

POLICIES AND PROCEDURE MANUAL

Policy: MBP 267.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Skyrizi IV (risankizumab intravenous)

I. Policy:

Skyrizi IV (risankizumab intravenous)

II. Purpose/Objective:

To provide a policy of coverage regarding Skyrizi IV (risankizumab intravenous).

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

- Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than
- 3. the department requiring/authoring the policy.
- 4. Devised the date the policy was implemented.
- 5. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 6. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

<u>Medically Necessary</u> — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION: Risankizumab is a human IgG1 monoclonal antibody which selectively binds to the p19 subunit of interleukin (IL)-23, thereby inhibiting its interaction with the IL-23 receptor, resulting in inhibition of the release of proinflammatory cytokines and chemokines.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Skyrizi IV (risankizumab intravenous) will be considered medically necessary for commercial, exchange, CHIP, and Medicare lines of business when all of the following criteria are met:

- Prescription must be written by a gastroenterologist AND
- Member must be at least 18 years of age AND
- Medical record documentation of moderately to severely active Crohn's disease AND
- Medical record documentation that Skyrizi is not being used concurrently with a TNF blocker or other biologic agent AND
- Medical record documentation of Skyrizi 600 mg/ 10 mL vials for IV infusion is being prescribed for induction therapy at weeks 0, 4 and 8.

AUTHORIZATION DURATION: One-time 3-month authorization (maximum of 3 visits for loading dose administration)

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 10/25/22

Revised: 10/16/23 (Medicaid business segment)

Reviewed: