

## SPECIALTY GUIDELINE MANAGEMENT

### SKYRIZI (risankizumab-rzaa)

#### 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.

##### FDA-Approved Indication

Treatment of moderate-to-severe plaque psoriasis in adults 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 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.
- B. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:
  1. At least 3% 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:
    - a. Member has had an inadequate response to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
    - b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix).
    - c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy (i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected).

##### III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are using Skyrizi for an indication outlined in section II and who achieve or maintain positive clinical response Skyrizi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

##### IV. OTHER

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)\* within 6 months of initiating therapy for persons

who are naïve to biologic DMARDs or targeted synthetic DMARDs (e.g., Xeljanz), and repeated yearly for members with risk factors\*\* for TB that are continuing therapy with biologics.

\* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer risankizumab-rzaa to members with active TB infection. If there is latent disease, TB treatment must be started before initiation risankizumab-rzaa.

\*\* Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Skyrizi concomitantly with any other biologic DMARD or targeted synthetic DMARD.

## V. APPENDIX

### Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine and 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)

## VI. REFERENCES

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; April 2019.
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.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
4. Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet*. 2018;392(10148):650-661.
5. 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;80(4):1029-1072.
6. Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on 21 June 2019 from: <https://www.cdc.gov/tb/topic/basics/risk.htm>.