Otezla (apremilast) Prior Authorization with Quantity Limit Program Summary

This program applies to Commercial, GenPlus, NetResults A series, SourceRx, and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Otezla (apremilast) Prior Authorization with Quantity Limit criteria is to ensure that patients prescribed therapy are properly selected according to Food and Drug Administration (FDA)-approved product labeling and/or clinical guidelines and/or clinical trials. The criteria will encourage the use of first-line conventional agents.

TARGET DRUG

Otezla® (apremilast)

QUANTITY LIMITS FOR TARGET DRUG

Brand (generic)	GPI	Quantity Limit	Multisource Code
Otezla® (apremilast)			
10 mg, 20 mg & 30 mg tablet starter pack (two week)	6670001500B720	1 starter kit of 27 tablets/180 days	M, N, O, or Y
10 mg, 20 mg & 30 mg tablet starter pack (4 week)	6670001500B720	1 starter kit of 55 tablets/180 days	M, N, O, or Y
30mg tablets	66700015000330	60 tablets/30 days	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

1. The patient has a diagnosis of ONE of the following:
    a. Moderate-to-severe plaque psoriasis and ONE of the following:
        i. There is documentation that the patient is currently being treated with the requested agent
        OR
        ii. The prescriber states the patient is using the requested agent AND is at risk if therapy is changed
        OR
        iii. The patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication
        OR
        iv. The patient's medication history indicates use of one conventional agent prerequisite
        OR
        v. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE conventional agent

    OR

    b. Active psoriatic arthritis ONE of the following:
        i. There is documentation that the patient is currently being treated with the requested agent
        OR
        ii. The prescriber states the patient is using the requested agent AND is at risk if therapy is changed
        OR
        iii. The patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication
        OR

iv. The patient's medication history indicates use of one conventional agent prerequisite
OR
v. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least ONE conventional agent

OR

c. Another FDA labeled indication

AND

2. The patient is not currently being treated with a biologic immunomodulator agent
AND
3. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent
AND
4. ONE of the following:
    a. The prescribed dosage is within the program limit (FDA approved labeled dosage)
    OR
    b. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling, and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: 12 months

Renewal Evaluation

Otezla (apremilast) will be approved for renewal when the following criteria are met:

1. The patient has been previously approved for therapy through Prime Therapeutics PA process
AND
2. The patient has shown clinical improvement (i.e. slowing of disease progression or decrease in symptom severity and/or frequency)
AND
3. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent
AND
4. The patient is not currently being treated with a biologic immunomodulator agent
AND
5. ONE of the following:
    A. The prescribed dosage is within the program set limit (FDA approved labeled dosage)
    OR
    B. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling, and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1]

Otezla (apremilast) is indicated for the following:

- Treatment of adult patients with active psoriatic arthritis
- Treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

The recommended initial dosage titration of Otezla from Day 1 to Day 5 is shown in Table 1. Following the 5-day titration, the recommended maintenance dosage is 30 mg twice daily taken orally starting on Day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy.

Otezla can be administered without regard to meals. Do not crush, split, or chew the tablets.

Table 1: Dosage Titration Schedule

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6	
AM	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

CLINICAL RATIONALE

Psoriasis and Psoriatic Arthritis (PsA)

The American Academy of Dermatology guidelines state that 80% of psoriasis patients have limited disease involvement, typically defined <5% of body surface area, and can be effectively managed with topical agents such as corticosteroids, vitamin D analogues, tazarotene, etc. For more significant disease, biologics are utilized.[2]

Approximately 10-30% of patients with psoriasis will also have PsA. EULAR Recommendations on the management of psoriatic arthritis recommend the following[3]:

- Conventional synthetic DMARDs [(csDMARDs); i.e. MTX, sulfasalazine, leflunomide] should be considered in:
  - Early stage peripheral arthritis, particularly in those with poor prognosis (i.e. swollen joints, structural damage in the presence of inflammation, high erythrocyte sedimentation rate/C reactive protein and/or clinically relevant extra-articular manifestations). MTX is preferred in those with relevant skin involvement
- After failure to at least one csDMARD, therapy with a bDMARD (usually TNF-i followed by bDMARDs targeting IL-12/23 or IL-17 if TNF-i is not appropriate) should be considered
- After failure to at least one csDMARD, where a bDMARD is not appropriate, a targeted synthetic DMARD (tsDMARD), such as a PDE4-inhibitor should be considered
- In those with active enthesitis and/or dactylitis with failure to NSAIDs/local glucocorticoids injections, a bDMARD should be considered (current practice is a TNF-i)
- Predominantly active axial disease: after failure to NSAIDs, a bDMARD should be considered (current practice is a TNF-i)
- After failure to a bDMARD, switch to another bDMARD, including switching between TNF-inhibitors

Safety[1]

Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

REFERENCES

1. Otezla Prescribing Information. Celgene Corporation. December 2015.

2. Menter A, Korman N, Elmets C, et al. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol*. 10.1016/j.jaad.2008.12.032 (epub February 2009).
3. Gossec, L. et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis. December 2015.