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Subject: Abatacept (Orencia®) Injection and Infusion

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Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Abatacept (Orencia), a modulator of T-lymphocyte activation, was first approved as an intravenous (IV) infusion by the US Food and Drug Administration (FDA) in December 2005 for adult rheumatoid arthritis (RA) and then in April 2008 for polyarticular juvenile idiopathic arthritis (JIA) in pediatric patients 6 years of age and older. In July 2011, a subcutaneous (SQ) injection was approved for the treatment of RA. In March 2017, the FDA-approved indication for the SQ injection was expanded to include the treatment of JIA in pediatric patients 2 years of age and older. In June 2017, the FDA approved a new indication of "treatment of adult patients with active psoriatic arthritis (PsA)" for both the IV and SQ routes of administration. Abatacept (as sponsored by the innovator drug company) has been granted orphan drug designation by the FDA for "treatment of idiopathic inflammatory myopathy (IMM)" in February 2017 and "treatment of giant cell arteritis" in February 2017. In December 2021, the FDA-approved indication for the IV infusion was expanded to include 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. This is the first drug to be approved for aGVHD prevention by the FDA. In October 2023, the PsA indication was expanded to include pediatric patients and now reads as "treatment of patients 2 years of age and older with active psoriatic arthritis (PsA)". Only the SQ route is approved for patients 2 to 17 years of age. In 2018 the National Comprehensive Cancer Network (NCCN) began publishing its guideline Management of Immunotherapy-Related-Toxicities. The NCCN eventually separated this guideline into two separate guidelines - Management of Immune Checkpoint Inhibitor-Related Toxicities and Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities. IV abatacept is recommended as additional immunosuppression for the management of immunotherapy-related myocarditis as a single agent if no improvement within 24 to 48 hours of starting high-dose methylprednisolone, and for the management of immunotherapy-related concomitant myositis and

myocarditis in combination with ruxolitinib. The NCCN also includes abatacept IV/SC as a category 2A recommendation for chronic graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options.

Abatacept's mechanism of action is distinct from the available non-biological disease-modifying anti-rheumatic drugs (DMARDs) and other biologics (e.g., tumor necrosis factor antagonists [TNFs], interleukin antagonists). Abatacept is a human protein designed to selectively inhibit T-cell activation, a process that plays a central role in the immunopathogenesis of RA. It exerts this mechanism of action by binding to the natural ligands CD80 and CD86, ultimately preventing CD80 and CD86 interaction with CD28 on the T-lymphocyte. Additionally, abatacept indirectly inhibits the production of inflammatory cytokines and auto-antibodies, which are also hypothesized to play a role in the pathogenesis of RA.

RHEUMATOID DISORDERS

Rheumatoid arthritis (RA)

Rheumatoid arthritis (RA) is an inflammatory autoimmune disease that primarily affects the joints but can also damage extra-articular organs. The main goal of therapy is to achieve remission, but additional goals include decreased disease activity, prevention of systemic complications, and improved physical functioning. The choice of therapy depends on several factors, including the severity of disease activity when therapy is initiated and the response of the patient to prior therapeutic interventions. American College of Rheumatology (ACR) guidelines list the following guiding principles in the treatment of RA:

- RA requires early evaluation, diagnosis, and management
- Treatment decisions should follow a shared decision-making process
- Treatment decisions should be reevaluated within a minimum of 3 months based on efficacy and tolerability of the disease-modifying antirheumatic drug(s) (DMARDs) chosen
- Recommendations are limited to DMARDs approved by the US FDA for treatment of RA:
    - Conventional synthetic DMARDs (csDMARDs): hydroxychloroquine, sulfasalazine, methotrexate (MTX), leflunomide
    - Biologic DMARDs (bDMARDs): Tumor necrosis factor (TNF) inhibitors (e.g., etanercept, adalimumab, infliximab, golimumab, certolizumab pegol), T cell costimulatory inhibitor (e.g., abatacept), Interleukin (IL)-6 receptor inhibitors (e.g., tocilizumab, sarilumab), anti-CD20 antibody* (e.g., rituximab)

        *Recommendations referring to bDMARDs exclude rituximab unless patients have had an inadequate response to TNF inhibitors (in order to be consistent with FDA approval) or have a history of lymphoproliferative disorder for which rituximab is an approved therapy

    - Targeted synthetic DMARDs (tsDMARDs): Janus kinase (JAK) inhibitors (e.g., tofacitinib, baricitinib, upadacitinib)
- Triple therapy refers to hydroxychloroquine, sulfasalazine, and either methotrexate or leflunomide
- Biosimilars are considered equivalent to FDA-approved originator bDMARDs

- Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modifications of treatment to minimize disease activity with the goal of reaching a predefined target (low disease activity or remission)

ACR guidelines (2021) are broken down by previous treatment and disease activity:

- DMARD-naïve patients with moderate-to-high disease activity initial treatment:
    - MTX monotherapy is strongly recommended over hydroxychloroquine, sulfasalazine, bDMARDs monotherapy, tsDMARD monotherapy, or combination of MTX plus a non-TNF bDMARD or tsDMARD
    - MTX monotherapy is conditionally recommended over leflunomide, dual or triple csDMARD therapy, or combination MTX plus a TNF inhibitor
- DMARD-naïve patients with low disease activity initial treatment
    - Hydroxychloroquine is conditionally recommended over other csDMARDs
    - Sulfasalazine is conditionally recommended over MTX
    - MTX is conditionally recommended over leflunomide
- Initial therapy in csDMARD-treated patients, but MTX naïve, with moderate-to high disease activity:
    - MTX monotherapy is conditionally recommended over combination MTX and a bDMARD or tsDMARD
- Treatment modifications in patients treated with DMARDs who are not at target:
    - Addition of a bDMARD or tsDMARD is conditionally recommended over triple therapy for patients taking maximally tolerated doses of MTX who are not at target
    - Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target.

The European Alliance of Associations for Rheumatology (EULAR) guidelines for RA (2022 update) also recommend a treat-to-target approach in therapy. MTX is recommended as first line therapy and should be initiated as soon as the diagnosis of RA is made. If MTX is not clinically appropriate, then an alternative csDMARD should be used as part of the (first) treatment strategy. If initial csDMARD therapy does not produce adequate improvement after 3 months, another csDMARD may be added or switched to as long as poor prognosis factors are absent. In the presence of poor prognosis factors, a bDMARD or JAK inhibitor should be added to csDMARD therapy. If treatment failure occurs with the initial bDMARD or JAK inhibitor, another bDMARD or JAK inhibitor should be considered. If a TNF- or IL-6 receptor inhibitor therapy was initially failed, patients may receive an agent with another mode of action or a second TNF- or IL-6 receptor inhibitor.

Initial dosing of MTX for RA should optimally be 15 mg once weekly, with the dose increased as tolerated and as needed to control signs and symptoms. A fast dose escalation of 5 mg/month to 25-30 mg/week has been associated with higher efficacy, but toxicity with this dosing regimen is a limiting factor. In the presence of sufficient folic acid supplementation, the MTX dose can be rapidly escalated to 25 mg once weekly. The MTX target dose is 25 mg weekly, or the highest tolerable dose.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Juvenile idiopathic arthritis (JIA) is arthritis that begins before the 16th birthday and persists for at least 6 weeks with other known conditions excluded. Polyarticular juvenile idiopathic arthritis (PJIA) is a subset of JIA. The ACR defines PJIA as arthritis in more than 4 joints during their disease course and excludes systemic JIA. Treatment goals are aimed at achieving clinically inactive disease and to prevent long-term morbidities, including growth disturbances, joint contractures and destruction, functional limitations, and blindness or visual impairment from chronic uveitis.

The American College of Rheumatology guidelines (2019) (ACR)/Arthritis Foundation recommend the following treatment approach for PJIA:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are conditionally recommended as adjunct therapy
- Disease modifying antirheumatic drug (DMARD) therapy:
    - Methotrexate (MTX) is conditionally recommended over leflunomide and sulfasalazine
    - Subcutaneous MTX is conditionally recommended over oral MTX
- Intraarticular glucocorticoids are conditionally recommended as adjunct therapy and conditionally recommended for bridging only in patients with moderate to high disease activity
- Strongly recommend against chronic low-dose glucocorticoid use, irrespective of disease activity and/or risk factors
- Strongly recommend combination use of a DMARD and infliximab
- Initial therapy for all patients:
    - DMARD is strongly recommended over NSAID monotherapy
    - MTX monotherapy is conditionally recommended over triple DMARD therapy
    - DMARD is conditionally recommended over a biologic
    - Initial biologic therapy may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage
- Subsequent therapy:
    - Low disease activity:
        - Escalating therapy (e.g., intraarticular glucocorticoid injections, optimization of DMARD dose, trial of MTX if not already done, and adding or changing biologic agent)
    - Moderate to high disease activity:
        - Add a biologic to original DMARD over changing to a second DMARD or changing to triple DMARD therapy
        - Switch to a non- tumor necrosis factor (TNF) biologic if currently treated with first TNF-inhibitor ± DMARD over switching to another TNF-inhibitor (unless the patient had good initial response to first TNF-inhibitor)
        - TNF-inhibitor, abatacept, or tocilizumab (depending on prior biologics received) over rituximab after trial of second biologic

Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis (PS), most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient due to one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and/or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Disease severity is based on the assessment of the level of disease activity at a given point in time, and the presence/absence of poor prognostic factors and long-term damage. Severe PsA is defined in the American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA and includes the presence of one or more of the following:

- Erosive disease
- Elevated markers of inflammation (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP]) attributable to PsA
- Long-term damage that interferes with function (e.g., joint deformities, vision loss)
- Highly active disease that causes a major impairment in quality of life, such as:
    - Active PsA at many sites including dactylitis and enthesitis
    - Function-limiting PsA at a few sites
- Rapidly progressive disease

Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis disorders, particularly spondyloarthritis and rheumatoid arthritis, and other management strategies of the cutaneous manifestations of psoriasis. Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and local glucocorticoid injections. Only patients with very mild peripheral disease may sufficiently benefit from NSAIDs as monotherapy, and instead patients are typically treated with disease-modifying antirheumatic drugs (DMARDs) and/or biologics. Efficacy of DMARD and biologic therapies should be assessed 3 months after initiation, and if adequate improvement is not seen then the treatment regimen should be updated or changed. The ACR-NPF guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and treatment recommendations for active disease are as follows:

- Treatment naïve patients:
    - First line options include oral small molecules (OSM), tumor necrosis factor (TNF) inhibitors, interleukin (IL)-17 inhibitors, and IL-12/23 inhibitors
        - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe PS, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitors
        - Biologics (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe PS
- Previous treatment with OSM and continued active disease:
    - Switch to a biologic (i.e., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor); recommended over switching to a different OSM

        - Biologic monotherapy is conditionally recommended over biologic plus MTX combination therapy
    - Switch to a different OSM (except apremilast) OR add on apremilast to current OSM therapy; recommended over adding another OSM
    - Add another OSM (except apremilast) to current OSM therapy; may consider for patients that have exhibited partial response to current OSM
    - Switch to apremilast monotherapy; may be considered instead of adding apremilast to current OSM therapy if the patient has intolerable side effects with the current OSM
- Previous treatment with a biologic and continued active disease:
    - Switch to another biologic (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) as monotherapy
    - Add MTX to the current biologic; may consider adding MTX in patients with a partial response to current biologic therapy

The European Alliance of Associations for Rheumatology (EULAR) guidelines for PsA (2023 update) also recommend a treat-to-target approach in therapy. MTX (preferred) or another conventional synthetic disease-modifying antirheumatic drug (csDMARD) (e.g., sulfasalazine, leflunomide) should be used for initial therapy. If the treatment target is not achieved with a csDMARD, a biologic should be initiated with preference of product being based on patient specific disease characteristics. Biologics include TNF inhibitors, IL-12/23 inhibitors, IL-17A inhibitors, IL-17A/F inhibitors, IL-23 inhibitors, and cytotoxic T-lymphocyte–associated antigen 4 (CTLA4) analogs. No order of preference of biologics is provided since none have demonstrated superiority for joint involvement, however, CTLA4 analogs are least preferred due to limited efficacy in clinical trials. The use of a Janus kinase (JAK) inhibitor (e.g., tofacitinib, upadacitinib) may be used after failure of a biologic or if biologics are not clinically appropriate for the patient. However, careful consideration should be applied prior to using a JAK inhibitor due to the increased risk of cardiovascular and malignancy events in older patients with RA and cardiovascular risk factors. A phosphodiesterase-4 (PDE4) inhibitor (i.e., apremilast) may be considered in patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a biologic nor a JAK inhibitor is appropriate. Patients with an inadequate response to a biologic or JAK inhibitor may switch to a different drug within the same class or switch to a different mode of action. Adding MTX to a biologic may increase drug survival by limiting the development of antidrug antibodies, especially for TNF inhibitors.

POSITION STATEMENT:

Site of Care: If intravenous abatacept (Orencia) is administered in a hospital-affiliated outpatient setting, additional requirements may apply depending on the member's benefit. Refer to 09-J3000-46: Site of Care Policy for Select Specialty Medications.

Comparative Effectiveness

The Food and Drug Administration has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) of the subcutaneous formulation of abatacept in

a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary. This statement does not apply to the intravenous (IV) formulation of abatacept.

NOTE: The list of self-administered products with prerequisites for certain indications can be found at Preferred Agents and Drug List.

SUBCUTANEOUS ORENCIA (PHARMACY BENEFIT)

Initiation of subcutaneous abatacept (Orencia) meets the definition of medical necessity when **ALL** of the following are met ("1" to "5"):

1. **ONE** of the following ("a", "b", or "c"):
    a. The member has been treated with subcutaneous abatacept (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with subcutaneous abatacept (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
    c. **BOTH** of the following ('i" and "ii"):
        i. Subcutaneous abatacept will be used for the treatment of an indication listed in Table 1, and ALL of the indication-specific criteria are met
        ii. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II")
            I. The member's age is within FDA labeling for the requested indication for subcutaneous abatacept
            II. The prescriber has provided information in support of using subcutaneous abatacept for the member's age for the requested indication for
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, RA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to subcutaneous abatacept
4. Member will **NOT** be using subcutaneous abatacept in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed 125 mg once every week
        - QL: 50 mg/0.4 mL syringe – 4 syringes (1.6 mL)/28 days
        - QL: 87.5 mg/ 0.7 mL syringe – 4 syringes (2.8 mL)/28 days
        - QL: 125 mg/mL syringe – 4 syringes (4 mL)/28 days
        - QL: 125 mg/mL ClickJect autoinjector – 4 autoinjectors (4 mL)/28 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. **ALL** of the following ("1", "2", and "3"):

      1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication

      2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)

      3. **EITHER** of the following ("a" or "b"):

         a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

         b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

   ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

   i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

Table 1

Diagnosis	Criteria
Moderately to severely active rheumatoid arthritis (RA)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** b. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** c. The member has an intolerance or hypersensitivity to **ONE** conventional agent (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** d. The member has an FDA labeled contraindication to **ALL** conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** e. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of RA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR**

	c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred RA products are:** • Adalimumab-aaty • Adalimumab-adaz • Enbrel (etanercept) • Humira (adalimumab) • Hadlima (adalimumab-bwwd) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib)
Active psoriatic arthritis (PsA)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PsA **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PsA **OR** d. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-

	term damage that interferes with function [i.e., joint deformities, vision loss], rapidly progressive) **OR** e. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** f. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla/Otezla XR that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products. **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products. **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred PsA products are:** • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab)

	• Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla/Otezla XR (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce)
Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PJIA **OR** c. The member has a labeled contraindication to **ALL** conventional agents used in the treatment of PJIA **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PJIA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **TWO** preferred products after at least a 3-month trial per product

	OR b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried poroducts for the requested indication **The preferred PJIA products are:** • Adalimumab-aaty • Adalimumab-adaz • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Tyenne (tocilizumab-aazg) • Xeljanz (tofacitinib)
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of subcutaneous abatacept (Orencia) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for subcutaneous abatacept has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]

2. Member has had clinical benefit with subcutaneous abatacept therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, RA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to subcutaneous abatacept
5. Member will **NOT** be using subcutaneous abatacept in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed 125 mg once every week
        - QL: 50 mg/0.4 mL syringe – 4 syringes (1.6 mL)/28 days
        - QL: 87.5 mg/ 0.7 mL syringe – 4 syringes (2.8 mL)/28 days
        - QL: 125 mg/mL syringe – 4 syringes (4 mL)/28 days
        - QL: 125 mg/mL ClickJect autoinjector – 4 autoinjectors (4 mL)/28 days
    b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
        ii. **ALL** of the following ("1", "2", and "3"):
            1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
            2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
            3. **EITHER** of the following ("a" or "b"):
                a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
                b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
    c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

b. the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: 12 months

INTRAVENOUS ORENCIA (MEDICAL BENEFIT)

Initiation of intravenous (IV) abatacept (Orencia) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "4"):

1. Intravenous abatacept is administered for an indication listed in Table 2, and **ALL** indication-specific and maximum-allowable dose criteria are met
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, RA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to IV abatacept
4. Member will **NOT** be using IV abatacept in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

Approval duration: 6 months [except for prophylaxis of acute GVHD or immune checkpoint inhibitor-related adverse effects, approve for 1 month only]

Table 2

Indications and Specific Criteria		
Indication	**Specific Criteria**	**Maximum Allowable Dose***

Active psoriatic arthritis (PsA)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PsA **OR** 4. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], rapidly progressive) **OR** 5. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla/Otezla XR that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA	Initial: ○ >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ 60 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ <60 kg: 500 mg every 2 weeks for 3 total doses (week 0, 2, and 4) Maintenance: ○ >100 kg: 1,000 mg every 4 weeks starting at week 8 ○ 60 to 100 kg: 750 mg every 4 weeks starting at week 8 ○ <60 kg: 500 mg every 4 weeks starting at week

Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PJIA **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PJIA **OR** 4. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PJIA	Initial dose: ○ >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ 75 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ <75 kg: 10 mg/kg every 2 weeks for 3 total doses (week 0, 2, and 4) Maintenance: ○ >100 kg: 1,000 mg every 4 weeks starting at week 8 ○ 75 to 100 kg: 750 mg every 4 weeks starting at week 8 ○ <75 kg: 10 mg/kg every 4 weeks starting at
Moderately to severely active rheumatoid arthritis (RA)	**ONE** of the following: 1. The member has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** 2. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** 3. The member has an intolerance or hypersensitivity to **ONE** conventional	Initial: ○ >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ 60 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ <60 kg: 500 mg every 2 weeks for 3 total doses (week 0, 2, and 4) Maintenance: ○ >100 kg: 1,000 mg every 4 weeks starting at week 8 ○ 60 to 100 kg: 750 mg every 4 weeks starting at week 8

	agent (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 4. The member has an FDA labeled contraindication to **ALL** conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 5. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of RA	○ <60 kg: 500 mg every 4 weeks starting at week 8
Prophylaxis of acute graft-versus-host disease (GVHD)	**ALL** of the following: 1. Member is undergoing an allogeneic hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor **AND** 2. Abatacept will be used in combination with a calcineurin inhibitor **AND** methotrexate [use of only one drug or neither drug is permitted if the member has intolerance(s) and/or contraindication(s) to one or both drugs – the specific intolerance(s) and/or contraindication(s) must be provided] **AND** 3. Member is at least 2 years of age or older	6 years and older ○ 10 mg/kg (maximum dose of 1,000 mg) on the day before transplantation (Day -1), followed by administration on Days 5, 14, and 28 after transplantation 2 to less than 6 years old ○ 15 mg/kg on the day before transplantation (Day -1), followed by 12 mg/kg on Days 5, 14, and 28 after transplantation

Chronic graft-versus-host disease (GVHD)	**ALL** of the following: 1. The member has previously received an allogeneic hematopoietic stem cell transplantation (HSCT) **AND** 2. Abatacept will be used as additional therapy in conjunction with systemic corticosteroids **AND** 3. The member has steroid-refractory disease	Initial: ○ >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ 60 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ <60 kg: 500 mg every 2 weeks for 3 total doses (week 0, 2, and 4) Maintenance: ○ >100 kg: 1,000 mg every 4 weeks starting at week 8 ○ 60 to 100 kg: 750 mg every 4 weeks starting at week 8 ○ <60 kg: 500 mg every 4 weeks starting at week 8
Immune checkpoint inhibitor-related adverse effects/toxicity	**ALL** of the following: 1. Member has been receiving treatment with an immune checkpoint inhibitor (e.g., ipilimumab, nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab) **AND** 2. **EITHER** of the following ("a" or "b"): a. **ALL** of the following ("i", "ii", and "iii"): i. The member has immunotherapy-related myocarditis **AND** ii. Abatacept will be used as monotherapy **AND** iii. Member has had no improvement within 24 hours	○ >100 kg: 1,000 mg X 1 dose; may repeat one additional dose if the member does not have adequate improvement in symptoms. ○ 60 to 100 kg: 750 mg X 1 dose; may repeat one additional dose if the member does not have adequate improvement in symptoms. ○ <60 kg: 500 mg X 1 dose; may repeat one additional dose if the member does not have adequate improvement in symptoms.

	of starting high-dose methylprednisolone, **OR** has intolerable adverse effects with or a contraindication to methylprednisolone **OR** b. **BOTH** of the following ("i" and "ii"): i. The member has immunotherapy-related concomitant myositis **AND** myocarditis **AND** ii. Abatacept will be used combination with ruxolitinib **AND** 3. The members immune checkpoint inhibitor therapy will be either permanently discontinued or held during treatment with abatacept	
Orphan Indications		
Giant cell arteritis (GCA)	**ONE** of the following: 1. The member has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA after at least 7 days **OR** 2. The member has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The member has an FDA labeled contraindication to **ALL** systemic corticosteroids **OR**	Initial: o >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) o 60 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) o <60 kg: 500 mg every 2 weeks for 3 total doses (week 0, 2, and 4) Maintenance: o >100 kg: 1,000 mg every 4 weeks starting at week 8 o 60 to 100 kg: 750 mg every 4 weeks starting at week 8

	4. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of GCA	○ <60 kg: 500 mg every 4 weeks starting at week 8
Idiopathic inflammatory myopathy (IMM) [includes dermatomyositis (DM) and polymyositis (PM)]	**BOTH** of the following: 1. The member's diagnosis has been confirmed by muscle biopsy **AND** 2. The member disease is refractory to at least 3 months of continuous combination treatment with a corticosteroid and an immunosuppressant (either azathioprine or methotrexate), **OR** the member has intolerable adverse effects with or a contraindication to either treatment	Initial: ○ >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ 60 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) ○ <60 kg: 500 mg every 2 weeks for 3 total doses (week 0, 2, and 4) Maintenance: ○ >100 kg: 1,000 mg every 4 weeks starting at week 8 ○ 60 to 100 kg: 750 mg every 4 weeks starting at week 8 ○ <60 kg: 500 mg every 4 weeks starting at week 8
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a	Maximum dose supported by the FDA labeled indication or maximum dose supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a
*The maximum allowable dose can be exceeded if (1) the dose is supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the requested indication, OR (2) the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)		

Continuation of **intravenous (IV)** abatacept **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. An authorization or reauthorization for IV abatacept has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of a condition in Table 2 [except prophylaxis of acute GVHD and immune checkpoint inhibitor-related adverse effects – see initiation criteria], **OR** the member previously met **ALL** indication-specific initiation criteria
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, RA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to IV abatacept
4. Member has had clinical benefit with IV abatacept therapy
5. Member will **NOT** be using IV abatacept in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **EITHER** of the following ("a" or "b"):
    a. The member's dosage does not exceed the following based on their weight and indication for use:
        - Rheumatoid arthritis, psoriatic arthritis, GCA, chronic GVHD, and IMM
            - >100 kg: 1,000 mg every 4 weeks
            - 60 to 100 kg: 750 mg every 4 weeks
            - <60 kg: 500 mg every 4 weeks
        - JIA
            - >100 kg: 1,000 mg every 4 weeks
            - 75 to 100 kg: 750 mg every 4 weeks
            - <75 kg: 10 mg/kg every 4 weeks
    b. The dose is supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the requested indication, **OR** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval Duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved:

Abatacept is indicated for the following:

- Treatment of adult patients with moderately to severely active rheumatoid arthritis
- Treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis
- Treatment of patients 2 years of age and older with active psoriatic arthritis (PsA)
- 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 [IV formulation only]

Limitations of Use – The concomitant use of abatacept with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

ADULT RHEUMATOID ARTHRITIS

Abatacept is administered as an intravenous (IV) or subcutaneous (SQ) injection.

- IV infusions should be administered as a 30-minute infusion utilizing weight range-based dosing specified in Table 4. Following the initial IV administration, an IV infusion should be administered at 2 and 4 weeks after the first infusion and every 4 weeks thereafter.

Table 3

Abatacept IV dose in adult RA persons		
Body weight	**Dose**	**Number of vials**
Less than 60 kg	500 mg	2
60 to 100 kg	750 mg	3
More than 100 kg	1,000 mg	4
Each vial provides 250 mg of abatacept for administration		

- Following a single IV loading dose (as per body weight categories listed in Table 3), the first 125 mg SQ injection of abatacept should be given within a day, followed by 125 mg SQ injections once weekly.
    - Persons unable to receive an infusion may initiate weekly injections of SQ abatacept without an IV loading dose
    - Persons transitioning from abatacept IV therapy to SQ administration should administer the first SQ dose instead of the next scheduled IV dose.

JUVENILE IDIOPATHIC ARTHRITIS

- The recommended intravenous dosage for persons aged 6 to 17 years of age:
    - Less than 75 kg: 10 mg/kg IV on week 0, 2, 4, and every 4 weeks thereafter
    - Greater than 75 kg: use adult IV dosing regimen, not to exceed a maximum dose of 1,000 mg
    - Intravenous dosing has not been studied in patients younger than 6 years of age
- The recommended subcutaneous dosage for persons aged 2 to 17 years of age:

- 10 to less than 25 kg: 50 kg once weekly
- 25 to less than 50 kg: 87.5 mg once weekly
- 50 kg or more: 125 mg once weekly

ADULT PSORIATIC ARTHRITIS

Abatacept is administered as an intravenous (IV) or subcutaneous (SQ) injection with or without non-biological DMARDs.

- IV infusions should be administered as a 30-minute infusion utilizing weight range-based dosing specified in Table 3. Following the initial IV administration, an IV infusion should be administered at 2 and 4 weeks after the first infusion and every 4 weeks thereafter.
- The SQ injections administered once weekly without the need for an IV loading dose. Persons transitioning from abatacept IV therapy to SQ administration should administer the first SQ dose instead of the next scheduled IV dose.

JUVENILE PSORIATIC ARTHRITIS

Abatacept may be used as monotherapy or concomitantly with methotrexate. Intravenous administration is not approved for pediatric patients with psoriatic arthritis.

- The recommended subcutaneous dosage for persons aged 2 to 17 years of age:
  - 10 to less than 25 kg: 50 kg once weekly
  - 25 to less than 50 kg: 87.5 mg once weekly
  - 50 kg or more: 125 mg once weekly

PROPHYLAXIS OF aGVHD

- For patients 6 years and older, administer 10 mg/kg (maximum dose of 1,000 mg) as an IV infusion over 60 minutes on the day before transplantation (Day -1), followed by administration on Days 5, 14, and 28 after transplantation.

- For patients 2 to less than 6 years old, administer 15 mg/kg as an IV infusion over 60 minutes on the day before transplantation (Day -1), followed by 12 mg/kg as an intravenous infusion over 60 minutes on Days 5, 14, and 28 after transplantation.

- Before administering abatacept, administer recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation, and continue for six months following HSCT. In addition, consider prophylactic antivirals for Cytomegalovirus (CMV) infection/reactivation during treatment and for six months following HSCT

Drug Availability:

- Intravenous infusion:
  - 250 mg lyophilized powder in a single use vial

- Subcutaneous injection:
  - 50 mg/0.4 mL, 87.5 mg/0.7 mL, and 125 mg/mL single-dose prefilled glass syringes
  - 125 mg/mL solution in a single-dose prefilled autoinjector (ClickJect)

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Warnings:

- **Concomitant Use with TNF Antagonists:** concomitant use with a TNF antagonist can increase the risk of infections and serious infections.
- **Hypersensitivity:** hypersensitivity, anaphylaxis, and anaphylactoid reactions have occurred following abatacept administration.
- **Infections:** persons with a history of recurrent infections or underlying conditions predisposing to infections may experience more infections; discontinue if a serious infection occurs.
- **Tuberculosis:** screen for latent TB infection prior to initiating therapy. Members testing positive should be treated prior to initiating abatacept.
- **Immunizations:** update vaccinations prior to initiating abatacept. Live vaccines should not be given concurrently or within 3 months of discontinuation. Abatacept may blunt the effectiveness of some immunizations.
- **Chronic Obstructive Pulmonary Disease (COPD):** Persons with COPD may develop more frequent respiratory events.
- **Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) Reactivation in aGVHD Prophylaxis after Hematopoietic Stem Cell Transplant (HSCT):** monitor patients for EBV reactivation in accordance with institutional practices. Provide prophylaxis for EBV infection for 6 months post-transplantation to prevent EBV-associated Post-Transplant Lymphoproliferative Disorder (PTLD). Monitor patients for CMV infection/reactivation for 6 months post-transplant regardless of the results of donor and recipient pre-transplant CMV serology. Consider prophylaxis for CMV infection/reactivation.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding:

J0129	Injection, abatacept, 10mg

ICD-10 Diagnosis Codes That Support Medical Necessity:

D89.810 – D89.813	Graft-versus-host disease
L40.50 – L40.59	Arthropathic psoriasis
M05.00 – M05.09	Felty's syndrome
M05.10 – M05.19	Rheumatoid lung disease with rheumatoid arthritis
M05.20 – M05.29	Rheumatoid vasculitis with rheumatoid arthritis
M05.30 – M05.39	Rheumatoid heart disease with rheumatoid arthritis
M05.40 – M05.49	Rheumatoid myopathy with rheumatoid arthritis
M05.50 – M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis
M05.60 – M05.69	Rheumatoid arthritis with involvement of other organs and systems
M05.70 – M05.7A	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80 – M05.8A	Other rheumatoid arthritis with rheumatoid factor
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M05.A	Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M06.00 – M06.0A	Rheumatoid arthritis without rheumatoid factor
M06.20 – M06.29	Rheumatoid bursitis
M06.30 – M06.39	Rheumatoid nodule
M06.80 – M06.8A	Other specified rheumatoid arthritis
M06.9	Rheumatoid arthritis, unspecified
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.89	Other juvenile arthritis, multiple sites
M31.5	Giant cell arteritis with polymyalgia rheumatica
M31.6	Other giant cell arteritis
M33.00 – M33.09	Juvenile dermatopolymyositis
M33.10 – M33.19	Other dermatopolymyositis
M33.20 – M33.29	Polymyositis
M33.90 – M33.99	Dermatopolymyositis, unspecified
T45.AX5A	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, initial encounter
T45.AX5D	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, subsequent encounter
T45.AX5S	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, sequela

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date. LCD Abatacept (L33257) was retired effective 12/15/2018. The Site of Care Policy for Select Specialty Medications does not apply to Medicare Advantage members.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

DMARD: An acronym for disease-modifying antirheumatic drug. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., apremilast, baricitinib, tofacitinib), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

Psoriatic arthritis (PsA): joint inflammation that occurs in about 5% to 10% of people with psoriasis (a common skin disorder). It is a severe form of arthritis accompanied by inflammation, psoriasis of the skin or nails, and a negative test for rheumatoid factor. Enthesitis refers to inflammation of entheses, the site where ligaments or tendons insert into the bones. It is a distinctive feature of PsA and does not occur with other forms of arthritis. Common locations for enthesitis include the bottoms of the feet, the Achilles' tendons, and the places where ligaments attach to the ribs, spine, and pelvis.

Rheumatoid arthritis: An inflammatory disease of the synovium or lining of the joint that results in pain stiffness and swelling of multiple joints. The inflammation may extend to other joints and cause bone and cartilage erosion, joint deformities, movement problems, and activity limitations.

RELATED GUIDELINES:

Adalimumab Products , 09-J0000-46
Anakinra (Kineret), 09-J0000-45
Apremilast (Otezla) Tablet, 09-J2000-19
Certolizumab Pegol (Cimzia), 09-J0000-77
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria™), 09-J1000-11

Infliximab Products, 09-J0000-39
Ixekizumab (Taltz), 09-J2000-62
Rituximab Products, 09-J0000-59
Sarilumab (Kevzara), 09-J2000-87
Tocilizumab Products (Actemra. Tofidence, Tyenne), 09-J1000-21
Tofacitinib (Xeljanz, Xeljanz XR) Oral Solution, Tablet and Extended-Release Tablet, 09-J1000-86
Upadacitinib (Rinvoq), 09-J3000-51

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

Table 4: Conventional Synthetic DMARDs

Generic Name	Brand Name
Auranofin (oral gold)	Ridaura
Azathioprine	Imuran
Cyclosporine	Neoral, Sandimmune
Hydroxychloroquine	Plaquenil
Leflunomide	Arava
Methotrexate	Rheumatrex, Trexall
Sulfasalazine	Azulfidine, Azulfidine EN-Tabs

Table 5: Grading of Severity of Rheumatoid Arthritis

Severity	Criteria
Mild	Joint pain Inflammation of at least 3 joints No inflammation in tissues other than the joints Usually, a negative result on a rheumatoid factor test An elevated erythrocyte sedimentation rate (ESR) or C reactive protein (CRP) level No evidence of bone or cartilage damage on x-rays
Moderate	Between 6 and 20 inflamed joints Usually no inflammation in tissues other than the joints An elevated ESR or CRP levels A positive rheumatoid factor test or anti-cyclic citrullinated peptide (anti-CCP) antibodies Evidence of inflammation but no evidence of bone damage on x-rays
Severe	More than 20 persistently inflamed joints or a rapid loss of functional abilities Elevated ESR or CRP levels Anemia related to chronic illness Low blood albumin level A positive rheumatoid factor test, often with a high level Evidence of bone and cartilage damage on x-ray Inflammation in tissues other than joints

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Coverage Committee on 11/12/25.

GUIDELINE UPDATE INFORMATION:

06/15/07	New Medical Coverage Guideline.

10/15/07	Revision; consisting of updating ICD-9 coding.
05/15/08	Review and revision; consisting of adding new JIA indication, updating dosage and administration section, updating references and updating ICD-9 file.
09/15/09	Review and revision; consisting of updating references and updating precautions.
04/15/10	Revision; consisting of adding specific continuation criteria.
08/15/10	Review and revision; consisting of updating references, description and precautions.
02/15/11	Revision; consisting of formatting changes and ICD-10 codes.
08/15/11	Review and revision to guideline; consisting of updating coding and references.
11/15/11	Revision to guideline; consisting of adding new dosage formulation and maximum dose.
08/15/12	Review and revision to guideline; consisting of updating position statement, precautions, exceptions and references.
09/15/12	Revision to guideline; consisting of modifying continuation criteria.
04/15/13	Revision to guideline; consisting of revising and reformatting position statement; revising and reformatting description, dosage/administration, and precautions sections; updating references and related guidelines.
09/15/13	Review and revision to guideline; consisting of updating quantity limit, adding Orphan drug indications, program exceptions, and updating references.
01/01/14	Revision to guideline; consisting of updating preferred language.
04/15/14	Revision to guideline; consisting of revising position statement.
09/15/14	Review and revision to guideline; consisting of updating position statement, references, coding, and related guidelines.
09/15/15	Review and revision to guideline; consisting of updating description section, position statement, billing/coding, and references.
10/01/15	Revision consisting of update to Program Exceptions section.
12/15/15	Revision consisting of ICD-10 coding updates.
09/15/16	Review and revision to guideline consisting of updating description section, position statement, billing/coding, and references.
06/15/17	Revision to guideline consisting of updating description section, position statement, dosage/administration section, and references based on expanded FDA-approval of JIA indication to age 2 years of age and older and new SQ dosage recommendations for JIA.
10/15/17	Review and revision to guideline consisting of updating description, position statement, dosage/administration, coding/billing, definitions, related guidelines, and references.
01/01/18	Revision to guideline consisting of updating the preferred self-administered biologic products according to indication for use. Secukinumab is now a preferred product for psoriatic arthritis, and use of three preferred products is required. Tofacitinib (Xeljanz, Xeljanz XR) added as prerequisite therapy for rheumatoid arthritis indication.
07/01/18	Revision to guideline consisting of updating the position statement.
10/15/18	Review and revision to guideline consisting of updating the position statement, billing/coding, related guidelines, and references.
10/15/19	Review and revision to guideline consisting of updating the position statement, related guidelines, program exceptions, and references.
11/11/19	Revision to guideline consisting of adding a reference to the Site of Care Policy for Select Specialty Medications and updating the Program Exceptions.

01/01/20	Revision to guideline consisting of updating the position statement due to changes in preferred and non-preferred products.
07/01/20	Revision to guideline consisting of updating the description, position statement, other, and definitions.
01/01/21	Review and revision to guideline consisting of updating the position statement, billing/coding, and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
09/15/21	Update to Table 1 in Position Statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the position statement, billing/coding, related guidelines, other section, and references.
02/15/22	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, and references.
03/15/22	Revision to guideline consisting of updating the position statement and other section.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Update to Table 1 in Position Statement.
10/15/22	Revision to guideline consisting of updating the position statement to include two new preferred agents (an infliximab product and Simponi Aria) prior to the use of Orencia IV infusion for the treatment of PsA and RA.
09/15/22	Update to Table 1 in Position Statement.
01/01/23	Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination. Removed the preferred agents prior to the use of Orencia IV infusion for the treatment of PsA and RA.
04/15/23	Revision to guideline consisting of updating the position statement and other section.
07/01/23	Revision to guideline consisting of updating the position statement and other section. Amjevita and Hadlima added as Step 1a agents. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/24	Review and revision to guideline consisting of updating the position statement (FDA and NCCN info), dosage/administration, billing/coding, other section, and references. Orencia subcutaneous indication for PsA expanded to included pediatric patients 2 years of age and older. Amjevita low-concentration [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only] clarified as the preferred prerequisite product. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/24	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
10/01/24	Revision to guideline consisting of updating the position statement and billing/coding. Updates to Table 1. Simlandi added among the required prerequisite agents for

	subcutaneous Orencia for RA, PJIA, and PsA. Rinvoq LQ added among the required prerequisite agents for subcutaneous Orencia for PJIA and PsA. New ICD-10 codes related to adverse effect of immune checkpoint inhibitors.
01/01/25	Review and revision to guideline consisting of updating the description (NCCN info), position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for Orencia SC for for RA, PJIA, and PsA. Removed Actemra and added Tyenne among the prerequisite therapies for Orencia SC for PJIA. Update the immune checkpoint inhibitor-related adverse effects indication for Orencia IV. Update to original Table 1 which is now a link out from the Position Statement. Table titles update. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/25	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PsA for Orencia SC.
10/01/25	Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA.
01/01/26	Review and revision to guideline consisting of updating the description, position statement, and references.