Risankizumab

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-21	**Version Control:** Version No. V1.0	**Effective Date:** 01st April 2023	**Last Update:** 05/06/23
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** NA		

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1. Abstract

1.1 For Members

Risankizumab can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating plaque psoriasis, psoriatic arthritis or Crohn's disease.

1.2 For Medical Professionals

Risankizumab is a humanised immunoglobulin G1 (IgG1) monoclonal antibody selective to the interleukin (IL)-23 protein produced in Chinese Hamster Ovary cells using recombinant DNA technology.

2. Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details for Risankizumab as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

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

1. **Plaque psoriasis** [1,2]: is indicated to treat adults with moderate to severe plaque psoriasis. It reduces inflammation and can therefore help reduce symptoms of plaque psoriasis such as burning, itching, pain, redness, and scaling.

2. **Psoriatic arthritis (PsA)** [1,2]: is indicated to treat adults with psoriatic arthritis.

3. **Moderate-to-severe Crohn's disease** [3]**:** IS indicated in adults when conventional or biological treatments do not work well enough or cause unacceptable side effects.

Pre-treatment Evaluation [1]**:**
- Evaluate patients for tuberculosis (TB) infection prior to initiating treatment.
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines.

Dosage and Administration [1,2]:
The recommended dosage is 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter, (either as two 75 mg pre-filled syringe injections or one 150 mg pre-filled pen or pre-filled syringe injection).

Two formulations are used for Crohn's disease. The first, a concentrate, is used to make a solution which is given at the start of treatment as an infusion (drip into a vein) three times over eight weeks. The second formulation, a solution for injection in a cartridge, is for long-term maintenance treatment and is given as an injection under the skin 4 weeks after the last infusion and then every 8 weeks thereafter [3].

Missed dose [2]**:**
If a dose is missed, the dose should be administered as soon as possible. Thereafter, dosing should be resumed at the regular scheduled time

Dosage forms and strengths available [1]**:**

1. **Risankizumab Pen Injection**: 150 mg/mL as a colourless to yellow and clear to slightly opalescent solution in each single-dose prefilled pen.
2. **Risankizumab Prefilled Syringe Injection**: 150 mg/mL as a colourless to yellow and clear to slightly opalescent solution in each single-dose prefilled syringe.
3. **Risankizumab Injection**: 75 mg/0.83 mL as a colourless to slightly yellow and clear to slightly opalescent solution in each single-dose prefilled syringe.

WARNINGS AND PRECAUTIONS [1]**:**

- Avoid use of live vaccines in patients treated with Risankizumab
- In patients with a chronic infection, a history of recurrent infection, or known risk factors for infection, Risankizumab should be used with caution. Treatment with Risankizumab should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Pediatric Use [1]**:**

The safety and efficacy of RISANKIZUMAB in pediatric patients younger than 18 years of age have not yet been established.

Discontinuing treatment [2]**:**

Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Some plaque psoriasis patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible clinician specialities

Eligible clinician speciality
Dermatologist
Rheumatologist
Gastroenterologist

3.3 Non-Coverage

- Not covered for visitor plan
- Age less than 6 years

3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC 004	Service is not clinically indicated based on good clinical practice
MNEC 003	Diagnoses are not covered
AUTH-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

1. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761105s014lbl.pdf*
2. *https://www.medicines.org.uk/emc/product/12625/pil#gref*
3. *https://www.ema.europa.eu/en/documents/overview/risankizumab-epar-medicine-overview_en.pd*

5.2 Revision History

Date	Change(s)
31/03/2023	Release of V1.0
05/06/2023	Updated: added Gastroenterologist