Risankizumab

Adjudication Guideline

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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, Crohn's disease and Ulcerative colitis.

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

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

1. **Plaque psoriasis**: moderate-to-severe plaque psoriasis in adults and pediatric patients 6 years of age and older who are candidates for systemic therapy or phototherapy.
2. **Psoriatic arthritis (PsA):** active psoriatic arthritis in adults and pediatric patients 6 years of age and older.
3. **Moderate-to-severe Crohn's disease:** Is indicated in adults when conventional or biological treatments do not work well enough or cause unacceptable side effects.
4. **Moderate-to-severe Ulcerative Colitis:** Is indicated in adults when conventional or biological treatments do not work well enough or cause unacceptable side effects.

Pre-treatment Evaluation:

- Evaluate patients for tuberculosis (TB) infection prior to initiating treatment.
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines.

Dosage and Administration:

Moderate-to-Severe Plaque Psoriasis:

• Adults: o 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

• Pediatric Patients 6 Years of Age and Older: o Patients weighing less than 40 kg: 55 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter. o Patients weighing 40 kg or greater: 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

Active Psoriatic Arthritis:

• Adults: o 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

• Pediatric Patients 6 Years of Age and Older: o Patients weighing less than 40 kg: 55 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter. o Patients weighing 40 kg or greater: 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks

Crohn's Disease:

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 "600 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8".

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 "recommended maintenance dosage is 180 mg or 360 mg".

Ulcerative Colitis:

Two formulations are used for Ulcerative Colitis. 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 "1200 mg administered by intravenous infusion over at least 2 hours at Week 0, Week 4, and Week 8". 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 "recommended maintenance dosage is 180 mg or 360 mg".

It is recommended to use the lowest effective dosage to maintain the therapeutic response.

Missed dose:

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:

Generic	Dose strength	Dosage Form
Risankizumab	60 mg	Solution for Intravenous infusion/ Subcutaneous Injection
	75 mg	Subcutaneous Injection
	150 mg	Subcutaneous Injection
	360 mg	Subcutaneous Injection
	600 mg	Solution for Intravenous infusion

WARNINGS AND PRECAUTIONS:

- 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.

Discontinuing treatment:

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 specialties.

Eligible Clinician Specialties	
Plaque psoriasis	Dermatologist, Pediatric Dermatologist
Psoriatic arthritis	Rheumatologist, dermatologist, Pediatric Rheumatologist, Pediatric Dermatologist
Crohn's disease	Gastroenterologist
Ulcerative colitis	Gastroenterologist

3.3 Non-Coverage

- Not covered for visitor plan
- Age less than 18 years Crohn's disease and Ulcerative Colitis
- Age less than 6 years for moderate to severe Plaque Psoriasis and Psoriatic Arthritis.

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

CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761105s029,761262s007lbl.pdf
https://www.medicines.org.uk/emc/product/12625/smpc#about-medicine
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761105s014lbl.pdf
https://www.medicines.org.uk/emc/product/12625/pil#gref
https://www.ema.europa.eu/en/documents/overview/risankizumab-epar-medicine-overview_en.pd
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5.2 Revision History

Date	Version No.	Change(s)
31/03/2023	V1.0	Release of V1.0
05/06/2023	V2.0	Updated: added Gastroenterologist
30/10/2024	V3.0	Content Update (added Ulcerative Colitis)
30/10/2025	V4.0	Guideline review/ No changes
9/10/026	V4.0	Add pediatric indication Update pediatric dosing Update clinician list

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