PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**OTEZLA**
(generic)	**(apremilast)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 1129-A***

FDA-APPROVED INDICATIONS[1]

Active psoriatic arthritis

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Moderate to severe plaque psoriasis

Otezla is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

CRITERIA FOR APPROVAL

1	Has the patient previously received Otezla for one of the following conditions: A) Plaque psoriasis, or B) Psoriatic arthritis? [If yes, no further questions.]	Yes	No
2	Does the patient have a diagnosis of active psoriatic arthritis (PsA)? [If no, skip to question 4.]	Yes	No
3	Does the patient meet either of the following: A) Patient had an inadequate response or intolerable adverse event to at least one prior biologic disease-modifying antirheumatic drug (DMARD) indicated for PsA (e.g., adalimumab), OR B) Biologic DMARDs indicated for PsA are not appropriate for the patient (e.g., due to comorbidities or a history of infections contraindicating any biologic DMARD)? [No further questions.]	Yes	No
4	Does the patient have a diagnosis of moderate to severe plaque psoriasis? [If no, no further questions.]	Yes	No
5	Does the patient meet one of the following criteria: A) At least 5 percent of body surface area was affected by plaque psoriasis at the time of diagnosis, or B) Crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis? [If no, no further questions.]	Yes	No
6	Does the patient meet one of the following criteria: A) Patient has experienced an inadequate response or intolerance to either phototherapy (e.g., ultraviolet B, psoralen plus ultraviolet A [PUVA]) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, or B) Pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated?	Yes	No

Guidelines for Approval					
Duration of Approval		**12 Months**			
Set 1: Renewal		**Set 2: PsA**		**Set 3: PsO**	
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
		3		5	2
				6	

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	Deny
5	Go to 6	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. Otezla [package insert]. Summit, NJ: Celgene Corporation; June 2017.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (DK) 04/2014
Revised:	09/2014 (CMS), 01/2015 (label change), PK 08/2015 (CMS), IP 09/2015, 07/2016 (CMS), KF 08/2016 (annual), KF 02/2017 (2018 trade, simplification), KF 07/2017 (CMS)
Reviewed:	CDPR/LB 04/2014, SES 09/2014; MM 09/2015, 10/2015, LCB 09/2016; SD 02/2017
External Review:	04/2014, 10/2015, 10/2016