Effective Date: 04/01/2019
Last P&T Approval/Version:10/27/2021
Next Review Due By: 11/2022
Policy Number: C15971-A

Ilumya (tildrakizumab)

PRODUCTS AFFECTED

Ilumya (tildrakizumab)

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:
ICD-10: L40.0 Psoriasis vulgaris

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

A. PLAQUE PSORIASIS:
1. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months)

OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Member is not on concurrent treatment or will be used in combination with other TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
3. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
4. Documented diagnosis of moderate to severe psoriasis (BSA 3%-10%-moderate, >10%- severe) OR ≤10% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (ex.face, neck, hands, feet, genitals)
   AND
5. (a) Documentation of treatment failure with 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, sulfasalazine, 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 type2 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
6. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
   AND
7. IF THIS IS A NON-FORMULARY 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. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. PLAQUE PSORIASIS

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 (documentation required)
   AND
2. Documentation of no 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.
   AND
4. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified dermatologist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Loading: Ilumya 100 mg prefilled syringe: 100 mg at weeks 0 and 4
Maintenance: Ilumya 100 mg prefilled syringe: 1 every 12 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Ilumya (tildrakizumab). For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Antipsoriatics-Systemic

FDA-APPROVED USES:
indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Ilumya is a humanized immunoglobulin (Ig)G monoclonal antibody that binds to interleukin (IL)-23, a pro- inflammatory cytokine. It binds to the p19 subunit of IL-23 and inhibits the intracellular and downstream signaling of IL-23 which is required for the terminal differentiation and survival of T helper (Th)17 cells.
Ilumya is indicated for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is administered subcutaneously (SC) at

Weeks 0 and 4 and then once every 12 weeks (Q12W) thereafter. Ilumya is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self- inject when deemed appropriate

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Ilumya (tildrakizumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Concurrent Use with other Biologics or with Targeted Synthetic Disease- Modifying Antirheumatic Drugs (DMARDs) or Methotrexate. Ilumya (tildrakizumab) should not be administered in combination with other biologics or with a targeted synthetic DMARD or Methotrexate for an inflammatory condition. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of additive efficacy. Therapy may be discontinued if member is noncompliant with medical or pharmacologic

therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

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:

Ilumya SOSY 100MG/ML prefilled syringe

REFERENCES

1. Ilumya™ injection [prescribing information]. Whitehouse Station,NJ:Sun Pharmaceuticals/Merck; March 2021.
2. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the managementof plaque psoriasis. Arch Dermatol. 2012;148(1):95-102.
3. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management ofpsoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines ofcare for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008;58:826-850.
4. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation withEADV and IPC.J Eur Acad Dermatol Venereol. 2015;29(12):2277-2294.
5. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (resurface 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. Lancet. 2017;390(10091):276-288.
6. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents forthe treatment of rheumatic diseases, 2012. Ann Rheum Dis. 2013;72 Suppl2:ii2-34.