Effective Date: 2/2020
Reviewed: 11/2019, 8/2020, 12/2020, 5/2021, 5/2022, 8/2022, 8/2023 Scope: Medicaid

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

1. Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis in adults
3. Moderately to severely active Crohn's disease in adults

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

II. CRITERIA FOR INTIAL AND RENEWAL CRITERIA

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

III. DOCUMENTATION

A. Plaque psoriasis
   1. Initial requests:
      a. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
      b. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B. Psoriatic arthritis: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Crohn's disease:

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

IV. CRITERIA FOR INITIAL APPROVAL

For all indications:

- 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 Cosentyx or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.];* AND

A. Moderate to severe plaque psoriasis

Authorization of 6 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. Skyrizi is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
3. Member meets either of the following criteria:
   a. Member has had an inadequate response to at least a 3 month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
   b. Member has had an inadequate response to at least a 3 month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
4. Member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream within the last 12 months Contraindications, adverse effects and/or intolerance must be documented (Note: If the member's BSA is greater than or equal to 20%, they are not required to trial Zoryve before Skyrizi)
5. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses
   a.
6. Skyrizi will not be used concomitantly with any Zoryve (roflumilast) or Vtama (tapinarof) cream or any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis in members who are 18 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
2. Documented moderate to severe active disease and member meets either of the following criteria:

a. If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
b. If member has peripheral arthritis, member has experienced an inadequate response to at least a 3-month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced

3. Member has had an inadequate response, intolerance, or contraindication to at least a 3- month trial of adalimumab at maximum tolerated doses

C. . Moderately to severely active Crohn's disease (CD)

Authorization of 6 months may be granted for treatment of moderate to severe active Crohn's Disease in members who are 18 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in gastroenterology; AND
2. Documented moderate to severe disease: AND
3. Skyrizi will not be used concomitantly with any other biologic DMARD (e.g., adalimumab, infliximab) or targeted synthetic DMARD (e.g., apremilast, tofacitinib).
4. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate) at maximum tolerated doses.
5. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

V. CONTINUATION OF THERAPY

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

C. Moderately to severely active Crohn's disease (CD)

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    i. Abdominal pain or tenderness
    ii. Diarrhea
    iii. Body weight
    iv. Abdominal mass
    v. Hematocrit
    vi. Endoscopic appearance of the mucosa
    vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

VI. OTHER

Crohn's Disease

Induction: 600 mg administered intravenously at Week 0, Week 4, and Week 8.

Maintenance: 360 mg administered subcutaneously at Week 12 and every 8 weeks thereafter

Note: If requesting IV dose, this must be indicated on the request with the following information: A. Where drug will be obtained - through pharmacy benefit (filled at specialty pharmacy) or through medical benefit ('buy and bill') B. Servicing provider name and NPI for Skyrizi administration if requesting through medical benefit

VII. QUANTITY LIMIT

Indication	Dose (subcutaneous)	Quantity Limit
Plaque Psoriasis & Psoriatic Arthritis	150mg at Week 0, Week 4, and every 12 weeks thereafter	150mg (1 box) per 12 weeks, with post-limit for loading dose of 300mg per month
Crohn's disease (maintenance dose)	360mg at week 12, and then every 8 weeks	360mg per 8 weeks or a daily dose of 0.05.

VIII. REFERENCES

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; May 2023.
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.