Wellmark Advantage Health Plan

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Effective Date: 12/01/2022

Simponi Aria® (golimumab)

HCPCS: J1602

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. Diagnosis of rheumatoid arthritis (RA):
      i. Trial and failure of at least a 3-month trial of one disease-modifying anti-rheumatic drug (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine
      ii. Used in combination with methotrexate (unless contraindicated)
   c. Diagnosis of psoriatic arthritis (PsA)
   d. Diagnosis of ankylosing spondylitis (AS)
   e. Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)
      i. Trial and failure of at least a 3-month trial of one DMARD unless contraindicated or not tolerated. Examples include methotrexate and leflunomide
   f. Not to be used in combination with other biologics or targeted DMARDs
   g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in Wellmark Advantage Health Plan's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: Align with FDA recommended dosing
   b. Initial Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Simponi Aria (golimumab) is a tumor necrosis factor inhibitor (TNFi) indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA; in combination with methotrexate) or active ankylosing spondylitis, and for pediatric patients 2 years of age and older with active psoriatic arthritis or active polyarticular juvenile idiopathic arthritis.

- The use of Simponi Aria in combination with other biologic agents or targeted disease-modifying antirheumatic drugs is not recommended due to an increased risk of infection and a lack of robust safety and efficacy data to support combination use.

- Ankylosing Spondylitis

    - Axial spondyloarthritis, comprising ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (NRAS), is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

    - The 2019 American College of Rheumatology recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with nonsteroidal anti-inflammatory drugs (NSAIDS), treatment with tumor necrosis factor inhibitors (TNFi) are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient.

    - Cosentyx® (secukinumab) or Taltz® (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class.

- Rheumatoid Arthritis

    - The 2021 American College of Rheumatology (ACR) Guidelines for the Treatment of Rheumatoid Arthritis (RA) established recommendations for the care of adult RA patients. The guidelines state that treatment decisions should follow a shared decision-making process and should be reevaluated within a minimum of 3 months based on the efficacy and tolerability of the DMARD(s) chosen.

    - For the initial treatment of symptomatic RA, the guidelines strongly recommend the use of conventional synthetic DMARD (csDMARD) monotherapy in those who are DMARD-naive. csDMARD monotherapy is a less costly first line treatment option with an extensive safety record accompanied by well-documented clinical efficacy and a large body of clinical experience and familiarity among prescribers. csDMARDs in the guidelines refer to methotrexate (MTX), hydroxychloroquine, leflunomide (LEF), and sulfasalazine. Azathioprine, cyclosporine, minocycline, and gold were not included due to their infrequent use in RA and lack of new data since the prior guidelines were published. Oral MTX is recommended as the preferred initial DMARD for patients with moderate-to-high disease activity, and hydroxychloroquine is recommended as the preferred initial DMARD for patients with low disease activity.

    - If disease activity remains moderate or high despite optimal dosing of methotrexate monotherapy, the use of dual therapy with methotrexate plus biologic DMARD (bDMARD; etanercept, adalimumab, infliximab, golimumab, certolizumab pegol, abatacept, tocilizumab, sarilumab, rituximab) or targeted synthetic DMARD

(tsDMARD; tofacitinib, baricitinib, upadacitinib) therapy is conditionally recommended over the use of triple therapy (i.e., addition of sulfasalazine and hydroxychloroquine). The guidelines do not inform preference of bDMARD over tsDMARD therapy, or vice-versa, for use in combination with methotrexate. No one agent has been shown to be superior to another. The guidelines do acknowledge the emergence of safety signals for the JAK inhibitor class (tsDMARD), and state that further modification of this recommendation may be necessary as additional data are published.

- A treat-to-target approach is conditionally recommended over usual care for patients who have had an inadequate response to bDMARDs or tsDMARDs. Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modification of treatment to minimize disease activity with the goal of reaching a pre-defined target (low disease activity or remission)

- Psoriatic Arthritis

  - PsA is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.

  - Per the 2018 American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF) guideline for the treatment of psoriatic arthritis, all recommendations for treatment-naive patients with active PsA are conditional based on low- to very-low quality evidence.

  - In treatment-naïve patients, oral systemic medications (OSMs), such as methotrexate, sulfasalazine, cyclosporine, and leflunomide, may be used in patients without severe psoriatic arthritis and without severe psoriasis. OSMs have robust longitudinal safety and efficacy data in patients with PsA. Maximal response to OSMs are most commonly achieved within 3 months of therapy.

  - If PsA remains active despite OSM therapy, switching to a TNFi, an IL-17i, or an IL-12/23i biologic is recommended over switching to a different OSM; switching to a TNFi biologic over an IL-17i or IL-12/23i biologic is conditionally recommended in this scenario based on moderate quality evidence. The detailed recommendations for subsequent therapies can be found in the 2018 ACR/NPF guideline for the treatment of psoriatic arthritis.

- Juvenile Idiopathic Arthritis

  - Juvenile idiopathic arthritis (JIA) defines a collection of inflammatory arthritides of unknown etiology. Onset is prior to 16 years of age with a minimum duration of 6 weeks and other potential causes of synovitis are excluded. JIA can be subdivided into polyarticular JIA and systemic JIA.

  - pJIA is defined by the presence of more than 4 affected joints in the first 6 months of illness and comprises 20-30% of children with JIA. Therapy is directed toward treating the underlying inflammation and preventing JIA-associated complications and adverse effects of its treatment.

  - The 2019 American College of Rheumatology/Arthritis Foundation (ACR/AF) guideline for the treatment of JIA strongly recommends initial therapy for pJIA with a disease-modifying anti-rheumatic agent (DMARD) such as methotrexate (MTX) or leflunomide. MTX is conditionally recommended over leflunomide as it has a greater volume of data supporting its effectiveness compared to leflunomide and can be administered

subcutaneously (recommended) or orally. The guidelines consider an adequate trial of a DMARD to be 3 months.

- If moderate or high disease activity persists despite DMARD use, the ACR/AF guidelines recommend biologic agents either in combination with a DMARD or as monotherapy in certain situations. Biologic agents FDA approved for pJIA in patients 2 years of age and older include Humira® (adalimumab), Enbrel® (etanercept), Actemra® (tocilizumab), Orencia® (abatacept), Simponi Aria® (golimumab), Xeljanz® (tofacitinib), and Xeljanz (tofacitinib) oral solution.

    - Of note, biologic therapy may be an appropriate initial therapy option in certain pJIA patients with risk factors and involvement of high-risk joints, high disease activity, and/or for those judged to be at high risk of disabling joint damage

- There is the most experience with TNFi (Humira, Enbrel, Simponi Aria) as initial biologic therapy; however, the preferred class of initial biologic is not specified in the guideline recommendations due to a lack of comparative data and the consideration that non-TNFi biologics may be preferred in certain patient-specific scenarios.

- If a TNFi is started as the initial biologic, switching to a non-TNFi (tocilizumab or abatacept) is recommended over switching to a second TNFi. An exception to this is for those who had a good initial response to the first TNFi.

References:

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Policy History		
#	Date	Change Description
1.1	Effective Date: 12/01/2022	Annual review of criteria performed, no changes were made
1.0	Effective Date: 01/01/2022	Effective date of policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*