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Subject: Abatacept (Orencia®) Injection and Infusion

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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. IV abatacept is recommended as further intervention for the management of myocarditis if no improvement within 24 to 48 hours of starting high-dose methylprednisolone. 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 the most common inflammatory autoimmune arthritis in adults. The main goal of therapy is to achieve remission, but additional goals include decrease inflammation, relieve symptoms, prevent joint and organ damage, improve physical function/overall well-being, and reduce long term complications. 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 DMARD(s) chosen
- Recommendations are limited to DMARDs approved by the US FDA for treatment of RA:
    - csDMARDs: hydroxychloroquine, sulfasalazine, methotrexate (MTX), leflunomide
    - bDMARDs: TNF inhibitors (etanercept, adalimumab, infliximab, golimumab, certolizumab pegol), T cell costimulatory inhibitor (abatacept), IL-6 receptor inhibitors (tocilizumab, sarilumab), anti-CD20 antibody (rituximab)
    - tsDMARDs: JAK inhibitors (tofacitinib, baricitinib, upadacitinib)
- Triple therapy refers to hydroxychloroquine, sulfasalazine, and either methotrexate or leflunomide
- Biosimilars are considered equivalent to FDA-approved originator bDMARDs
- 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
- 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 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

Early use of DMARD, particularly MTX, is recommended as soon as possible following diagnosis of RA. Dosing of MTX for RA is once weekly dosing with starting doses at 7.5 mg or 15 mg once weekly.[26-28] MTX dose is increased as tolerated and as needed to control symptoms and signs of RA disease. The usual target dose is at least 15 mg weekly and the usual maximum dose is 25 mg weekly.[27,28] ACR defines optimal dosing for RA treatments as 1) dosing to achieve a therapeutic target derived from mutual patient-clinician consideration of patient priorities and 2) given for at least 3 months before therapy escalation or switching. For patients who are unable to take MTX, hydroxychloroquine, sulfasalazine, or leflunomide are other DMARD options. In patients resistant to initial MTX treatment, combination DMARD (e.g., MTX plus sulfasalazine or hydroxychloroquine or a TNF-inhibitor) is recommended.

For patients who are resistant to MTX after 3 months of treatment at optimal doses (usually 25 mg per week), it is recommended to either use DMARD triple therapy with MTX plus sulfasalazine and hydroxychloroquine or combination of MTX with TNF inhibitor. Triple therapy regimen has been found to be of similar clinical efficacy to MTX with biologics in several randomized trials, including in patients with high level of disease activity or with adverse prognostic features. The use of triple therapy has been shown to be highly cost-effective compared with combining a biologic with MTX, providing comparable or near comparable clinical benefit. The use of biologic with MTX combination is preferred when patients have high disease activity and clinical benefit from a more rapid response is needed and when patients who do not achieve satisfactory response within 3 months with non-biologic triple therapy following an inadequate response to MTX therapy.

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 ACR 2019 guidelines recommend the following treatment approach for PJIA:

- NSAIDs are conditionally recommended as adjunct therapy
- 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-TNF biologic if currently treated with first TNF ± DMARD over switching to another TNF (unless the patient had good initial response to first TNF)
        - TNF, 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, most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis, particularly spondyloarthritis and RA, and other management strategies of the cutaneous manifestations of psoriasis.

The American Academy of Dermatology (AAD) recommends initiating MTX in most patients with moderate to severe PsA. After 12 to 16 weeks of MTX therapy with appropriate dose escalation, the AAD recommends adding or switching to a TNF inhibitor if there is minimal improvement on MTX monotherapy.

The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and the following:

- Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
    - Actively inflamed joints
    - Dactylitis
    - Enthesitis
    - Axial disease
    - Active skin and/or nail involvement
    - Extraarticular manifestations such as uveitis or inflammatory bowel disease
- Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage
- Severe PsA disease includes the presence of 1 or more of the following:
    - Erosive disease
    - Elevated markers of inflammation (ESR, CRP) attributable to PsA
    - Long-term damage that interferes with function (i.e., joint deformities)
    - Highly active disease that causes a major impairment in quality of life
    - Active PsA at many sites including dactylitis, enthesitis
    - Function limiting PsA at a few sites
    - Rapidly progressive disease
- Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
- Treatment recommendations for active disease:
    - Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
        - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis,

prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor

- Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis

- Previous treatment with OSM and continued active disease:
  - Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy
  - May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy
  - Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy
- Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease:
  - Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic

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 self-administered products with prerequisites for certain indications are as follows:

Table 1

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						

Ankylosing Spondylitis (AS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: **Orencia**	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Kevzara, Yuflyma**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, **Orencia**, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Rheumatoid Arthritis (RA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, **Orencia**, Simponi	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Dermatological Disorders						
Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira,	N/A	Oral: Sotyktu	SQ: Cimzia	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**,

	Simlandi, Skyrizi, Stelara, Tremfya Oral: Otezla					Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yuflyma**, Yusimry**
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, Humira, or Simlandi is a required Step 1 agent)	SQ: Entyvio	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**, Zymfentra
Ulcerative Colitis (UC)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Entyvio. Omvoh Oral: Zeposia (Hadlima, Humira, Rinvoq, Simlandi, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**, Zymfentra Oral: Velsipity
Other						
Uveitis	SQ: Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators						
Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA)	N/A	N/A	N/A	N/A	N/A	N/A

Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

**Note: Hadlima, Humira, and Simlandi are required Step 1 agents

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as **ONE** product

Note: Branded generic available for Cyltezo, Hulio, Hyrimoz, Idacio, and Yuflyma are included as a target at the same step level in this program

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 2, 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
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), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib),

Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

5. **ANY** of the following ("a", "b", or "c"):
   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 requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose, **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) 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
   c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose, **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** 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

Table 2

Diagnosis	Criteria
Moderately to severely active rheumatoid arthritis (RA)	**BOTH** of the following: 1. **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 another 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** of the following conventional agents (i.e., methotrexate,

	hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 4. The member has an FDA labeled contraindication to **ALL** of the following 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 **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** of the following preferred products after at least a 3-month trial per product: • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib) **OR** b. 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** of the following: • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib) **OR**

	c. The member has an FDA labeled contraindication to **ALL** of the following: • Enbrel (etanercept) • Humira (adalimumab) • Hadlima (adalimumab-bwwd) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • 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** of the conventional agents used in the treatment of PsA **OR** c. The member has an FDA labeled contraindication to **ALL** of the 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], 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 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** of the following preferred products after at least a 3-month trial per product: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **OR** b. 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** of the following: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab)

	• Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa)

	• Stelara (ustekinumab) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib)
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** of the conventional agents used in the treatment of PJIA **OR** c. The member has a labeled contraindication to **ALL** of the 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 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** of the following preferred products after at least a 3-month trial per product: • Actemra (tocilizumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz (tofacitinib) **OR** b. 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** of the following:

	• Actemra (tocilizumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz (tofacitinib) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Actemra (tocilizumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz (tofacitinib) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Actemra (tocilizumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • 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), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", or "c"):
    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 requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) 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
    c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the requested indication, **AND** 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

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 3,** 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 subcutaneous abatacept in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (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 3

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** of the conventional agents used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to **ALL** of the 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,	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

	CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], 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 that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA	
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** of the conventional agents used in the treatment of PJIA **OR** 3. The member has an FDA labeled contraindication to **ALL** of the 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	Initial dose: o >100 kg: 1,000 mg every 2 weeks for 3 total doses (week 0, 2, and 4) o 75 to 100 kg: 750 mg every 2 weeks for 3 total doses (week 0, 2, and 4) o <75 kg: 10 mg/kg 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 75 to 100 kg: 750 mg every 4 weeks starting at week 8 o <75 kg: 10 mg/kg every 4 weeks starting at

	labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PJIA	
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 another 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** of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 4. The member has an FDA labeled contraindication to **ALL** of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 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	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

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	**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. The member has myocarditis **AND** 3. Member has had no improvement within 24 hours of starting high-dose methylprednisolone, **OR** has intolerable adverse effects with or a contraindication to methylprednisolone **AND** 4. The members immune checkpoint inhibitor therapy will be either permanently discontinued or held during treatment with abatacept	○ >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.
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 to 10 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	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

	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 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 3** [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 subcutaneous abatacept in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **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 4

Table 2: 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 1), 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 2. 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 – M05.79	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80 – M05.89	Other rheumatoid arthritis with rheumatoid factor
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00 – M06.09	Rheumatoid arthritis without rheumatoid factor
M06.20 – M06.29	Rheumatoid bursitis
M06.30 – M06.39	Rheumatoid nodule
M06.80 – M06.89	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.

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:

Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizumab)
Omvoh (mirikizumab-mrkz)
Orencia (abatacept)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)

Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi Aria (golimumab)
Skyrizi (risankizumab-rzaa)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence ((tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tyruko (natalizumab-sztn)
Tysabri (natalizumab)
Wezlana (ustekinumab-auub)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zymfentra (infliximab-dyyb)

Table 5: 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 6: 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 11/08/23.

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.