Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Skyrizi® (risankizumab-rzaa)

Effective: June 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:

SKYRIZI is an interleukin-23 antagonist indicated for the treatment of:

- moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- active psoriatic arthritis in adults
- moderately to severely active Crohn's disease in adults

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Skyrizi (risankizumab-rzaa) when the following criteria is met:

Crohn's Disease

1. The Member has a documented diagnosis of Crohn's disease (CD)

AND

2. The Member is 18 years of age or older

AND

3. Skyrizi is being prescribed by or in consultation with a gastroenterologist

AND

4. Documentation of one (1) of the following (a, b, c, d, or e) criteria is met:
   a. Inadequate response or adverse reaction to at least two (2) of the following:
      i. Corticosteroids
      ii. 5-aminosalycylates
      iii. 6-mercaptopurine, or
      iv. Methotrexate

OR

   b. The Member has contraindications to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate

OR

   c. The Member is at moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease

OR

   d. The Member has had prior treatment with another biologic agent indicated for the requested use

OR

   e. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Plaque Psoriasis

1. The Member has a documented diagnosis of plaque psoriasis

AND

2. The Member is at least 18 years of age or older

AND

3. Skyrizi is being prescribed by or in consultation with a dermatologist

AND

4. Documentation of one (1) of the following criteria is met:
   a. Inadequate response to one of the following topical therapies: a corticosteroid, a vitamin D analog, tazarotene, calcineurin inhibitor, anthralin, or coal tar

OR

   b. Contraindication to all of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, and coal tar

OR

   c. Previous treatment with a biologic agent indicated for the requested use

OR

   d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Psoriatic Arthritis

1. The Member has a documented diagnosis of psoriatic arthritis

AND

2. The Member is at least 18 years of age

AND

3. Skyrizi is being prescribed by or consultation with a rheumatologist or dermatologist

Limitations

- The Plan may authorize coverage of Skyrizi (risankizumab-rzaa) for up to 12 months when coverage criteria are met
- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan
- Skyrizi (risankizumab-rzaa) pens and pre-filled syringes for subcutaneous injection are covered under the Member's Prescription drug Benefit when Skyrizi is being self-administered

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2327	Injection, risankizumab-rzaa, intravenous, 1mg

References:

1. Skyrizi (risankizumab-rzaa) [prescribing information]. North Chicago, IL: AbbVie Inc; January 2022

Approval And Revision History

February 15, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

March 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.