

Abatacept (Orencia®)

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr. Go to "Comunicados a Proveedores", and click "Cartas Circulares".]

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| Medical Policy: | MP-RX-05-08 |
| Original Effective Date: | November 20, 2008 |
| Revised: | June 6, 2024 |
| Next Revision: | June 2025 |

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider's contract, unless specific contract limitations, exclusions or exceptions apply. Please refer to the member's benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

All medical policies are developed taking into consideration the Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

DESCRIPTION

Abatacept (CTLA-4Ig) is a fully human recombinant fusion protein categorized as a costimulatory or second-signal blocker of T cell activation. Abatacept disrupts the activation pathway of T cells causing a disturbance in key mechanisms of inflammation and progressive joint destruction in Rheumatoid Arthritis (RA) and other inflammatory arthritic diseases.

The FDA approved Abatacept in December 2005 for RA and in April 2008 for polyarticular Juvenile Idiopathic Arthritis (juvenile rheumatoid arthritis, JRA). In July 2011, a subcutaneous injection, in a prefilled syringe, was approved for the treatment of RA in adults. In July 2017, Abatacept was approved the treatment of adults with active Psoriatic Arthritis (PsA) in both intravenous (IV) and subcutaneous (SC) injection formulations. On December 15, 2021, FDA approved abatacept for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor (CNI) and methotrexate (MTX), in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. This is the first drug approved to prevent aGVHD.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests and benefits coverage.

Medical Card System, (MCS), will consider off-labeled drug uses as reasonable and medically necessary, in so far as they fully meet the requirements and compendia recognized in our [Off-Labeled Drug Use Medical Policy](#), linked herein.

INDICATIONS

I. Medical Card System, Inc. (MCS) considers the use of Abatacept (Orencia®) **medically necessary** when requested by a practicing rheumatologist or dermatologist, for the following indications:

1. For the treatment of moderate to severe Active Rheumatoid Arthritis (RA) in Adults:
 - a. To reduce signs and symptoms of the disease;
 - b. To induce a major clinical response;
 - c. To inhibit the progression of structural damage; and
 - d. To improve physical function
2. For the treatment of moderate to severely active polyarticular Juvenile Rheumatoid Arthritis (JRA)/Juvenile Idiopathic Arthritis (JIA) as an intravenous infusion to reduce signs and symptoms of the disease, in pediatric patients (6 years of age and older) or a subcutaneous injection (2 years of age and older).
3. For the treatment of adult patients with Active Psoriatic Arthritis (PsA)
4. For the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients \geq 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

II. Medical Card System, Inc. (MCS) will consider the administration of Abatacept (Orencia®) **medically necessary** when requested by a practicing rheumatologist or dermatologist and the following criteria are met:

1. Patient is not on any other of the following medications (for concomitant use): Enbrel, Humira, Simponi, Cimzia or Remicade.
2. The patient has a documented inadequate response, or inability to tolerate at least two or more of the following medications:
 - a. Tumor Necrosis Factors (TNF) antagonists (e.g., Enbrel, Remicade, Humira, Kineret); or
 - b. Other biologic DMARDs (e.g., Enbrel, Remicade, Infectra, Renflexis, Humira, Ilaris and Kineret); or

- c. Other non-biologic DMARDs (for at least three months): Leflunomide and/or Methotrexate.

CONTRAINDICATIONS /LIMITATIONS

1. Abatacept is contraindicated in patients with known hypersensitivity to abatacept or to any of its components. In addition, each vial of abatacept contains 500 mg of maltose; use caution in patients with maltose hypersensitivity.
2. Abatacept may be used alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) with the exception of TNF antagonists
3. Patients with a history of recurrent infections or an underlying condition that may predispose them to infections (i.e., advanced or uncontrolled diabetes mellitus, malignancy, immunosuppression [including long-term corticosteroid therapy], or a history of active or chronic infections) may not be appropriate candidates for abatacept therapy.
4. It is recommended that patients with juvenile idiopathic arthritis be brought up to date with all immunizations in agreement with current immunization guidelines prior to abatacept initiation.
5. As this medication may affect immune system function, careful consideration of vaccination history and scheduling is needed prior to Abatacept initiation. The efficacy of vaccination in treated patients is unknown and live vaccines should not be given concurrently with Abatacept or within 3 months of its discontinuation.
6. Data with abatacept use during human pregnancy are insufficient to inform a drug associated risk. There are no adequate and well-controlled studies of Abatacept in pregnant women. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to abatacept during pregnancy; Healthcare providers are encouraged to register patients and pregnant women are encouraged to enroll.
7. Abatacept is not recommended for use concomitantly with other biologic rheumatoid arthritis (RA) therapy such as anakinra or Janus Kinase (JAK) inhibitors.

PRECAUTIONS

1. Safety of Abatacept receipt by patients with latent tuberculosis infection is unknown. Patients with a positive tuberculosis test should be treated by standard medical practice before Abatacept receipt.
2. Screen patients for viral hepatitis in accordance with published guidelines before starting abatacept, as anti-rheumatic therapies have been associated with hepatitis B reactivation.

3. Patients with a predisposition for respiratory infection such as patients who are actively tobacco smoking or patients with asthma, COPD, emphysema, cystic fibrosis, or compromised immunity should be monitored closely for the development of infection when Abatacept is administered.
4. Patients who develop a new infection during therapy should be closely monitored. If a patient develops a serious infection, sepsis, signs of hematological disease (i.e., agranulocytosis or persistent fever, bleeding, bruising, or pallor), or if significant hematologic abnormalities are confirmed during abatacept therapy, the drug should be discontinued.
5. Abatacept could affect host defense against neoplastic disease. Patients with rheumatoid arthritis may be at an increased risk (up to several folds), compared to the general population for developing lymphoma. Moreover, some therapies for rheumatoid arthritis including TNF blockers have a possible association with the development of lymphomas. As malignancy is a possible risk of immunosuppressive therapy, practitioners should exercise caution in prescribing Abatacept to patients with a history of malignancies.
6. In general, geriatric patients, by virtue of decreased immunity, are more susceptible to developing a serious infection, and caution should be used when treating the elderly with Abatacept.
7. There is no data regarding the presence of abatacept in human milk, the effects on the breastfeeding infant, or the effects on milk production. Abatacept was detected in the milk of lactating rats.
8. Blood glucose testing systems based on the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or on the glucose-dye-oxidoreductase methods falsely interpret the maltose contained in Abatacept for intravenous infusion as glucose. False elevated glucose readings (false hyperglycemia) led to life-threatening hypoglycemia because of inappropriate administration of insulin. False elevated glucose readings could also mask true cases of hypoglycemia. Measurement of blood glucose must be done with a glucose-specific method if a patient takes a parenteral product that contains maltose. The prefilled syringe of Abatacept for subcutaneous administration does not contain maltose.
9. Safety and efficacy in patients with bone marrow suppression has not been studied.
10. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving this medication.
11. Prior to administering abatacept, initiate antiviral prophylaxis for Epstein-Barr virus (EBV) reactivation, according to clinical/institutional practice guidelines; continue antiviral prophylaxis for 6 months following hematopoietic stem cell transplant (HSCT). Consider prophylactic antivirals for cytomegalovirus (CMV) infection/reactivation during abatacept treatment and for 6 months following HSCT.

12. Safety and efficacy of subcutaneous abatacept have not been studied in infants and children less than 2 years of age. Intravenous abatacept has not been administered in pediatric patients younger than 6 years of age.
13. The impact of abatacept therapy on the development of a new primary malignancy and course of malignancies is not fully understood. Malignancies, including skin cancer, have been reported with abatacept therapy. Periodic skin examinations are recommended for all patients treated with abatacept, especially those with risk factors for skin cancer.

RATIONALE

Orencia is indicated for treatment of various inflammatory conditions. Orencia is not recommended for use concomitantly with other potent immunosuppressants such as biologics or Janus kinase inhibitors. Orencia is available as an intravenous infusion that is dosed on body weight. Because of the specialized skills required for evaluation and diagnosis of patients treated with Orencia intravenous as well as the monitoring required for adverse events and long-term efficacy, all requests will be evaluated individually for medical necessity and taking into consideration patient safety based on the policy criteria.

CODING INFORMATION

HCPCS CODES (List may not be all inclusive)

| HCPCS® CODES | DESCRIPTION |
|--------------|--|
| J0129 | Injection, abatacept 10 mg (Code may be used for Medicare when drug administered under the direct supervision of a Physician, not for use when drug is self-administered.) |

2024 HCPCS LEVEL II Professional Edition® (American Medical Association).

ICD-10 Codes (List may not be all inclusive)

| ICD-10-CODES | DESCRIPTION |
|----------------|--|
| D89.810 | Acute graft-versus-host-disease |
| D89.811 | Chronic graft-versus-host disease |
| D89.812 | Acute on chronic graft-versus-host disease |
| D89.813 | Graft-versus-host disease, unspecified |
| I30.8 | Other forms of acute pericarditis |
| I30.9 | Acute pericarditis, unspecified |
| I40.8 | Other acute myocarditis |
| I40.9 | Acute myocarditis, unspecified |
| L40.50 | Arthropathic psoriasis, unspecified |
| L40.51 | Distal interphalangeal psoriatic arthropathy |

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| L40.52 | Psoriatic arthritis mutilans |
| L40.53 | Psoriatic spondylitis |
| L40.59 | Other psoriatic arthropathy |
| 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 |
| 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 |

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| 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 |

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| 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 |

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| M05.571 | Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot |
| M05.572 | Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot |
| M05.579 | Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot |
| M05.59 | Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites |
| M05.60 | Rheumatoid arthritis of unspecified site with involvement of other organs and systems |
| M05.611 | Rheumatoid arthritis of right shoulder with involvement of other organs and systems |
| M05.612 | Rheumatoid arthritis of left shoulder with involvement of other organs and systems |
| M05.619 | Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems |
| M05.621 | Rheumatoid arthritis of right elbow with involvement of other organs and systems |
| M05.622 | Rheumatoid arthritis of left elbow with involvement of other organs and systems |
| M05.629 | Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems |
| M05.631 | Rheumatoid arthritis of right wrist with involvement of other organs and systems |
| M05.632 | Rheumatoid arthritis of left wrist with involvement of other organs and systems |
| M05.639 | Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems |
| M05.641 | Rheumatoid arthritis of right hand with involvement of other organs and systems |
| M05.642 | Rheumatoid arthritis of left hand with involvement of other organs and systems |
| M05.649 | Rheumatoid arthritis of unspecified hand with involvement of other organs and systems |
| M05.651 | Rheumatoid arthritis of right hip with involvement of other organs and systems |
| M05.652 | Rheumatoid arthritis of left hip with involvement of other organs and systems |
| M05.659 | Rheumatoid arthritis of unspecified hip with involvement of other organs and systems |
| M05.661 | Rheumatoid arthritis of right knee with involvement of other organs and systems |
| M05.662 | Rheumatoid arthritis of left knee with involvement of other organs and systems |
| M05.669 | Rheumatoid arthritis of unspecified knee with involvement of other organs and systems |
| M05.671 | Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems |
| M05.672 | Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems |
| M05.679 | Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems |
| M05.69 | Rheumatoid arthritis of multiple sites with involvement of other organs and systems |
| M05.70 | Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement |
| M05.711 | Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement |
| M05.712 | Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement |

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| M05.719 | Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement |
| M05.721 | Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement |
| M05.722 | Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement |
| M05.729 | Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement |
| M05.731 | Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement |
| M05.732 | Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement |
| M05.739 | Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement |
| M05.741 | Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement |
| M05.742 | Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement |
| M05.749 | Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement |
| M05.751 | Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement |
| M05.752 | Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement |
| M05.759 | Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement |
| M05.761 | Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement |
| M05.762 | Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement |
| M05.769 | Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement |
| M05.771 | Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement |
| M05.772 | Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement |
| M05.779 | Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement |
| M05.79 | Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement |
| M05.80 | Other rheumatoid arthritis with rheumatoid factor of unspecified site |
| M05.811 | Other rheumatoid arthritis with rheumatoid factor of right shoulder |
| M05.812 | Other rheumatoid arthritis with rheumatoid factor of left shoulder |
| M05.819 | Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder |

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| 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 |
| 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 |

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| 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 |
| M08.00 | Unspecified juvenile rheumatoid arthritis of unspecified site |
| M08.011 | Unspecified juvenile rheumatoid arthritis, right shoulder |
| M08.012 | Unspecified juvenile rheumatoid arthritis, left shoulder |
| M08.019 | Unspecified juvenile rheumatoid arthritis, unspecified shoulder |
| M08.021 | Unspecified juvenile rheumatoid arthritis, right elbow |
| M08.022 | Unspecified juvenile rheumatoid arthritis, left elbow |
| M08.029 | Unspecified juvenile rheumatoid arthritis, unspecified elbow |
| M08.031 | Unspecified juvenile rheumatoid arthritis, right wrist |
| M08.032 | Unspecified juvenile rheumatoid arthritis, left wrist |
| M08.039 | Unspecified juvenile rheumatoid arthritis, unspecified wrist |
| M08.041 | Unspecified juvenile rheumatoid arthritis, right hand |
| M08.042 | Unspecified juvenile rheumatoid arthritis, left hand |
| M08.049 | Unspecified juvenile rheumatoid arthritis, unspecified hand |
| M08.051 | Unspecified juvenile rheumatoid arthritis, right hip |
| M08.052 | Unspecified juvenile rheumatoid arthritis, left hip |
| M08.059 | Unspecified juvenile rheumatoid arthritis, unspecified hip |
| M08.061 | Unspecified juvenile rheumatoid arthritis, right knee |
| M08.062 | Unspecified juvenile rheumatoid arthritis, left knee |
| M08.069 | Unspecified juvenile rheumatoid arthritis, unspecified knee |
| M08.071 | Unspecified juvenile rheumatoid arthritis, right ankle and foot |
| M08.072 | Unspecified juvenile rheumatoid arthritis, left ankle and foot |
| M08.079 | Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot |
| M08.08 | Unspecified juvenile rheumatoid arthritis, vertebrae |
| M08.09 | Unspecified juvenile rheumatoid arthritis, multiple sites |
| M08.1 | Juvenile ankylosing spondylitis |
| M08.20 | Juvenile rheumatoid arthritis with systemic onset, unspecified site |
| M08.211 | Juvenile rheumatoid arthritis with systemic onset, right shoulder |
| M08.212 | Juvenile rheumatoid arthritis with systemic onset, left shoulder |
| M08.219 | Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder |
| M08.221 | Juvenile rheumatoid arthritis with systemic onset, right elbow |

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| M08.222 | Juvenile rheumatoid arthritis with systemic onset, left elbow |
| M08.229 | Juvenile rheumatoid arthritis with systemic onset, unspecified elbow |
| M08.231 | Juvenile rheumatoid arthritis with systemic onset, right wrist |
| M08.232 | Juvenile rheumatoid arthritis with systemic onset, left wrist |
| M08.239 | Juvenile rheumatoid arthritis with systemic onset, unspecified wrist |
| M08.241 | Juvenile rheumatoid arthritis with systemic onset, right hand |
| M08.242 | Juvenile rheumatoid arthritis with systemic onset, left hand |
| M08.249 | Juvenile rheumatoid arthritis with systemic onset, unspecified hand |
| M08.251 | Juvenile rheumatoid arthritis with systemic onset, right hip |
| M08.252 | Juvenile rheumatoid arthritis with systemic onset, left hip |
| M08.259 | Juvenile rheumatoid arthritis with systemic onset, unspecified hip |
| M08.261 | Juvenile rheumatoid arthritis with systemic onset, right knee |
| M08.262 | Juvenile rheumatoid arthritis with systemic onset, left knee |
| M08.269 | Juvenile rheumatoid arthritis with systemic onset, unspecified knee |
| M08.271 | Juvenile rheumatoid arthritis with systemic onset, right ankle and foot |
| M08.272 | Juvenile rheumatoid arthritis with systemic onset, left ankle and foot |
| M08.279 | Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot |
| M08.28 | Juvenile rheumatoid arthritis with systemic onset, vertebrae |
| M08.29 | Juvenile rheumatoid arthritis with systemic onset, multiple sites |
| M08.3 | Juvenile rheumatoid polyarthritis (seronegative) |
| M08.40 | Pauciarticular juvenile rheumatoid arthritis, unspecified site |
| M08.411 | Pauciarticular juvenile rheumatoid arthritis, right shoulder |
| M08.412 | Pauciarticular juvenile rheumatoid arthritis, left shoulder |
| M08.419 | Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder |
| M08.421 | Pauciarticular juvenile rheumatoid arthritis, right elbow |
| M08.422 | Pauciarticular juvenile rheumatoid arthritis, left elbow |
| M08.429 | Pauciarticular juvenile rheumatoid arthritis, unspecified elbow |
| M08.431 | Pauciarticular juvenile rheumatoid arthritis, right wrist |
| M08.432 | Pauciarticular juvenile rheumatoid arthritis, left wrist |
| M08.439 | Pauciarticular juvenile rheumatoid arthritis, unspecified wrist |
| M08.441 | Pauciarticular juvenile rheumatoid arthritis, right hand |
| M08.442 | Pauciarticular juvenile rheumatoid arthritis, left hand |
| M08.449 | Pauciarticular juvenile rheumatoid arthritis, unspecified hand |
| M08.451 | Pauciarticular juvenile rheumatoid arthritis, right hip |
| M08.452 | Pauciarticular juvenile rheumatoid arthritis, left hip |
| M08.459 | Pauciarticular juvenile rheumatoid arthritis, unspecified hip |
| M08.461 | Pauciarticular juvenile rheumatoid arthritis, right knee |

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| M08.462 | Pauciarticular juvenile rheumatoid arthritis, left knee |
| M08.469 | Pauciarticular juvenile rheumatoid arthritis, unspecified knee |
| M08.471 | Pauciarticular juvenile rheumatoid arthritis, right ankle and foot |
| M08.472 | Pauciarticular juvenile rheumatoid arthritis, left ankle and foot |
| M08.479 | Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot |
| M08.48 | Pauciarticular juvenile rheumatoid arthritis, vertebrae |
| M08.811 | Other juvenile arthritis, right shoulder |
| M08.812 | Other juvenile arthritis, left shoulder |
| M08.819 | Other juvenile arthritis, unspecified shoulder |
| M08.821 | Other juvenile arthritis, right elbow |
| M08.822 | Other juvenile arthritis, left elbow |
| M08.829 | Other juvenile arthritis, unspecified elbow |
| M08.831 | Other juvenile arthritis, right wrist |
| M08.832 | Other juvenile arthritis, left wrist |
| M08.839 | Other juvenile arthritis, unspecified wrist |
| M08.841 | Other juvenile arthritis, right hand |
| M08.842 | Other juvenile arthritis, left hand |
| M08.849 | Other juvenile arthritis, unspecified hand |
| M08.851 | Other juvenile arthritis, right hip |
| M08.852 | Other juvenile arthritis, left hip |
| M08.859 | Other juvenile arthritis, unspecified hip |
| M08.861 | Other juvenile arthritis, right knee |
| M08.862 | Other juvenile arthritis, left knee |
| M08.869 | Other juvenile arthritis, unspecified knee |
| M08.871 | Other juvenile arthritis, right ankle and foot |
| M08.872 | Other juvenile arthritis, left ankle and foot |
| M08.879 | Other juvenile arthritis, unspecified ankle and foot |
| M08.88 | Other juvenile arthritis, other specified site |
| M08.89 | Other juvenile arthritis, multiple sites |
| M08.911 | Juvenile arthritis, unspecified, right shoulder |
| M08.912 | Juvenile arthritis, unspecified, left shoulder |
| M08.919 | Juvenile arthritis, unspecified, unspecified shoulder |
| M08.921 | Juvenile arthritis, unspecified, right elbow |
| M08.922 | Juvenile arthritis, unspecified, left elbow |
| M08.929 | Juvenile arthritis, unspecified, unspecified elbow |
| M08.931 | Juvenile arthritis, unspecified, right wrist |
| M08.932 | Juvenile arthritis, unspecified, left wrist |

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| M08.939 | Juvenile arthritis, unspecified, unspecified wrist |
| M08.941 | Juvenile arthritis, unspecified, right hand |
| M08.942 | Juvenile arthritis, unspecified, left hand |
| M08.949 | Juvenile arthritis, unspecified, unspecified hand |
| M08.951 | Juvenile arthritis, unspecified, right hip |
| M08.952 | Juvenile arthritis, unspecified, left hip |
| M08.959 | Juvenile arthritis, unspecified, unspecified hip |
| M08.961 | Juvenile arthritis, unspecified, right knee |
| M08.962 | Juvenile arthritis, unspecified, left knee |
| M08.969 | Juvenile arthritis, unspecified, unspecified knee |
| M08.971 | Juvenile arthritis, unspecified, right ankle and foot |
| M08.972 | Juvenile arthritis, unspecified, left ankle and foot |
| M08.979 | Juvenile arthritis, unspecified, unspecified ankle and foot |
| M08.98 | Juvenile arthritis, unspecified, vertebrae |
| M08.99 | Juvenile arthritis, unspecified, multiple sites |
| M60.811 | Other myositis, right shoulder |
| M60.812 | Other myositis, left shoulder |
| M60.819 | Other myositis, unspecified shoulder |
| M60.821 | Other myositis, right upper arm |
| M60.822 | Other myositis, left upper arm |
| M60.829 | Other myositis, unspecified upper arm |
| M60.831 | Other myositis, right forearm |
| M60.832 | Other myositis, left forearm |
| M60.839 | Other myositis, unspecified forearm |
| M60.841 | Other myositis, right hand |
| M60.842 | Other myositis, left hand |
| M60.849 | Other myositis, unspecified hand |
| M60.851 | Other myositis, right thigh |
| M60.852 | Other myositis, left thigh |
| M60.859 | Other myositis, unspecified thigh |
| M60.861 | Other myositis, right lower leg |
| M60.862 | Other myositis, left lower leg |
| M60.869 | Other myositis, unspecified lower leg |
| M60.871 | Other myositis, right ankle and foot |
| M60.872 | Other myositis, left ankle and foot |
| M60.879 | Other myositis, unspecified ankle and foot |
| M60.88 | Other myositis, other site |

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| M60.89 | Other myositis, multiple sites |
| T86.09 | Other complications of bone marrow transplant |

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POLICY HISTORY

| DATE | ACTION | COMMENT |
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| November 20, 2008 | Origination of Policy | |
| January 21, 2010 | Revised | <p>References were updated.</p> <p>To the Dosage and Recommendation section, the following paragraph was added, "The recommended dose of ABATACEPT for patients 6 to 17 years of</p> |

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| | | <p>age with Juvenile idiopathic arthritis who weigh less than 75 Kg is 10 mg/Kg is calculated based on the patient body weight at each Administration.</p> <p>Pediatric patients weighing 75 kg or more should be administered abatacept following the adult dosing regimen, not to exceed a maximum dose of 1000 mg".</p> <p>Updated Indications and Contraindications were added and revised.</p> |
| January 31, 2011 | Yearly Revision | <p>Under Description Section, Dosage and Recommendation was deleted from this section.</p> |
| January 31, 2012 | Revised | <p>References updated.</p> <p>Contraindications 11 – 21 added from Clinical Pharmacology's last update.</p> |
| January 10, 2013 | Revised | <p>References updated. Added new references: numbers 1, 7 & 10.</p> <p>To the Indications Section: Added: in pediatric patients (6 years of age and older), for the following indication: For the treatment of moderate to severe polyarticular juvenile rheumatoid arthritis (JRA)/juvenile idiopathic arthritis (JIA) to reduce signs and symptoms of the disease.</p> |
| February 21, 2014 | Revised | <p>To the Coding Section: Added new ICD-10 Codes (Preview Draft) section was added to the medical policy.</p> |
| March 18, 2014 | Revised | <p>References updated.</p> <p>To the Description Section: <ul style="list-style-type: none"> Added the correspondent citation: (Clinical Pharmacology, 2013). </p> <p>To the Indications Section: <ul style="list-style-type: none"> To Heading I, rewrote statement as to read: Medical Card System, Inc. (MCS) considers medically necessary the use of Abatacept (Orencia®) for the following indications. Deleted Note: For members with Rheumatoid arthritis (RA) for at least six (6) months have failed methotrexate combination therapy or sequential administration of other non-biologic DMARDs and have both poor prognostic features and moderate or high disease activity. Deleted Note: As an alternative treatment, options are a tumor necrosis factor (TNF) modifier or rituximab (only high disease activity) (Clinical Pharmacology, 2013). Deleted Note: Abatacept may be used alone or in combination with methotrexate or other disease modifying anti-rheumatic drugs (DMARDs) with the exception of TNF antagonists (CMS L29069, 2012). Deleted Note: Abatacept may be used as monotherapy or concomitantly with methotrexate; do not use with TNF antagonists (CMS L29069, 2012). Added the correspondent citations: (Clinical Pharmacology, 2013) & (CMS L29069, 2012). To the Indication: c. Medication should be requested by a practicing rheumatologist, added: (This applies to Part 1 & 2 from the Indications Section). </p> <p>To the Contraindications/ Limitations /Precautions Section: <ul style="list-style-type: none"> Added the correspondent citations: (Clinical Pharmacology, 2013) & (CMS L29069, 2012). To #3 added: Safety of Abatacept receipt by patients with latent tuberculosis infection is unknown. Deleted: As Abatacept inhibits a key mechanism of T-cell activation, its use appears to be associated with an increased risk of developing infection (specifically upper respiratory infection). Serious, and sometimes fatal, infections have developed in Abatacept recipients, with many occurring in patients receiving concomitant immunosuppressive therapies. Deleted: Although Abatacept for infusion is FDA approved for use in children 6 years and older, the subcutaneous formulation is indicated for </p> |

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| | | <p>adult use only. Further, safety and efficacy of Abatacept have not been studied in neonates, infants, and children less than 6 years of age and the products are not recommended for these age groups. Similar to adults, pediatric patients treated with this medication may be at an increased risk of infection and have a decreased response to immunizations. If possible, administer all needed vaccinations to patients before Abatacept initiation.</p> <ul style="list-style-type: none"> Deleted: Read the product information of the blood glucose testing system including the information about the test strips to determine if the system is appropriate for use with maltose-containing parenteral products such as Abatacept for intravenous infusion. If any uncertainty exists, contact the manufacturer of the testing system. Added: Safety and efficacy in patients with bone marrow suppression has not been studied (Clinical Pharmacology, 2013). |
| April 2, 2015 | Revised | <p>References updated.</p> <p>To the Description Section:</p> <ul style="list-style-type: none"> Some information was eliminated because is included in the indications section: "Although Abatacept may be used with methotrexate, concurrent use of Abatacept and TNF-inhibitors is not recommended." <p>To the Contraindications/Limitations/ Precautions Section:</p> <ul style="list-style-type: none"> This Section was divided in two sections; one for contraindications/limitations and another for the Precautions. <p>To the Coding Section:</p> <ul style="list-style-type: none"> ICD9 Code 714.31 was eliminated from the policy because the medical condition "ACUTE" for Juvenile Rheumatoid arthritis is not contemplated in this medical policy. <p>To the Reference Section:</p> <ul style="list-style-type: none"> New Reference #11 was added to the Policy. April 2, 2015 was reviewed with the AHFS Compendium. |
| November 23, 2015 | Revised | <p>To the coding section:</p> <ul style="list-style-type: none"> Eliminate ICD-9 codes since they are no longer valid for diagnosis classification. Add new section of ICD-10 codes which are the valid diagnosis classification system since October 1, 2015. |
| March 03, 2016 | Revised | <p>References were updated.</p> <p>To the Indication Section:</p> <ul style="list-style-type: none"> To the Section II.2 - Word "Should" was substitute by the word "Must" as requested by Dr. Sergio Baerga at the Criteria. <p>To the Coding Section:</p> <p>The Following ICD-10 Codes were added to the Policy:</p> <p>M05.10, M05.111, M05.112, M05.119, M05.121, M05.122, M05.129, M05.131, M05.132, M05.139, M05.141, M05.142, M05.149, M05.151, M05.152, M05.159, M05.161, M05.162, M05.169, M05.171, M05.172, M05.179, M05.19, M05.20, M05.211, M05.212, M05.219, M05.221, M05.222, M05.229, M05.231, M05.232, M05.239, M05.241, M05.242, M05.249, M05.251, M05.252, M05.259, M05.261, M05.262, M05.269, M05.271, M05.272, M05.279, M05.29, M05.30, M05.311, M05.312, M05.319, M05.321, M05.322, M05.329, M05.331, M05.332, M05.339, M05.341, M05.342, M05.349, M05.351, M05.352, M05.359, M05.361, M05.362, M05.369, M05.371, M05.372, M05.379, M05.39, M05.60, M05.611, M05.612, M05.619, M05.621, M05.622, M05.629, M05.631, M05.632, M05.639, M05.641, M05.642, M05.649, M05.651, M05.652, M05.659, M05.661, M05.662, M05.669, M05.671, M05.672, M05.679, M05.69, M08.1, M08.3, M08.40, M08.411, M08.412, M08.419, M08.421, M08.422, M08.429, M08.431, M08.432, M08.439, M08.441, M08.442, M08.449, M08.451, M08.452,</p> |

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| | | <p>M08.459, M08.461, M08.462, M08.469, M08.471, M08.472, M08.479, and M08.48.</p> <p>To the References Section:</p> <p>New References #10 and 13 were added to the Policy.</p> |
| June 30, 2017 | Revised | <p>References updated. Deleted #8 & #13.</p> <p>To the Indications Section:</p> <ul style="list-style-type: none"> To Indications Set I: Modified #2 to read as follows: For the treatment of moderate to severely active polyarticular Juvenile Rheumatoid Arthritis (JRA)/Juvenile Idiopathic Arthritis (JIA) as an intravenous infusion to reduce signs and symptoms of the disease, in pediatric patients (6 years of age and older) or a subcutaneous injection (2 years of age and older). To Indications Set I: Modified Coverage Statement to read as follows: Medical Card System, Inc. (MCS) considers the use of Abatacept (Orencia®) medically necessary when requested by a practicing rheumatologist for the following indications: To Indications Set II: Modified Coverage Statement to read: Medical Card System, Inc. (MCS) will consider the administration of Abatacept (Orencia®) medically necessary when requested by a practicing rheumatologist and the following criteria are met: To Indications Set II: Deleted former #2 bullet c: Medication must be requested by a practicing rheumatologist (This applies to Part 1 and 2 from the Indications Section). To Indications Set II: To #2 – Modified to read as follows: Patient is not on any other of the following medications (for concomitant use): Enbrel, Humira, Simponi, Cimzia or Remicade. To Indications Set II: Modified 3b (Former 2b) to read: Other biologic DMARDs (e.g., Enbrel, Remicade, Humira, Ilaris and Kineret). To Indications Set II: Added new #3c, which reads: Other non-biologic DMARDs (for at least three months): Leflunomide and/or Methotrexate To Indications Set II: Added note to read: Abatacept can be used alone or in conjunction with Methotrexate. <p>To the Contraindications/Limitations Section:</p> <ul style="list-style-type: none"> Deleted #4 which read: The safety and efficacy of abatacept have not been studied in neonates, infants and children less than 6 years of age and is not recommended for these age groups Deleted #5 which read: Abatacept is only indicated for the treatment of polyarticular juvenile idiopathic arthritis (juvenile rheumatoid arthritis, JRA) in patients at least 6 years of age. If possible, Administer all needed vaccinations to patients with juvenile idiopathic arthritis (juvenile rheumatoid arthritis, JRA) before abatacept initiation. Added new #4 to read: It is recommended that patients with juvenile idiopathic arthritis be brought up to date with all immunizations in agreement with current immunization guidelines prior to abatacept initiation. Modified #6, which now read as follows: Data with abatacept use during human pregnancy are insufficient to inform a drug associated risk. There are no adequate and well-controlled studies of Abatacept in pregnant women. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to abatacept during pregnancy; Healthcare providers are encouraged to register patients and pregnant women are encouraged to enroll. <p>To the Precautions Section:</p> <ul style="list-style-type: none"> To #7 added: There is no data regarding the presence of abatacept |

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| | | <p>in human milk, the effects on the breastfeeding infant, or the effects on milk production. Abatacept was detected in the milk of lactating rats. Deleted: Women who are breast-feeding should not take Abatacept. It is not known whether Abatacept is excreted in human milk or is absorbed systemically after ingestion. However, because many drugs are excreted in human milk and because of the potential for serious adverse reactions such as effects on the developing immune system in nursing infants from Abatacept, a decision should be made whether to discontinue nursing or to discontinue the drug. The importance of the drug to the mother should be considered.</p> |
| December 31, 2018 | Revised | Medicare retired the LCD 33257 |
| November 2, 2019 | Revised | <p>References updated. Added #4 & #5.</p> <p>To the Description Section:</p> <ul style="list-style-type: none"> • To 1st paragraph, 2nd sentence, added phrase “and other inflammatory arthritic diseases.” • To 1st paragraph - Deleted 3rd sentence with citation, which read: Because a large number of patients with RA have an inadequate or unsustained response to anti-tumor necrosis factor (TNF) therapy, Abatacept, with its novel mechanism of action, has been studied in the population of patients with RA. (Clinical Pharmacology, 2015). • To 2nd paragraph - Added sentence: “In July 2017, Abatacept was approved the treatment of adults with active Psoriatic Arthritis (PsA) in both intravenous (IV) and subcutaneous (SC) injection formulations. Deleted citation: (Clinical Pharmacology, 2015). <p>To the Indications Section:</p> <ul style="list-style-type: none"> • To Indications set I - Added new indication #3: For the treatment of adult patients with Active Psoriatic Arthritis (PsA). <p>To the Contraindications/Limitations Section:</p> <ul style="list-style-type: none"> • Added new #7 which reads: Abatacept is not recommended for use concomitantly with other biologic rheumatoid arthritis (RA) therapy such as anakinra. <p>To the Coding Information Section:</p> <ul style="list-style-type: none"> • Deleted ICD-10 Code L40.54 and replaced with correct code for descriptor L40.59. |
| April 15, 2020 | Revised | To add the off-label statement, approve by the MAC under the coverage section within this medical policy. |
| December 17, 2020 | Revised | References updated. |
| December 22, 2021 | Revised | <p>References updated. Added new #12.</p> <p>To the Description Section:</p> <ul style="list-style-type: none"> • To 2nd paragraph: Added On December 15, 2021, FDA approved abatacept for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor (CNI) and methotrexate (MTX), in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. This is the first drug approved to prevent aGVHD. <p>To the Indications Section:</p> <ul style="list-style-type: none"> • To Section I. Added new #4, which reads: For the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor |

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| | | <p>To the Precautions Section:</p> <ul style="list-style-type: none"> Added new #11: Prior to administering abatacept, initiate antiviral prophylaxis for Epstein-Barr virus (EBV) reactivation, according to clinical/institutional practice guidelines; continue antiviral prophylaxis for 6 months following hematopoietic stem cell transplant (HSCT). Consider prophylactic antivirals for cytomegalovirus (CMV) infection/reactivation during abatacept treatment and for 6 months following HSCT. <p>To the Coding Information Section:</p> <ul style="list-style-type: none"> Added new ICD-10 Code D89.810 |
| December 09, 2022 | Revised | <p>To the Indications Section:</p> <ul style="list-style-type: none"> To the Indications Section I: Medical Specialist was added according to the MCS Pharmacy Department Approval Preauthorization List to the Statement. To the Section I4: Symbol “≥” was added according to American Hospital Formulary Service Clinical Drug Information (AHFSDI). To the Section II: Medical Specialist was added according to the MCS Pharmacy Department Approval Preauthorization List to the Statement. <p>To the Contraindications /Limitations Section: New information was added to the Contraindication #7 from Drug details – MICROMEDEX: “or Janus Kinase (JAK) inhibitors”.</p> <p>To the Precautions Section: New Precaution # 12 was added from Clinical Pharmacology 2022.</p> <p>To the Coding Information Section:</p> <ul style="list-style-type: none"> New ICD-10 Codes were added to the Policy: D89.811, D89.812, D89.813, I30.8, I30.9, I40.8, I40.9, and T86.09. The following ICD-10 Codes were deleted from this Policy: M08.80, and M08.90. <p>To the References Section: The following Reference was added to the Policy: #10.</p> |
| April 11, 2024 | UMC Approval | |
| June 6, 2024 | Revised | <p>To the Title Section: New statement was added from Sra. Jessica Figueroa Suggestion: All medical policies are developed taking into consideration the Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)</p> <p>To the Indications Section: Note #2 was deleted because was reviewed with CMS – Retired LCD for Abatacept (L33257).</p> <p>To the Precautions Section: New Precaution # 13 was added to the Policy from Clinical Pharmacology 2024.</p> <p>New Rationale Section was added to the Policy.</p> <p>To the Coding Information Section:</p> |

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| | | <p>To the HCPCS Section: Information for the note#1 was deleted and moved to the Code Descriptor. This Information was part of the description of the HCPCS code included in the retired LCD L33257: Code may be used for Medicare when drug administered under the direct supervision of a Physician, not for use when drug is self-administered.</p> <p>To the ICD-10 Codes Section:</p> <ul style="list-style-type: none">New ICD-10 Codes were added to the Policy: Phrase "vertebrae" was deleted and Phrase "Other specified site" added to the ICD-10 Code M08.88. M60.811, M60.812, M60.819, M60.821, M60.822, M60.829, M60.831, M60.832, M60.839, M60.841, M60.842, M60.849, M60.851, M60.852, M60.859, M60.861, M60.862, M60.869, M60.871, M60.872, M60.879, M60.88, and M60.89.The following ICD-10 Codes were deleted from this Policy: <u>N/A.</u> <p>To the References Section: The following References were added to the Policy: #7 and 12.</p> |
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This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Medical Card System, Inc., (MCS) medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Medical Card System, Inc., (MCS) reserves the right to review and update its medical policies at its discretion. Medical Card System, Inc. (MCS) medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.