Clinical Policy: Golimumab (Simponi, Simponi Aria, Immgolis, Immgolis Intri)

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Description
Golimumab (Simponi®, Simponi Aria®) and golimumab-sldi (Immgolis™, Immgolis Intri™) are a tumor necrosis (TNF) blocker.

FDA Approved Indication(s)
Simponi is indicated for the treatment of:
- Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)
- Adult patients with active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Adult patients with active ankylosing spondylitis (AS)
- Adult and pediatric patients weighing at least 15 kg with moderate to severely active ulcerative colitis (UC)

Simponi Aria is indicated for the treatment of:
- Adult patients with moderately to severely active RA in combination with MTX
- Active PsA in patients 2 years of age and older
- Adult patients with active AS
- Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Immgolis is indicated for the treatment of:
- Adult patients with moderately to severely active RA in combination with MTX
- Adult patients with moderately to severely active UC

Immgolis Intri is indicated for the treatment of:
- Adult patients with moderately to severely active RA in combination with MTX

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria.

It is the policy of PA Health & Wellness® that Simponi, Simponi Aria, Immgolis, and Immgolis Intri are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all)**:**
1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at

up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;

5. Member meets both* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, *see Appendix D*):
   a. Failure of one adalimumab product (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for adalimumab products and Xeljanz/Xeljanz XR*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
   a. SC golimumab product: 50 mg SC once monthly;
   b. IV golimumab product: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*).

   Approval duration: 12 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 IV golimumab product;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 2 years;
5. Member meets one of the following (a, b, c, or d):
   a. Failure of a ≥ 3 consecutive month 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 month trial of sulfasalazine or leflunomide 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. Documentation of high disease activity;
6. Failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated (a, b, and c, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;

b. Actemra®;
c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

**Prior authorization may be required for adalimumab products, Actemra,, and Xeljanz*

7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed 80 mg/m^2 IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

C. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of PsA;
2. Prescribed in consultation with a dermatologist or rheumatologist;
3. Member meets one of the following (a or b):
   a. Age ≥ 2 years and request is for IV golimumab product;
   b. Age ≥ 18 years;
4. For members ≥ 18 years, failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c and d, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. Otezla®/ Otezla XR™;
   c. One ustekinumab product (e.g., *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*);
   d. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   ** Prior authorization may be required for adalimumab products, Otezla/Otezla XR, ustekinumab products, and Xeljanz/Xeljanz XR R*
5. For members 6 to 17 years, failure of a ≥ 3 consecutive month trial of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Otezla/Otezla XR;
   b. One ustekinumab product (e.g., *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*);

**Prior authorization may be required for Otezla/Otezla XR and ustekinumab products*

6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
   a. SC golimumab product: 50 mg SC once monthly;
   b. IV golimumab product (i or ii):

i. Adults: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*);
ii. Pediatrics: 80 mg/m^2 IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

D. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix G*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month 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 month 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;
5. Failure of ALL* of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (a, b, and c, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. Actemra;
   c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for adalimumab products, Actemra, and Xeljanz/Xeljanz XR*
6. Prescribed concomitantly with MTX, or another DMARD if intolerance or contraindication to MTX;
7. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (*see Appendix H*);
   b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix I*);
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed one of the following (a or b):
   a. SC golimumab product: 50 mg SC once monthly;
   b. IV golimumab product: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

E. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of UC;
2. Request is for SC golimumab product;
3. Prescribed by or in consultation with a gastroenterologist;
5. 4. If member is < 18 years old, then weight ≥ 15 kg;
6. Documentation of a Mayo Score ≥ 6 or modified Mayo Score ≥ 5, or Mayo Endoscopic Score ≥ 2 (*see Appendix E*);
7. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
8. Failure of one of the following used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. One ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*);

**Prior authorization may be required for adalimumab products and ustekinumab products*

9. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
10. Dose does not exceed one of the following (a or b):
    a. Weight ≥ 15 kg to < 40 kg: 100 mg at Week 0, 50 mg at Week 2, followed by maintenance dose of 50 mg every 4 weeks;
    b. 200 mg at Week 0, 100 mg at Week 2, followed by maintenance dose of 100 mg every 4 weeks.

Approval duration: 12 months

F. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:
   CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT

authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member meets one of the following (a or b):
   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 H*) or RAPID3 (*see Appendix I*) score from baseline;
      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 all other indications: Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase 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 one of the following (a, b, c, or d):
   a. AS, PsA, RA (SC golimumab product): 50 mg SC once monthly;
   b. AS, PsA, RA (IV golimumab product) Adults: 2 mg/kg IV every 8 weeks;*
   c. UC (SC golimumab product) (i or ii):
      i. Weight ≥ 15 kg to < 40 kg: 50 mg SC every 4 weeks;
      ii. Weight ≥ 40 kg: 100 mg SC every 4 weeks;
   d. PJIA, PsA (IV golimumab product) Pediatrics: 80 mg/m^2 IV every 8 weeks.*

   **see Appendix F for dose rounding guidelines*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:
      CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use with 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, Remicade® and its biosimilars, Simponi® and its biosimilars], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] 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

6MP: 6-mercaptopurine
AS: ankylosing spondylitis
CDAI: clinical disease activity index
cJADAS: clinical juvenile arthritis disease activity score
DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
JAKi: Janus kinase inhibitors
MTX: methotrexate
NSAID: non-steroidal anti-inflammatory drug
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritis RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3
TNF: tumor necrosis factor UC: ulcerative colitis

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	2.5 mg/kg/day
corticosteroids	**UC** Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks	Varies
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	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg PO QD Maintenance dose: 200 – 400 mg PO QD	600 mg/day
leflunomide (Arava®)	**RA** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD **pJIA*** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **pJIA*** 10 – 20 mg/m^2/week PO, SC, or IM	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
sulfasalazine (Azulfidine®)	**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 gm/day PO in divided doses **pJIA*** 30-50 mg/kg/day PO divided BID	RA: 3 g/day pJIA: 2 g/day
Actemra® (tocilizumab)	**pJIA** • Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks • Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks **RA** IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response Weight ≥ 100 kg: 162 mg SC every week	PJIA: • IV: 10 mg/kg every 4 weeks • SC: 162 mg every 2 weeks RA: IV: 800 mg every 4 weeks SC: 162 mg every week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	**RA, AS, PsA** 40 mg SC every other week **pJIA** **Cyltezo, Hadlima, Hyrimoz:** Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week **Cyltezo, Hadlima, Hulio, Yuflyma:** Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week **Cyltezo, Hadlima, Hulio, Hyrimoz, Simlandi, Yuflyma, Yusimry:** Weight ≥ 30 kg (66 lbs): 40 mg SC every other week **UC** Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15 Maintenance dose: 40 mg SC every other week starting on Day 29	40 mg every other week
Otezla® (apremilast)	**PsA** **Adults:** Initial dose: Otezla only: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: • Otezla: 30 mg PO BID • Otezla XR: 75 mg PO QD **Pediatric:** Otezla only: *Weight ≥ 50 kg:* Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM	Adults: • Otezla: 60 mg/day • Otezla XR: 75 mg/day Pediatric: *Weight ≥ 50 kg:* • Otezla: 60 mg/day • Otezla XR: 75 mg/day *Weight 20 kg to < 50 kg:* 40 mg/day

	Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM <u>Maintenance dose:</u> Day 6 and thereafter: • Otezla: 30 mg PO BID • Otezla XR: 75 mg PO QD *Weight 20 kg to < 50 kg:* <u>Initial dose:</u> Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 20 mg PO QPM <u>Maintenance dose:</u> Day 6 and thereafter, Otezla only: 20 mg PO BID	
Otulfi® (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Steqeyma® (ustekinumab-stba),	**UC** <u>Weight based dosing IV at initial dose:</u> Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg <u>Maintenance dose:</u>	UC: 90 mg every 8 weeks PsA: 45 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Yesintek™ (ustekinumab-kfce)	90 mg SC every 8 weeks **PsA** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks *Pediatrics (age 6 years to 17 years):* Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter **Otulfi, Pyzchiva, Yesintek:** Weight < 60 kg: 0.75 mg/kg **Otulfi, Pyzchiva, Steqeyma, Yesintek:** Weight ≥ 60 kg: 45 mg	
Xeljanz® (tofacitinib)	**AS, PsA, RA** 5 mg PO BID **pJIA** • 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID • 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID • Body weight ≥ 40 kg: 5 mg PO BID	10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Xeljanz XR® (tofacitinib extended-release)	**AS, PsA, RA** 11 mg PO QD	11 mg/day

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

- Contraindication(s): none reported
- Boxed warning(s): serious infections and malignancy

Appendix D: General Information

- Definition of failure of MTX or 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.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- 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®) and its biosimilars (Immgolis™, Immgolis Intri™).

Appendix E: Mayo Score or Modified Mayo Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA

currently accepts the modified Mayo Score for the assessment of disease activity in pivotal UC clinical trials.

- Mayo Endoscopic Score: tool used to assess severity based on endoscopic findings during a colonoscopy and ranges from 0 to 3. A score of 2 or higher means there is moderate-to-severe inflammation.

Score	Decoding
0	Normal or inactive disease
1	Mild disease (erythema, decreased vascular pattern, mild friability)
2	Moderate disease (marked erythema, absent vascular pattern, moderate friability, erosions)
3	Severe disease (spontaneous bleeding, ulcerations)

Appendix F: Dose Rounding Guidelines

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 vials of 50 mg/4 mL
157.5 to 209.99 mg	4 vials of 50 mg/4 mL
210 to 262.49 mg	5 vials of 50 mg/4 mL

Appendix G: 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)**	
	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)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix H: 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 I: 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

Appendix J: Polyarticular Juvenile Idiopathic Arthritis Disease Activity
According to 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis, disease activity (moderate/high and low) as defined by the clinical Juvenile Disease Activity score based on 10 joints (cJADAS-10) is provided as a general parameter and should be interpreted within the clinical context.
The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;
- Count of joints with active disease to a maximum count of 10 active joints*

**ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both*

cJADAS-10	Disease state interpretation
≤ 1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Golimumab-sldi (Immgolis)	RA	50 mg SC once monthly	50 mg/month
	UC	Initial dose: 200 mg SC at Week 0, then 100 mg SC at Week 2 Maintenance dose: 100 mg SC every 4 weeks	100 mg every 4 weeks
Golimumab-sldi (Immgolis Intri)	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
Golimumab (Simponi)	AS PsA RA	50 mg SC once monthly	50 mg/month
	UC	Initial dose: 200 mg SC at week 0, then 100 mg SC at week 2 Maintenance dose: 100 mg SC every 4 weeks	100 mg every 4 weeks
Golimumab (Simponi Aria)	AS PsA RA	Adults: Initial dose (AS, PsA, RA): 2 mg/kg IV at weeks 0 and 4 Adults: Maintenance dose (AS, PsA, RA): 2 mg/kg IV every 8 weeks Pediatrics: Initial dose (PsA, PJIA): 80 mg/m^2 IV at weeks 0 and 4 Pediatrics: Maintenance dose (PsA, PJIA): 80 mg/m^2 IV every 8 weeks	Adults (AS, PsA, RA): 2 mg/kg every 8 weeks Pediatrics (PsA, PJIA): 80 mg/m^2 every 8 weeks
	PJIA	Adults: Maintenance dose (AS, PsA, RA): 2 mg/kg IV every 8 weeks Pediatrics: Initial dose (PsA, PJIA): 80 mg/m^2 IV at weeks 0 and 4 Pediatrics: Maintenance dose (PsA, PJIA): 80 mg/m^2 IV every 8 weeks	mg/kg every 8 weeks Pediatrics (PsA, PJIA): 80 mg/m^2 every 8 weeks

VI. Product Availability

Drug Name	Availability
Golimumab (Simponi)	Single-dose prefilled SmartJect® autoinjector: 50 mg/0.5 mL, 100 mg/1 mL Single-dose prefilled syringe: 50 mg/0.5 mL, 100 mg/1 mL
Golimumab (Simponi Aria)	Single-use vial: 50 mg/4 mL
Golimumab-sldi (Immgolis)	Single-dose prefilled syringe: 50 mg/0.5 mL, 100 mg/mL
Golimumab-sldi (Immgolis Intri)	Single-dose vial: 50 mg/4 mL

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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
J3590, C9399	Unclassified drugs or biologicals (subcutaneous golimumab)

Reviews, Revisions, and Approvals	Date
Policy created	09/2025
3Q 2026 annual review: For PsA, applied step therapy to Otezla for pediatric age redirection as Otezla has a newly approved pediatric extension for 6 years and older; for UC, added option for Mayo Endoscopic Score ≥ 2 to define moderate-to-severe UC; for AS, pJIA,RA, and UC, added bypass of conventional therapies if a member has failed a biologic agent to clarify intention of not stepping back from biologic agent to conventional therapy.RT4: reflected pediatric age extension for UC per PI. RT4: added FDA approved biosimilars Immgolis and Immgolis Intri to criteria. Extended initial approval durations to 12 months for chronic conditions.	07/2026