Clinical Policy: Tildrakizumab (Ilumya)

Reference Number: QCP.PHAR.009
Date of Last Revision: 06/2024

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Tildrakizumab (Ilumya)

I. Initial Approval Criteria

Plaque Psoriasis (must meet all):

1. Diagnosis of PsO and PsO is moderate-to-severe as evidenced by involvement of one of the following (I or ii):

    i. ≥ 3% of total body surface area;

    ii. Hands, feet, scalp, face, or genital area;

2. Prescribed by or in consultation with a dermatologist or rheumatologist;

3. Age ≥ 18 years;

4. Member meets one of the following (a or b):

    a. Member has moderate-to-severe disease, and one of the following (i, ii, or iii):

        i. Failure of a ≥ 3 consecutive months trial of methotrexate (MTX) at up to maximally indicated doses;

        ii. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a ≥ 3 consecutive months trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;

        iii. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;

5. For Ilumya, member meets BOTH of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):

    a. One of the following (i, ii, or iii, see Appendix D):

        i. Failure of BOTH of the following, each used for ≥ 3 consecutive months (1 and 2):

            1) ONE of the following adalimumab products**: Humira, or Cyltezo**

            2) **Enbrel;**

        ii. If member has had a history of failure of one TNF blocker, then failure of ONE of the following TNF blockers used for ≥ 3 consecutive months: **Enbrel, Humira, or Cyltezo;**

iii. History of failure of two TNF blockers;

b. Failure of ALL of the following, each used for ≥ 3 consecutive months: **Skyrizi, Stelara, Tremfya, Cosentyx, Otezla;**

6. member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors;

7. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

II. Continued Therapy

All Indications in Section I (must meet all):

1. Member currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
4. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V.

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – HIM.PA.154 for health insurance marketplace or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Tofidence™ (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Wezlana™ (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DMARDs: disease-modifying antirheumatic drugs

JAK: Janus kinase

MTX: methotrexate
NSAIDs: non-steroidal anti inflammatory drugs
PsO: plaque psoriasis
TNF: tumor necrosis factor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	**PsO** 25 or 50 mg PO QD	50 mg/day
Corticosteroids Medium to very high potency topical: e.g., desoximetasone 0.05%, fluocinolone acetonide 0.025%, mometasone 0.1% cream, triamcinolone acetonide 0.1%, augmented betamethasone dipropionate 0.05%, clobetasol propionate 0.05% cream, ointment, gel, or solution, halobetasol propionate 0.05% cream, ointment	**PsO** Applied topically to the affected area(s) BID	Various
cyclosporine (Sandimmune®, Neoral®)	**PsO** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**PsO** 10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
biologic DMARDs (e.g., Humira, Enbrel, Cosentyx, Remicade, Simponi Aria, Otezla, Xeljanz/Xeljanz XR, Kevzara)	See Section V. Dosing and Administration	See Section V. Dosing and Administration

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

Contraindications: Serious hypersensitivity reaction to tildrakizumab or to any of the excipients

BBW: None

Appendix D: General Information

- Definition of failure of MTX or DMARDs
  - Failure of a trial of conventional DMARDs:
    - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.

- Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.

- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Tildrakizumab-asmn (Ilumya)	PsO	Initial dose: 100 mg SC at weeks 0 and 4 Maintenance dose: 100 mg SC every 12 weeks Ilumya should only be administered by a healthcare professional.	100 mg every 12 weeks

VI. Product Availability

Single-dose prefilled syringe: 100 mg/1 mL

References

1. Ilumya Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; March 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761067s014lbl.pdf. Accessed February 10, 2023

Psoriasis

2. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021 Feb;84(2):432-470. doi: 10.1016/j.jaad.2020.07.087.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Apr;80(4):1029-1072. doi: 10.1016/j.jaad.2018.11.057.
4. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic

nonbiologic therapies. J Am Acad Dermatol. 2020 Jun;82(6):1445-1486. doi: 10.1016/j.jaad.2020.02.044
5. ClinicalTrials.gov. A study of Ustekinumab to Evaluate a "Subject-tailored" Maintenance Dosing Approach in Subjects with Moderate-to-Severe Plaque Psoriasis (PSTELLAR). Available at https://clinicaltrials.gov/ct2/show/NCT01550744. Accessed February 10, 2023

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3245	Injection, tildrakizumab, 1 mg

Revision Log

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created.		05.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed healthcare professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.