Clinical Policy Title:	abatacept
Policy Number:	RxA.741
Drug(s) Applied:	Orencia®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Orencia® is a selective T cell costimulation modulator indicated for:

Adult Rheumatoid Arthritis: The treatment of adult patients with moderately to severely active rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis: The treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis.

Adult Psoriatic Arthritis: The treatment of adult patients with active psoriatic arthritis (PsA).

Prophylaxis for Acute Graft versus Host Disease: The prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
abatacept (Orencia®)	RA, PsA	Intravenous: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose Subcutaneous: 125 mg once weekly RA and PsA: Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose. (For RA: Prior to the first subcutaneous dose, may administer	Intravenous: 1,000 mg every 4 weeks Subcutaneous: 125 mg/week

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
		an optional loading dose as a single intravenous infusion as per body weight categories above.) For PsA: Intravenous loading dose is not recommended.	
	PJIA	Intravenous: in pediatric patients ≥ 6 years old weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 75 kg: 10 mg/kg per dose Weight 75 to 100 kg: 750 mg per dose Weight >100 kg: 1,000 mg per dose Subcutaneous: In pediatric patients ≥ 2 years old weight-based dose once weekly Weight 10 to < 25 kg: 50 mg per dose Weight 25 to < 50 kg: 87.5 mg per dose Weight ≥ 50 kg: 125 mg per dose	Intravenous: 1,000 mg every 4 weeks Subcutaneous: 125 mg/week
	Acute Graft Vs Host Disease prophylaxis (aGVHD)	For patients 6 years and older, administer at a 10 mg/kg dose (maximum dose 1,000 mg) as a 60-minute intravenous infusion on the day before transplantation, followed by a dose on Day 5, 14, and 28 after transplant. For patients 2 to less than 6 years old, administer a 15 mg/kg dose as a 60-minute infusion on the day before transplantation, followed by a 12 mg/kg dose as a 60-minute infusion on Day 5, 14, and 28 after transplant	Intravenous: 1000 mg on day before transplant followed by a dose on day 5, 14, and 28 after transplant

Dosage Forms

- Intravenous Infusion: For injection: 250 mg lyophilized powder in a single-dose vial (may use less than full contents of vial or use more than one vial).
- Subcutaneous Use: Injection: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL solution in single-dose prefilled syringes, Injection: 125 mg/mL solution in a single-dose prefilled ClickJect™ autoinjectors.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;
5. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced or attestation demonstrating a trial may be inappropriate*;
   *Exception: If a total of two TNF inhibitors (Cimzia, Humira, Simponi/Simponi Aria, Enbrel) has previously been tried and failed, trial of a third TNF inhibitor is not required.
6. Member meets any one of the followings (a or b);
   a. Dose does not exceed 1,000 mg every 4 weeks (intravenous).
   b. Dose does not exceed 125 mg/week (subcutaneous).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of Psoriatic Arthritis (Ps)A;
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of at least two (2) first line agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Stelara®, Skyrizi®, Tremfya® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required;
5. Dose does not exceed 125 mg/week (subcutaneous)

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**

1. Diagnosis of PJIA;
2. Prescribed by or in consultation with a rheumatologist;
3. Member is ≥ 2 years for subcutaneous infusion and ≥6 years for intravenous infusion;
4. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX] or leflunomide [Arava®]) at up to maximally indicated doses, unless contraindicated or clinically

significant adverse effects are experienced;
*Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;

5. Trial and failure of Humira® unless contraindicated or clinically significant adverse effects are experienced;
*Exception: If a total of two TNF inhibitors (Humira, Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.
6. Dose does not exceed Member meets any one of the followings (a or b);
   a. Dose does not exceed 1,000 mg every 4 weeks (intravenous).
   b. Dose does not exceed 125 mg/week (subcutaneous).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Prophylaxis for Acute Graft Vs host disease (aGVHD) (must meet all):
1. Prophylaxis for Acute Graft Vs host disease undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele mismatched unrelated- donor;
2. Member is ≥ 2 years;
3. Used in combination with a calcineurin inhibitor and methotrexate;
4. Dose does not exceed 1000 mg intravenous on day before transplant followed by a dose on day 5, 14, and 28 after transplant.

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, c or d):
   a. RA:
      i. Dose does not exceed 1,000 mg every 4 weeks (intravenous).
      ii. Dose does not exceed 125 mg/week (subcutaneous).
   b. **PsA:** Dose does not exceed 125 mg/week (subcutaneous)
   c. PJIA:
      i. Dose does not exceed 1,000 mg every 4 weeks (intravenous).
      ii. Dose does not exceed 125 mg/week (subcutaneous).
   d. **aGVHD**: Dose does not exceed 1000 mg intravenous on day before transplant followed by a dose on day 5, 14, and 28 after transplant.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DMARDs: Disease-Modifying Antirheumatic Drugs
MTX: Methotrexate

PJIA: Polyarticular Juvenile Idiopathic Arthritis
PsA: Psoriatic Arthritis
RA: Rheumatoid Arthritis
aGVHD : Acute Graft Vs Host Disease
TB: Tuberculosis
JAK: Janus kinase inhibitors
HSCT: hematopoietic stem cell transplantation

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA:** 1 mg/kg/day orally once daily or divided twice daily	2.5 mg/kg/day
d-penicillamine (Cuprimine®)	**RA (off-label)** Initial dose: 125 or 250 mg orally once daily Maintenance dose: 500 – 750 mg/day orally once daily	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA:** 2.5 – 4 mg/kg/day orally divided twice daily	RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA (off-label)** Initial dose: 400 – 600 mg/day orally once daily Maintenance dose: 200 – 400 mg/day orally once daily	600 mg/day
leflunomide (Arava®)	**PJIA (off-label)** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day **RA:** 100 mg orally once daily for 3 days, then 20 mg orally once daily	PJIA, RA: 20 mg/day
methotrexate	**PJIA(off-label):** 10 – 20 mg/m^2/week orally, subcutaneous, or intramuscular **RA:** 7.5 mg/week orally, subcutaneous, or intramuscular or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week
Ridaura®	**RA:** 6 mg orally once daily or 3 mg orally twice daily	9 mg/day (3 mg three times daily)
sulfasalazine (Azulfidine®)	**PJIA*:** 30-50 mg/kg/day orally divided twice daily **RA:** 2 g/day orally in divided doses	PJIA: 2 g/day RA: 3 g/day
Biologic DMARDs		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Humira®	**RA**: 40 mg subcutaneously every other week Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every Week or 80 mg every other week **PJIA:** Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg subcutaneously every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg subcutaneously every other week Weight ≥ 30 kg (66 lbs): 40 mg subcutaneously every other week **PsA**: 40 mg subcutaneously every other week	**RA**: 40 mg/week **PJIA:** 40 mg every other week **PsA**: 40 mg every other week
Cosentyx®	**PsA:** <u>With loading dose:</u> 150 mg subcutaneous lyat week 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks <u>Without loading dose:</u> 150 mg subcutaneously every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks. Pediatric Patients 2 years and older: Recommended dosage is administered by subcutaneous injection at weeks 0,1 ,2,3, and 4 and every 4 weeks after: For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.	**PsA:** 300 mg every 4 weeks
infliximab (Remicade®, Renflexis™, Inflectra®, Avsola®)	**PsA:** <u>Initial dose:</u> 5 mg/kg intravenous at weeks 0, 2 and 6 <u>Maintenance dose:</u> 5 mg/kg intravenous every 8 weeks **RA:** In conjunction with MTX <u>Initial dose:</u> 3 mg/kg intravenous at weeks 0, 2 and 6 <u>Maintenance dose:</u> 3 mg/kg intravenous every 8 weeks Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks	**PsA:** 5 mg/kg every 8 weeks **RA:**10 mg/kg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Simponi Aria®	**PsA RA:** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenous every 8 weeks **PJIA:** Initial dose: 80 mg/m^2 at weeks 0 and 4 Maintenance dose: 80 mg/m^2 intravenous every 8 weeks	**PsA, RA**: 2 mg/kg every 8 weeks **PJIA:** 80 mg/m^2 every 8 weeks
Otezla®	**PsA:** Initial dose: Day 1: 10 mg orally in morning Day 2: 10 mg orally in morning and 10 mg orally in evening Day 3: 10 mg orally in morning and 20 mg orally in evening Day 4: 20 mg orally in morning and 20 mg orally in evening Day 5: 20 mg orall in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	60 mg/day
Xeljanz® / Xeljanz® oral Solution, Xeljanz® XR	Xeljanz®: **PsA, RA**: 5 mg orally twice daily PsA: use in combination with nonbiologic disease-modifying antirheumatic drugs RA: monotherapy or use in combination with nonbiologic disease-modifying antirheumatic drugs Xeljanz® / Xeljanz® oral Solution: **PJIA**: 5 mg twice daily or weight-based equivalent twice daily: • 10 kg ≤ body weight <20 kg: 3.2 mg (3.2 mL oral solution) twice daily • 20 kg ≤ body weight <40 kg: 4 mg (4 mL oral solution) twice daily Body weight ≥40 kg: 5 mg (one 5 mg tablet or 5 mL oral solution) twice daily Xeljanz® XR: **PsA, RA**: 11 mg orally once daily	Xeljanz®: **PsA, RA:** 10 mg/day Xeljanz® / Xeljanz® oral Solution: 5 mg or 5 ml twice daily Xeljanz® XR: 11 mg/day
Kevzara®	**RA:** 200 mg subcutaneous once every two weeks	200 mg/2 Weeks
Kineret®	**RA:** 100 mg subcutaneous once daily	100 mg/day
Olumiant®	**RA:** 2 mg orally once daily	2 mg/day
Cimzia®	**RA, PsA:** Initial dose: 400 mg subcutaneous at 0, 2, and 4 weeks. Maintenance dose: 200 mg subcutaneous every other week (or 400 mg subcutaneous every 4 weeks)	**RA, PsA:** 400 mg every 4 weeks
Simponi®	**PsA, RA:** 50 mg subcutaneous once monthly	50 mg/month
Tremfya®	**PsA:** Initial dose: 100 mg subcutaneous at weeks 0 and 4 Maintenance dose:	100 mg every 8 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	100 mg subcutaneous every 8 weeks Can be used alone or in combination with conventional DMARD e.g. methotrexate	
Taltz®	**PsA:** Initial dose: 160 mg (two 80 mg injections) subcutaneous Maintenance dose: 80 mg subcutaneous every 4 weeks.	**PsA:** 80 mg every 4 weeks
Actemra®	**RA:** Intravenous: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Subcutaneous: Weight < 100 kg: 162 mg every other week, followed by an increase to every week based on clinical response. Weight ≥ 100 kg: 162 mg every week. **PJIA:** Weight < 30 kg: 10 mg/kg intravenously every 4 weeks or 162 mg subcutaneously every 3 weeks. Weight ≥ 30 kg: 8 mg/kg intravenously every 4 weeks or 162 mg subcutaneously every 2 weeks.	**RA**: Intravenous: 800 mg every 4 weeks Subcutaneous: 162 mg every week **PJIA:** Intravenous: 10 mg/kg every 4 weeks Subcutaneous: 162 mg every 2 weeks
Rinvoq®	**RA, PsA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	15 mg/day
Stelara®	**PsA:** 45 mg subcutaneous at weeks 0 and 4, followed by 45 mg every 12 weeks	**PsA:** 45 mg every 12 weeks
Enbrel®	**RA, PsA:** 25 mg subcutaneous twice weekly or 50 mg subcutaneous once Weekly **PJIA:** Weight < 63 kg: 0.8 mg/kg subcutaneous once weekly Weight ≥ 63 kg: 50 mg subcutaneous once weekly	50 mg/week

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Concomitant use with a TNF antagonist can increase the risk of infections and serious infections.
- Serious infections have been reported. Patients with a history of recurrent infections or underlying conditions predisposing to infections may experience more infections. Discontinue if a serious infection develops.
- Screen for latent TB infection prior to initiating therapy. Patients testing positive should be treated prior to initiating Orencia®.
- Should screen for viral hepatitis prior to initiating Orencia®.
- Update vaccinations prior to initiating Orencia®. Live vaccines should not be given concurrently or within 3 months of discontinuation. Orencia® may blunt the effectiveness of some immunizations.
- COPD patients may develop more frequent respiratory adverse events.
- Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) reactivation in patients treated for aGVHD prophylaxis.
- Polyarticular Juvenile Idiopathic Arthritis:
  - Failure of MTX in PJIA is defined as disease activity remaining moderate to high despite treatment with MTX.
  - In PJIA, response to treatment is reflected by improvement of disease activity level and poor prognostic features including: reduction in the number of active joints, ESR or CRP, Physician global assessment, patient/parent global assessment, arthritis of the hip or cervical spine, positive RF or ACPA, radiographic damage.

References

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Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Tysabri was created based on RxA.592.Biologic_DMARDs 1. Dosing Information for (Orencia®) was updated to include indication and dosing information for Acute Graft Vs Host Disease prophylaxis (aGVHD). 2. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Humira®, Cimzia®, Inflectra®, Rinvoq™, Renflexis™, Simponi®, Simponi Aria®, or Xeljanz®/ Xeljanz XR®". 3. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria Trial and failure of at least two (2) of the following agents: Cimzia®, Humira®, Simponi®/ Simponi Aria®, Rinvoq® or Xeljanz/XR® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.	02/14/2022	04/18/2022

4. Initial Approval Criteria, I.B.5: Updated to remove prior trial and failure criteria Failure of a trial of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Rinvoq™, Simponi®, Simponi Aria®, Stelara®, Taltz®, or Xeljanz®/ Xeljanz XR®; 5. Initial Approval Criteria, I.C.5: Updated to include new trial and failure criteria Trial and failure of Humira® unless contraindicated or clinically significant adverse effects experienced; *Exception: If a total of two TNF inhibitors (Humira, Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required. 6. Initial Approval Criteria, I.D: Updated to include approval criteria for indication Prophylaxis for Acute Graft Vs host disease (aGVHD). 7. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 8. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 9. Appendix D, General Information: Updated to remove information regarding: Rheumatoid Arthritis. 10. References were reviewed and updated.		