Certolizumab

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Link to Codes

MCG Health
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Clinical Indications

- Certolizumab may be indicated when **ALL** of the following are present(1)(2)(3):
  - Clinical diagnosis of **1 or more** of the following:
    - Axial spondyloarthritis (ankylosing spondylitis, nonradiographic axial spondyloarthritis), as indicated by **1 or more** of the following(6)(7)(8)(9)(10)(11):
      - Initial course, as indicated by **ALL** of the following:
        - Age 18 years or older
        - Axial spondyloarthritis and **ALL** of the following(6)(7)(9)(18)(19)(20)(21):
          - Clinical evidence of axial spondyloarthritis, as indicated by **ALL** of the following:
            - Back pain of 3 months' or more duration and age of onset of 45 years or younger
            - Diagnostic criteria met, as indicated by **1 or more** of the following:
              - HLA-B27 positive, and **1 or more** of the following:
                - MRI of sacroiliac joint with sacroiliitis
                - Spondyloarthritis signs and symptoms, as indicated by **2 or more** of the following:
                  - Arthritis
                  - Dactylitis[A]
                  - Elevated C-reactive protein
                  - Enthesitis (eg, inflammation of Achilles tendon insertion)
                  - Family history of spondylarthritis
                  - Inflammatory back pain[B]
                  - Inflammatory bowel disease (Crohn disease, ulcerative colitis)
                  - Psoriasis
                  - Uveitis
              - Pelvic x-ray with evidence of sacroiliitis
              - Pelvic x-ray without evidence of sacroiliitis, with spondyloarthritis signs and symptoms, as indicated by **4 or more** of the following:
                - Arthritis
                - Dactylitis[A]
                - Elevated C-reactive protein
                - Enthesitis (eg, inflammation of Achilles tendon insertion)
                - Family history of spondylarthritis

                - HLA-B27
                - Inflammatory back pain[B]
                - Inflammatory bowel disease (Crohn disease, ulcerative colitis)
                - Psoriasis
                - Uveitis
            - Disease activity and treatment scenario, as indicated by **1 or more** of the following:
                - Axial (spinal) disease
                - Loss of response or intolerance to treatment with tumor necrosis factor inhibitor(24)
                - Peripheral arthritis without axial involvement, and failure or intolerance of 3 or more months of therapy with sulfasalazine
            - Failure or intolerance of 2 or more different NSAIDs (at maximum recommended doses) over total period of at least 4 or more weeks of therapy, or documented contraindication to NSAIDs
    - Subsequent course, as indicated by **ALL** of the following:
        - Age 18 years or older
        - Favorable response to prior administration of certolizumab

- Crohn disease, as indicated by **1 or more** of the following(25)(26)(27)(28)(29):N
    - Initial course, as indicated by **ALL** of the following(36):
        - Age 18 years or older
        - Disease activity, as indicated by **1 or more** of the following:
            - Moderate to severe active Crohn disease,[C] as indicated by **1 or more** of the following(25)(28)(37):
                - Anemia
                - Dehydration
                - Elevated serum C-reactive protein level
                - Fever
                - Intermittent vomiting
                - Perianal or rectal disease on endoscopy(38)(39)
                - Weight loss of greater than 10% of body weight
            - Perianal fistula(32)(39)
    - Subsequent course, as indicated by **ALL** of the following:
        - Age 18 years or older
        - Favorable response to prior administration of certolizumab
- Juvenile idiopathic arthritis, as indicated by **1 or more** of the following(40):N
    - Initial course, as indicated by **ALL** of the following:
        - Age 2 years or older
        - Polyarticular juvenile idiopathic arthritis, as indicated by **ALL** of the following:
            - Five or more joints involved
            - Intolerance or inadequate response to traditional disease-modifying antirheumatic drugs (eg, methotrexate)
    - Subsequent course, and favorable response to prior administration of certolizumab
- Plaque psoriasis, as indicated by **1 or more** of the following(4)(41)(42)(43)(44):N
    - Initial course, as indicated by **ALL** of the following:
        - Age 18 years or older
        - Moderate to severe plaque psoriasis, as indicated by **ALL** of the following(46)(47)(48)(49)(50):
            - Candidate for systemic therapy or phototherapy
            - Clinical need for systemic treatment, as indicated by **1 or more** of the following:
                - Body surface area involvement of 10% or more
                - Involvement of scalp, face, feet, hands, or genitalia that impacts patient quality of life
            - Failure of other treatments to control psoriasis, as indicated by **1 or more** of the following(46)(47):
                - Immunosuppressive treatments (eg, cyclosporine, methotrexate)
                - Photochemotherapy (ie, psoralen plus ultraviolet A therapy)(51)
                - Phototherapy (ie, ultraviolet light therapy)(51)
                - Topical agents (eg, anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)(47)
                - Tumor necrosis factor inhibitor(52)
    - Subsequent course, as indicated by **ALL** of the following:
        - Age 18 years or older
        - Favorable response to prior administration of certolizumab
- Psoriatic arthritis, as indicated by **1 or more** of the following(4)(53)(54)(55):N
    - Initial course, as indicated by **ALL** of the following:
        - Age 18 years or older
        - Active arthritis, as indicated by **1 or more** of the following:
            - Axial disease with inflammatory back pain, and failure of or intolerance to NSAIDs

        - Dactylitis[D]
        - Enthesitis[E] that is tender on examination
        - Peripheral disease with one or more tender and swollen joints, and failure of, intolerance to, or contraindication to methotrexate
    - Inadequate response, intolerance, or contraindication to 3 or more months of treatment with NSAIDs
  - Subsequent course, as indicated by **ALL** of the following:
    - Age 18 years or older
    - Favorable response to prior administration of certolizumab
- Rheumatoid arthritis, as indicated by **1 or more** of the following(60)(61)(62)(63):
  - Initial course, as indicated by **ALL** of the following(81)(82):
    - Age 18 years or older
    - Inadequate response to 3 or more months of treatment with disease-modifying antirheumatic drug, including **1 or more** of the following(61)(83)(84)(85)(86):
      - Hydroxychloroquine
      - Leflunomide
      - Methotrexate
      - Sulfasalazine
      - Tumor necrosis factor inhibitor (eg, adalimumab, certolizumab, etanercept, golimumab, infliximab)(83)(84)(87)
    - Moderate to severe active rheumatoid arthritis,[F] as indicated by **1 or more** of the following(89)(90):
      - Clinical Disease Activity Index[G] score greater than 10
      - Disease Activity Score using 28-joint counts (DAS28)[H] of 3.2 or greater
      - Patient Activity Scale-II[I] of 3.71 or greater
      - Routine Assessment of Patient Index Data 3[J] score of 7 or greater
      - Simplified Disease Activity Index[K] score greater than 11
  - Subsequent course, as indicated by **ALL** of the following:
    - Age 18 years or older
    - Favorable response to prior administration of certolizumab
- Hepatitis B surface antigen negative, or concurrent treatment with antiviral therapy[L](86)(91)
- No active serious infection(92)(93)(94)
- No concurrent treatment with anakinra, abatacept, rituximab, natalizumab, or another tumor necrosis factor inhibitor
- No concurrent use of live vaccine[M](60)(95)(97)(98)
- No untreated latent or active tuberculosis(92)(94)(99)(100)

Evidence Summary

Background

Certolizumab is a recombinant anti-tumor necrosis factor-alpha monoclonal antibody that reduces the inflammatory response.(1)(4) **(EG 2)** Use of certolizumab has been associated with an increased risk of worsening or new onset of demyelinating diseases; caution is recommended when used in patients with an existing demyelinating disease.(1)(5) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 73 published peer reviewed articles, 16 specialty society or other evidence-based guidelines, and 8 Cochrane systematic reviews.

For axial spondyloarthritis (ankylosing spondylitis, nonradiographic axial spondyloarthritis), evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** In a double-blind randomized controlled trial of 325 adult patients with active axial spondyloarthritis, administration of certolizumab every 2 or 4 weeks was associated with significant and rapid improvement in Assessment of SpondyloArthritis international Society 20 (ASAS20) score at 12 weeks as compared with placebo (58% when given every 2 weeks, 64% when given every 4 weeks, and 38% for placebo); at 24 weeks, patients in the combined certolizumab arms showed significant improvement in secondary outcomes, including the Bath Ankylosing Spondylitis Functional Index, Disease Activity Index, and Metrology Index.(12) **(EG 1)** No deaths or malignancies were reported in this study, and no additional adverse safety information was noted as compared with administration in patients with rheumatoid arthritis.(12) **(EG 1)** A meta-analysis and a systematic review of the use of biologics for ankylosing spondylitis have found that certolizumab and similar drugs were effective in improving some extra-articular disease manifestations, including uveitis.(13)(14) **(EG 1)** A randomized study has demonstrated longer-term efficacy for up to 96 weeks.(15) **(EG 1)** A randomized trial of 317 adult patients with active nonradiographic axial spondyloarthritis compared treatment with certolizumab or placebo (both could be combined with nonbiologic medications) and found, at 1-year follow-up, that certolizumab was associated with more patients achieving a 2-point or more improvement in Ankylosing Spondylitis Disease Activity Score (ASDAS) and a 40% improvement in Assessment of SpondyloArthritis international Society (ASAS40) scores compared with placebo.(16) **(EG 1)** An open-label extension of this study including 243 patients (all patients received certolizumab starting at week 52) found that clinical improvements were maintained at 3-year follow-up.(17) **(EG 2)**

For Crohn disease, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Systematic reviews and meta-analyses have concluded that certolizumab is moderately effective for the induction and maintenance of disease remission.(30)(31) **(EG 1)** A subgroup analysis from a randomized trial reported efficacy of certolizumab for closure of perianal fistulas in Crohn disease.(32) **(EG 1)** Extension studies have demonstrated continuing efficacy and safety for up to 7 years of administration.(33) **(EG 2)** An open-label study of 539 patients with Crohn disease reported that 62% of patients had a significant response with certolizumab when refractory to infliximab therapy.(34) **(EG 2)** Specialty society guidelines recommend certolizumab therapy for induction and maintenance of remission in patients with moderate to severe Crohn disease.(25)(28) **(EG 2)** Expert opinion has suggested that early use of tumor necrosis factor inhibitors in combination with immunomodulators (ie, a "top-down" approach) may be an effective treatment strategy in patients with severe disease.(25)(29)(35) **(EG 2)**

For juvenile idiopathic arthritis, evidence demonstrates an incomplete assessment of net benefit vs harm; the drug is currently approved by a federal regulatory agency. **(RG A3)** A specialty society guideline recommends treatment with biologic medication, such as tumor necrosis factor inhibitors, for patients with polyarticular juvenile idiopathic arthritis with moderate to severe disease activity and intolerance or inadequate response to disease-modifying antirheumatic drugs.(40) **(EG 2)**

For plaque psoriasis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Two phase III randomized trials (461 patients with moderate to severe chronic plaque psoriasis) compared treatment with certolizumab at 2 dosage strengths with placebo and found, at 16 weeks, that certolizumab at either dose was associated with more patients achieving 75% improvement in Psoriasis Area and Severity Index (PASI 75) scores and Physician's Global Assessment (PGA) scores of clear or almost clear; these results were maintained at 48-week follow-up.(41) **(EG 1)** An open-label extension of these trials (433 patients, all treated with certolizumab by 48 weeks) found, at 144-week follow-up, that PASI 75 and PGA scores of clear or almost clear were maintained.(45) **(EG 2)** A phase III randomized trial (559 patients with moderate to severe chronic plaque psoriasis) compared treatment with certolizumab (at 2 dosage strengths), etanercept, and placebo and found, at 12-week follow-up, that certolizumab at either dose was associated with more patients achieving PASI 75 scores compared with placebo. Certolizumab at 400 mg every other week was associated with higher PASI 75 scores compared with etanercept, and certolizumab at 200 mg every other week was found to be noninferior to etanercept.(42) **(EG 1)**

For psoriatic arthritis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** In a randomized controlled trial of 409 adult patients with active psoriatic arthritis, of whom 368 completed 24 weeks of treatment, administration of certolizumab every 2 or 4 weeks was associated with significant and rapid improvement in American College of Rheumatology 20% improvement criteria (ACR20) score as compared with placebo (58% when given every 2 weeks, 52% when given every 4 weeks, and 24% for placebo); patients in the combined certolizumab arms showed significant improvement in secondary outcomes, including physical function, psoriatic skin involvement, enthesitis, dactylitis, and nail disease. No additional significant adverse safety information was noted.(56) **(EG 1)** In an open-label continuation study, 183 patients continued certolizumab for 216 weeks; improvements in joint disease (measured by the ACR20, ACR50, and ACR70), disease activity (measured by the Disease Activity Index for Psoriatic Arthritis), skin involvement (measured by the Psoriasis Area and Severity Index), and enthesitis, dactylitis, and nail psoriasis were all maintained through the treatment period.(57) **(EG 2)** Randomized controlled trials have indicated significant improvement in work productivity and participation in social activities in patients with psoriatic arthritis after therapy with certolizumab.(58) **(EG 2)**

For rheumatoid arthritis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Technology assessments and systematic reviews with meta-analysis of randomized trials have concluded that certolizumab is an effective treatment option for moderate to severe disease.(63)(64)(65) **(EG 1)** A practice guideline, systematic reviews, and meta-analyses recommend that biologic therapy, such as certolizumab, is indicated for patients who fail first-line therapy with methotrexate or other disease-modifying antirheumatic drugs.(61)(66)(67)(68) **(EG 1)** A network meta-analysis of 67 randomized controlled trials (20,898 patients) evaluating the efficacy and safety of antirheumatic therapies for rheumatoid arthritis concluded that the combination of certolizumab and methotrexate ranked highest in clinical efficacy; due to the relatively low risk of adverse events, the combination was recommended as the best therapy for rheumatoid arthritis.(69) **(EG 1)** A randomized controlled trial of 316 patients with early rheumatoid arthritis and poor prognostic factors compared initial therapy with methotrexate combined with either certolizumab or placebo and found, at 24-week and 52-week follow-up, that certolizumab was associated with greater inhibition of radiographic progression compared with placebo.(70) **(EG 1)** A similar randomized controlled study with 879 such patients found that administration of certolizumab plus methotrexate was associated with significantly greater rates of sustained remission and low disease activity, as well as improved physical function and reduced structural damage at 40 weeks and 52 weeks, as compared with placebo plus methotrexate.(71) **(EG 1)** An open-label randomized controlled trial of 812 patients with treatment-naive early rheumatoid arthritis (all of whom had moderate to severe disease activity) compared treatment with methotrexate and either active conventional therapy (eg, prednisolone taper, sulfasalazine, hydroxychloroquine with or without glucocorticoid injections in swollen joints), certolizumab, abatacept, or tocilizumab and found, at 48-week follow-up, that treatment with either certolizumab or abatacept was associated with improved adjusted Clinical Disease Activity Index (CDAI) remission rates compared with active conventional therapy.(72) **(EG 1)** Concerns exist regarding the potential development of malignancy in patients with rheumatoid arthritis receiving biologic therapies, including tumor necrosis factor inhibitors such as certolizumab. However, a meta-analysis of 29,423 patients from 63 randomized controlled trials reported that the use of such biologic therapies for at least 6 months' duration was not significantly associated with an increased risk of malignancy, as compared with other nonbiologic disease-modifying antirheumatic drugs or with placebo.(73) **(EG 1)** Indirect comparisons of certolizumab with other biologic agents have shown comparable efficacy, especially when administered with methotrexate.(74)(75)(76)(77)(78)(79) **(EG 1)** A multiple treatment comparison regression analysis estimated that certolizumab was the most effective of the biologics tested in terms of achieving American College of Rheumatology 50% improvement criteria (ACR50) score, whether given with or without disease-modifying drugs.(80) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(101); 42 CFR 422.101(102)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(103); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(104); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(105)

Medicare Coverage Determinations: Medicare Coverage Database(106)

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Footnotes

[A] Dactylitis is inflammation of an entire digit.(22) [A in Context Link 1, 2]

[B] Inflammatory back pain is characterized by an insidious onset of pain that improves with exercise, but not with rest, as well as nocturnal pain that improves upon getting up.(6)(23) [B in Context Link 1, 2]

[C] Crohn disease activity can be described by endoscopic findings, clinical symptoms, and the impact of the disease on a patient's quality of life; there is not a single accepted measurement of disease activity, although the Crohn's Disease Activity Index (CDAI) has often been used in clinical trials. Using clinical symptoms to categorize Crohn disease severity can help guide clinicians when making treatment decisions. Clinical remission usually corresponds to a CDAI score of less than 150. Mild to moderate disease usually corresponds to a CDAI score of 150 to 220, and moderate to severe disease usually corresponds to a CDAI score of 220 to 450. Severe to fulminant disease, despite the use of corticosteroids or biologic agents, usually corresponds to a CDAI score of greater than 450.(28)(37) [C in Context Link 1]

[D] Dactylitis is characterized by diffuse swelling of a digit (either a finger or toe); it is a characteristic extra-articular manifestation of psoriatic arthritis.(53)(59) [D in Context Link 1]

[E] Enthesitis is characterized by inflammation at the site of tendon insertion; it is a characteristic extra-articular manifestation of psoriatic arthritis.(53)(59) [E in Context Link 1]

[F] Rheumatoid arthritis disease activity should be evaluated by a validated tool that assesses disease severity; validated disease activity tools typically include a combination of patient self-assessment, physical examination of joints by a physician, and laboratory assessment of inflammatory response. An expert consensus recommendation supports use of the following instruments: the Clinical Disease Activity Index, the Disease Activity Score using 28-joint counts, the Patient Activity Scale-II, the Routine Assessment of Patient Index Data 3, and the Simplified Disease Activity Index.(88) [F in Context Link 1]

[G] The Clinical Disease Activity Index is a scale from 0 to 76 that uses physician joint count and both patient and physician global score to assess rheumatoid arthritis disease severity. A score of 2.8 or less indicates remission, while a score greater than 2.8 to 10 indicates low disease severity. Moderate disease activity is indicated by a score of greater than 10 to 22, and severe disease activity is indicated by a score of greater than 22.(89) [G in Context Link 1]

[H] The Disease Activity Score using 28-joint counts (DAS28) is a scale from 0 to 9.4 that is calculated by counting affected joints, the patient global score, and either the erythrocyte sedimentation rate or C-reactive protein level. A score of less than 2.6 indicates remission, while a score of 2.6 to less than 3.2 demonstrates low disease activity. Moderate disease activity is indicated by a score of 3.2 to 5.1, and severe disease activity is indicated by a score higher than 5.1.(89) [H in Context Link 1]

[I] The Patient Activity Scale and Patient Activity Scale-II consist of scales from 0 to 10 and use health assessment questionnaires to determine disease severity; they do not utilize affected joint counts or laboratory results. A score of 0.25 or less indicates remission. Low-severity disease is represented by a score of 0.26 to 3.7, and moderate disease activity is indicated by a score of 3.71 to less than 8. Severe disease activity is indicated by a score of 8 to 10.(89) [I in Context Link 1]

[J] The Routine Assessment of Patient Index Data 3 is a scale from 0 to 30 that is commonly used in clinical practice and uses a health assessment questionnaire and a patient global score to determine disease severity; it does not require joint counts or laboratory results. A score of 3 or less indicates remission. Low-severity disease is represented by a score of 4 to 6, and moderate disease activity is indicated by a score of 7 to 12. Severe disease activity is indicated by a score of 13 or greater.(89) [J in Context Link 1]

[K] The Simplified Disease Activity Index is a scale from 0 to 86 and is calculated by counting affected joints, the patient and provider global score, and the C-reactive protein level. A score of 3.3 or less indicates remission, while a score greater than 3.3 to 11 indicates low disease activity. Moderate disease activity is indicated by a score greater than 11 to 26, and severe disease activity is indicated by a score higher than 26.(89) [K in Context Link 1]

[L] Patients who are HBsAg positive are at high risk for reactivation of hepatitis B virus (HBV) and should receive anti-HBV prophylaxis before initiating immunosuppressive or cytotoxic treatment. Patients who are HBsAg negative and HBcAb positive are at lower risk for reactivation and can be monitored closely for reactivation (eg, every 1 to 3 months) or started on anti-HBV prophylaxis, depending on the clinical situation.(91) [L in Context Link 1]

[M] An expert consensus guideline recommends that live vaccines should be administered at least 2 weeks, and ideally 4 weeks, before starting treatment or administering the next dose of a tumor necrosis factor inhibitor, such as certolizumab.(95)(96) [M in Context Link 1]

Codes

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