatory disorder that affects tissues and organs. RA can cause pain, stiffness, swelling, and limited motion and function of many joints. In RA, the focus of the inflammation is in the synovium, the tissue that lines the joint. Immune cells release inflammation-causing chemicals. These chemicals can damage cartilage (the tissue that cushions between joints)

and bone.

The FDA approved an IV form of golimumab (Simponi Aria®) on July 18, 2013, for the treatment of adult individuals with moderately to severely active RA, in combination with methotrexate (MTX).

The FDA's approval of golimumab (Simponi Aria®) is based on a double-blind, placebo-controlled clinical study involving 592 individuals. The study participants were 18 years and older, with moderately to severely active RA, who were simultaneously treated with MTX. The individuals in the study were diagnosed with RA according to the ACR classification criteria 3 months prior to the start of the study. All participants were required to have at least six swollen and six tender joints. These individuals were randomly assigned into either the treatment group (n=395) or the placebo group (n=197). Individuals in the treatment group received golimumab (Simponi Aria®) with MTX. The golimumab (Simponi Aria®) dose regimen administered was 2 mg/kg given as an intravenous infusion at weeks 0 and 4, then every 8 weeks thereafter. The placebo group received a placebo with MTX up until week 24. After week 24, individuals in the placebo group, while still blinded, received golimumab (Simponi Aria®) and MTX through week 52.

All participants completed 52 weeks of treatment. Participants were able to continue stable doses of concurrent low-dose corticosteriods (≤10 mg of prednisone a day). The use of other DMARDS, including cytotoxic agents or other biologics, was prohibited.

The clinical response was measured using the ACR response criteria for RA. The ACR criteria are used, in most clinical trials, to assess efficacy of the treatment for RA. The results are reported as a percentage of study participants who achieve ACR20 (20% improvement in swollen joints), ACR50 (50% improvement), and ACR70 (70% improvement) in three of the five criteria:

- Acute phase reactant (e.g., sedimentation rate)
- Patient assessment
- Physician assessment
- Pain scale
- Disability/functional questionnaire

Fifty-nine percent of participants in the golimumab (Simponi Aria®) and MTX group achieved an ACR20 at week 14, with 63% achieving ACR20 at week 24. Twenty-five percent of participants in the placebo group achieved an ACR20 at week 14, with 32% achieving ACR20 at week 24. A higher percentage of participants in the treatment group achieved ACR50 and ACR70 when compared with the placebo group at weeks 14 and 24.

The data revealed that treatment with golimumab (Simponi Aria®) plus MTX significantly improved signs and symptoms and physical function at week 24, and inhibited the progression of structural damage in individuals with moderate to severe RA at weeks 24 and 52. A greater percentage of individuals who received golimumab (Simponi Aria®) and MTX had improvements in their RA when compared with the placebo group.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
MEDICALLY NECESSARY

L40.50 Arthropathic psoriasis, unspecified
L40.51 Distal interphalangeal psoriatic arthropathy
L40.52 Psoriatic arthritis mutilans
L40.53 Psoriatic spondylitis
L40.54 Psoriatic juvenile arthropathy
L40.59 Other psoriatic arthropathy
M05.7A Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
M05.8A Other rheumatoid arthritis with rheumatoid factor of other specified site
M05.00 Felty's syndrome, unspecified site
M05.011 Felty's syndrome, right shoulder
M05.012 Felty's syndrome, left shoulder
M05.021 Felty's syndrome, right elbow
M05.022 Felty's syndrome, left elbow
M05.031 Felty's syndrome, right wrist
M05.032 Felty's syndrome, left wrist

M05.041 Felty's syndrome, right hand
M05.042 Felty's syndrome, left hand
M05.051 Felty's syndrome, right hip
M05.052 Felty's syndrome, left hip
M05.061 Felty's syndrome, right knee
M05.062 Felty's syndrome, left knee
M05.071 Felty's syndrome, right ankle and foot
M05.072 Felty's syndrome, left ankle and foot
M05.09 Felty's syndrome, multiple sites
M05.10 Rheumatoid lung disease with rheumatoid arthritis of unspecified site
M05.111 Rheumatoid lung disease with rheumatoid arthritis of right shoulder
M05.112 Rheumatoid lung disease with rheumatoid arthritis of left shoulder
M05.121 Rheumatoid lung disease with rheumatoid arthritis of right elbow
M05.122 Rheumatoid lung disease with rheumatoid arthritis of left elbow
M05.131 Rheumatoid lung disease with rheumatoid arthritis of right wrist
M05.132 Rheumatoid lung disease with rheumatoid arthritis of left wrist
M05.141 Rheumatoid lung disease with rheumatoid arthritis of right hand
M05.142 Rheumatoid lung disease with rheumatoid arthritis of left hand
M05.151 Rheumatoid lung disease with rheumatoid arthritis of right hip
M05.152 Rheumatoid lung disease with rheumatoid arthritis of left hip
M05.161 Rheumatoid lung disease with rheumatoid arthritis of right knee
M05.162 Rheumatoid lung disease with rheumatoid arthritis of left knee
M05.171 Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot
M05.172 Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot
M05.19 Rheumatoid lung disease with rheumatoid arthritis of multiple sites
M05.20 Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211 Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212 Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.221 Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222 Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.231 Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232 Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.241 Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242 Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.251 Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252 Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.261 Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262 Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.271 Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272 Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.29 Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30 Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311 Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312 Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.321 Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322 Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.331 Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332 Rheumatoid heart disease with rheumatoid arthritis of left wrist

M05.341 Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342 Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.351 Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352 Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.361 Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362 Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.371 Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372 Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.39 Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40 Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411 Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412 Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.421 Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422 Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.431 Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432 Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.441 Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442 Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.451 Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452 Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.461 Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462 Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.471 Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472 Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.49 Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50 Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511 Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512 Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.521 Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522 Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.531 Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532 Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.541 Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542 Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.551 Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552 Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.561 Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562 Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.571 Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572 Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.59 Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60 Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611 Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612 Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.621 Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622 Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.631 Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632 Rheumatoid arthritis of left wrist with involvement of other organs and systems

M05.641 Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642 Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.651 Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652 Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.661 Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662 Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.671 Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672 Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.69 Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70 Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711 Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712 Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.721 Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722 Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.731 Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732 Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.741 Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742 Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.751 Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752 Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.761 Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762 Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.771 Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772 Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.79 Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.80 Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811 Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812 Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.821 Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822 Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.831 Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832 Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.841 Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842 Other rheumatoid arthritis with rheumatoid factor of left hand
M05.851 Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852 Other rheumatoid arthritis with rheumatoid factor of left hip
M05.861 Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862 Other rheumatoid arthritis with rheumatoid factor of left knee
M05.871 Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872 Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.89 Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9 Rheumatoid arthritis with rheumatoid factor, unspecified
M05.A Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M06.0A Rheumatoid arthritis without rheumatoid factor, other specified site
M06.8A Other specified rheumatoid arthritis, other specified site
M06.00 Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011 Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012 Rheumatoid arthritis without rheumatoid factor, left shoulder

M06.021 Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022 Rheumatoid arthritis without rheumatoid factor, left elbow
M06.031 Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032 Rheumatoid arthritis without rheumatoid factor, left wrist
M06.041 Rheumatoid arthritis without rheumatoid factor, right hand
M06.042 Rheumatoid arthritis without rheumatoid factor, left hand
M06.051 Rheumatoid arthritis without rheumatoid factor, right hip
M06.052 Rheumatoid arthritis without rheumatoid factor, left hip
M06.061 Rheumatoid arthritis without rheumatoid factor, right knee
M06.062 Rheumatoid arthritis without rheumatoid factor, left knee
M06.071 Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072 Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.08 Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09 Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.4 Inflammatory polyarthropathy
M06.80 Other specified rheumatoid arthritis, unspecified site
M06.811 Other specified rheumatoid arthritis, right shoulder
M06.812 Other specified rheumatoid arthritis, left shoulder
M06.821 Other specified rheumatoid arthritis, right elbow
M06.822 Other specified rheumatoid arthritis, left elbow
M06.831 Other specified rheumatoid arthritis, right wrist
M06.832 Other specified rheumatoid arthritis, left wrist
M06.841 Other specified rheumatoid arthritis, right hand
M06.842 Other specified rheumatoid arthritis, left hand
M06.851 Other specified rheumatoid arthritis, right hip
M06.852 Other specified rheumatoid arthritis, left hip
M06.861 Other specified rheumatoid arthritis, right knee
M06.862 Other specified rheumatoid arthritis, left knee
M06.871 Other specified rheumatoid arthritis, right ankle and foot
M06.872 Other specified rheumatoid arthritis, left ankle and foot
M06.88 Other specified rheumatoid arthritis, vertebrae
M06.89 Other specified rheumatoid arthritis, multiple sites
M06.9 Rheumatoid arthritis, unspecified
M08.3 Juvenile rheumatoid polyarthritis (seronegative)
M45.0 Ankylosing spondylitis of multiple sites in spine
M45.1 Ankylosing spondylitis of occipito-atlanto-axial region
M45.2 Ankylosing spondylitis of cervical region
M45.3 Ankylosing spondylitis of cervicothoracic region
M45.4 Ankylosing spondylitis of thoracic region
M45.5 Ankylosing spondylitis of thoracolumbar region
M45.6 Ankylosing spondylitis lumbar region
M45.7 Ankylosing spondylitis of lumbosacral region
M45.8 Ankylosing spondylitis sacral and sacrococcygeal region
M45.9 Ankylosing spondylitis of unspecified sites in spine

HCPCS Level II Code Number(s)

J1602 Injection, golimumab, 1mg, for intravenous use

Revenue Code Number(s)

N/A

Policy History

Revisions From MA08.070g:

12/15/2025	This version of the policy will become effective 12/15/2025. The following ICD-10 CM codes have been added to this policy: M05.A Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis

Revisions From MA08.070f:

03/28/2025	The policy has been reviewed and reissued to communicate the Company's continuing position on golimumab (Simponi Aria®) Intravenous (IV) Injection.
05/07/2024	The policy has been reviewed and reissued to communicate the Company's continuing position on golimumab (Simponi Aria®) Intravenous (IV) Injection.
10/30/2023	This version of the policy will become effective 10/30/2023. This policy has been updated to communicate the Company's coverage position for Immune Checkpoint Inhibitor-Related Toxicities, in accordance with the National Comprehensive Cancer Network (NCCN). Additionally, Continuation Therapy was added as a policy criterion. The following ICD-10 CM code has been **added** to this policy: M06.4 Inflammatory polyarthropathy The following ICD-10 CM codes for Felty's syndrome and rheumatoid arthritis have been **deleted** from this policy, due to unspecified laterality: M05.019, M05.029, M05.039, M05.049, M05.059, M05.069, M05.079, M05.119, M05.129, M05.139, M05.149, M05.159, M05.169, M05.179, M05.219, M05.229, M05.239, M05.249, M05.259, M05.269, M05.279, M05.319, M05.329, M05.339, M05.349, M05.359, M05.369, M05.379, M05.419, M05.429, M05.439, M05.449, M05.459, M05.469, M05.479, M05.519, M05.529, M05.539, M05.549, M05.559, M05.569, M05.579, M05.619, M05.629, M05.639, M05.649, M05.659, M05.669, M05.679, M05.719, M05.729, M05.739, M05.749, M05.759, M05.769, M05.779, M05.819, M05.829, M05.839, M05.849, M05.859, M05.869, M05.879, M06.019, M06.029, M06.039, M06.049, M06.059, M06.069, M06.079, M06.819, M06.829, M06.839, M06.849, M06.859, M06.869, M06.879.

Revisions from MA08.070e:

10/05/2022	The policy has been reviewed and reissued to communicate the Company's continuing position on golimumab (Simponi Aria®) Intravenous (IV) Injection.
09/08/2021	This policy has been reissued in accordance with the Company's annual review process.
12/21/2020	This policy has been updated to communicate the Company's coverage position in accordance with the newly FDA-approved indication for active polyarticular juvenile idiopathic arthritis (pJIA) in

	individuals 2 years of age and older. Additionally, the FDA approved the expanded age for psoriatic arthritis (PsA) indication from 18 years and older to 2 years of age and older. The following ICD-10 codes were **added** to Attachment A (Coding Table) of this policy: L40.54 Psoriatic juvenile arthropathy M08.3 Juvenile rheumatoid polyarthritis (seronegative)

Revisions from MA08.070d:

10/01/2020	This policy has been identified for the ICD-10 CM code update, effective 10/01/2020. The following ICD-10 CM codes have been **added** to this policy: M05.7A Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement M05.8A Other rheumatoid arthritis with rheumatoid factor of other specified site M06.0A Rheumatoid arthritis without rheumatoid factor, other specified site M06.8A Other specified rheumatoid arthritis, other specified site

Revisions from MA08.070c:

03/13/2019	This policy has been reissued in accordance with the Company's annual review process.
03/07/2018	This policy has undergone a routine review, and the medical necessity criteria have been revised as follows: Two new FDA-approved indications, ankylosing spondylitis and psoriatic arthritis, have been added to this policy.

Revisions from MA08.070b:

07/12/2017	This policy was updated to include Medically Necessary criteria to rule out tuberculosis prior to therapy.

Revisions from MA08.070a:

12/28/2016	This version of the policy will become effective **12/28/2016.** • The following policy requirements have been **revised**: **FROM:** Golimumab (Simponi® Aria™) (IV), in combination with methotrexate, is considered medically necessary and, therefore, covered for the treatment of moderately to severely active rheumatoid arthritis (RA) in adults 18 years of age who have failed at least 3 months of methotrexate. **TO:** Golimumab (Simponi Aria®) is considered medically necessary and, therefore, covered for the treatment of moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX) (or a different DMARD when MTX is contraindicated or the individual is intolerant (e.g., sulfasalazine, hydroxychloroquine and leflunomide) when both of the following criteria are met: o The individual is at least 18 years old o The individual has persistent disease despite at least three months of MTX In individuals where MTX is contraindicated or the individual is intolerant to MTX a 3 month trial of a different disease modifying antirheumatic drugs (DMARDs) (e.g., sulfasalazine, hydroxychloroquine and leflunomide) is acceptable. • The following ICD-10 codes have been **added** to this policy: M05.019, M05.029, M05.039, M05.049, M05.059, M05.069, M05.079, M05.10, M05.111, M05.112, M05.119, M05.121, M05.122, M05.129, M05.131, M05.132, M05.139, M05.141, M05.142, M05.149, M05.151, M05.152, M05.159, M05.161, M05.162, M05.169, M05.171, M05.172, M05.179, M05.19, M05.219, M05.229, M05.239, M05.249,

	M05.259, M05.269, M05.279, M05.319, M05.329, M05.339, M05.349, M05.359, M05.369, M05.379, M05.40, M05.419, M05.429, M05.439, M05.449, M05.459, M05.469, M05.479, M05.519, M05.529, M05.539, M05.549, M05.559, M05.569, M05.579, M05.619, M05.629, M05.639, M05.649, M05.659, M05.679, M05.719, M05.729, M05.739, M05.749, M05.759, M05.769, M05.779, M05.819, M05.829, M05.839, M05.849, M05.859, M05.869, M05.879, M06.019, M06.029, M06.039, M06.049, M06.059, M06.069, M06.079, M06.819, M06.829, M06.839, M06.849, M06.859, M06.869, M06.879

Revisions from MA08.070:

05/27/2015	The policy has been reviewed and reissued to communicate the Company's continuing position on Golimumab (Simponi® Aria™) Intravenous (IV) Injection.
01/01/2015	This is a new policy.

Version Effective Date:
12/15/2025
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N/A