Guselkumab

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines: NA
Daman	Pharmaceutical Standards & Governance	

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1. Abstract

1.1 For Members

Guselkumab is an Interleukin inhibitor (IL-23) blocker that is indicated for the treatment of Plaque Psoriasis, Psoriatic Arthritis, Ulcerative Colitis and Crohn's disease in adult patients.

1.2 For Medical Professionals

Guselkumab is an interleukin-23 (IL-23) inhibitor indicated for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severely active ulcerative colitis and moderate to severely active Crohn's disease in adult patients

2. Scope

This adjudication rule aims to highlight the medical necessity and coverage details of Guselkumab for all health insurance plans administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Guselkumab is an interluken-23(IL-23) blocker that is indicated for adults with the following conditions:

1. **Plaque Psoriasis (Psoriasis Vulgaris):** Guselkumab is indicated for cases of moderate to severe Plaque Psoriasis if a patient (above the age of 18) meets one of the following criteria when prescribed by an eligible clinician:
    a) Moderate to severe Plaque Psoriasis
    b) Inadequate response to topical treatment
    c) Inadequate response to systemic treatment
    d) Contraindications to topical treatment, systemic treatment and phototherapy

2. **Psoriatic Arthritis Psoriatic arthritis:** Guselkumab is indicated for cases of Active Psoriatic Arthritis if a patient (above the age of 18) meets one of the following criteria when prescribed by an eligible clinician:
    a) Inadequate response to systemic therapy
    b) Contraindication to topical therapy, systemic therapy and Phototherapy

3. Inflammatory bowel disease (IBD)

Eligibility Criteria for Treatment of Moderate-to-Severe Ulcerative Colitis (UC) and Crohn's Disease (CD):

The patient is eligible for treatment if they meet **two** scenarios :

First scenario : meet **ALL** of the following criteria (**1,2,3**) :

1. Age Requirement:
    a. Patient is ≥ 18 years of age.

2. Diagnosis Confirmation:
    a. The patient has a confirmed diagnosis of Moderate-to-Severe UC or Moderate-to-Severe CD, as verified through clinical, endoscopic, histologic, or imaging findings.

    Disease Activity Assessment:

    b. Moderate-to-severe disease activity is defined as:

        - UC: Partial Mayo score ≥5
        - CD: CDAI score ≥220

    c. Endoscopic Confirmation of inflammation is required.

3. Prior Treatment History:

    a. The patient must have inadequate response, loss of response, or intolerance to any of the following:

        - Anti-TNF (e.g., infliximab, adalimumab)
        - Anti-integrin (e.g., vedolizumab)
        - Anti-IL12/23 (e.g., ustekinumab)
        - JAK inhibitors (e.g., tofacitinib)
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    b. Alternatively, patients with high-risk disease may be eligible, with documented evidence of any of the following:

        - Extensive colonic involvement, pancolitis, or perianal disease
        - Deep ulcerations on endoscopy
        - History of early relapses or refractory disease

    c. Confirmation through clinical scores, endoscopic findings, or biomarker assessment (e.g., fecal calprotectin, CRP) is required.

OR

Second scenario :

Biologic-Naïve Patients:

Guselkumab may be considered for biologic-naïve patients who meet the following:

- Criteria 1, 2, and 3-b.

Treatment for IBD must be prescribed by a gastroenterologist consultant.

Criteria for Re-assessment of UC and CD:

- Continued Diagnosis Confirmation: Ongoing confirmation of the diagnosis.
- Monitoring Disease Activity and Response to Therapy: Continuous assessment of treatment efficacy.

- Assessment Methods:
  - Clinical scores
  - Endoscopic findings
  - Biomarker assessment (e.g., fecal calprotectin, CRP)

Dosage and Administration:

Indication	Induction dose	Maintenance dose	Dose Optimizing
Plaque Psoriasis	100 mg SC at week 0 and 4	100 mg every 8 weeks	NA
Psoriatic Arthritis	100 mg SC at week 0 and week 4	100 mg every 8 weeks	100 mg every 4 weeks*
Ulcerative Colitis & Crohn's disease	200 mg IV at week 0 and week 4 and week 8	100 mg SC every 8 weeks starting from week 16 **OR** 200 mg SC at Week 12, and every 4 weeks thereafter	NA

* For patients with high risk of joint damage according to clinical judgment.

3.2 Requirements for Coverage

1. Failure to submit, upon request or when requesting a clinical history, an indication and the need for testing will result in the rejection of the claim.
2. The Questionnaire or medical report must be submitted with the required documents for preauthorization request.
3. Eligible Clinician Specialty:

Eligible Clinician Specialty
Dermatology
Rheumatology
Internal Medicine
Gastroenterology

Treatment for IBD must be prescribed by a gastroenterologist consultant

3.3 Non-Coverage

- Guselkumab is not covered when the above criteria (Coverage and Billing and CLN) are not met.
- Age less than 18
- Visitor plan

3.4 Payment and Coding Rules

Please apply DOH payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

4. Denial Codes

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

Code	Code Description
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
MNEC-005	Service/supply may be appropriate, but too frequent
MNEC-006	Alternative treatment should be used prior
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender
AUTH-001	Prior approval is required and was not obtained
CODE-010	Activity/diagnosis inconsistent with clinician specialty

Questionnaire:
https://www.damanhealth.ae/main/pdf/support/coverage-medical/Questionnaire/GuselkumabPre authform.pdf

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761061s027lbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761061s021lbl.pdf
Tremfya 100 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc)

5.2 Revision History

Date	Version No.	Change(s)
27.12.2022	V1.0	Creation of Adjudication Guideline-External Instruction Template.
04.11.2024	V2.0	Content Update – (Ulcerative Colitis indication, Dose optimising is PsA)
15.05.2025	V3.0	Content update with new references added, inclusion of Crohn's disease indications, and updated criteria

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