Clinical Policy: Abatacept (Orencia)

Reference Number: PA.CP.PHAR.241
Effective Date: 01/18
Last Review Date 4/19 Revision Log

Coding Implications

Description
Abatacept (Orencia®) is a selective T cell costimulation modulator.

FDA Approved Indication(s)
Orencia is indicated for:

- Reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). Orencia may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.
- Reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Orencia may be used as monotherapy or concomitantly with methotrexate (MTX).
- Treatment of adult patients with active psoriatic arthritis (PsA)

Limitation(s) of use: Orencia should not be administered concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Orencia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
   b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a ≥ 3 consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effect are experienced;

5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced, or member is currently receiving Orencia;
   **Prior authorization is required for etanercept and adalimumab*
6. Dose does not exceed one of the following:
   a. Intravenous (IV):
      i. < 60kg: 500mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      ii. 60-100 kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      iii. > 100kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
   b. Subcutaneous (SC): 125mg once weekly.

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of PJIA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX (see Appendix D), failure of a ≥ 3 consecutive month trial of sulfasalazine or leflunomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* AND adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced, or member is currently receiving Orencia;
   **Prior authorization is required for etanercept and adalimumab*
6. For members 2 to 5 years of age, prescribed route of administration is SC;
7. Dose does not exceed one of the following (a or b):
   a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks;
      i. Weight < 75 kg: 10 mg/kg per dose;
      ii. Weight 75 kg to 100 kg: 750 mg per dose;
      iii. Weight > 100 kg: 1,000 mg per dose;
   b. SC: weight-based dose once weekly;
      i. Weight 10 to <25 kg: 50 mg per dose;
      ii. Weight 25 to <50 kg: 87.5 mg per dose;
      iii. Weight ≥ 50 kg: 125 mg per dose

      Approval duration: 6 months

C. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of active PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;

3. Age ≥ 18 years;
4. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced, or member is currently receiving Orencia;
   **Prior authorization is required for etanercept and adalimumab*
5. Dose does not exceed the following (a or b):
   a. IV (weight based)
      i. < 60kg: 500mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      ii. 60-100 kg: 750mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
      iii. > 100kg: 1000mg every 2 weeks for 3 doses (i.e., a dose at weeks 0, 2, and 4), and then every 4 weeks thereafter;
   b. Subcutaneous (SC): 125mg once weekly.

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. For RA and PsA (i or ii):
      i. IV (weight based):
         1) < 60 kg: 500mg every 4 weeks;
         2) 60-100 kg: 750mg every 4 weeks;
         3) > 100kg: 1000mg every 4 weeks;
      ii. SC: 125mg once weekly;
   b. PJIA (i or ii):
      i. IV: weight-based dose every 4 weeks;
         1) Weight < 75 kg: 10 mg/kg per dose;
         2) Weight 75 kg to 100 kg: 750 mg per dose;
         3) Weight > 100 kg: 1,000 mg per dose;
      ii. SC: weight-based dose once weekly;
         1) Weight 10 to <25 kg: 50 mg per dose;
         2) Weight 25 to <50 kg: 87.5 mg per dose;
         3) Weight ≥ 50 kg: 125 mg per dose.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
MTX: methotrexate
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritis
RA: rheumatoid arthritis
TNF: tumor necrosis factor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO Maintenance dose: 200 – 400 mg/day PO	600 mg/day
leflunomide (Arava®)	**PJIA*** Weight 10 mg/1.73 m^2/day Or < 20 kg: 10 mg every other day	20 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day **RA** 100 mg PO QD for 3 days, then 20 mg PO QD	
methotrexate (Rheumatrex®)	**PJIA*** 10 – 20 mg/m^2/week PO, SC, or IM **RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**RA** 2 g/day PO in divided doses	RA: 3 g/day
Enbrel® (etanercept)	**PsA, RA** 25 mg SC twice weekly or 50 mg SC once weekly **PJIA** Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
Humira® (adalimumab)	**PJIA** Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week Weight ≥ 30 kg (66 lbs): 40 mg every other week **PsA** 40 mg SC every other week **RA** 40 mg SC every other week (may increase to once weekly)	PJIA, PsA: 40 mg every other week RA: 40 mg/week

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

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA PsA	IV: 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 SC: 125 mg once weekly (For RA: if single IV loading dose is given, start first SC injection within one day of IV dose)	IV: 1,000 mg every 4 weeks SC: 125 mg/week
PJIA	IV: 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 SC: 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	IV: 1,000 mg every 4 weeks SC: 125 mg/week

VI. Product Availability

- Single-use vial for IV infusion: 250 mg
- Single-dose prefilled syringes for SC injection: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL
- Single-dose prefilled ClickJect™ autoinjector for SC injection: 125 mg/mL

VII. References

1. Orencia Prescribing Information. Princeton, NJ: Bristol-Meyers Squibb Company; June 2017. Available at: http://www.orenciahcp.com/. Accessed February 26, 2019.
2. Ringold, S., Weiss, P. F., Beukelman, T., DeWitt, E. M., Ilowite, N. T., Kimura, Y., Laxer, R. M., Lovell, D. J., Nigrovic, P. A., Robinson, A. B. and Vehe, R. K. (2013), 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. Arthritis & Rheumatism, 65: 2499–2512.
3. Gossec L, Smolen JS, Ramiro S, et al European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337.
4. Gottlieb, Alice et al.Guidelines of care for the management of psoriasis and psoriatic arthritis: Journal of the American Academy of Dermatology, Volume 58, Issue 5, 851 – 864.
5. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Rheumatology 2016. 68(1):1-26.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

J0129	Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed TB testing from RA and PJIA; revised dosing in initial and continuation approval criteria for PJIA per package insert; references reviewed and updated.	2.27.18	

2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for PsA per ACR/NPF 2018 guidelines; references reviewed and updated.	04/19	