PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**ORENCIA**
(generic)	**(abatacept)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref #159-A***

FDA-APPROVED INDICATIONS[1]

Moderately to severely active rheumatoid arthritis

Orencia is indicated for reducing signs and symptoms, inducing 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.

Moderately to severely active polyarticular juvenile idiopathic arthritis

Orencia is indicated for reducing signs and symptoms in pediatric patients 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA). Orencia may be used as monotherapy or concomitantly with methotrexate (MTX).

Psoriatic arthritis

Orencia is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

CRITERIA FOR APPROVAL

1	Has the patient previously received Orencia for one of the following conditions: A) Rheumatoid arthritis, or B) Polyarticular juvenile idiopathic arthritis, C) Psoriatic arthritis? [If yes, no further questions.]	Yes	No
2	Is Orencia prescribed for a patient with moderately to severely active rheumatoid arthritis? [If no, skip to question 4.]	Yes	No
3	Does the patient meet either of the following criteria: A) Patient had an inadequate response, intolerance, or contraindication to methotrexate (MTX), or B) Patient had an inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) (e.g., adalimumab) or a targeted synthetic DMARD (e.g., tofacitinib)? [No further questions.]	Yes	No
4	Is Orencia prescribed for a patient with moderately to severely active polyarticular juvenile idiopathic arthritis? [If no, skip to question 6.]	Yes	No
5	Did the patient have an inadequate response, intolerance or contraindication to a tumor necrosis factor (TNF) inhibitor (e.g., adalimumab)? [No further questions.]	Yes	No
6	Is Orencia prescribed for a patient with active psoriatic arthritis?	Yes	No

Guidelines for Approval							
Duration of Approval				**12 months**			
Set 1: Renewal		**Set 2:** RA		**Set 3:** pJIA		**Set 4:** PsA	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	2	1	4	1	6	1
		3		5	2		2
							4

Mapping Instructions		
	Yes	**No**
1	Approve, 12 months	Go to 2
2	Go to 3	Go to 4
3	Approve, 12 months	Deny
4	Go to 5	Go to 6
5	Approve, 12 months	Deny
6	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; June 2017.
2. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2012;64(5):625-639.
3. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.

DOCUMENT HISTORY

Written:	JG 01/2006
Revised:	AK 11/2006; Specialty Clinical Development (MG) 04/2008 (JIA added), 07/2008; TG 03/2009; AC 03/2010; GY 04/2011, 10/2011 (CMS), KR 09/2012 (CMS), KW 09/2013 (CMS), DK 09/2014 (CMS), JP 08/2015 (CMS), IP 09/2015 (annual review), HY 10/2015 (CMS – TNF example). IP 07/2016 (CMS), KF 08/2016 (annual), KF 02/2017 (trade, simplification), KF 07/2017 (CMS, PsA label update)
Reviewed:	CDPR/MM 01/2006, 11/2006; WLF 04/2008, 07/2008, 04/2009, 04/2010; KP 05/2011, 06/2012, LMS 05/2013, SES 09/2014, MM 09/2015, 10/2015, LMS 04/2016; ME 09/2016; SD 02/2017
External Review:	04/2006, 11/2007, 11/2008, 06/2009, 07/2010, 07/2011, 08/2012, 07/2013, 07/2014, 11/2014, 10/2015, 11/2016