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Policy Number: C6356-B

Otezla (apremilast)

PRODUCTS AFFECTED

Otezla (apremilast)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Active psoriatic arthritis, Plaque psoriasis, Oral ulcers associated with Behcet's Disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. Otezla will not be used in combination with a targeted synthetic DMARD (e.g., Xeljanz) or a biologic DMARD (e.g., Actemra (IV, SC), Kineret, Orencia (IV, SC), Rituxan, or TNF antagonists [Cimzia, Enbrel, Humira, Remicade, or Simponi (Aria, SC)])

AND

2. Prescriber attests to review of members concurrent medications and member will not be. using Otezla with strong cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)

A. PSORIATIC ARTHRITIS (PsA):
1. Documentation of active psoriatic arthritis
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
3. (a) Document treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
   OR
   (b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
   OR
   (c) Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]
   AND
4. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) [DOCUMENTATION REQUIRED]

B. CHRONIC PLAQUE PSORIASIS:
1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
   AND
2. (a) Documentation of treatment failure, serious side effects, or a clinical contraindication to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
   OR
   (b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Member weighs 20kg or more
   AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s). [DOCUMENTATION REQUIRED]

C. BEHCET'S DISEASE:
1. Documented diagnosis of Behcet's syndrome
   AND
2. Documentation of recurrent oral aphthae (at least three times in one year) plus two of the following clinical features: (a) Recurrent genital aphthae (aphthous ulceration or scarring), (b) Eye lesions (including anterior or posterior uveitis, cells in vitreous on slit lamp examination, or retinal vasculitis observed by an ophthalmologist), (c) Skin lesions (including erythema nodosum, pseudofolliculitis, papulopustular lesions, or acneiform nodules consistent with Behçet syndrome) or (d) A positive pathergy test
   AND
3. (a) The member has tried at least ONE conventional therapy (e.g., systemic corticosteroids [for example, methylprednisolone], immunosuppressants [azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran® (chlorambucil), cyclophosphamide], interferon alfa, colchicine, sucralfate suspension or triamcinolone in Orabase).
   NOTE: An exception to the requirement for a trial of one conventional therapy can be made if the member has already had a trial of at least one tumor necrosis factor inhibitor (e.g., an adalimumab product [e.g., Humira], an etanercept product [e.g., Enbrel]). These members who have already tried a biologic for Behcet's disease are not required to "step back" and try a conventional therapy.)
   OR
   b) The member has ophthalmic manifestations of Behcet's disease.
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of strong cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)

DURATION OF APPROVAL:

Initial authorization: 6 months. Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified rheumatologist or dermatologist, or ophthalmologist (for Behcet's). [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Plaque Psoriasis: 6 years of age and older
Psoriatic Arthritis, Bechet's disease: 18 years of age and older

QUANTITY:

Maximum 30mg twice daily

Maximum Quantity Limits – Otezla Starter Pack – one starter package containing 55 tablets will initially be authorized for a 28 day supply, followed by Otezla 30 mg tablets – 60 tablets per 30 days

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Phosphodiesterase 4 (PDE4) Inhibitors

FDA-APPROVED USES:
Indicated for the treatment of:

- adult patients with active psoriatic arthritis
- adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
- pediatric patients 6 years of age and older and weighing at least 20kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- adult patients with oral ulcers associated with Behçet's disease

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

APPENDIX 1:
There is no single generally agreed upon definition or conceptual model of health-related quality of life at the present time. The choice of the different measures of health-related quality of life in PsA depends on its content, respondent burden, administrative burden, translation and adaptations, acceptability, reliability, validity, and ability to detect change. PsAQoL is the only measure specific to PsA. It is now being used for randomized controlled trial, from which more will be learned about its performance characteristics.

American College of Rheumatology (ACR) Response Criteria/ACR20

ACR20 requires a 20% reduction in the tender joint count (TJC), a 20% reduction in the swollen joint count (SJC), and a 20% reduction in three out of five additional measures: member global self- assessment (PtGA), physician global assessment (PhGA), pain, disability, and an acute-phase reactant (erythrocyte sedimentation rate [ESR] or C-reactive protein [CRP]). Distal interphalangeal (DIP) joints should be included for PsA trials.3 Since the ACR response criteria assess absolute changes (i.e., from swollen to not swollen or from tender to not tender joints), analyses by oligoarthritis and polyarthritis subgroups would be desirable in clinical trials since patients with oligoarthritis may seem to respond less well than patients with polyarthritis. ACR20 has been shown to have discriminatory validity in PsA.4 The ACR20 and other levels of ACR response may be interpreted as follows:

ACR20: generally accepted to be the minimal clinically important difference (MCID); reflects 'some' response to an intervention.

ACR50: reflects significant and important changes ACR70: reflects major changes; near remission Health Assessment Questionnaire (HAQ)

Full HAQ covers five generic patient-centered health dimensions: (1) disability; (2) pain and discomfort; (3) adverse treatment effects; (4) economics; and (5) death.

Short HAQ is the 2-page version of the HAQ that is commonly referred to in the literature as "the HAQ." The short HAQ contains the HAQ Disability Index (HAQ-DI), the HAQ visual analog (VAS) pain scale, and the VAS member global health scale.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Otezla is an inhibitor of phosphodiesterase 4 (PDE4) and is indicated for the treatment of adult patients with active psoriatic arthritis or plaque psoriasis. PDE4 regulates immune and inflammatory processes through control of intracellular cAMP levels and downstream protein kinase A pathways. The production of a number of key inflammatory cytokines is affected by PDE4 including interferon (IFN)γ, tumor necrosis factor (TNF)α, interleukin (IL)-12, and IL-23, thus shaping the immune response. Otezla is a targeted synthetic disease-modifying anti-rheumatic drug (DMARD) that specifically targets intracellular PDE4 and, therefore, has an inhibitory effect on multiple cytokines involved in the inflammatory process.

MEASURES OF CHANGE IN PSA DISEASE STATUS

There is no single generally agreed upon definition or conceptual model of health-related quality of life at the present time. The choice of the different measures of health-related quality of life in PsA depends on its content, respondent burden, administrative burden, translation and adaptations, acceptability, reliability, validity, and ability to detect change. PsAQoL is the only measure specific to PsA. It is now being used for randomized controlled trial, from which more will be learned about its performance characteristics.

American College of Rheumatology (ACR) Response Criteria/ACR20

ACR20 requires a 20% reduction in the tender joint count (TJC), a 20% reduction in the swollen joint count (SJC), and a 20% reduction in three out of five additional measures: member global self-assessment (PtGA), physician global assessment (PhGA), pain, disability, and an acute-phase reactant (erythrocyte sedimentation rate [ESR] or C-reactive protein [CRP]). Distal interphalangeal (DIP) joints should be included for PsA trials. Since the ACR response criteria assess absolute changes (i.e., from swollen to not swollen or from tender to not tender joints), analyses by oligoarthritis and polyarthritis subgroups would be desirable in clinical trials since patients with oligoarthritis may seem to respond less well than patients with polyarthritis. ACR20 has been shown to have discriminatory validity in PsA.4 The ACR20 and other levels of ACR response may be interpreted as follows: ACR20: generally accepted to be the minimal clinically important difference (MCID); reflects 'some' response to an intervention. ACR50: reflects significant and important changes. ACR70: reflects major changes; near remission.

Health Assessment Questionnaire (HAQ)

Full HAQ covers five generic patient-centered health dimensions: (1) disability; (2) pain and discomfort; (3) adverse treatment effects; (4) economics; and (5) death.

Short HAQ is the 2-page version of the HAQ that is commonly referred to in the literature as "the HAQ." The short HAQ contains the HAQ Disability Index (HAQ-DI), the HAQ visual analog (VAS) pain scale, and the VAS member global health scale.

HAQ Disability Index (HAQ-DI).
This index is composed of 20 questions that ask the member to rate his/her ability to perform activities over the past week in eight categories of functional ability - dressing, rising, eating, walking, hygiene, reach, grip, and usual activities. The rating scale ranges from 0 (no disability) to 3 (completely disabled). The eight category scores are averaged into an overall HAQ-DI score on a non- continuous scale with 25 possible values (i.e., 0, 0.125, 0.250, 0.375 c 3), where 0 = no disability and 3 = completely disabled. Scores of 0 to 1 are generally considered to represent mild to moderate difficulty, 1 to 2 moderate to severe disability, and 1 to 3 severe to very severe disability. The MCID for the overall HAQ-DI score in PsA has been shown to be about 0.35.142Negative changes (e.g., -0.35) represent improvements in disability scores. Available: http://aramis.stanford.edu/downloads/HAQ%20-%20DI%202007.pdf
RAPID3 (Routine Assessment of Member Index Data 3
RAPID3 on a multidimensional health assessment questionnaire (MDHAQ) is scored in 5 to 10 seconds, versus 90 to 94 seconds for a formal 28-joint count, 108 seconds for a CDAI, and 114 seconds for a DAS28. An MDHAQ can be completed by each member at each visit in the waiting room in 5 to 10 minutes, as a component of the infrastructure of routine care, with minimal effort of the rheumatologist and staff, to provide RAPID3 scores as well as additional data including a self- report joint count, fatigue, review of systems, and recent medical history. In all rheumatic diseases RAPID3 is able to provide a baseline quantitative value, and to quantitatively monitor and document improvement or worsening over time.
Available at: http://www.rheumatology.org/Practice/Clinical/Quality/RAPID3/
Medical Outcomes Study Short Form 36 (SF-36)
a generic health assessment questionnaire intended to measure general health concepts not specific to any age, disease, or treatment group [53]. It measures 8 health domains: physical functioning, pain, vitality, social functioning, psychological functioning, general health perceptions, and role limitations due to physical and emotional problems. It also can be subdivided into two summary scores, the physical component summary, and the mental component summary scores. This instrument has been validated in PsA. It was found to be reliable in patients with PsA and could be used to distinguish PsA patients from the general population. http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html
Psoriatic Arthritis Quality of Life (PsAQoL)
is a 20-item, PsA-specific health-related QOL instrument. It has shown reliability and construct validity, but its use in clinical trial has not yet been published. Dermatology Life Quality Index (DLQI)
a 10-item questionnaire developed as a measure of disability for a wide range of dermatological conditions. It has been validated in assessment of psoriasis and shows discrimination and responsiveness in PsA trials. Available at: http://www.dermatology.org.uk/downloads/dlqiquest.pdf EuroQol 5-domain (EQ-5D)
comprised of a 5-dimension set of health status measures and a VAS. The 5 dimensions are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 3 levels: no problems, some problems, and extreme problems. The VAS records the respondent's self-rated health on a 20-centimeter vertical VAS where the endpoints are labelled "the best imaginable health state" and "the worst imaginable health status." The EQ-5D has shown discrimination and responsiveness in PsA trials.
Available: http://www.euroqol.org/fileadmin/user_upload/Documenten/PDF/Folders_Flyers/UserGuide_EQ-5D- 5L_v2.0_October_2013.pdf

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Otezla (apremilast) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Otezla (apremilast) include: Known hypersensitivity to apremilast or to any of the excipients in the formulation.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:
Otezla tablets 30MG
Otezla TBPK 10 & 20 & 30MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Age Restrictions FDA-Approved Uses References	Q3 2024
REVISION- Notable revisions: Required Medical Information Quantity	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file