Mepolizumab

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines: NA
Daman	Medical Standards & Research	

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1. Abstract

1.1 For Members

Mepolizumab is a humanised monoclonal antibody, it is indicated as an add-on treatment for several severe inflammatory conditions, including eosinophilic asthma, chronic rhinosinusitis with nasal polyps and inadequately controlled chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype.

Mepolizumab is also indicated as a prescription medicine for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) and hypereosinophilic syndrome (HES).

1.2 For Medical Professionals

Mepolizumab is indicated for the following indications:

- Add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older.
- Add-on maintenance treatment of adult patients aged 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- Add-on maintenance treatment of adult patients aged 18 years and older with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- Treatment of adult patients aged 18 years and older with eosinophilic granulomatosis with polyangiitis (EGPA also referred to as Churg-Strauss Syndrome).
- The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.

2. Scope

This adjudication rule highlights the coverage criteria for medically necessary indications of Mepolizumab injection for health insurance plans administered by Daman as per the policy terms and conditions.

3. Adjudication Policy

3.1 Eligibility

Mepolizumab is a speciality drug, which can be prescribed by a relevant speciality physician for the below indications as per policy term and conditions:

- **Add-on** maintenance treatment of patients with **severe asthma** aged 6 years and older, and with an **eosinophilic** phenotype.
  Add-on maintenance treatment of adult patients aged 18 years and older with **chronic rhinosinusitis with nasal polyps** (CRSwNP).
- **Add-on** maintenance treatment of adult patients aged 18 years and older with inadequately controlled **chronic obstructive pulmonary disease (COPD)** and an eosinophilic phenotype.
- The treatment of adult patients aged 18 years and older with **eosinophilic granulomatosis** with **polyangiitis** (**EGPA**).
- The treatment of adult and pediatric patients aged 12 years and older with **hypereosinophilic syndrome (HES)** for ≥6 months without an identifiable non-hematologic secondary cause

3.2 Dosage and Administration:

Population	Indication	Dose	Frequency & Administration
Adults	Severe eosinophilic asthma	100 mg SC	Once every 4 weeks
	Inadequately controlled COPD (eosinophilic phenotype)	100 mg SC	Once every 4 weeks
	Chronic rhinosinusitis with nasal polyps (CRSwNP)	100 mg SC	Once every 4 weeks
	Eosinophilic Granulomatosis with Polyangiitis (EGPA)	300 mg SC (as three 100 mg injections)	Once every 4 weeks
	Hypereosinophilic syndrome (HES)	300 mg SC (as three 100 mg injections)	Once every 4 weeks
Pediatric (6–11 years)	Severe eosinophilic asthma	40 mg SC	Once every 4 weeks
Pediatric (≥12 years)	Severe eosinophilic asthma	100 mg SC	Once every 4 weeks
	Hypereosinophilic syndrome (HES)	300 mg SC (as three 100 mg injections)	Once every 4 weeks

3.3 Coverage criteria

Indication	Initiation Criteria	Continuation Criteria
Severe Eosinophilic Asthma	1. Age ≥6 years 2. Prescriber consultation (allergist/immunologist or pulmonologist) 3. Used as add-on for severe uncontrolled eosinophilic asthma 4. To prevent/manage uncontrolled asthma despite: - High-dose inhaled corticosteroids + LABA - Leukotriene modifier/theophylline - Systemic corticosteroids (≥50% of previous year) 5. Eosinophil levels: - ≥150 cells/µL (within 6 months) - OR ≥300 cells/µL (within 12 months) 6. Clinical features: - Repeated hospital/ER visits - Regular use of oral/high-dose inhaled corticosteroids 7. Current non-smoker 8. Not used with other IL-5 inhibitors 9. 12-month review: discontinue if no response; continue if response	1. Currently on medication or previously met initial criteria 2. Demonstrated adherence to therapy 3. Responding positively (reduction in exacerbations, corticosteroid use, improved lung function) 4. Dose increase not exceeding 100 mg every 4 weeks
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	1. Adults ≥18 years 2. Post-FESS or not candidate for FESS 3. Meets at least 3 of the 5 criteria: - Evidence of type 2 inflammation - ≥2 courses/year or ≥3 months low-dose steroids - QoL score ≥40 - Significant loss of smell - Comorbid asthma requiring inhaled steroids	1. Currently on medication or previously met initial criteria 2. Responding positively (improvement in nasal congestion, QoL, NPS)

Indication	Initiation Criteria	Continuation Criteria
Chronic Obstructive Pulmonary Disease (COPD)	1. Adults ≥18 years 2. Inadequately controlled COPD with eosinophilic phenotype 3. Mepolizumab as add-on therapy 4. Blood eos ≥150 cells/µL 5. Refractory to standard therapies (LAMA, LABA, ICS)	1. Currently on medication or previously met initial criteria 2. Responding positively (fewer exacerbations, symptom control, lung function)
Eosinophilic Granulomatosis with Polyangiitis (EGPA)	1. Medical history or presence of asthma 2. Blood eos ≥10% or eos ≥1,000 cells/µL at diagnosis 3. At least 2 of the following: - Eosinophilic vasculitis/granulomatous inflammation - Neuropathy - Pulmonary infiltrates - Sinonasal abnormality - Cardiomyopathy - Glomerulonephritis - Alveolar hemorrhage - Palpable purpura - ANCA positive 4. Age ≥18 5. Failure of 3-month glucocorticoid trial or contraindications	1. Currently on medication or previously met initial criteria 2. Responding positively 3. Dose increase not exceeding 300 mg every 4 weeks
Hypereosinophilic Syndrome (HES)	1. Age ≥12 years 2. Confirmed diagnosis: - AEC ≥1500 eos/µL on ≥2 occasions, ≥2 weeks apart 3. Evidence of organ involvement/dysfunction -No secondary cause	1. Currently on medication or previously met initial criteria 2. Responding positively (reduction in eos, symptom improvement, disease progression prevention)

***N. B:** *Daman may request the patient's data/ questioners from the providers prior to any approval and for audit purposes.*

Eligible clinician specialty:

Eligible clinician specialty
Allergy and Immunology
Clinical Immunology & Allergy
Paediatrics/ Allergy
Rheumatology/Immunology and Allergy
Allergy
Internal Medicine
Nephrology
Paediatric
Immunology
Pulmonary Disease/ Critical Care Medicine
Paediatric Pulmonology
Rheumatology
Paediatric Rheumatology

3.4 Requirements for Coverage

- ICD and Drug codes must be coded to the highest level of specificity.
- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.

3.5 Non-Coverage

- All other uses of mepolizumab that are not an FDA approved indication will be considered experimental/investigational.
- Not covered as per policy terms and conditions.
- Not covered for Basic and visitor plans.
- This drug will not be covered for age groups not recommended by FDA.
- Non-FDA approved dosing regimen(s).
- Individuals who have had previous anaphylactic reaction to mepolizumab
- Concurrent use with other IL-5 inhibitors [Reslizumab, Benralizumab].

3.6 Payment and Coding Rules

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

4. Denial Codes

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 clinician practise, without additional supporting diagnosis /activities.
MNEC-005	Service / supply may be appropriate, but too frequent
CLN-001	Activity/diagnosis inconsistent with clinician speciality
AUTH-001	Prior approval is required and was not obtained
CODE-014	Activity/diagnosis is inconsistent with patient's age/gender
NCOV-003	Services is (are) not covered

5. Appendices

5.1 References

- https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761122Orig1s000MultidisciplineR.pdf
- https://careweb.careguidelines.com/ed22/index.html
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761122s000lbl.pdf
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125526Orig1s000Lbl.pdf
- https://www.ncbi.nlm.nih.gov/pubmed/27856823
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- https://www.nice.org.uk/guidance/ta431/chapter/1-Recommendations
- https://ca.gsk.com/media/1209435/nucala.pdf
- https://www.ema.europa.eu/en/documents/assessment-report/nucala-epar-public-assessmentreport_en.pdf - https://reference.medscape.com/drug/nucala-mepolizumab-1000034
- https://www.cambridgeshireandpeterboroughccg.nhs.uk/easysiteweb/getresource.axd?assetid=3413&t ype=0&servicetype=1
- http://www.annenberg.net/medEd/56620/downloads/CHEST-CME_Transcript.pdf
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125526Orig1s021,761122Orig1s011Corrected_lbl.pdf

- https://www.medicines.org.uk/emc/product/10563/smpc#gref
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125526s007lbl.pdf

5.2 Revision History

Date	Change(s)
28.11.2019	Creation of Adjudication Guideline-External Instruction Template.
09/08/2024	Update: Indications, Dosage and Administration
30/09/2025	Update: Indications Update
	Initiation and continuation criteria update

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