Simponi (golimumab),
Simponi ARIA (golimumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications
Simponi (golimumab) Simponi Aria (golimumab)

Medication	Dosing/Quantity Limit
Simponi (golimumab) 50mg/0.5 mL SmartJect autoinjector/prefilled syringe	1 autoinjector/syringe per 28 days
Simponi (golimumab) 100mg/1 mL SmartJect autoinjector*/prefilled syringe*	1 autoinjector/syringe per 28 days
Simponi (golimumab) 100mg/1 mL prefilled syringe*	1 syringe per 28 days
Simponi Aria (golimumab) 50 mg vial**	Adult (≥18 years): 2 mg/kg as frequently as every 8 weeks Pediatric (<18 years): 80 mg/m^2 as frequently as every 8 weeks

*Initiation of therapy for Ulcerative Colitis (UC): May approve up to 2 (two) additional syringes or autoinjectors (100 mg/1 mL) in the first month (28 days) of treatment.

*For UC, may approve increased dosing, up to 200 mg (two 100 mg syringes/autoinjectors) every 4 weeks if the following criteria are met:

A. Individual has been treated with standard maintenance dosing (i.e. 100 mg every 4 weeks) for *at least* 4 doses or 16 weeks; **AND**
B. The increased dosing is being prescribed by or in consultation with a gastroenterologist;
   AND
C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber;
   AND
E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
F. Requested dosing does not exceed up to 200 mg (two 100 mg syringes/autoinjectors) every 4 weeks.

Initial approval duration for increased dosing for UC: 16 weeks

*Requests for continued escalated dosing for UC may be approved if the following criteria are met:

A. Requested dosing does not exceed up to 200 mg (two 100 mg syringes/autoinjectors) every 4 weeks; **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for UC: 6 months

*For UC, Increased dosing may not be approved for the following:

A. Individual has had no response to Simponi at standard maintenance dosing (i.e. 100 mg every 4 weeks); **OR**
B. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

Dosing Override Criteria (Simponi Aria):

**For initiation of therapy, may approve up to 2 mg/kg (or 80 mg mg/m^2 for individuals <18 years of age) at weeks 0 and 4.

APPROVAL CRITERIA

Initial requests for Simponi (golimumab) may be approved for the following:

I. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe UC; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
   C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**

C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

Initial requests for Simponi Aria (golimumab) may be approved for the following:

I. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
A. Individual is 2 years of age or older with moderate to severe PJIA;
AND
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019); **OR**
C. Individual has a contraindication to methotrexate;

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
A. Individual is 2 years of age or older with moderate to severe PsA;
AND
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

Initial requests for Simponi (golimumab) and Simponi Aria (golimumab) may be approved for the following:

I. Ankylosing spondylitis (AS) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe AS;
AND
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)]; **OR**
C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe RA;
AND
B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021);
OR
C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine.

OR

III. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
    A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs.

Continuation requests for Simponi and Simponi Aria (golimumab) may be approved if the following criterion is met:

I. Individual has been receiving and is maintained on a stable dose of Simponi/Simponi Aria; **AND**
II. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Simponi (golimumab) and Simponi Aria (golimumab) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Preventions -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Note:
TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

Key References:

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13. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheum. 2022; 74(4):553-569.
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15. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care & Research. 2011; 63(4):465-482

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.