# Cimzia® (Certolizumab Pegol)

**Policy Number**: CS2023D0083K
**Effective Date**: October 1, 2023

Instructions for Use

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## Application

This Medical Benefit Drug Policy only applies to the states of Colorado, Kentucky, Minnesota, Nebraska, New York, Tennessee, Texas, and Wisconsin.

Refer to the guideline listed below for the following states:

| State | Policy/Guideline |
|---|---|
| Indiana | Immunomodulators for Inflammatory Conditions (for Indiana Only) |
| Louisiana | Refer to the state's Medicaid clinical policy |
| Ohio | Cimzia® (Certolizumab Pegol) (for Ohio Only) |

## Coverage Rationale

This policy refers to Cimzia (certolizumab pegol) injection. Cimzia (certolizumab pegol) for self-administered subcutaneous injection is obtained under the pharmacy benefit.

**Cimzia is proven and/or medically necessary for the treatment of**:[1]

- **Crohn's disease (CD) when all of the following criteria are met**:
  - For **initial therapy**, **all** of the following:
    - Diagnosis of moderately to severely active Crohn's disease; **and**
    - **One** of the following:
      - History of failure to **one** of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:
        - Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
        - 6-mercaptopurine (Purinethol)
        - Azathioprine (Imuran)
        - Methotrexate (Rheumatrex, Trexall)

        **or**

        - Patient is currently on Cimzia; **or**
        - Patient has been previously treated with a biologic DMARD FDA-approved for the treatment of Crohn's disease [e.g., Humira (adalimumab), Stelara (ustekinumb)]

      **and**
    - Cimzia is initiated and titrated according to U.S. Food and Drug Administration labeled dosing for CD; **and**
    - Patient is not receiving Cimzia in combination with either of the following:
        - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      **and**
    - Prescribed by or in consultation with a gastroenterologist; **and**
    - Initial authorization will be issued for 12 months
  - For **continuation of therapy**, **all** of the following:
    - Documentation of positive clinical response; **and**
    - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for CD; **and**
    - Patient is not receiving Cimzia in combination with either of the following:
        - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      **and**
    - Authorization will be issued for 12 months
- **Rheumatoid Arthritis (RA) when all of the following criteria are met**:
  - For **initial therapy**, **all** of the following:
    - Diagnosis of moderately to severely active rheumatoid arthritis; **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 biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Humira (adalimumab), Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]; or
        - Patient is currently on Cimzia

      **and**
    - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for RA; **and**
    - Patient is not receiving Cimzia in combination with either of the following:
        - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      **and**
    - Prescribed by or in consultation with a rheumatologist; **and**
    - Initial authorization will be issued for 12 months
  - For **continuation of therapy**, **all** of the following:
    - Documentation of positive clinical response; **and**
    - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for RA; **and**
    - Patient is not receiving Cimzia in combination with either of the following:
        - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
        - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      **and**
    - Authorization will be issued for 12 months
- **Psoriatic Arthritis (PsA) when all of the following criteria are met**:
  - For **initial therapy**, **all** of the following:
    - Diagnosis of active psoriatic arthritis; **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 biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis [e.g., Humira (adalimumab), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast)]; **or**
- Patient is currently on Cimzia

**and**

- Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for PsA; **and**
- Patient is not receiving Cimzia in combination with either of the following:
  - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]
  - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

**and**

- Prescribed by or in consultation with **one** of the following:
  - Rheumatologist
  - Dermatologist

**and**

- Initial authorization will be issued for 12 months

- For **continuation of therapy**, **all** of the following:
  - Documentation of positive clinical response; **and**
  - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for PsA; **and**
  - Patient is not receiving Cimzia in combination with either of the following:
    - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

    **and**
  - Authorization will be issued for 12 months

- **Ankylosing Spondylitis (AS) and non-radiographic Axial Spondyloarthritis (nr-axSpA) when all of the following criteria are met**:
  - For **initial therapy**, **all** of the following:
    - Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis; **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 biologic or targeted synthetic DMARD FDA-approved for the treatment of ankylosing spondylitis or **nr-axSpA** [e.g., Humira (adalimumab), Simponi (golimumab)]; **or**
      - Patient is currently on Cimzia

      **and**
    - Cimzia is initiated and titrated according to U.S. Food and Drug Administration labeled dosing for AS or nr-axSpA; **and**
    - Patient is not receiving Cimzia in combination with either of the following:
      - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]
      - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

      **and**
    - Prescribed by or in consultation with a rheumatologist; **and**
    - Initial authorization will be issued for 12 months
  - For **continuation of therapy**, **all** of the following:
    - Documentation of positive clinical response; **and**
    - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for AS or nr-axSpA; **and**
    - Patient is not receiving Cimzia in combination with either of the following:
      - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]
      - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

      **and**

        - Authorization will be issued for 12 months
- **Plaque Psoriasis (PS) when all of the following criteria are met**:
    - For **initial therapy**, **all** of the following:
        - Diagnosis of moderate to severe plaque psoriasis; **and**
        - **One** of the following:
            - **All** of the following:
                - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **and**
                - History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced:
                    - Corticosteroids (e.g., betamethasone, clobetasol, desonide)
                    - Vitamin D analogs (e.g., calcitriol, calcipotriene)
                    - Tazarotene
                    - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
                    - Anthralin
                    - Coal tar

                **and**
                - 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 is currently on Cimzia; **or**
            - Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis [e.g., Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)]

        **and**
        - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for PS; **and**
        - Patient is not receiving Cimzia in combination with either of the following:
            - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
            - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
            - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

        **and**
        - Prescribed by or in consultation with a dermatologist; **and**
        - Initial authorization will be issued for 12 months
    - For **continuation of therapy**, **all** of the following:
        - Documentation of positive clinical response; **and**
        - Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for PS; **and**
        - Patient is not receiving Cimzia in combination with either of the following:
            - Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]
            - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
            - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

        **and**
        - Authorization will be issued for 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 federal, state, or contractual requirements 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.

| CPT Code | Description |
|---|---|
| 96372 | Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |

| CPT Code | Description |
|---|---|
| 96401 | Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic |

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| HCPCS Code | Description |
|---|---|
| J0717 | Injection, certolizumab pegol, 1 mg (code may be used when drug administered under the direct supervision of a physician, not for use when drug is self-administered) |

| Diagnosis Code | Description |
|---|---|
| K31.6 | Fistula of stomach and duodenum |
| K50.00 | Crohn's disease of small intestine without complications |
| K50.011 | Crohn's disease of small intestine with rectal bleeding |
| K50.012 | Crohn's disease of small intestine with intestinal obstruction |
| K50.013 | Crohn's disease of small intestine with fistula |
| K50.014 | Crohn's disease of small intestine with abscess |
| K50.018 | Crohn's disease of small intestine with other complication |
| K50.019 | Crohn's disease of small intestine with unspecified complications |
| K50.10 | Crohn's disease of large intestine without complications |
| K50.111 | Crohn's disease of large intestine with rectal bleeding |
| K50.112 | Crohn's disease of large intestine with intestinal obstruction |
| K50.113 | Crohn's disease of large intestine with fistula |
| K50.114 | Crohn's disease of large intestine with abscess |
| K50.118 | Crohn's disease of large intestine with other complication |
| K50.119 | Crohn's disease of large intestine with unspecified complications |
| K50.80 | Crohn's disease of both small and large intestine without complications |
| K50.811 | Crohn's disease of both small and large intestine with rectal bleeding |
| K50.812 | Crohn's disease of both small and large intestine with intestinal obstruction |
| K50.813 | Crohn's disease of both small and large intestine with fistula |
| K50.814 | Crohn's disease of both small and large intestine with abscess |
| K50.818 | Crohn's disease of both small and large intestine with other complication |
| K50.819 | Crohn's disease of both small and large intestine with unspecified complications |
| K50.90 | Crohn's disease, unspecified, without complications |
| K50.911 | Crohn's disease, unspecified, with rectal bleeding |
| K50.912 | Crohn's disease, unspecified, with intestinal obstruction |
| K50.913 | Crohn's disease, unspecified, with fistula |
| K50.914 | Crohn's disease, unspecified, with abscess |
| K50.918 | Crohn's disease, unspecified, with other complication |
| K50.919 | Crohn's disease, unspecified, with unspecified complications |
| K60.3 | Anal fistula |
| K60.4 | Rectal fistula |
| K60.5 | Anorectal fistula |
| K63.2 | Fistula of intestine |
| L40.0 | Psoriasis vulgaris |
| L40.50 | Arthropathic psoriasis, unspecified |

| Diagnosis Code | Description |
|---|---|
| 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 |
| M05.00 | 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 |
| M05.10 | Rheumatoid lung disease with rheumatoid arthritis of unspecified site |
| M05.111 | Rheumatoid lung disease with rheumatoid arthritis of right shoulder |
| M05.112 | Rheumatoid lung disease with rheumatoid arthritis of left shoulder |
| M05.119 | Rheumatoid lung disease with rheumatoid arthritis of unspecified shoulder |
| M05.121 | Rheumatoid lung disease with rheumatoid arthritis of right elbow |
| M05.122 | Rheumatoid lung disease with rheumatoid arthritis of left elbow |
| M05.129 | Rheumatoid lung disease with rheumatoid arthritis of unspecified elbow |
| M05.131 | Rheumatoid lung disease with rheumatoid arthritis of right wrist |
| M05.132 | Rheumatoid lung disease with rheumatoid arthritis of left wrist |
| M05.139 | Rheumatoid lung disease with rheumatoid arthritis of unspecified wrist |
| M05.141 | Rheumatoid lung disease with rheumatoid arthritis of right hand |
| M05.142 | Rheumatoid lung disease with rheumatoid arthritis of left hand |
| M05.149 | Rheumatoid lung disease with rheumatoid arthritis of unspecified hand |
| M05.151 | Rheumatoid lung disease with rheumatoid arthritis of right hip |

| Diagnosis Code | Description |
|---|---|
| M05.152 | Rheumatoid lung disease with rheumatoid arthritis of left hip |
| M05.159 | Rheumatoid lung disease with rheumatoid arthritis of unspecified hip |
| M05.161 | Rheumatoid lung disease with rheumatoid arthritis of right knee |
| M05.162 | Rheumatoid lung disease with rheumatoid arthritis of left knee |
| M05.169 | Rheumatoid lung disease with rheumatoid arthritis of unspecified knee |
| M05.171 | Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot |
| M05.172 | Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot |
| M05.179 | Rheumatoid lung disease with rheumatoid arthritis of unspecified ankle and foot |
| M05.19 | Rheumatoid lung disease with rheumatoid arthritis of 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 |
| 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 |

| Diagnosis Code | Description |
|---|---|
| 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 |
| 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 |

| Diagnosis Code | Description |
|---|---|
| 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 |
| 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 |

| Diagnosis Code | Description |
|---|---|
| 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 |
| 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 |
| M05.80 | 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 |

| Diagnosis Code | Description |
|---|---|
| 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 |
| M05.9 | 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 |
| 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 |
| M06.1 | 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 |

| Diagnosis Code | Description |
|---|---|
| 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 |
| 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 |
| M06.4 | Inflammatory polyarthropathy |
| 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 |

| Diagnosis Code | Description |
|---|---|
| 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 |
| M06.9 | Rheumatoid arthritis, unspecified |
| M08.1 | Juvenile ankylosing spondylitis |
| 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 |
| M45.5 | Ankylosing spondylitis of thoracolumbar 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 |
| M45.A0 | Non-radiographic axial spondyloarthritis of unspecified sites in spine |
| M45.A1 | Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region |
| M45.A2 | Non-radiographic axial spondyloarthritis of cervical region |
| M45.A3 | Non-radiographic axial spondyloarthritis of cervicothoracic region |
| M45.A4 | Non-radiographic axial spondyloarthritis of thoracic region |
| M45.A5 | Non-radiographic axial spondyloarthritis of thoracolumbar region |
| M45.A6 | Non-radiographic axial spondyloarthritis of lumbar region |
| M45.A7 | Non-radiographic axial spondyloarthritis of lumbosacral region |
| M45.A8 | Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region |
| M45.AB | Non-radiographic axial spondyloarthritis of multiple sites in spine |
| M46.80 | Other specified inflammatory spondylopathies, site unspecified |

| Diagnosis Code | Description |
|---|---|
| M46.81 | Other specified inflammatory spondylopathies, occipito-atlanto-axial region |
| M46.82 | Other specified inflammatory spondylopathies, cervical region |
| M46.83 | Other specified inflammatory spondylopathies, cervicothoracic region |
| M46.84 | Other specified inflammatory spondylopathies, thoracic region |
| M46.85 | Other specified inflammatory spondylopathies, thoracolumbar region |
| M46.86 | Other specified inflammatory spondylopathies, lumbar region |
| M46.87 | Other specified inflammatory spondylopathies, lumbosacral region |
| M46.88 | Other specified inflammatory spondylopathies, sacral and sacrococcygeal region |
| M46.89 | Other specified inflammatory spondylopathies, multiple sites in spine |
| M48.8X1 | Other specified spondylopathies, occipito-atlanto-axial region |
| M48.8X2 | Other specified spondylopathies, cervical region |
| M48.8X3 | Other specified spondylopathies, cervicothoracic region |
| M48.8X4 | Other specified spondylopathies, thoracic region |
| M48.8X5 | Other specified spondylopathies, thoracolumbar region |
| M48.8X6 | Other specified spondylopathies, lumbar region |
| M48.8X7 | Other specified spondylopathies, lumbosacral region |
| M48.8X8 | Other specified spondylopathies, sacral and sacrococcygeal region |
| M48.8X9 | Other specified spondylopathies, site unspecified |
| N82.2 | Fistula of vagina to small intestine |
| N82.3 | Fistula of vagina to large intestine |
| N82.4 | Other female intestinal-genital tract fistulae |

## Maximum Dosage Requirements

### *HCPCS Code Based Maximum Dosage Information*

This section provides information about the maximum dosage per administration for certolizumab pegol administered by a medical professional.

| Medication Name | | Maximum Dosage per Administration | HCPCS Code | Maximum Allowed |
|---|---|---|---|---|
| Brand | Generic | | | |
| Cimzia | certolizumab pegol | 400 mg | J0717 | 400 HCPCS units (1 mg per unit) |

### *Maximum Allowed Quantities by National Drug Code (NDC) Units*

The allowed quantities in this section are calculated based upon both the maximum dosage information supplied within this policy as well as the process by which NDC claims are billed. This list may not be inclusive of all available NDCs for each drug product and is subject to change.

| Medication Name | | How Supplied | National Drug Code | Maximum Allowed |
|---|---|---|---|---|
| Brand | Generic | | | |
| Cimzia | certolizumab pegol | 2 x 200 mg kit | 50474-0700-62 | 2 vials |
| | | 2 x 200 mg/ml prefilled syringe kit | 50474-0710-79 | 2 mL |
| | | 6 x 200 mg/ml prefilled syringe kit | 50474-0710-81 | 2 mL |

# Background

Cimzia (certolizumab pegol) is a recombinant, humanized antibody Fab' fragment, with specificity for human tumor necrosis factor alpha (TNFα). TNFα is a key pro-inflammatory cytokine with a central role in inflammatory processes. Certolizumab pegol selectively neutralizes TNFα but does not neutralize lymphotoxin α (TNFβ). Certolizumab pegol does not contain a fragment crystallizable (Fc) region, which is normally present in a complete antibody, and therefore does not fix complement or cause antibody-dependent cell-mediated cytotoxicity in vitro. It does not induce apoptosis in vitro in human peripheral blood-derived monocytes or lymphocytes, nor does certolizumab pegol induce neutrophil degranulation.

TNFα induces the upregulation of cellular adhesion molecules and chemokines, upregulation of major histocompatibility complex (MHC) class I and class II molecules, and direct leukocyte activation. TNFα stimulates the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor, and nitric oxide. Elevated levels of TNFα have been implicated in the pathology of Crohn's disease and rheumatoid arthritis. Certolizumab pegol binds to TNFα, inhibiting its role as a key mediator of inflammation. TNFα is strongly expressed in the bowel wall in areas involved by Crohn's disease and fecal concentrations of TNFα in patients with Crohn's disease have been shown to reflect clinical severity of the disease. After treatment with certolizumab pegol, patients with Crohn's disease demonstrated a decrease in the levels of C-reactive protein (CRP). Increased TNFα levels are found in the synovial fluid of rheumatoid arthritis patients and play an important role in the joint destruction that is a hallmark of this disease.

# Clinical Evidence

## Proven

Cimzia (certolizumab pegol) is indicated for:[1]

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with active ankylosing spondylitis
- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

## Professional Societies

### *Crohn's Disease*

According to the American College of Gastroenterology Practice Guidelines for the Management of Crohn's Disease in Adults (ACG Practice Guidelines) published in February 2009, patients with moderate-severe disease usually have a Crohn's Disease Activity Index (CDAI) of 220-450. They have failed to respond to treatment for mild-moderate disease, or have more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting (without obstructive findings), or significant anemia.

The CDAI is the sum of the following clinical or laboratory variables after multiplying by their weighting factor given in parentheses:

- Number of liquid or soft stools each day for seven days (2)
- Abdominal pain graded from 0 - 3 in severity each day for seven days (5)
- General well-being, subjectively assessed from 0 (well) to 4 (terrible) each day for seven days (7)
- Presence of complications where 1 point is added for each complication (20). Complications include:
  - The presence of joint pains (arthralgia) or frank arthritis
  - Inflammation of the iris or uveitis
  - Presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers
  - Anal fissures, fistulae, or abscesses
  - Other fistulae (e.g., Enterocutaneous, vesicle, vaginal)
  - Fever (> 37.8 C) during the previous week
- Taking diphenoxylate/atropine [Lomotil®] or opiates for diarrhea (30)
- Presence of an abdominal mass where 0 = none, 2 = questionable, 5 = definite (10);

- Absolute deviation of hematocrit from 47% in males and 42% in females (6)
- Percentage deviation from standard body weight (1)

The 2018 ACG Practice Guidelines support the use of infliximab for treatment and maintenance of patients with moderate to severely active Crohn's disease which is resistant or refractory to corticosteroids, thiopurines or methotrexate. In addition, they state anti-TNF agents can be considered to treat severely active Crohn's disease.

The 2021 AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease made the following recommendations regarding certolizumab.

- In adult outpatients with moderate to severe CD, the AGA recommends the use of anti-TNFa over no treatment for induction and maintenance of remission. (Strong recommendation, moderate certainty evidence) Comment: Although the evidence supporting infliximab and adalimumab was moderate quality, the evidence for certolizumab pegol was low quality
- In adult outpatients with moderate to severe CD who are naïve to biologic drugs, the AGA recommends the use of infliximab, adalimumab, or ustekinumab over certolizumab pegol for the induction of remission and suggests the use of vedolizumab over certolizumab pegol for the induction of remission. (Strong, conditional recommendation, Moderate, low certainty evidence)
- In adult outpatients with CD and active perianal fistula, the AGA suggests the use of adalimumab, ustekinumab, or vedolizumab over no treatment for the induction or maintenance of fistula remission. Comment: Evidence suggests certolizumab pegol may not be effective for induction of fistula remission

### *Rheumatoid Arthritis*

The 2021 American College of Rheumatology (ACR) RA updated treatment guideline addresses the use of DMARDS, including conventional synthetic DMARDs, biologic DMARDs, and targeted synthetic DMARDS, , glucocorticoids, and the use of DMARDs in certain high-risk populations (i.e., those with liver disease, heart failure, lymphoproliferative disorders, previous serious infections, and nontuberculosis myobacterial lung disease).18 The guideline recommendations apply to common clinical situations, since the panel considered issues common to most patients, not exceptions. Recommendations are classified as either strong or conditional. A strong recommendation means that the panel was confident that the desirable effects of following the recommendation outweigh the undesirable effects (or vice versa), so the course of action would apply to most patients, and only a small proportion would not want to follow the recommendation. A conditional recommendation means that the desirable effects of following the recommendation probably outweigh the undesirable effects, so the course of action would apply to the majority of patients, but some may not want to follow the recommendation. As a result, conditional recommendations are preference sensitive and warrant a shared decision-making approach.

### Recommendations for DMARD-Naïve Patients

- A treat-to-target approach is strongly recommended over usual care for patients who have not been previously treated with bDMARDs or tsDMARDs regardless of disease activity level
- A minimal initial treatment goal of low disease activity is conditionally recommended over a goal of remission
- Moderate-to-high disease activity
    - Methotrexate is strongly recommended over hydroxychloroquine or sulfasalazine
    - Methotrexate is conditionally recommended over leflunomide
    - Methotrexate monotherapy is strongly recommended over bDMARD or tsDMARD monotherapy
    - Methotrexate monotherapy is conditionally recommended over dual or triple csDMARD therapy
    - Methotrexate monotherapy is conditionally recommended over methotrexate plus a tumor necrosis factor (TNF) inhibitor
    - Initiation of a csDMARD without short-erm (< 3 months) glucocorticoids is conditional recommended over initiation of a csDMARD with short-term glucocorticoids
    - Initiation of a csDMARD without longer term (≥ 3 months) glucocorticoids is strongly recommended over initiation of a csDMARD with longer-term glucocorticoids
- Low disease activity
    - Hydroxychloroquine is conditionally recommended over other csDMARDs, sulfasalazine is conditionally recommended over methotrexate, and methotrexate is conditionally recommended over leflunomide

## Recommendations for DMARD-Experienced Patients

- A treat-to-target approach is conditionally recommended over usual care for patients who have had an inadequate response to bDMARDs or tsDMARDs
- Methotrexate monotherapy is conditionally recommended over the combination of methotrexate plus a bDMARD or tsDMARD
- Oral methotrexate is conditionally recommended over subcutaneous methotrexate for patients initiating methotrexate
- Initiation/titration of methotrexate to a weekly dose of at least 15 mg within 4 to 6 weeks is conditionally recommended over initiation/ titration to a weekly dose of less than 15 mg
- A split dose of oral methotrexate over 24 hours or weekly subcutaneous injections, and/or an increased dose of folic/folinic acid, is conditionally recommended over switching to alternative DMARD(s) for patients not tolerating oral weekly methotrexate
- Switching to subcutaneous methotrexate is conditionally recommended over the addition of/ switching to alternative DMARD(s) for patients taking oral methotrexate who are not at target

## Recommendations for Treatment Modification

- Addition of a bDMARD or tsDMARD is conditionally recommended over triple therapy (i.e., addition of sulfasalazine and hydroxychloroquine) for patients taking maximally tolerated doses of methotrexate who are not at target
- Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target
- Addition of/switching to DMARDs is conditionally recommended over continuation of glucocorticoids for patients taking glucocorticoids to remain at target
- Addition of/switching to DMARDs (with or without intraarticular [IA] glucocorticoids) is conditionally recommended over the use of IA glucocorticoids alone for patients taking DMARDs who are not at target
- Continuation of all DMARDs at their current dose is conditionally recommended over a dose reduction of a DMARD, dose reduction is conditionally recommended over gradual discontinuation of a DMARD, and gradual discontinuation is conditionally recommended over abrupt discontinuation of a DMARD for patients who are at target for at least 6 months
- Gradual discontinuation of sulfasalazine is conditionally recommended over gradual discontinuation of hydroxychloroquine for patients taking triple therapy who wish to discontinue a DMARD
- Gradual discontinuation of methotrexate is conditionally recommended over gradual discontinuation of the bDMARD or tsDMARD for patients taking methotrexate plus a bDMARD or tsDMARD who wish to discontinue a DMARD

## Recommendations for Specific Patient Populations

- Subcutaneous nodules
  - Methotrexate is conditionally recommended over alternative DMARDs for patients with subcutaneous nodules who have moderate-to high disease activity Switching to a non-methotrexate DMARD is conditionally recommended over continuation of methotrexate for patients taking methotrexate with progressive subcutaneous nodules
- Pulmonary disease
  - Methotrexate is conditionally recommended over alternative DMARDs for the treatment of inflammatory arthritis for patients with clinically diagnosed mild and stable airway or parenchymal lung disease, or incidental disease detected on imaging, who have moderate-to-high disease activity
- Lymphoproliferative Disorder
  - Rituximab is conditionally recommended over other DMARDs for patients who have a previous lymphoproliferative disorder for which rituximab is an approved treatment and who have moderate-to-high disease activity
- Heart Failure
  - Addition of a non–TNF inhibitor bDMARD or tsDMARD is conditionally recommended over addition of a TNF inhibitor for patients with New York Heart Association (NYHA) class III or IV heart failure and an inadequate response to csDMARDs
  - Switching to a non–TNF inhibitor bDMARD or tsDMARD is conditionally recommended over continuation of a TNF inhibitor for patients taking a TNF inhibitor who develop heart failure
- Hepatitis B
  - Prophylactic antiviral therapy is strongly recommended over frequent monitoring of viral load and liver enzymes alone for patients initiating rituximab who are hepatitis B core antibody positive (regardless of hepatitis B surface antigen status)

- Prophylactic antiviral therapy is strongly recommended over frequent monitoring alone for patients initiating any bDMARD or tsDMARD who are hepatitis B core antibody positive and hepatitis B surface antigen positive
- Frequent monitoring alone of viral load and liver enzymes is conditionally recommended over prophylactic antiviral therapy for patients initiating a bDMARD other than rituximab or a tsDMARD who are hepatitis B core antibody positive and hepatitis B surface antigen negative

- Nonalcoholic fatty liver disease (NAFLD)
  - Methotrexate is conditionally recommended over alternative DMARDs for DMARD-naive patients with NAFLD, normal liver enzymes and liver function tests, and no evidence of advanced liver fibrosis who have moderate-to-high disease activity
  - Persistent hypogammaglobulinemia without infection
  - In the setting of persistent hypogammaglobulinemia without infection, continuation of rituximab therapy for patients at target is conditionally recommended over switching to a different bDMARD or tsDMARD
- Serious Infections
  - Addition of csDMARDs is conditionally recommended over addition of a bDMARD or tsDMARD for patients with a serious infection within the previous 12 months who have moderate-to-high disease activity despite csDMARD monotherapy
  - Addition of/switching to DMARDs is conditionally recommended over initiation/dose escalation of glucocorticoids for patients with a serious infection within the previous 12 months who have moderate-to-high disease activity
- Lung Disease
  - Use of the lowest possible dose of glucocorticoids (discontinuation if possible) is conditionally recommended over continuation of glucocorticoids without dose modification for patients with NTM lung disease This recommendation is based on studies suggesting an increased risk of NTM lung disease in patients receiving either inhaled or oral glucocorticoids (54,55)
  - Addition of csDMARDs is conditionally recommended over addition of a bDMARD or tsDMARD for patients with NTM lung disease who have moderate-to-high disease activity despite csDMARD monotherapy This recommendation is based on the lower expected risk of NTM lung disease associated with csDMARDs compared to bDMARDs and tsDMARDs (56)
  - Abatacept is conditionally recommended over other bDMARDs and tsDMARDs for patients with NTM lung disease who have moderate-to high disease activity despite csDMARDs

## *Plaque Psoriasis*

### American Academy of Dermatology (AAD)

In 2019, the AAD and the National Psoriasis Foundation published updated treatment guidelines for the management and treatment of psoriasis with biologic therapies. In regard to certolizumab and/or TNF inhibitors, the guidelines state:

- Certolizumab is likely to have class characteristics similar to those of other TNF-a inhibitors regarding treatment combination, efficacy in difficult-to-treat areas, and possibly, immunogenicity
- The approved dosing for moderate-to-severe psoriasis is 400 mg (given as two subcutaneous injections of 200 mg each) every other week. Another dosing option may be considered for people who weigh 90 kg (198 pounds) or less: 400 mg (given as two injections of 200 mg each) initially and at week 2 and week 4, followed by a dose of 200 mg every other week
- Definitive response (positive or negative) to treatment with most TNF-a inhibitors is best ascertained after 12 to 16 weeks of continuous therapy, except for infliximab, for which the best time is after 8 to 10 weeks
- Consider dose escalation, an increase in frequency, or the addition of other modalities (such as topical corticosteroids or vitamin D analogues, methotrexate, acitretin, apremilast, or NB-UVB) in partially responding patients

## *Psoriatic Arthritis*

In 2019, the American Academy of Dermatology (AAD) and the National Psoriasis Foundation published updated treatment guidelines for the management and treatment of psoriasis with biologic therapies. In regard to psoriatic arthritis (PsA), certolizumab and/or TNF inhibitors, the guidelines state:

- All TNF-a inhibitors have long-established efficacy and FDA approval for PsA
- Improve the signs and symptoms of the disease
- Improve functional status and quality of life
- Inhibit progression of radiographically detected damage of joints
- Among the biologics TNF-a inhibitors should be considered as a preferred treatment option for patients with concomitant PsA

The AAD defines psoriatic arthritis (PsA) as mild, moderate, or severe. Where mild disease responds to NSAIDs, moderate disease requires DMARDs or TNF blockers. Appropriate treatment of severe PsA requires DMARDs plus TNF blockers or other biologic therapies. If PsA is diagnosed, treatment should be initiated to alleviate signs and symptoms of PsA, inhibit structural damage, and maximize quality of life (QOL). According to the AAD Practice Guidelines for the management of psoriatic arthritis, the potential importance of TNF-α in the pathophysiology of PsA is underscored by the observation that there are elevated levels of TNF-α in the synovium, joint fluid, and skin of patients with PsA. The guidelines support the use of infliximab for PsA based on evidence ranked as consistent, good quality, and patient oriented. (Strength of Recommendation: A).

## *Ankylosing Spondylitis*

In 2019, the American College of Rheumatology, Spondylitis Association of America and Spondyloarthritis Research and Treatment Network published updated recommendations for the treatment of patients with ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (SpA) which addressed the use of Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), tumor necrosis factor inhibitor (TNFi) biosimilars, and biologic tapering/discontinuation. Recommendations for AS and non-radiographic axial SpA are similar.

- TNFi are recommended over Cosentyx (secukinumab) or Taltz (ixekizumab) as the first biologic to be used
- Cosentyx (secukinumab) or Taltz (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi
- TNFi, Cosentyx (secukinumab), and Taltz (ixekizumab) are favored over Xeljanz (tofacitinib)
- Co-administration of low-dose methotrexate with TNFi is not recommended, nor is a strict treat-to-target strategy or discontinuation or tapering of biologics in patients with stable disease
- Sulfasalazine is recommended only for persistent peripheral arthritis when TNFi are contraindicated
- For patients with unclear disease activity, spine or pelvis magnetic resonance imaging could aid assessment
- Routine monitoring of radiographic changes with serial spine radiographs is not recommended

In 2017, the **British Society for Rheumatology (BSR)** and the **British Health Professionals in Rheumatology** published a revision to their 2005 BSR guidelines to provide guidance for clinicians in the United Kingdom prescribing biologic drugs for the treatment of axial spondyloarthritis (axSpA), including ankylosing spondylitis. This includes the criteria for starting treatment, choice of drug, and assessing response. In regard to tumor necrosis factor inhibitors (TNFi), the guidelines recommend:

- The effectiveness of biologics in axSpA:
  - Anti-TNF therapy is effective at reducing disease activity and spinal pain in axSpA. While short-term MRI data support the efficacy of anti-TNF therapy in treating inflammatory SIJ and spinal lesions in axSpA, evidence for anti-TNF therapy on radiographic disease progression is currently limited
  - Currently there is insufficient evidence to recommend the use of other biologic agents in axSpA
- Initiating treatment:
  - Patients should be considered for anti-TNF therapy if they have active axSpA
- Choice of Drug:
  - Extra-articular manifestations and patient choice should be considered when selecting an anti-TNF agent. In the absence of head-to-head studies, systematic reviews have shown no statistical difference in efficacy between infliximab, golimumab, etanercept and adalimumab in the treatment of AS (certolizumab data were not included in these comparative reviews, but its efficacy has been established in clinical trials)
  - There are insufficient data to comment on relative efficacy in nr-axSpA. However, not all biologics are licensed for or effective in the treatment of extra-articular disease, so drug choice should take into account co-morbidities and the preferred route and frequency of administration
- Assessing Response:
  - Initial efficacy response should be assessed following 3–6 months of therapy and responders should then be reassessed every 6 months
- Withdrawal of Therapy:
  - In the absence of an initial clinical response by 6 months, or failure to maintain response at two consecutive assessments, withdrawal of that anti-TNF agent should be considered
  - There is no evidence to support the withdrawal of anti-TNF therapy in treatment responders
- Switching:
  - In the event of anti-TNF failure due to inefficacy or adverse events, an alternative anti-TNF agent should be offered if clinically appropriate

- Safety:
  - The safety of anti-TNF therapies in axSpA is comparable to other inflammatory joint diseases such as RA. There is little evidence to suggest that safety issues differ hugely with different disease groups, and the 2010 British Society for Rheumatology (BSR) guidelines on the safety of anti-TNF therapies in RA are applicable in axSpA

In 2016, the Assessment of SpondyloArthritis international Society (ASAS) and European League Against Rheumatism (EULAR) updated and integrated the recommendations for ankylosing spondylitis (AS) and the recommendations for the use of tumour necrosis factor inhibitors (TNFi) in axial spondyloarthritis (axSpA) into one guideline applicable to the full spectrum of patients with axSpA. The recommendations describe all aspects of the management of patients with a diagnosis of axSpA. The recommendations related to biologic DMARDs (bDMARDs) are:

- bDMARDs should be considered in patients with persistently high disease activity despite conventional treatments (e.g., non-biologic DMARDs); current practice is to start with TNFi therapy
- If TNFi therapy fails, switching to another TNFi or IL-17i therapy should be considered
- If a patient is in sustained remission, tapering of a bDMARD can be considered

## 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.

Cimzia (certolizumab pegol) is a tumor necrosis factor (TNF) blocker indicated for:

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with active ankylosing spondylitis
- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 10/01/2023 | **Application**<br>***California***<br>• Removed language indicating this Medical Benefit Drug Policy applies to the state of **California**<br>***Colorado and Minnesota***<br>• Added language to indicate this Medical Benefit Drug Policy applies to the states of **Colorado** and **Minnesota**<br>**Supporting Information**<br>• Archived previous policy version CS2023D0083J |

# Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The 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.