Simponi Aria® (Golimumab) Injection for Intravenous Infusion

Policy Number: 2026D0051S
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➲ Instructions for Use

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Coverage Rationale

➲ See Benefit Considerations

This policy refers only to Simponi Aria (golimumab) injection for intravenous infusion. Simponi for self-administered subcutaneous injection is obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents. **Exception**: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Simponi may be obtained under the medical benefit.

Ankylosing Spondylitis

Simponi Aria is proven for the treatment of ankylosing spondylitis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
  - Diagnosis of active ankylosing spondylitis (AS); **and**
  - Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis; **and**
  - Patient is not receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
  - Documentation of positive clinical response to Simponi Aria; **and**
  - Simponi Aria dosing for ankylosing spondylitis is in accordance with the FDA labeled dosing; **and**
  - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

Simponi Aria is medically necessary for the treatment of ankylosing spondylitis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
  - Diagnosis of active ankylosing spondylitis (AS); **and**
  - **One** of the following:
    - History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)]; **or**
    - Patient is currently on Simponi Aria

    and
  - Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis; **and**
  - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and**
  - Prescribed by or in consultation with a rheumatologist; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
  - Documentation of positive clinical response to Simponi Aria; **and**
  - Simponi Aria dosing for ankylosing spondylitis is in accordance with the FDA labeled dosing; **and**
  - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

Psoriatic Arthritis

Simponi Aria is proven for the treatment of psoriatic arthritis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
  - Diagnosis of active psoriatic arthritis (PsA); **and**
  - Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis; **and**
  - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and**
  - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
  - Documentation of positive clinical response to Simponi Aria; **and**
  - Simponi Aria dosing for psoriatic arthritis is in accordance with the FDA labeled dosing; **and**
  - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and**
  - Reauthorization is for no more than 12 months

Simponi Aria is medically necessary for the treatment of psoriatic arthritis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
  - Diagnosis of active psoriatic arthritis (PsA); **and**
  - **One** of the following:
    - History of failure to a 3-month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab),

Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]; **or**
        - Patient is currently on Simponi Aria

      and
    - Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis; **and**
    - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and**
    - Prescribed by or in consultation with **one** of the following:
        - Rheumatologist
        - Dermatologist

      and
    - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
    - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
    - Documentation of positive clinical response to Simponi Aria; **and**
    - Simponi Aria dosing for psoriatic arthritis is in accordance with the FDA labeled dosing; **and**
    - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and**
    - Reauthorization is for no more than 12 months

Rheumatoid Arthritis

Simponi Aria is proven for the treatment of rheumatoid arthritis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
    - Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and**
    - **One** of the following:
        - Patient is receiving concurrent therapy with methotrexate
        - History of contraindication or intolerance to methotrexate

      and
    - Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for rheumatoid arthritis; **and**
    - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
    - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
    - Documentation of positive clinical response to Simponi Aria; **and**
    - Simponi Aria dosing for rheumatoid arthritis is in accordance with the FDA labeled dosing; **and**
    - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Reauthorization is for no more than 12 months

Simponi Aria is medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
    - Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and**
    - **One** of the following:
        - History of failure intolerance to a 3-month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; **or**

        - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]; **or**
        - Patient is currently on Simponi Aria

      and
    - Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for rheumatoid arthritis; **and**
    - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Prescribed by or in consultation with a rheumatologist; **and**
    - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
    - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
    - Documentation of positive clinical response to Simponi Aria; **and**
    - Simponi Aria dosing for rheumatoid arthritis is in accordance with the FDA labeled dosing; **and**
    - Patient is **not** receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Reauthorization is for no more than 12 months

Polyarticular Juvenile Idiopathic Arthritis

Simponi Aria is proven for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
    - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); **and**
    - Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; **and**
    - Patient is not receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
    - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
    - Documentation of positive clinical response; **and**
    - Simponi Aria is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; **and**
    - Patient is not receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Reauthorization is for no more than 12 months

Simponi Aria is medically necessary for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met:

- For **initial therapy**, **all** of the following:
    - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); **and**
    - Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; **and**
    - Patient is not receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**
    - Prescribed by or in consultation with a rheumatologist; **and**
    - Initial authorization is for no more than 12 months
- For **continuation of therapy**, **all** of the following:
    - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
    - Documentation of positive clinical response; **and**
    - Simponi Aria is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; **and**
    - Patient is not receiving Simponi Aria in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication; **and**

- Reauthorization is for no more than 12 months

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

Diagnosis Code	Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M05.A	Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow

Diagnosis Code	Description
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder

Diagnosis Code	Description
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems

Diagnosis Code	Description
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement

Diagnosis Code	Description
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.8A	Other rheumatoid arthritis with rheumatoid factor of other specified site
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip

Diagnosis Code	Description
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site
M06.1	Adult-onset Still's disease
M06.20	Rheumatoid bursitis, unspecified site
M06.211	Rheumatoid bursitis, right shoulder
M06.212	Rheumatoid bursitis, left shoulder
M06.219	Rheumatoid bursitis, unspecified shoulder
M06.221	Rheumatoid bursitis, right elbow
M06.222	Rheumatoid bursitis, left elbow
M06.229	Rheumatoid bursitis, unspecified elbow
M06.231	Rheumatoid bursitis, right wrist
M06.232	Rheumatoid bursitis, left wrist
M06.239	Rheumatoid bursitis, unspecified wrist
M06.241	Rheumatoid bursitis, right hand
M06.242	Rheumatoid bursitis, left hand
M06.249	Rheumatoid bursitis, unspecified hand
M06.251	Rheumatoid bursitis, right hip
M06.252	Rheumatoid bursitis, left hip
M06.259	Rheumatoid bursitis, unspecified hip
M06.261	Rheumatoid bursitis, right knee
M06.262	Rheumatoid bursitis, left knee
M06.269	Rheumatoid bursitis, unspecified knee
M06.271	Rheumatoid bursitis, right ankle and foot
M06.272	Rheumatoid bursitis, left ankle and foot
M06.279	Rheumatoid bursitis, unspecified ankle and foot
M06.28	Rheumatoid bursitis, vertebrae
M06.29	Rheumatoid bursitis, multiple sites
M06.30	Rheumatoid nodule, unspecified site
M06.311	Rheumatoid nodule, right shoulder
M06.312	Rheumatoid nodule, left shoulder
M06.319	Rheumatoid nodule, unspecified shoulder
M06.321	Rheumatoid nodule, right elbow
M06.322	Rheumatoid nodule, left elbow
M06.329	Rheumatoid nodule, unspecified elbow
M06.331	Rheumatoid nodule, right wrist
M06.332	Rheumatoid nodule, left wrist

Diagnosis Code	Description
M06.339	Rheumatoid nodule, unspecified wrist
M06.341	Rheumatoid nodule, right hand
M06.342	Rheumatoid nodule, left hand
M06.349	Rheumatoid nodule, unspecified hand
M06.351	Rheumatoid nodule, right hip
M06.352	Rheumatoid nodule, left hip
M06.359	Rheumatoid nodule, unspecified hip
M06.361	Rheumatoid nodule, right knee
M06.362	Rheumatoid nodule, left knee
M06.369	Rheumatoid nodule, unspecified knee
M06.371	Rheumatoid nodule, right ankle and foot
M06.372	Rheumatoid nodule, left ankle and foot
M06.379	Rheumatoid nodule, unspecified ankle and foot
M06.38	Rheumatoid nodule, vertebrae
M06.39	Rheumatoid nodule, multiple sites
M06.80	Other specified rheumatoid arthritis, unspecified site
M06.811	Other specified rheumatoid arthritis, right shoulder
M06.812	Other specified rheumatoid arthritis, left shoulder
M06.819	Other specified rheumatoid arthritis, unspecified shoulder
M06.821	Other specified rheumatoid arthritis, right elbow
M06.822	Other specified rheumatoid arthritis, left elbow
M06.829	Other specified rheumatoid arthritis, unspecified elbow
M06.831	Other specified rheumatoid arthritis, right wrist
M06.832	Other specified rheumatoid arthritis, left wrist
M06.839	Other specified rheumatoid arthritis, unspecified wrist
M06.841	Other specified rheumatoid arthritis, right hand
M06.842	Other specified rheumatoid arthritis, left hand
M06.849	Other specified rheumatoid arthritis, unspecified hand
M06.851	Other specified rheumatoid arthritis, right hip
M06.852	Other specified rheumatoid arthritis, left hip
M06.859	Other specified rheumatoid arthritis, unspecified hip
M06.861	Other specified rheumatoid arthritis, right knee
M06.862	Other specified rheumatoid arthritis, left knee
M06.869	Other specified rheumatoid arthritis, unspecified knee
M06.871	Other specified rheumatoid arthritis, right ankle and foot
M06.872	Other specified rheumatoid arthritis, left ankle and foot
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot
M06.88	Other specified rheumatoid arthritis, vertebrae
M06.89	Other specified rheumatoid arthritis, multiple sites
M06.8A	Other specified rheumatoid arthritis, other specified site
M06.9	Rheumatoid arthritis, unspecified
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder

Diagnosis Code	Description
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.0A	Unspecified juvenile rheumatoid arthritis, other specified site
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites

Diagnosis Code	Description
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, vertebrae
M08.89	Other juvenile arthritis, multiple sites
M08.90	Juvenile arthritis, unspecified, unspecified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee

Diagnosis Code	Description
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.1	Juvenile ankylosing spondylitis
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.6	Ankylosing spondylitis lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine

Background

Golimumab is a human anti-tumor necrosis factor (TNF) monoclonal antibody that targets both soluble and transmembrane bioactive forms of TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage, and tissue.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.

Clinical Evidence

Proven

Ankylosing Spondylitis

The efficacy and safety of golimumab were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 208 adult patients with active ankylosing spondylitis (AS) and inadequate response or intolerance to NSAIDs. Patients had a diagnosis of definite AS for at least 3 months according to modified New York criteria. Patients had symptoms of active disease [Bath AS Disease Activity Index (BASDAI) ≥ 4, VAS for total back pain of ≥ 4, on scales of 0 to 10 cm (0 to 100 mm), and a hsCRP level of ≥ 0.3 mg/dL (3 mg/L)]. Patients were randomized to receive either golimumab 2 mg/kg (n = 105) or placebo (n = 103) as a 30-minute intravenous infusion at Weeks 0, 4 and 12. All patients on placebo received golimumab at Week 16, Week 20, and every 8 weeks thereafter through Week 52. Patients in the golimumab treatment group continued to receive golimumab infusions at Week 20 and every 8 weeks through Week 52. Patients were allowed to continue stable doses of concomitant methotrexate (MTX), sulfasalazine (SSZ), hydroxychloroquine (HCQ), low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day), and/or NSAIDs during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited.

The primary endpoint was the percentage of patients achieving an Assessment in Ankylosing Spondylitis (ASAS) 20 response at Week 16. In this trial, golimumab, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ASAS 20 response at Week 16, where a greater percentage of patients treated with golimumab achieved a low level of disease activity [< 2 (on a scale of 0 to 10 cm) in all

four ASAS domains] compared with patients treated with placebo (16.2% vs. 3.9%). General health status was assessed by the 36-item Short Form Health Survey (SF-36). Patients receiving golimumab demonstrated greater improvement from baseline compared with placebo in physical component summary and mental component summary scores and in all 8 domains of the SF-36. Golimumab-treated patients showed significant improvement compared with placebo-treated patients in health related quality of life as assessed by the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL).

Psoriatic Arthritis

The efficacy and safety of golimumab were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 480 adult patients with active psoriatic arthritis (PsA) despite NSAID or DMARD therapy. Previous treatment with a biologic was not allowed. Patients in this trial had a diagnosis of PsA for at least six months and had symptoms of active disease (≥ 5 swollen joints and ≥ 5 tender joints and a CRP level of ≥ 0.6 mg/dL). Patients were randomized to either receive golimumab 2 mg/kg (n = 241) or placebo (n = 239) as a 30-minute intravenous infusion at Weeks 0, 4, 12 and 20. All patients on placebo received golimumab at Week 24, Week 28, and every 8 weeks thereafter through Week 52. Patients in the golimumab treatment group continued to receive golimumab infusions at Week 28 and every 8 weeks through Week 52. Patients were allowed to continue stable doses of MTX, NSAIDs, and low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day) during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited. The primary endpoint was the percentage of patients achieving an ACR 20 response at Week 14. Patients with each subtype of PsA were enrolled, including polyarticular arthritis with absence of rheumatoid nodules (44%), asymmetric peripheral arthritis (19%), distal interphalangeal joint involvement (8.1%), spondylitis with peripheral arthritis (25%), and arthritis mutilans (4.8%). During the trial, concomitant medications used included MTX (70%), oral corticosteroids (28%), and NSAIDs (71%). Golimumab, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ACR 20 response at Week 14. Similar ACR 20 responses at Week 24 were observed in patients with different PsA subtypes. ACR 20 responses observed in the golimumab-treated groups were similar in patients who were or were not receiving concomitant MTX. Patients with enthesitis at baseline were evaluated for mean improvement using the Leeds Enthesitis Index (LEI) on a scale of 0-6. Golimumab-treated patients showed a significantly greater improvement in enthesitis, with a mean reduction of 1.8 as compared with a mean reduction in placebo-treated patients of 0.8 at Week 14. Patients with dactylitis at baseline were evaluated for mean improvement on a scale of 0-60. Golimumab-treated patients showed a significantly greater improvement, with a mean reduction of 7.8 compared with a mean reduction of 2.8 in placebo-treated patients at Week 14. Golimumab inhibited the progression of structural damage compared with placebo, as assessed by total modified vdH-S score. At Week 24, a greater proportion of patients in the golimumab group (72%) had no progression of structural damage (change in the total modified vdH-S score ≤ 0), compared to 43% of patients in the placebo group. Improvement in physical function as assessed by the Health Assessment Questionnaire Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved clinically meaningful improvement of ≥ 0.3 in HAQ-DI score from baseline was greater in the golimumab-treated group compared to placebo at Week 14 (69% compared to 32%). General health status was assessed by the 36-item Short Form Health Survey (SF-36). Patients receiving golimumab demonstrated greater improvement from baseline compared with placebo in physical component summary, mental component summary scores and in all 8 domains of the SF-36.

Rheumatoid Arthritis

In the extension phase to the GO-FURTHER pivotal study, the long-term extension study of golimumab plus methotrexate (MTX) for rheumatoid arthritis evaluated the efficacy, pharmacokinetics, immunogenicity, and radiographic progression, through 100 weeks of therapy, where safety was monitored through 112 weeks. In the original trial 592 patients with active RA were randomized (2:1) to receive intravenous (IV) golimumab 2mg/kg plus MTX or placebo plus MTX at weeks 0, 4, and every 8 weeks thereafter. Patients receiving placebo were able to cross over at either week 16 or week 24 to active therapy. In total, 486 patients (82.1%) continued golimumab therapy for 100 weeks. Efficacy assessments included the American College of Rheumatology 20%, 50%, 70% (ACR 20, ACR50, ACR70) response criteria, 28 joint count disease activity score using the C-reactive protein level, physical function, and quality of life (QoL) measures, and changes in the modified Sharp/van der Heijde scores (SHS). Following treatment at week 100, in both groups combined, 68.1% of patients had an ACR20 response, 43.8% had an ACR50, and 23.5% had an ACR70 response. More than 80% of all patients had a good or moderate DAS28-CRP response at week 100, and approximately 28% achieved DAS28-CRP < 2.6. For patient reported outcomes, improvements in SF-36 PCS, MCS, FACIT-Fatigue, EQ-5D VAS scores were sustained through week 112 in both treatment groups. At week 100, the mean change from baseline in total SHS score was significantly lower in Group 1 than in Group 2 (0.74 vs. 2.10; p = 0.005) and 61.8% (n = 244 of 395) of patients in Group 1 and 54.8% (n = 108 of 197) of patients in Group 2 had a change from baseline in total SHS of ≤ 0. When evaluated by progression beyond the smallest detectable change (3.22) in total SHS, 16.7% (n = 66 of 395) of patients in Group 1 and 23.9% (n = 47 of 197) in Group 2 demonstrated radiographic progression from baseline to week 100. The mean change in total SHS score from week 52 to week 100 when all patients were receiving golimumab was numerically lower in Group 1 (0.56) than in Group 2 (0.80); the median change was 0 in both groups. After 112 weeks, a total of 481

patients completed the safety follow-up with 79.1% had at least one adverse event, and 18.2% having had a serious adverse event. After 100 weeks of treatment only 6.7% (n = 37 of 553) of patients developed antibodies to golimumab, with 86.5% positive for neutralizing antibodies. The authors concluded that treatment with IV golimumab plus MTX afforded a clinical response that was maintained through week 100. Radiographic progression following treatment was clinically insignificant between week 52 and week 100.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

The efficacy of golimumab in pediatric patients with pJIA is based on the pharmacokinetic exposure and extrapolation of the established efficacy of golimumab in RA patients. Efficacy of golimumab was also assessed in a multicenter, open-label, single-arm study in 127 children (2 to < 18 years of age) with JIA with active polyarthritis despite treatment with MTX for at least 2 months (Trial pJIA, NCT02277444). The polyarticular JIA patient subtypes at study entry included: rheumatoid factor negative (43%), rheumatoid factor positive (35%), enthesitis-related arthritis (9%), oligoarticular extended (6%), juvenile psoriatic arthritis (4%), and systemic JIA without systemic manifestations (3%). All patients received golimumab 80 mg/m2 as an intravenous infusion at Week 0, 4, and every 8 weeks through Week 52. Patients continued stable doses of MTX weekly through Week 28; after Week 28, changes in MTX dose were permitted. Efficacy was assessed as supportive endpoints through Week 52. The efficacy was generally consistent with responses in patients with RA.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Simponi Aria for intravenous infusion is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active RA in combination with methotrexate (MTX), active PsA in patients 2 years of age or older, active AS, and active pJIA in patients 2 years of age and older.

Simponi, for subcutaneous injection, is indicated in adult patients for the following: treatment of moderately to severely active RA in combination with MTX; treatment of active psoriatic arthritis (PsA) alone, or in combination with MTX; treatment of active ankylosing spondylitis (AS); and the treatment of moderately to severely active ulcerative colitis (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate prior treatment (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, and achieving and sustaining clinical remission in induction responders.

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8. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2021 Jul;73(7):924-939.

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Policy History/Revision Information

Date	Summary of Changes
03/01/2026	**Coverage Rationale** • Replaced references to "targeted immunomodulator" with "*systemic* targeted immunomodulator" • Revised coverage criteria for: ***Ankylosing Spondylitis*** ○ Updated list of examples of systemic targeted immunomodulators U.S. FDA approved for the treatment of ankylosing spondylitis with which the patient has been previously treated for initial therapy; added: ▪ Adalimumab ▪ Bimzelx (bimekizumab-bkzx) ▪ Cosentyx (secukinumab) ▪ Olumiant (baricitinib) ▪ Orencia (abatacept) ▪ Taltz (ixekizumab) ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Simponi Aria for treatment of the same indication; added: ▪ Bimzelx (bimekizumab-bkzx) ▪ Cosentyx (secukinumab) ▪ Taltz (ixekizumab) ***Psoriatic Arthritis*** ○ Updated list of examples of systemic targeted immunomodulators U.S. FDA approved for the treatment of psoriatic arthritis with which the patient has been previously treated for initial therapy: ▪ Added "Bimzelx (bimekizumab-bkzx)" ▪ Replaced: – "*Stelara* (ustekinumab)" with "ustekinumab" – "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Simponi Aria for treatment of the same indication: ▪ Added "Bimzelx (bimekizumab-bkzx)" ▪ Removed "Olumiant (baricitinib)" ▪ Replaced: – "*Stelara* (ustekinumab)" with "ustekinumab" – "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" ***Rheumatoid Arthritis*** ○ Updated list of examples of systemic targeted immunomodulators U.S. FDA approved for the treatment of rheumatoid arthritis with which the patient has been previously treated for initial therapy: ▪ Removed "Simponi (golimumab)" ▪ Replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Simponi Aria for treatment of the same indication; replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" ***Polyarticular Juvenile Idiopathic Arthritis*** ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Simponi Aria for treatment of the same indication for: ▪ Removed "Simponi (golimumab)" ▪ Replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2025D0051R

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.