

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”.]

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 (RI) 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 ≥ 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, Inflectra, 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. Falsely elevated glucose readings (false hyperglycemia) led to life-threatening hypoglycemia because of inappropriate administration of insulin. Falsely 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

This document is designated for informational purposes only and is not an authorization, or an explanation of benefits (EOB), or a contract. Medical technology is constantly changing and we reserve the right to review and update our policies periodically.

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

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

M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee

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

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

M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee

M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
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

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

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

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

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

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POLICY HISTORY

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

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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	Under Description Section, Dosage and Recommendation was deleted from this section.
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:</p> <ul style="list-style-type: none"> Added the correspondent citation: (Clinical Pharmacology, 2013). <p>To the Indications Section:</p> <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>To the Contraindications/ Limitations /Precautions Section:</p> <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>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><u>To the Description Section:</u></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><u>To the Contraindications/Limitations/ Precautions Section:</u></p> <ul style="list-style-type: none"> This Section was divided in two sections; one for contraindications/limitations and another for the Precautions. <p><u>To the Coding Section:</u></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><u>To the Reference Section:</u></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><u>To the coding section:</u></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><u>To the Indication Section:</u></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><u>To the Coding Section:</u></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>

		<p>M08.459, M08.461, M08.462, M08.469, M08.471, M08.472, M08.479, and M08.48.</p> <p><u>To the References Section:</u></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><u>To the Indications Section:</u></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><u>To the Contraindications/Limitations Section:</u></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><u>To the Precautions Section:</u></p> <ul style="list-style-type: none"> To #7 added: There is no data regarding the presence of abatacept

		<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

		<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 from Clinical Pharmacology 2024.</p> <p>New Rationale Section was added to the Policy.</p> <p>To the Coding Information Section:</p>

		<p><u>To the HCPCS Section:</u> 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><u>To the ICD-10 Codes Section:</u></p> <ul style="list-style-type: none"> • <u>New ICD-10 Codes were added to the Policy:</u> 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. • <u>The following ICD-10 Codes were deleted from this Policy:</u> N/A. <p><u>To the References Section:</u> <u>The following References were added to the Policy:</u> #7 and 12.</p>
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