Cimzia® (Certolizumab Pegol)

Policy Number: 2023D0083G
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Instructions for Use

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Coverage Rationale

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

Crohn's Disease (CD)

Cimzia is proven for the treatment of 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
  - Patient has had an inadequate response to conventional therapies (examples include anti-inflammatory drugs, corticosteroids, or oral immunosuppressive agents); and
  - Cimzia is initiated and titrated according to US 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
  - 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 US 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.

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

and
- Cimzia is initiated and titrated according to US 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
- 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 US 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)

Cimzia is proven for the treatment of 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
  - Cimzia is initiated and titrated according to US 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
  - 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 US 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.

Cimzia is medically necessary for the treatment of 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 US 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 US 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)

Cimzia is proven for the treatment of psoriatic arthritis (PsA) when all of the following criteria are met:

- For initial therapy, all of the following:
    - Diagnosis of active psoriatic arthritis; and
    - Cimzia is initiated and titrated according to US 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
    - 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 US 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.

Cimzia is medically necessary for the treatment of 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), Rinvoq (upadacitinib)]; or
        - Patient is currently on Cimzia

      and
    - Cimzia is initiated and titrated according to US 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 US 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)

Cimzia is proven for the treatment of 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
  - Cimzia is initiated and titrated according to US 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
  - 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 US 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.

Cimzia is medically necessary for the treatment of 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), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]; or
    - Patient is currently on Cimzia

    and
  - Cimzia is initiated and titrated according to US 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
- 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 US 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)

Cimzia is proven for the treatment of 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
  - Cimzia is initiated and titrated according to US 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
  - 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 US 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.

Cimzia is medically necessary for the treatment of 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 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)]; or
    - Patient is currently on Cimzia

  and
- Cimzia is initiated and titrated according to US 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 US 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 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.

CPT Code	Description
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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 200mg kit	50474-0700-62	2 vials
		2 x 200mg/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 2 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 2 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 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 American Academy of Dermatology (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 tumor 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
02/01/2023	Coverage Rationale *Crohn's Disease (CD), Rheumatoid Arthritis (RA),* and *Psoriatic Arthritis (PsA)* • Updated list of examples of Janus kinase inhibitors; added "Rinvoq (upadacitinib)" *Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)* • Updated list of examples of Janus kinase inhibitors; added "Rinvoq (upadacitinib)" • Revised coverage criteria for initial therapy; replaced criterion requiring "patient has been previously treated with a biologic DMARD FDA-approved for the treatment of ankylosing spondylitis [e.g., Humira (adalimumab), Simponi (golimumab)]" with "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), *Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)*]" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2022D0083F

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, please 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.