Medical Policy Bulletin

Title:
Abatacept (Orencia®) for Injection for Intravenous Use
Policy #:
MA08.028k

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

INITIAL THERAPY
Hematopoietic Cell Transplantation

Prophylaxis of Acute Graft-Versus-Host Disease (aGVHD)

Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered for the prophylaxis of acute graft-versus-host disease (aGVHD), in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate up to four doses when all the following criteria are met:

- The individual is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or one allele–mismatched unrelated donor.
- Active or latent tuberculosis (TB) has been ruled out.
- The individual is 2 years of age or older.
- Abatacept (Orencia) will not be used in combination with other biologic disease-modifying antirheumatic drugs [bDMARDs (tumor necrosis factor [TNF] antagonists, e.g., certolizumab, adalimumab, etanercept] or Janus kinase (JAK) inhibitors (e.g., baricitinib, tofacitinib, upadacitinib).

Treatment of Chronic Graft-Versus-Host Disease (GVHD)

Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered for the treatment of chronic GVHD as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options.

IMMUNE CHECKPOINT INHIBITOR–RELATED TOXICITIES

Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered as additional therapy for the management of the following immune checkpoint inhibitor–related (e.g., pembrolizumab [Keytruda], nivolumab [Opdivo]) autoimmune-like toxicity (also known as immune-related adverse event):

- Myocarditis, as a single agent if no improvement within 24 to 48 hours of starting high-dose methylprednisolone
- Concomitant myositis and myocarditis in combination with ruxolitinib (Jakavi)

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA)

Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered when used in individuals who have moderately to severely active pJIA. Abatacept (Orencia) injection for intravenous use may be covered as monotherapy or concomitantly with methotrexate when **all** of the following inclusion criteria are met:

- If the individual has not previously received a bDMARD to treat pJIA, abatacept (Orencia) injection for intravenous use is only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to golimumab (Simponi Aria), or there is a clinical reason that a trial of golimumab (Simponi Aria) would be otherwise inappropriate for the member.
- Active or latent TB has been ruled out.
- The individual has had an inadequate response after at least 3 months of one or more DMARDs, or the use of all DMARDs is contraindicated in the individual.
- The individual is 6 years of age or older.
- Abatacept (Orencia) will not be used in combination with other bDMARDs or JAK inhibitors.

PSORIATIC ARTHRITIS (PsA)

Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered for the treatment of active PsA. Abatacept (Orencia) injection for intravenous use may be covered as monotherapy or concomitantly with non-bDMARDs when **all** of the following inclusion criteria are met:

- If the individual has not previously received a bDMARD to treat adult rheumatoid arthritis (RA), abatacept (Orencia) injection for intravenous use is only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to infliximab (Remicade), ustekinumab (Stelara), or golimumab (Simponi Aria), or there is a clinical reason that a trial of infliximab (Remicade), ustekinumab (Stelara), or golimumab (Simponi Aria) would be otherwise inappropriate for the member.
- Active or latent TB has been ruled out.
- The individual has had an inadequate response after at least 3 months of one or more DMARDs, or the use of all DMARDs is contraindicated in the individual.
- The individual is 18 years of age or older.
- Abatacept (Orencia) will not be used in combination with other bDMARDs or JAK inhibitors.

RHEUMATOID ARTHRITIS (RA)

Abatacept (Orencia) injection for intravenous use is considered medically necessary and, therefore, covered in individuals who have moderately to severely active RA. Abatacept (Orencia) injection for intravenous use may be covered as monotherapy or concomitantly with DMARDs, other than JAK inhibitors or biologic DMARDs (bDMARDs) when **all** of the following inclusion criteria are met:

- If the individual has not previously received a bDMARD to treat adult RA, abatacept (Orencia) injection for intravenous use is only eligible for coverage when the individual has a documented failure, contraindication, or intolerance to infliximab (Remicade) or golimumab (Simponi Aria), or there is a clinical reason that a trial of infliximab (Remicade) or golimumab (Simponi Aria) would be otherwise inappropriate for the member.
- Active or latent tuberculosis (TB) has been ruled out.

- The individual has had an inadequate response after at least 3 months to one or more non-bDMARDs or tumor necrosis factor (TNF) antagonists, or the use of all non-bDMARDs or TNF-antagonists is contraindicated in the individual.
- The individual is 18 years of age or older.
- Abatacept (Orencia) will not be used in combination with other bDMARDs or JAK inhibitors.

CONTINUATION THERAPY

CHRONIC GVHD

Abatacept (Orencia) injection for intravenous use is considered medically necessary for the treatment of chronic GVHD and, therefore, covered for the continuation therapy when the individual meets **both** of the following:

- Individual continues to experience chronic GVHD
- There is documentation of positive clinical response to therapy (e.g., reduction in symptoms, Global Scoring of Chronic GVHD, and steroid dose)

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS

Abatacept (Orencia) injection for intravenous use is considered medically necessary for the treatment of pJIA, RA, and PsA, and, therefore, covered for the continuation therapy when the individual meets **both** of the following:

- Individual has met the medical necessity criteria for initial therapy
- There is documentation of positive clinical response or stabilization to therapy as evidenced by at least one of the following:
    - Reduction in total active (swollen and tender) joint count from baseline
    - Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

EXPERIMENTAL/INVESTIGATIONAL

All other uses for abatacept (Orencia) injection for intravenous use are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

BILLING REQUIREMENTS

For drugs that have more than one method of administration, application of the JA modifier is required to indicate the route of administration.

- To report the intravenous route of administration, append the following modifier: JA Administered Intravenously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

Guidelines

This policy is consistent with Medicare’s coverage determination. The Company’s payment methodology may differ from Medicare.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, abatacept (Orencia) injection for intravenous use is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

Certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when abatacept (Orencia) injection for intravenous use is covered under a member's medical benefit. It does not address instances when abatacept (Orencia) injection for intravenous use is covered under a member's pharmacy benefit.

Abatacept (Orencia) injection for *subcutaneous* use is not covered under the medical benefits for most of the Company's products. Abatacept (Orencia) injection for *subcutaneous* use may be covered under a member's pharmacy benefit, if applicable.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Initial FDA approval for abatacept (Orencia) injection for intravenous use was granted on December 23, 2005. Supplemental approvals for abatacept (Orencia) injection for intravenous use have since been issued. Abatacept (Orencia) injection for subcutaneous use was approved by the FDA on July 29, 2011.

A single loading dose infusion of abatacept (Orencia) injection for intravenous use may be given to an individual who will receive subcutaneous abatacept (Orencia) for treatment of adult rheumatoid arthritis.

PEDIATRIC USE
For pediatric juvenile idiopathic arthritis, the safety and effectiveness of abatacept (Orencia) injection for intravenous use in pediatric individuals younger than 6 years of age have not been established. Therefore, abatacept (Orencia) injection for intravenous use in pJIA is not recommended for use in individuals younger than six years of age.

For the prophylaxis of acute graft-versus-host disease (aGVHD), the safety and effectiveness of abatacept (Orencia) injection for intravenous use in pediatric individuals younger than 2 years of age have not been established. Therefore, abatacept (Orencia) injection for intravenous use in aGVHD is not recommended for use in individuals younger than 2 years of age.

DRUG INTERACTIONS
Concurrent administration of a TNF antagonist (e.g., adalimumab [Humira], etanercept [Enbrel], golimumab [Simponi, Simponi Aria], infliximab [Remicade]) with abatacept (Orencia) injection for intravenous use has been associated with an increased risk of serious infections and no significant additional efficacy over use of the TNF antagonists alone. Concurrent therapy with abatacept (Orencia) injection for intravenous use and TNF antagonists is not recommended.

There is insufficient experience to assess the safety and efficacy of abatacept (Orencia) administered concurrently with other biologic RA therapy, such as anakinra (Kineret), or other biologic RA/PsA therapy, and JAK inhibitors. Therefore, such use is not recommended.

Description

Abatacept (Orencia) injection for intravenous use is a soluble fusion protein that is produced by recombinant deoxyribonucleic acid (DNA) technology. It is a selective co-stimulation modulator that consists of human cytotoxic T-lymphocyte-associated antigen-4 linked to a modified portion of human immunoglobulin G1 (IgG1).

The activation of T lymphocytes has been implicated in the pathogenesis of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), and psoriatic arthritis (PsA). Because abatacept (Orencia) injection for intravenous use interrupts T-lymphocyte activation, it has been studied to be effective for the treatment of RA and PsA, and is frequently used in the management of adults and children with pJIA.

The American College of Rheumatology (ACR) guidelines for the treatment of RA recommend that newly diagnosed individuals with RA begin treatment with disease-modifying antirheumatic drugs (DMARDs). DMARDs act to slow

down disease progression, and some act with mild chemotherapeutic action, causing immunosuppression. The ACR Guidelines for the treatment of pJIA recommend nonsteroidal anti-inflammatory drugs (NSAIDs) or DMARDs as initial therapy. The ACR Guidelines for PsA initial treatment recommend methotrexate (MTX) in individuals with less active disease and biologic tumor necrosis factor inhibitors with severe disease.

DMARDs can be subdivided into the traditional small-molecular-mass, chemically synthesized nonbiologic DMARDs (such as, but not limited to, methotrexate, sulfasalazine, azathioprine, leflunomide, hydroxychloroquine sulfate, and cyclosporine) and biologic DMARDs. Examples of biologic DMARDs include, but are not limited to, infliximab (Remicade), etanercept (Enbrel), adalimumab (Humira), anakinra (Kineret), golimumab (Simponi, Simponi Aria), tocilizumab (Actemra), and rituximab (Rituxan).

Abatacept (Orencia) is available in two forms: injection for intravenous use and injection for subcutaneous use.

PEER-REVIEWED LITERATURE

SUMMARY
Acute Graft-versus-Host Disease (aGVHD), Prophylaxis

The safety and efficacy of abatacept (Orencia) injection for intravenous use, in combination with a calcineurin inhibitor (CNI) (e.g., cyclosporine, tacrolimus) and MTX for the prophylaxis of aGVHD was accessed in two clinical studies.

The first was a Phase 2, double-blind, multicenter, two-cohort clinical study (GVHD-1) in individuals 6 years of age and older who underwent hematopoietic stem cell transplantation (HSCT) from a matched or one-allele-mismatched unrelated donor. The two cohorts in GVHD-1 included:

- An open-label, single-arm study of 43 individuals who underwent a 7 of 8 human leukocyte antigen (HLA)-matched HSCT (7 of 8 cohort)
- A randomized (1:1), double-blind, placebo-controlled study of 142 individuals who underwent an 8 of 8 HLA-matched HSCT who received abatacept (Orencia) or placebo in combination with a CNI and MTX (8 of 8 cohort).

In both cohorts, individuals in the abatacept (Orencia) group received 10 mg/kg (1000 mg maximum dose) IV over 60 minutes on the day before transplantation (Day −1), followed by administration on Days 5, 14, and 28 after transplantation. In cohort 1, an exploratory analysis revealed the following rates of grade III to IV aGVHD-free survival (GFS) (95%), grade II to IV GFS (53%), and overall survival (OS) (98%) at day 180 posttransplantation. In cohort 2, at Day 180 posttransplantation, there was significantly improved OS rate in the abatacept (Orencia) plus CNI plus MTX group of 97% compared to 84% for the placebo group. There was also a significantly improved GFS rate for moderate-to-severe (grade II-IV) aGVHD in the abatacept (Orencia) plus CNI plus MTX group (50%), compared to the placebo group (32%). However, severe (grade III-IV) GFS was not significantly improved in the abatacept (Orencia) group (87%) compared to those who received a placebo (75%).

The second clinical study, GVHD-2, used real-world data from the Center for International Blood and Marrow Transplant Research (CIBMTR). The study analyzed the outcomes of individuals 6 years of age or older who underwent HSCT from one-allele-mismatched unrelated donors between 2011 and 2018 and received abatacept (Orencia) in combination with a CNI and MTX, versus a CNI plus MTX alone, for the prophylaxis of aGVHD. The abatacept (Orencia) plus CNI plus MTX group (n=54) included 42 individuals from the GVHD-1 study, in addition to 12 individuals treated with abatacept (Orencia) outside of GVHD-1. The comparator group (n=162) received CNI plus MTX alone, and were randomly selected in a 3:1 ratio to the abatacept (Orencia) plus CNI plus MTX group from the CIBMTR registry from individuals. The study measured OS 6 months after transplantation. Those in the abatacept (Orencia) + CNI + MTX group saw a 98% OS rate compared to 75% for those who received CNI + MTX alone.

The most common side effects of abatacept (Orencia) for prevention of aGVHD included anemia, hypertension, cytomegalovirus (CMV) reactivation/CMV infection, fever, pneumonia, nosebleed, decreased levels of specific white blood cells called CD4 lymphocytes, increased levels of magnesium in the blood, and acute kidney injury.

Polyarticular Juvenile Idiopathic Arthritis

The safety and efficacy of abatacept (Orencia) injection for intravenous use in the treatment of juvenile idiopathic arthritis (JIA) was assessed in a three-part study with individuals ages 6 years to 17 years with moderate to severely active pJIA with inadequate response to one or more DMARDs. The principal measure of clinical response in part A of this study was the ACR pediatric 30 definition of improvement (i.e., ≥30% improvement in at least 3 of 6 and ≥30%

deterioration in no more than 1 of 6 core set criteria that include physician and child/parent global assessments, active joint count, limitation of motion, functional assessment, and erythrocyte sedimentation rate). Individuals with an "ACR pediatric 30" response at the end of part A were randomly assigned into part B, the double-blind phase. In part B, the primary endpoint was time to disease flare (defined as a ≥30% deterioration in 3 of 6 and a ≥30% improvement in no more than 1 of 6 core set criteria). At the end of part B, study participants treated with abatacept (Orencia) injection for intravenous use reported significantly fewer disease flares as compared to individuals treated with placebo. (Part C of the study was an open-label extension.)

At the conclusion of part A, pediatric ACR 30/50/70 responses were 65%, 50%, and 28%, respectively. During part B, study participants reported significantly fewer disease flares compared to placebo-treated study participants. Among study participants who received abatacept (Orencia) injection for intravenous use throughout the study period (part A, B, and C), the proportion of pediatric ACR 30/50/70 responders remained consistent for 1 year.

Psoriatic Arthritis

The safety and efficacy of abatacept (Orencia) injection for intravenous use was assessed in a Phase 2, randomized, double-blind, multicenter, dose-ranging study of 170 adults with active arthritis (defined as the presence of three or more swollen joints and three or more tender joints), and active plaque psoriasis (with at least one qualifying target lesion of ≥2 cm in diameter). Participants had an inadequate response to DMARDs, including, but not limited to, MTX or anti-TNF agents. Participants were randomly assigned (1:1:1:1) to receive placebo or abatacept (Orencia) IV infusions at doses of 3 mg/kg, 10 mg/kg, or 30/10 mg/kg (two initial doses of 30 mg/kg, followed by 10 mg/kg) on days 1, 15, and 29 and then once every 28 days thereafter for 6 months. The primary endpoint of this study was ACR 20 response on day 169, resulting in 42% in those who received 30/10 mg/kg of abatacept (Orencia), 48% who received 10 mg/kg, 33% who received 3 mg/kg, and 19% who received placebo. Compared to placebo, the ACR20 responses were statistically significant for the 30/10 mg/kg (*P*=0.022) and the 10 mg/kg (*P*=0.006), but not the 3 mg/kg (*P*=0.121) doses of abatacept (Orencia).

Genovese et al. (2011) performed a noninferiority study in the treatment of RA showing the therapeutic equivalence of abatacept (Orencia) dosing at 10 mg/kg IV every 4 weeks and 125 mg subcutaneously (SC) weekly. Further, the safety and efficacy of abatacept (Orencia), 125 mg weekly SC injection, was performed in a randomized, double-blind, Phase 3 study in the treatment of 424 adults with active PsA (as defined in previous study). Participants had an inadequate response or intolerance to one or more DMARDs, including, but not limited to, MTX or anti-TNF agents. Participants were randomly assigned (1:1) to receive placebo or abatacept (Orencia) subcutaneous 125 mg weekly for 24 weeks followed by open-label subcutaneous abatacept. As the primary endpoint, abatacept (Orencia) significantly increased ACR20 response versus placebo at week 24 (39.4% vs 22.3%; *P*<0.001).

Rheumatoid Arthritis

Evidence of clinical benefit and safety of abatacept (Orencia) injection for intravenous use in the management of RA is based principally on the results of six randomized, double-blind, placebo-controlled clinical trials in adults (≥18 years of age) with the disease. Improvement in the signs and symptoms of RA after treatment with abatacept (Orencia) injection for intravenous use was consistently reported by the participants of the studies, according to the response rate measured by the ACR scores.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)

D89.811 Chronic graft-versus-host disease
D89.812 Acute on chronic graft-versus-host disease
I40.8 Other acute myocarditis
I40.9 Acute myocarditis, unspecified
I51.4 Myocarditis, unspecified
L40.50 Arthropathic psoriasis, unspecified
L40.51 Distal interphalangeal psoriatic arthropathy
L40.52 Psoriatic arthritis mutilans
L40.53 Psoriatic spondylitis
L40.59 Other psoriatic arthropathy
M05.011 Felty's syndrome, right shoulder
M05.012 Felty's syndrome, left shoulder
M05.021 Felty's syndrome, right elbow
M05.022 Felty's syndrome, left elbow
M05.031 Felty's syndrome, right wrist

M05.032 Felty's syndrome, left wrist
M05.041 Felty's syndrome, right hand
M05.042 Felty's syndrome, left hand
M05.051 Felty's syndrome, right hip
M05.052 Felty's syndrome, left hip
M05.061 Felty's syndrome, right knee
M05.062 Felty's syndrome, left knee
M05.071 Felty's syndrome, right ankle and foot
M05.072 Felty's syndrome, left ankle and foot
M05.09 Felty's syndrome, multiple sites
M05.111 Rheumatoid lung disease with rheumatoid arthritis of right shoulder
M05.112 Rheumatoid lung disease with rheumatoid arthritis of left shoulder
M05.121 Rheumatoid lung disease with rheumatoid arthritis of right elbow
M05.122 Rheumatoid lung disease with rheumatoid arthritis of left elbow
M05.131 Rheumatoid lung disease with rheumatoid arthritis of right wrist
M05.132 Rheumatoid lung disease with rheumatoid arthritis of left wrist
M05.141 Rheumatoid lung disease with rheumatoid arthritis of right hand
M05.142 Rheumatoid lung disease with rheumatoid arthritis of left hand
M05.151 Rheumatoid lung disease with rheumatoid arthritis of right hip
M05.152 Rheumatoid lung disease with rheumatoid arthritis of left hip
M05.161 Rheumatoid lung disease with rheumatoid arthritis of right knee
M05.162 Rheumatoid lung disease with rheumatoid arthritis of left 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
M05.19 Rheumatoid lung disease with rheumatoid arthritis of multiple sites
M05.211 Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212 Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.221 Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222 Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.231 Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232 Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.241 Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242 Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.251 Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252 Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.261 Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262 Rheumatoid vasculitis with rheumatoid arthritis of left 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
M05.29 Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.311 Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312 Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.321 Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322 Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.331 Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332 Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.341 Rheumatoid heart disease with rheumatoid arthritis of right hand

M05.342 Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.351 Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352 Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.361 Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362 Rheumatoid heart disease with rheumatoid arthritis of left 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
M05.39 Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.411 Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412 Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.421 Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422 Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.431 Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432 Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.441 Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442 Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.451 Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452 Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.461 Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462 Rheumatoid myopathy with rheumatoid arthritis of left 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
M05.49 Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.511 Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512 Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.521 Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522 Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.531 Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532 Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.541 Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542 Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.551 Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552 Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.561 Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562 Rheumatoid polyneuropathy with rheumatoid arthritis of left 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
M05.59 Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
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
M05.621 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
M05.631 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
M05.641 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
M05.651 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
M05.661 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
M05.671 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
M05.69 Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.7A Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
M05.8A Other rheumatoid arthritis with rheumatoid factor of other specified site
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
M05.721 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
M05.731 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
M05.741 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
M05.751 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
M05.761 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
M05.771 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
M05.79 Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.811 Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812 Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.821 Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822 Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.831 Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832 Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.841 Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842 Other rheumatoid arthritis with rheumatoid factor of left hand
M05.851 Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852 Other rheumatoid arthritis with rheumatoid factor of left hip
M05.861 Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862 Other rheumatoid arthritis with rheumatoid factor of left 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
M05.89 Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9 Rheumatoid arthritis with rheumatoid factor, unspecified
M05.A Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M06.0A Rheumatoid arthritis without rheumatoid factor, other specified site
M06.8A Other specified rheumatoid arthritis, other specified site
M06.011 Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012 Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.021 Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022 Rheumatoid arthritis without rheumatoid factor, left elbow
M06.031 Rheumatoid arthritis without rheumatoid factor, right wrist

M06.032 Rheumatoid arthritis without rheumatoid factor, left wrist
M06.041 Rheumatoid arthritis without rheumatoid factor, right hand
M06.042 Rheumatoid arthritis without rheumatoid factor, left hand
M06.051 Rheumatoid arthritis without rheumatoid factor, right hip
M06.052 Rheumatoid arthritis without rheumatoid factor, left hip
M06.061 Rheumatoid arthritis without rheumatoid factor, right knee
M06.062 Rheumatoid arthritis without rheumatoid factor, left knee
M06.071 Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072 Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.08 Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09 Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.811 Other specified rheumatoid arthritis, right shoulder
M06.812 Other specified rheumatoid arthritis, left shoulder
M06.821 Other specified rheumatoid arthritis, right elbow
M06.822 Other specified rheumatoid arthritis, left elbow
M06.831 Other specified rheumatoid arthritis, right wrist
M06.832 Other specified rheumatoid arthritis, left wrist
M06.841 Other specified rheumatoid arthritis, right hand
M06.842 Other specified rheumatoid arthritis, left hand
M06.851 Other specified rheumatoid arthritis, right hip
M06.852 Other specified rheumatoid arthritis, left hip
M06.861 Other specified rheumatoid arthritis, right knee
M06.862 Other specified rheumatoid arthritis, left knee
M06.871 Other specified rheumatoid arthritis, right ankle and foot
M06.872 Other specified rheumatoid arthritis, left ankle and foot
M06.88 Other specified rheumatoid arthritis, vertebrae
M06.89 Other specified rheumatoid arthritis, multiple sites
M06.9 Rheumatoid arthritis, unspecified
M08.3 Juvenile rheumatoid polyarthritis (seronegative)
M60.811 Other myositis, right shoulder
M60.812 Other myositis, left shoulder
M60.821 Other myositis, right upper arm
M60.822 Other myositis, left upper arm
M60.831 Other myositis, right forearm
M60.832 Other myositis, left forearm
M60.841 Other myositis, right hand
M60.842 Other myositis, left hand
M60.851 Other myositis, right thigh
M60.852 Other myositis, left thigh
M60.861 Other myositis, right lower leg
M60.862 Other myositis, left lower leg
M60.871 Other myositis, right ankle and foot
M60.872 Other myositis, left ankle and foot
M60.88 Other myositis, other site
M60.89 Other myositis, multiple sites
M60.9 Myositis, unspecified
Z94.84 Stem cell transplantation status

Z29.89 Encounter for other specified prophylactic measures

HCPCS Level II Code Number(s)

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)

Revenue Code Number(s)

N/A

Modifiers

THE FOLLOWING MODIFIER IS USED WHEN REPORTING ABATACEPT (ORENCIA) FOR INJECTION FOR INTRAVENOUS USE:

JA Intravenous administration

Coding and Billing Requirements

For drugs that have more than one method of administration, application of the JA modifier is required to indicate the route of administration.

- To report the intravenous route of administration, append the following modifier: JA Administered Intravenously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

Policy History

Revisions From MA08.028k:

12/15/2025	This version of the policy will become effective 12/15/2025. The following ICD-10 CM codes have been added to this policy: M05.A Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis

Revisions From MA08.028j:

12/16/2024	This version of the policy will become effective 12/16/2024. This policy has been updated to communicate the Company's coverage position for abatacept (Orencia) injection for intravenous use, in accordance with National Comprehensive Cancer Network (NCCN) compendia. The policy criteria for immune checkpoint inhibitor-related toxicities was **revised** to include combination therapy: • Concomitant myositis and myocarditis in combination with ruxolitinib (Jakavi). The following ICD-10 CM codes have been **added** to this policy as medically necessary: M60.811 Other myositis, right shoulder M60.812 Other myositis, left shoulder M60.821 Other myositis, right upper arm M60.822 Other myositis, left upper arm M60.831 Other myositis, right forearm M60.832 Other myositis, left forearm M60.841 Other myositis, right hand M60.842 Other myositis, left hand M60.851 Other myositis, right thigh

	M60.852 Other myositis, left thigh M60.861 Other myositis, right lower leg M60.862 Other myositis, left lower leg M60.871 Other myositis, right ankle and foot M60.872 Other myositis, left ankle and foot M60.88 Other myositis, other site M60.89 Other myositis, multiple sites M60.9 Myositis, unspecified

Revisions From MA08.028i:

12/11/2023	This version of the policy will become effective 12/11/2023. This policy has been updated to communicate the Company's coverage position for Abatacept (Orencia) injection for intravenous use, in accordance with US Food and Drug Administration (FDA) to include a 4 dose limit for the Prophylaxis of Acute Graft-Versus-Host Disease (aGVHD). The following ICD-10 CM codes have been removed from this policy, due to specificity: M05.00 Felty's syndrome, unspecified site M05.10 Rheumatoid lung disease with rheumatoid arthritis of unspecified site M05.20 Rheumatoid vasculitis with rheumatoid arthritis of unspecified site M05.30 Rheumatoid heart disease with rheumatoid arthritis of unspecified site M05.40 Rheumatoid myopathy with rheumatoid arthritis of unspecified site M05.50 Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site M05.60 Rheumatoid arthritis of unspecified site with involvement of other organs and systems M05.70 Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement M05.80 Other rheumatoid arthritis with rheumatoid factor of unspecified site M06.00 Rheumatoid arthritis without rheumatoid factor, unspecified site M06.80 Other specified rheumatoid arthritis, unspecified site Additionally, Continuation Therapy was added with specified criteria for the following indications: chronic graft-versus-host disease, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and rheumatoid arthritis.

Revisions From MA08.028h:

10/01/2023	This version of the policy will become effective 10/01/2023. The following ICD-10 CM codes have been **added** to this policy: Z29.89 Encounter for other specified prophylactic measures The following ICD-10 CM codes have been **termed** (no longer valid codes) and removed from this policy: Z29.8 Encounter for other specified prophylactic measures

Revisions From MA08.028g:

06/06/2022	This version of the policy will become effective 06/06/2022. The policy was updated to communicate the Medically Necessary coverage position of the FDA-approved indication for the Prophylaxis of Acute Graft-Versus-Host Disease (aGVHD).

	Additionally, immune checkpoint inhibitor-related autoimmune-like toxicity indication was revised from suspected myocarditis, to myocarditis. The following ICD CM codes have been **added** to this policy: D89.811 Chronic graft-versus-host disease D89.812 Acute on chronic graft-versus-host disease I40.8 Other acute myocarditis I40.9 Acute myocarditis, unspecified Z94.84 Stem cell transplantation status Z29.8 Encounter for other specified prophylactic measures The following ICD CM codes have been **deleted** from this policy, due to specificity/laterality: M05.019, M05.029, M05.039, M05.049, M05.059, M05.069, M05.079, M05.119, M05.129, M05.139, M05.149, M05.159, M05.169, M05.179, M05.219, M05.229, M05.239, M05.249, M05.259, M05.269, M05.279, M05.319, M05.329, M05.339, M05.349, M05.359, M05.369, M05.379, M05.419, M05.429, M05.439, M05.449, M05.459, M05.469, M05.479, M05.519, M05.529, M05.539, M05.549, M05.559, M05.569, M05.579, M05.619, M05.629, M05.639, M05.649, M05.659, M05.669, M05.679, M05.719, M05.729, M05.739, M05.749, M05.759, M05.769, M05.779, M05.819, M05.829, M05.839, M05.849, M05.859, M05.869, M05.879, M06.019, M06.029, M06.039, M06.049, M06.059, M06.069, M06.079, M06.819, M06.829, M06.839, M06.849, M06.859, M06.869, M06.879

Revisions From MA08.028f:

09/27/2021	This version of the policy will become effective 09/27/2021. The policy has been updated due to revisions to US Food and Drug Administration (FDA) prescribing information and National Comprehensive Cancer Network (NCCN) compendia for abatacept (Orencia®). The following indications were **added** to this policy as Medically Necessary, per NCCN Compendium: • chronic graft-versus-host disease (GVHD) after hematopoeitic cell transplantation • management of suspected myocarditis (as a result of immunotherapy-related toxicities) The policy criteria was **revised per FDA labeling** to state that there is insufficeient experience to assess the safety and efficacy of abatacept (Orencia) administered concurrently with other biologic DMARDs or Janus kinase (JAK) inhibitors; therefore such use together is not recommended. The following ICD-10 CM codes have been **added** to this policy: D89.811 Chronic graft-versus-host disease I51.4 Myocarditis, unspecified

Revisions From MA08.028e:

10/01/2020	This policy has been identified for the ICD-10 CM code update, effective 10/01/2020. The following ICD-10 CM codes have been **added** to this policy: M05.7A Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement

	M05.8A Other rheumatoid arthritis with rheumatoid factor of other specified site M06.0A Rheumatoid arthritis without rheumatoid factor, other specified site M06.8A Other specified rheumatoid arthritis, other specified site

Revisions From MA08.028d:

06/08/2020	This version of the policy will become effective 06/08/2020. This policy was updated to add a Billing Requirement regarding the Coding Modifier: JA Intravenous administration, per Novitas Solutions, Inc. Article (A53127) For Self-Administered Drug Exclusion List.

Revisions From MA08.028c:

03/13/2019	This policy has been reissued in accordance with the Company's annual review process.
04/23/2018	This policy has undergone a routine review, and the medical necessity criteria have been revised as follows: This policy was updated to expand the Company's coverage position for the indication of psoriatic arthritis.

Revisions From MA08.028b:

06/21/2017	This policy has been reissued in accordance with the Company's annual review process.
12/28/2016	This policy was modified by removing the criterion that a rheumatologist has to have recommended the use of the drug.

Revisions From MA08.028a:

06/17/2015	This policy was updated to clarify coverage of abatacept (Orencia®) injection for intravenous use for the treatment of adult rheumatoid arthritis.

Revisions From MA08.028:

01/01/2015	This is a new policy.

Version Effective Date:
12/15/2025
Version Issued Date:
12/15/2025
Version Reissued Date:
N/A