POLICY Document for Ilumya

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
DISEASE-MODIFYING ANTIRHEUMATIC DRUGS PRODUCTS

PREFERRED PRODUCTS: ENTYVIO, ILUMYA, REMICADE, SIMPONI ARIA, STELARA IV

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the disease-modifying antirheumatic drug (DMARD) products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. For psoriasis, this program applies to all adult members requesting treatment with a targeted product. For all other indications, this program applies to adult members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products	
Preferred	• **Entyvio** (vedolizumab) • **Ilumya** (tildrakizumab-asmn) • **Remicade** (infliximab)	• **Simponi Aria** (golimumab, intravenous) • **Stelara IV** (ustekinumab)*
Targeted	• **Actemra** (tocilizumab) • **Avsola** (infliximab-axxq) • **Cimzia** (certolizumab pegol)	• **Inflectra** (infliximab-dyyb) • **Orencia** (abatacept) • **Renflexis** (infliximab-abda)

*Stelara IV is indicated for a one time induction dose for Crohn's disease and ulcerative colitis.

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II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Avsola, Inflectra and Renflexis, when member meets both of the following:
   1. Member has a documented intolerable adverse event with the preferred product, Remicade, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, and Simponi Aria where the product's indications overlap.

B. For Cimzia, when any of the following criteria are met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs, unless the request is for psoriasis.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Remicade, and Simponi Aria where the product's indications overlap
   3. Member is currently pregnant or breastfeeding

C. For all other targeted products, when any of the following criteria are met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Remicade, and Simponi Aria where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (Appendix)

III. Appendix: Clinical reasons to avoid TNF inhibitors

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- Risk of lymphoma

Section 2: Clinical Criteria

ILUMYA (tildrakizumab-asmn)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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FDA-Approved Indication

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Moderate to severe plaque psoriasis

A. Authorization of 24 months may be granted for members who are 18 years of age or older who have previously received Ilumya, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis.

B. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis for members who are 18 years of age or older when all of the following criteria are met:
   1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. Member meets any of the following criteria:
      i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix).
      iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Ilumya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. OTHER

Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Ilumya or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

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V. APPENDIX

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Cannot be used due to risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

REFERENCES

SECTION 1

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SECTION 2

1. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2018.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009;61:451-485.
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