Medical Policy

BlueCross BlueShield of Kansas
An independent licensee of the Blue Cross Blue Shield Association

Title: Otezla (apremilast)

- **Prime Therapeutics will review Prior Authorization requests**

  Prior Authorization Form:
  http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6343KS-OTEZ.pdf

  Link to Drug List (Formulary):
  http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.shtml

Professional
Original Effective Date: January 1, 2017
Revision Date(s): January 1, 2017
Current Effective Date: January 1, 2017

Institutional
Original Effective Date: January 1, 2017
Revision Date(s): January 1, 2017
Current Effective Date: January 1, 2017

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

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 Drugs

Otezla® (apremilast)

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

POLICY

Prior Authorization and Quantity Limits 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

Brand (generic)	Quantity Limit
Otezla (apremilast)	
10 mg, 20 mg & 30 mg tablet starter pack (two week)	1 starter kit of 27 tablets/180 days
10 mg, 20 mg & 30 mg tablet starter pack (4 week)	1 starter kit of 55 tablets/180 days
30mg tablets	60 tablets/30 days

FDA Labeled Indications	Conventional Agent Prerequisites	
Psoriatic arthritis (PSA)	▪ methotrexate ▪ leflunomide ▪ hydroxychloroquine	▪ minocycline ▪ sulfasalazine
Psoriasis (PS)	▪ methotrexate ▪ topical corticosteroids ▪ coal tar products ▪ anthralin ▪ calcipotriene ▪ calcitriol ▪ acitretin	▪ tazarotene ▪ cyclosporine ▪ methoxsalen ▪ tacrolimus ▪ pimecrolimus ▪ PUVA (phototherapy)

Biologic Agent Contraindicated as Concomitant Therapy	
▪ Actemra (tocilizumab) ▪ Arcalyst (rilonacept) ▪ Cimzia (certolizumab) ▪ Cosentyx (secukinumab) ▪ Enbrel (etanercept) ▪ Entyvio (vedolizumab) ▪ Humira (adalimumab) ▪ Ilaris (canakinumab) ▪ Kineret (anakinra) ▪ Orencia (abatacept)	▪ Remicade (infliximab) ▪ Rituxan (rituximab) ▪ Simponi (golimumab) ▪ Simponi ARIA (golimumab) ▪ Stelara (ustekinumab) ▪ Taltz (ixekizumab) ▪ Tysabri (natalizumab) ▪ Xeljanz (tofacitinib) ▪ Xeljanz XR (tofacitinib extended release)

Agent	Contraindications
Otezla (apremilast)	Hypersensitivity to apremilast or any of the excipients

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.

REVISIONS

01-01-2017	Policy published 12-29-2016. Policy effective 01-01-2017.

REFERENCES

1. Otezla Prescribing Information. Celgene Corporation. December 2014.
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.