Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: December 12, 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

Autoimmune diseases are conditions in which the body's immune response attacks or otherwise reacts to a normally functioning body part in an adverse manner. Conditions include, but are not limited to, ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis. Various biologic medications classes are Food and Drug Administration approved and recommended by treatment guidelines based on well-established efficacy and safety. Mechanisms of action include, but are not limited to, integrin receptor antagonists, phosphodiesterase 4 inhibitors, tumor necrosis factor inhibitors, interleukin antagonists, janus kinase inhibitors, and tyrosine kinase 2 inhibitors.

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:

Plaque Psoriasis

1. The Member has a diagnosis of moderately to severe plaque psoriasis

AND

2. Skyrizi has been prescribed by or in consultation with a dermatologist

Psoriatic Arthritis

1. The Member has a diagnosis of active psoriatic arthritis (PsA)

AND

2. Skyrizi has been prescribed by or in consultation with a rheumatologist

Crohn's Disease

1. The Member has a diagnosis of moderately to severely active Crohn's disease (CD)

AND

2. Skyrizi has been prescribed by or in consultation with a gastroenterologist

Limitations

- 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 Part D 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. Medicare Benefit Policy Manual. 1st ed.; 2017. Available at: https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed March 6, 2020.
2. Skyrizi® (risankizumab-rzaa). [package insert]. North Chicago, IL; Abbvie, Inc.; December 2022.
3. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 July;73(7):924-39.
4. Feuerstein JD, et al. American Gastroenterological Association (AGA) Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;18:1450-61.
5. Lichtenstein GR, et al. ACG Clinical Guideline: Management of Crohn's Disease and Adults. American Journal of Gastroenterology. 2018 April;113(4):481-517
6. Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Care & Research. 2021 August;73(8):1071-87
7. Menter A, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. 2019 April;80(4):1029-72.
8. Onel KB, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis & Rheumatology. 2022 April;74(4):553-69.
9. Singh JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019 January;71(1):5-32.
10. Ward MM, et al. 2019 Update of the American College of Rheumatology/ Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019 October;71(10):1599-1613.

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).

Subsequent endorsement date(s) and changes made:

- December 12, 2023: No changes. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP

Final Rule. Retire Medical Necessity Guideline effective 2/29/24. Refer to Targeted Immunomodulators – Skilled Administration Medical Necessity Guideline effective 3/1/24.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.