Abatacept

ACG: A-0453 (AC)
Link to Codes

MCG Health
Ambulatory Care
30th Edition

Clinical Indications

- Abatacept may be indicated when **ALL** of the following are present(1)(2):
  - Appropriate clinical scenario, as indicated by **1 or more** of the following:
    - Acute graft vs host disease prophylaxis, as indicated by **ALL** of the following(21)(22)(23):N
      - Age 2 years or older
      - Administered in combination with calcineurin inhibitor (eg, cyclosporine, tacrolimus) and methotrexate
      - Patient receiving concurrent antiviral prophylaxis for Epstein-Barr virus reactivation
      - Patient undergoing hematopoietic stem cell transplant from matched or 1-allele-mismatched unrelated donor
    - Juvenile idiopathic arthritis, as indicated by **1 or more** of the following(26)(27)(28)(29):N
      - Initial course, as indicated by **ALL** of the following:
        - Appropriate route for patient age, as indicated by **1 or more** of the following:
          - Intravenous, and age 6 years or older
          - Subcutaneous, and age 2 years or older
        - Intolerance of or inadequate response to **1 or more** of the following(27):
          - Methotrexate or leflunomide
          - Tumor necrosis factor inhibitor (eg, adalimumab, etanercept)
        - Joint involvement of 5 joints or more
      - Subsequent course, as indicated by **ALL** of the following:
        - Appropriate route for patient age, as indicated by **1 or more** of the following:
          - Intravenous, and age 6 years or older
          - Subcutaneous, and age 2 years or older
        - Favorable response to prior administration of abatacept
    - Psoriatic arthritis, as indicated by **1 or more** of the following(36)(37):N
      - Initial course, as indicated by **ALL** of the following:
        - Appropriate route for patient age, as indicated by **1 or more** of the following:
          - Intravenous, and age 18 years or older
          - Subcutaneous, and age 2 years or older
        - Active psoriatic arthritis, as indicated by **ALL** of the following(38)(39)(40)(41):
          - Active disease with one or more tender and swollen joints
          - Inadequate response, intolerance, or contraindication to **1 or more** of the following:
            - Apremilast

- Conventional synthetic DMARD (eg, methotrexate, sulfasalazine, hydroxychloroquine, leflunomide)
- Non-tumor necrosis factor inhibitor biologic medication (eg, abatacept, bimekizumab, guselkumab, ixekizumab, risankizumab, secukinumab, ustekinumab)
- NSAIDs
- Tumor necrosis factor inhibitor (eg, adalimumab, certolizumab, etanercept, golimumab, infliximab)

- Subsequent course, as indicated by **ALL** of the following:
  - Appropriate route for patient age, as indicated by **1 or more** of the following:
    - Intravenous, and age 18 years or older
    - Subcutaneous, and age 2 years or older
  - Favorable response to prior administration of abatacept

- Rheumatoid arthritis, as indicated by **1 or more** of the following(42)(43)(44):
  - Initial course, as indicated by **ALL** of the following:
    - 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(42)(43)(68)(69)(70):
      - Hydroxychloroquine
      - Leflunomide
      - Methotrexate
      - Sulfasalazine
      - Tumor necrosis factor inhibitor (eg, adalimumab, certolizumab, etanercept, golimumab, infliximab)(68)(69)(71)
    - Moderate to severe active rheumatoid arthritis,[A] as indicated by **1 or more** of the following(73)(74):
      - Clinical Disease Activity Index[B] score greater than 10
      - Disease Activity Score using 28-joint counts (DAS28)[C] of 3.2 or greater
      - Patient Activity Scale-II[D] of 3.71 or greater
      - Routine Assessment of Patient Index Data 3[E] score of 7 or greater
      - Simplified Disease Activity Index[F] score greater than 11
  - Subsequent course, as indicated by **ALL** of the following:
    - Age 18 years or older
    - Favorable response to prior administration of abatacept
- No active infection(2)(42)(75)(76)
- No concurrent treatment with Janus kinase inhibitor or other biologic drug (eg, tumor necrosis factor inhibitor, anakinra)
- No concurrent use of live vaccine during treatment or within 3 months of discontinuing treatment[G](1)
- No untreated latent or active tuberculosis(2)(42)(75)(77)(78)

Evidence Summary

Background

Abatacept functions as an immunologic agent to block costimulation of T cells, reducing their role in the inflammatory response.(1)(3) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 60 published peer reviewed articles, 10 specialty society or other evidence-based guidelines, and 3 Cochrane systematic reviews.

For acute graft vs host disease prophylaxis, evidence demonstrates an incomplete assessment of net benefit vs harm; the drug is currently approved by a federal regulatory agency. **(RG A3)** A phase II trial evaluating abatacept for acute graft vs host disease prophylaxis after hematopoietic stem cell transplant included 2 arms: a randomized double-blind arm including 142 patients with matched donors comparing treatment with a calcineurin inhibitor plus methotrexate with and without concurrent abatacept, and an open-label arm including 43 patients with 1-allele-mismatched donors treated with combination calcineurin inhibitor, methotrexate, and abatacept compared with a historical control cohort. At 100 days post transplant, patients who received abatacept had lower rates of acute graft vs host disease compared with patients who did not: in the double-blind arm, 6.8% and 14.8% of patients receiving abatacept and placebo, respectively; in the open-label arm, 2.3% and 30.2% in the abatacept and historical control groups, respectively.(24) **(EG 2)** An international specialty society guideline states that there is insufficient evidence to make a recommendation regarding the use of abatacept for prophylaxis of acute graft vs host disease.(25) **(EG 2)**

For juvenile idiopathic arthritis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Systematic reviews and health technology assessments have found evidence from clinical trials that abatacept demonstrated effectiveness in reducing signs and symptoms of moderate to severe polyarticular juvenile idiopathic arthritis in patients who had failed treatment with

disease-modifying antirheumatic drugs and tumor necrosis factor inhibitors.(26)(30)(31)(32) **(EG 1)** A phase III single-arm study of 219 pediatric patients with juvenile idiopathic arthritis who had failed treatment with at least one disease-modifying antirheumatic drug evaluated treatment with subcutaneous abatacept in 2 age cohorts (age 6 to 17 years and age 2 to 5 years). A 30% improvement in JIA-American College of Rheumatology response criteria (JIA-ACR30) was seen at 4 months in 83% and 89% of patients, respectively; at 24 months, the response was seen in 58% and 100% of patients, respectively.(33) **(EG 2)** A practice guideline recommends abatacept as a treatment option for patients with juvenile idiopathic arthritis who do not respond to first-line treatment with methotrexate or a tumor necrosis factor inhibitor.(27) **(EG 2)** Long-term extension studies of patients with juvenile idiopathic arthritis suggest continuing efficacy and safety of abatacept for up to at least 7 years.(34) **(EG 2)** A systematic review identified 3 trials that separately studied the effects of adalimumab, etanercept, and abatacept for treatment of juvenile idiopathic arthritis with polyarthritis; through indirect comparisons, the authors stated that all 3 agents seem to be equally efficacious in preventing disease flare after response to treatment.(35) **(EG 1)**

For psoriatic arthritis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A multicenter phase III trial randomized 424 patients with active psoriatic arthritis to weekly subcutaneous abatacept or placebo and found, at 24 weeks, that abatacept was associated with more patients achieving 20% improvement in American College of Rheumatology response criteria (ACR20). However, quality-of-life and disability parameters were not significantly improved, and there was limited improvement in psoriatic lesions.(37) **(EG 1)** A multicenter randomized phase II study of 170 patients with active psoriatic arthritis and active plaque psoriasis with disease duration of at least 3 months that had not adequately responded to disease-modifying antirheumatic drugs compared 3 abatacept dosing regimens to placebo; after 6 months, patients in the 3 treatment arms were all given a monthly dose of abatacept for a 12-month open-label period. Statistically significant improvement in ACR20 was seen in the patients treated with abatacept doses of 3 mg/kg and 10 mg/kg compared with placebo. The authors concluded that abatacept may be a treatment option in patients with active psoriatic arthritis previously treated with disease-modifying antirheumatic drugs and tumor necrosis factor inhibitors.(36) **(EG 1)** A subspecialty practice guideline cites low-quality evidence that abatacept is a second-line or third-line option for treatment of psoriatic arthritis that is unresponsive to oral medications (eg, methotrexate) or tumor necrosis factor inhibitors.(38) **(EG 2)**

For rheumatoid arthritis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Systematic reviews of randomized controlled trials and a technology assessment have concluded that abatacept is effective in patients with moderate to severe active disease that has not responded adequately to therapy with disease-modifying antirheumatic drugs, such as methotrexate, or tumor necrosis factor inhibitors.(45)(46)(47)(48) **(EG 1)** Abatacept is also effective in protecting against radiographic progression of joint disease.(49) **(EG 2)** A randomized controlled trial of 351 patients with less than 2 years of symptoms found that, after 12 months, abatacept administered with methotrexate was significantly more effective than methotrexate alone in terms of Disease Activity Score.(50) **(EG 1)** In an extension of this study, 225 patients with low disease activity at 12 months (defined as Disease Activity Score in 28 Joints using C-reactive protein level (DAS28-CRP) score of less than 3.2) entered a 3-month withdrawal period, after which patients with a subsequent disease flare (defined as meeting at least 2 of 3 criteria: DAS28-CRP score of 1.2 or more, a doubling of tender or swollen joints, and investigator judgment of rheumatoid arthritis flare) were eligible for retreatment with combination abatacept and methotrexate; among 172 patients who received retreatment, mean DAS28-CRP scores improved from 5.28 to 2.41, with 76.6% and 62.9% of patients reaching states of low disease activity and remission, respectively.(51) **(EG 2)** A multicenter, phase IIIb, randomized controlled trial of 646 patients reported that abatacept and adalimumab have comparable efficacy, over a period of at least 2 years, in patients with rheumatoid arthritis.(52)(53) **(EG 1)** A phase IIIb randomized controlled trial of 1457 patients with rheumatoid arthritis with inadequate response to methotrexate compared treatment with subcutaneous abatacept (administered weekly) or intravenous abatacept (on day 1, 15, 29, then monthly) and found, at 6 months, no difference between the groups in the number of patients achieving 20%, 50%, and 70% improvement in American College of Rheumatology response criteria (ACR20, ACR50, and ACR70). After the initial 6-month period, 1372 patients continued therapy with weekly subcutaneous abatacept; at 5-year follow-up, clinical efficacy was maintained, and 25.7% of patients had experienced a serious adverse event, with infection being the most common adverse event.(54)(55) **(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.(56) **(EG 1)** Indirect comparisons of abatacept and other biologic agents have reported comparable efficacy.(57)(58)(59)(60)(61) **(EG 1)** Long-term extension studies of patients with rheumatoid arthritis report that abatacept has an acceptable safety profile for continuous use for up to 8 years.(62)(63)(64) **(EG 2)** Concerns exist regarding the potential development of malignancy in patients with inflammatory arthritis (such as rheumatoid arthritis) receiving biologic therapies such as abatacept. 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.(65) **(EG 1)** An international specialty society states that biologic medications can be used for the treatment of inflammatory arthritis in patients with cancer in remission; however, because the evidence on the safety of abatacept in these patients is still emerging, abatacept should be considered only when other therapeutic options are unavailable.(66)(67) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For inflammatory bowel disease, evidence demonstrates a lack of net benefit; additional research is recommended. **(RG C1)** Results from 4 randomized placebo-controlled trials evaluating the safety and efficacy of abatacept as induction and maintenance therapy in 451 patients with Crohn disease and 490 patients with ulcerative colitis reported that abatacept was not efficacious for the treatment of these conditions.(4) **(EG 1)**

For inflammatory vasculitis (giant cell arteritis, Takayasu arteritis), evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** After an initial treatment of 49 patients with newly diagnosed or relapsing giant cell arteritis with a regimen of abatacept plus prednisone, the 41 patients who achieved remission were randomized to treatment with monthly abatacept maintenance therapy or placebo; at 12-month follow-up, the maintenance abatacept group was associated with a higher relapse-free survival rate and longer median duration of remission. However, the authors noted that the small sample size limited analysis of potential confounding variables in the study, and there are no standardized measures of disease activity.(5) **(EG 1)** Review articles note that, although abatacept looks promising as a therapy for giant cell arteritis, further studies with more patients are needed to confirm its effectiveness for reducing relapse or as a steroid-sparing agent.(6)(7) **(EG 2)** A randomized trial of 26 patients with Takayasu arteritis (all of whom achieved remission after receiving abatacept at day 1, 15, 29, and at week 8) compared maintenance therapy with monthly abatacept or placebo and found, at 12 months, no difference between the groups in relapse-free survival rates or duration of remission.(8) **(EG 1)** A specialty society guideline states that abatacept is not recommended for the treatment of Takayasu arteritis.(9) **(EG 2)**

For Sjogren syndrome, evidence demonstrates a lack of net benefit; additional research is recommended. **(RG C1)** A randomized phase III trial of 187 patients with active moderate to severe Sjogren syndrome compared treatment with either abatacept or placebo and found, at 169 days' follow-up, no difference in European League Against Rheumatism Sjogren's Syndrome Disease Activity Index (ESSDAI) scores between the groups.(10) **(EG 1)** A specialty society guideline states that the evidence is inconclusive as to whether abatacept is efficacious in the treatment of Sjogren disease.(11) **(EG 2)**

For systemic lupus erythematosus, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A phase II randomized placebo-controlled trial with 175 patients did not meet the primary endpoint of reduction in subsequent disease flares.(12) **(EG 1)** Subsequent trials have been terminated early due to lack of efficacy.(13)(14)(15) **(EG 2)** Lack of efficacy was also noted in studies of patients with lupus nephritis.(16)(17) **(EG 2)**

For systemic sclerosis, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A phase II randomized trial of 88 patients with diffuse cutaneous systemic sclerosis compared treatment with abatacept or placebo and found, at 12-month follow-up, no difference in modified Rodnan skin thickness scores between the groups; further randomized trials were recommended.(18) **(EG 1)** International specialty society guidelines do not endorse abatacept for treatment of patients with systemic sclerosis.(19)(20) **(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(79); 42 CFR 422.101(80)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(81); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(82); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(83)

Medicare Coverage Determinations: Medicare Coverage Database(84)

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Footnotes

[A] 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.(72) [A in Context Link 1]

[B] 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.(73) [B in Context Link 1]

[C] 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.(73) [C in Context Link 1]

[D] 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.(73) [D in Context Link 1]

[E] 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.(73) [E in Context Link 1]

[F] 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.(73) [F in Context Link 1]

[G] Patients should be brought up to date on all vaccines prior to administration of abatacept.(1) [G in Context Link 1]

Codes

HCPCS: J0129

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