

STANDARD MEDICARE PART B MANAGEMENT

SIMPONI ARIA (golimumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate
2. Treatment of active psoriatic arthritis in patients 2 years of age and older
3. Treatment of adult patients with active ankylosing spondylitis
4. Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis

Authorization of 24 months may be granted for treatment of rheumatoid arthritis when all of the following criteria are met:

1. Simponi Aria will be used in combination with methotrexate unless the member has a clinical reason to avoid methotrexate (e.g., breastfeeding, renal or hepatic impairment, previous intolerance to methotrexate)
2. The member meets one of the following:
 - a. The member has previously received any other biologic disease-modifying anti-rheumatic drug (DMARD) (e.g., Humira) or targeted synthetic DMARD (e.g., Xeljanz) indicated for rheumatoid arthritis
 - b. The member had an inadequate response to methotrexate
 - c. The member has a clinical reason to avoid therapy with methotrexate (e.g., hepatic or renal impairment)

B. Psoriatic arthritis (PsA)

Authorization of 24 months may be granted for treatment of active psoriatic arthritis.

C. Ankylosing spondylitis (AS)

Authorization of 24 months may be granted for treatment of active ankylosing spondylitis.

D. Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 24 months may be granted for treatment of active polyarticular juvenile idiopathic arthritis.

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| Reference number |
| 2394-A |

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 24 months may be granted when ALL of the following criteria are met:

- A. The member is currently receiving therapy with Simponi Aria
- B. Simponi Aria is being used to treat an indication enumerated in Section II
- C. The member is receiving benefit from therapy

IV. REFERENCE

1. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2020.