

# Mepolizumab Indication

## Adjudication Guideline

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Pharmaceutical

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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 severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older.

### 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 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- Treatment of adult patients 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  $\geq 6$  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 / Coverage Criteria

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.
- The treatment of adult patients with **eosinophilic granulomatosis with polyangiitis (EGPA)**, age 18 years and older.
- **Add-on** maintenance treatment of adult patients 18 years and older with **chronic rhinosinusitis with nasal polyps (CRSwNP)**.
- The treatment of adult and pediatric patients aged 12 years and older with **hypereosinophilic syndrome (HES)** for  $\geq 6$  months without an identifiable non-hematologic secondary cause.

#### Dosage and Administration:

- **Severe Eosinophilic Asthma:**  
100mg subcutaneous injection once every 4 weeks into upper-arm, thigh, or abdomen.
- **Eosinophilic Granulomatosis with Polyangiitis (EGPA):**  
300mg administered once every 4 weeks by subcutaneous injection as three separate 100-mg injections into the upper arm, thigh, or abdomen. It is recommended that the individual 100-mg injections be administered at least 5 cm (approximately 2 inches) apart if more than 1 injection is administered at the same site.

- **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):**  
100 mg administered subcutaneously once every 4 weeks.
- **Hypereosinophilic Syndrome (HES):**  
300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks.

**\*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

### 3.2 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.

### 3.3 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].

### 3.4 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://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/2019/761122s000lbl.pdf)
- [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125526Orig1s000Lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125526Orig1s000Lbl.pdf)
- <https://www.ncbi.nlm.nih.gov/pubmed/27856823>
- <https://www.ncbi.nlm.nih.gov/pubmed/24337046>
- <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://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](https://www.cambridgeshireandpeterboroughccg.nhs.uk/easysiteweb/getresource.axd?assetid=3413&t_ype=0&servicetype=1)
- [http://www.annenbergenet.com/medEd/56620/downloads/CHEST-CME\\_Transcript.pdf](http://www.annenbergenet.com/medEd/56620/downloads/CHEST-CME_Transcript.pdf)
- [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/125526Orig1s021,761122Orig1s011C\\_orrected\\_lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125526Orig1s021,761122Orig1s011C_orrected_lbl.pdf)

Questionnaire:

<https://www.damanhealth.ae/Website/misc/Prerequisite%20Form%20for%20Biologic%20Therapy.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

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