Clinical Policy: Golimumab (Simponi ARIA®)

Reference Number: QCP.PHAR.005
Date of Last Revision: 05.24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Golimumab (Simponi ARIA®) is an immunosuppressive drug.

Policy/Criteria
I. Initial Approval Criteria
A. Axial Spondyloarthritis (must meet all):
1. Diagnosis of AS or nr-axSpA;
2. Request is for Simponi Aria
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
6. For Simponi Aria: Member meets ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, and iii):
    i. One of the following (a, b, or c, see Appendix D):
        a) Failure of both of the following, each used for ≥ 3 consecutive months (1 and 2):
            1) Humira
            2) Enbrel;
        b) If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira
        c) History of failure of two TNF blockers and request is not for another TNF blocker; ii. Failure of Cosentyx, used for ≥ 3 consecutive months; iii. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR® and Rinvoq each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
7. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
8. Dose does not exceed maximum dose indicated in Section V.
*Maximum dose escalation allowed per prescriber information with documentation of inadequate response.

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all):
1. Diagnosis of PJIA as evidenced by ≥ 5 joints with active arthritis;
2. Request is for Simponi Aria
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years;
5. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) (see Appendix K);
6. Member meets one of the following (a, b, c, or d):
    a. Failure of a ≥ 3 consecutive months trial of MTX at up to maximally indicated doses;
    b. Member has intolerance or contraindication to MTX (see Appendix D), failure of a ≥ 3 consecutive months trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
    c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
    d. Documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 (see Appendix K);
7. For Simponi Aria: Member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
    a. One of the following (i, ii, or iii, see Appendix D):
        i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
            1) Humira
            2) Enbrel;
        ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira
        iii. History of failure of two TNF blockers and request is not for another TNF blocker;
    b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz, used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
9. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all):
1. Diagnosis of PsA;
2. Request is for Simponi Aria

3. Age ≥ 2 years;
4. For Simponi Aria: Member meets ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
    a. One of the following (i, ii, or iii, see Appendix D):
        i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):
            1) 1) Humira
            2) 2) Enbrel;
        ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira
        iii. History of failure of two TNF blockers and request is not for another TNF blocker;
    b. Failure of a trial of ALL of the following, each used for ≥ 3 consecutive months: Otezla, Cosentyx, Skyrizi, Stelara, Tremfya;
    c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR and Rinvoq, each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
5. For Orencia, member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
6. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

D. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per ACR criteria (see Appendix F);
2. Request is for Simponi Aria
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
    a. Failure of a ≥ 3 consecutive months trial of MTX at up to maximally indicated doses;
    b. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a ≥ 3 consecutive months trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
6. For Simponi Aria: Member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
    a. One of the following (i, ii, or iii, see Appendix D):
        i. Failure of both of the following, each used for ≥ 3 consecutive months (1 and 2):

1) Humira
2) Enbrel;

ii. If member has had a history of failure of one TNF blocker, then failure of one of the following TNF blockers used for ≥ 3 consecutive months: Enbrel or Humira

iii. History of failure of two TNF blockers and request is not for another TNF blocker;

b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR and Rinvoq, each used for ≥ 3 consecutive months, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

7. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (see Appendix G);
   b. Routine assessment of patient index data 3 (RAPID3) score (see Appendix H);
8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
9. Dose does not exceed maximum dose indicated in Section V.
   *Maximum dose escalation allowed per prescriber information with documentation of inadequate response.

Approval duration: 6 months

II. Continued Therapy

All Other Indications in Section I (must meet all):

1. Member currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member meets one of the following (a, b, or c):
   a. For RA: Member is responding positively to therapy as evidenced by one of the following (i or ii):
      i. A decrease in CDAI (see Appendix G) or RAPID3 (see Appendix H) score from baseline;3. member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors
      ii. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
   b. For pJIA: Member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline (see Appendix K);
   c. For all other indications: Member is responding positively to therapy;
3. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
4. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V.

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – HIM.PA.154 for health insurance marketplace or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACR: American College of Rheumatology
AS: ankylosing spondylitis
CDAI: clinical disease activity index
DMARDs: disease-modifying antirheumatic drugs
EULAR: European Union League Against Rheumatism
JAK: Janus kinase
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
NSAIDs: non-steroidal anti inflammatory drugs
PsA: psoriatic arthritiss
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3
TNF: tumor necrosis factor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	3 mg/kg/day

Cuprimine (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**PJIA*** • Weight < 20 kg: 10 mg every other day • Weight 20 - 40 kg: 10 mg/day • Weight > 40 kg: 20 mg/day **RA** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**PJIA*** 10 – 20 mg/m2 /week PO, SC, or IM **RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	AS, nr-axSpA, , PJIA*: Varies	Varies
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**PJIA*** 30-50 mg/kg/day PO divided BID **RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose: 2 g/day PO in divided doses	PJIA: 2 g/day RA: 3 g/day
biologic DMARDs (e.g., Humira, Enbrel, Cosentyx, Remicade, Simponi Aria,	See Section V. Dosing and Administration	See Section V. Dosing and Administration

Otezla, Xeljanz/Xeljanz XR, Kevzara)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
*Off-label

Appendix C: Contraindications/Boxed Warnings
Contraindications: None
BBW: Serious infections, malignancies

Appendix D: General Information
- Definition of failure of MTX or DMARDs
  - Failure of a trial of conventional DMARDs:
    - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
    - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Nr-axSpA: guideline recommendations are largely extrapolated from evidence in AS.
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: Dose Rounding Guidelines for Weight-Based Doses
Simponi Aria for All Indications

Weight-based Dose Range	Vial Quantity Recommendation
≤ 52.49 mg	1 vial of 50 mg/4 mL
52.5 to 104.99 mg	2 vials of 50 mg/4 mL
105 to 157.49 mg	3 vial of 50 mg/4 mL
157.5 to 209.99 mg	4 vial of 50 mg/4 mL
210 to 262.49 mg	5 vial of 50 mg/4 mL

Appendix F: The 2010 ACR Classification Criteria for RA
Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	Joint involvement	Score
	1 large joint	0

	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5

B	Serology (at least one test result is needed for classification)	Score
	Negative rheumatoid factor (RF) and negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF or low positive ACPA * Low: < 3 x upper limit of normal	2
	High positive RF or high positive ACPA * High: ≥ 3 x upper limit of normal	3

C	Acute phase reactants (at least one test result is needed for classification)	Score
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1

D	Duration of symptoms	Score
	< 6 weeks	0
	≥ 6 weeks	1

Appendix G: Clinical Disease Activity Index (CDAI) Score

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix H: Routine Assessment of Patient Index Data 3 (RAPID3) Score

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity

> 12	High disease activity

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Golimumab (Simponi Aria)* *Also see Appendix E: Dose Rounding Guidelines for Weight-Based Doses	AS PsA RA	Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg IV every 8 weeks	2 mg/kg every 8 weeks
	pJIA PsA (pediatric)	Initial dose: 80 mg/m2 at weeks 0 and 4 Maintenance dose: 80 mg/m2 IV every 8 weeks	80 mg/m2 IV every 8 weeks

VI. Product Availability

Golimumab (Simponi Aria):
Single-use vial: 50 mg/4 mL

References

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1602	Injection, golimumab, 1 mg, for intravenous use

Revision Log

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created.		05.24
2Q 2024: for axial spondyloarthritis and rheumatoid arthritis added that maximum dose escalation allowed per prescriber information with documentation of inadequate response	05.24	06.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed healthcare professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

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