Mepolizumab Indication

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2019-PH-01	**Version Control:** Version No. V3.0	**Effective Date:** 08/01/2020	**Revision Date:** 09/08/24
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines: NA**		

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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 ≥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 ≥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://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
- 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://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

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