SIMPONI / SIMPONI ARIA
(golimumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tumor necrosis factor-alpha (TNF-α) is a protein produced by the body's immune system. In certain autoimmune diseases, such as rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis, there is an overproduction of TNF-α which causes the immune system to attack parts of the body (1). Simponi and Simponi Aria work by binding to the tumor necrosis factor (TNF), preventing the binding of TNF-α to its receptors and reducing inflammation (2-3).

Regulatory Status

FDA-approved indications: Simponi and Simponi Aria are tumor necrosis factor (TNF) blockers indicated for the treatment of: (2-3)

1. Rheumatoid Arthritis (RA) - **Simponi** and **Simponi Aria**, in combination with methotrexate, are indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis

2. Psoriatic Arthritis (PsA) - **Simponi** and **Simponi Aria**, alone or in combination with methotrexate other non-biologic Disease-modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis. Simponi is only indicated in adults while Simponi Aria is indicated in patients 2 years of age and older

3. Ankylosing Spondylitis (AS) - **Simponi** and **Simponi Aria** alone or in combination with methotrexate other non-biologic Disease-modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of adult patients with active ankylosing spondylitis (and axial spondyloarthritis)

4. Ulcerative Colitis (UC) - **Simponi** is indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, achieving and sustaining clinical remission in induction responders

5. <u>Polyarticular Juvenile Idiopathic Arthritis (pJIA)</u> - **Simponi Aria** is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Simponi and Simponi Aria carry boxed warnings regarding serious infections and malignancies. Because Simponi and Simponi Aria suppress the immune system, patients are at a greater risk for getting serious infections leading to hospitalization or death, including tuberculosis (TB), invasive fungal infections, and infections due to other opportunistic pathogens. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers (2-3).

Patients should be screened for latent tuberculosis infection. Patients at risk for hepatitis B virus (HBV) infection should be evaluated for evidence of prior HBV infection. Hepatitis B virus carriers should be monitored for reactivation during and several months after therapy. Simponi and Simponi Aria should not be used in combination with other biologic agents. Simponi and Simponi Aria should not be initiated in patients with an active infection. Simponi and Simponi Aria should be discontinued if a patient develops a serious infection during treatment (2-3).

For the treatment of RA, Simponi and Simponi Aria should be used with methotrexate (MTX) or other conventional disease modifying anti-rheumatic drugs (DMARD). Since the presence or absence of concomitant MTX did not appear to influence the efficacy or safety of Simponi and Simponi Aria in the treatment of PsA or AS, Simponi and Simponi Aria can be used with or without MTX in the treatment of PsA and AS (2-3).

An increased risk of serious infections has been seen in clinical RA trials of other TNF-blockers used in combination with anakinra or abatacept, with no added benefit; therefore, use of Simponi and Simponi Aria with abatacept or anakinra is not recommended. 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 and Simponi Aria with biologics is not recommended because of the possibility of an increased risk of infection (2-3).

The safety and effectiveness of Simponi in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have been established in pediatric patients 2 years of

age and older (2-3).

Summary

Simponi and Simponi Aria are tumor necrosis factor (TNF) blockers indicated for the treatment of patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Simponi is also indicated in adult patients with ulcerative colitis (UC), and Simponi Aria is indicated in patients with polyarticular juvenile idiopathic arthritis (pJIA). Simponi and Simponi Aria carry boxed warnings regarding the increased risk of serious infections and malignancies. The safety and effectiveness of Simponi in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for active polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have been established in pediatric patients 2 years of age and older (2-3).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Simponi and Simponi Aria while maintaining optimal therapeutic outcomes.

References

1. American College of Rheumatology. American College of Rheumatology website. http://www.rheumatology.org/practice/clinical/patients/medications/anti_tnf.asp.
2. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
3. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.