At-home administration

Getting patients started

Nucala (mepolizumab) Injection 100 mg/mL

GSK is committed to supporting the continued care of patients. If you decide at-home administration with the **NUCALA Autoinjector** is right for your patient, Gateway to NUCALA is one of many resources to help get your patient started.

NUCALA Autoinjector

The NUCALA Autoinjector is only for use in patients aged ≥ 12 years.

Initiate a benefits investigation and submit a new prescription for NUCALA Autoinjector

Verify benefits by working with Gateway to NUCALA or by contacting the payer directly.

If your patient is enrolled in Gateway to NUCALA, call to request a new benefits investigation for the Autoinjector at **844-4-NUCALA** (844-468-2252).

If your patient is NOT enrolled in Gateway to NUCALA, please complete the enrollment form linked here, which is also available on the Access and Reimbursement page at NucalaHCP.com.

- Gateway to NUCALA cannot provide program services without a completed and signed enrollment form. To avoid delays in receiving Gateway program offerings, please ensure both provider and patient signatures are on the Enrollment Form
- Patients can sign the form in-office or electronically. If electronic signature is preferred, please include a valid patient email address and alert the patient that two emails from "DocuSign" will be coming

Submit a Prior Authorization to the patient's insurance, as required

Gateway to NUCALA will check the payer's prior authorization requirements and obtain plan-specific forms as needed and if available.

The specialty pharmacy will contact the patient to complete the process

- Upon receiving insurance approval and a new prescription, the designated specialty pharmacy will contact the patient directly to confirm, collect the co-pay, and ship NUCALA Autoinjector directly to the patient's home.
- **Instruct the patient to accept and return calls to prevent delays in starting treatment.** Specialty pharmacies may not mention NUCALA in messages, as brand names are omitted to protect privacy. Even if the patient is not sure the call is about NUCALA, encourage them to call the specialty pharmacy back.

INDICATIONS

NUCALA is indicated for the:

- add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.
- add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to mepolizumab or excipients.

Please see additional Important Safety Information on next page. Please see accompanying full Prescribing Information, including Patient Information, for NUCALA or visit NucalaHCP.com.

Questions on submitting a new NUCALA prescription?

Call **844-4-NUCALA** (844-468-2252) Monday – Friday 8am to 8pm ET or visit **GatewaytoNUCALA.com**.

Gateway to NUCALA services*

- Conduct benefits verification*; provide prior authorization research and appeals support
- Assess Patient Assistance Program (PAP) support for eligible uninsured and eligible Medicare patients
- Provide claims and billing support
- Assess Co-pay Program eligibility for commercially insured patients†
- Specialty pharmacy triage to patients' appropriate in-network pharmacy

*Gateway to NUCALA does not guarantee coverage or payer reimbursement for product treatment or administration. Specific eligibility requirements are determined by the payer.
†The NUCALA Co-pay Program helps eligible commercially insured patients with their out-of-pocket costs for NUCALA up to [$15,000] for 12 months. Eligibility for the NUCALA Co-Pay Program must be determined by the GSK Co-Pay Program.
Eligibility restrictions and program maximums apply visit www.GSKCopayPrograms.com for complete Program Terms and Conditions.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred with NUCALA. These reactions generally occur within hours of administration but can have a delayed onset (ie, days). Discontinue if a hypersensitivity reaction occurs.

Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster

Herpes zoster infections have occurred in patients receiving NUCALA. Consider vaccination if medically appropriate.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with NUCALA. Decreases in corticosteroid doses, if appropriate, should be gradual and under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving NUCALA and do not respond to anti-helminth treatment, discontinue NUCALA until infection resolves.

ADVERSE REACTIONS

Most common adverse reactions (≥5%) in patients receiving NUCALA:

- Severe asthma trials: headache, injection site reaction, back pain, fatigue
- CRSwNP trial: oropharyngeal pain, arthralgia
- EGPA and HES trials (300 mg of NUCALA): no additional adverse reactions were identified to those reported in severe asthma clinical trials

Systemic reactions, including hypersensitivity, occurred in clinical trials in patients receiving NUCALA. Manifestations included rash, pruritus, headache, myalgia, flushing, urticaria, erythema, fatigue, hypertension, warm sensation in trunk and neck, cold extremities, dyspnea, stridor, angioedema, and multifocal skin reaction. A majority of systemic reactions were experienced the day of dosing.

USE IN SPECIFIC POPULATIONS

The data on pregnancy exposures are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as the pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimesters.

Please see additional Important Safety Information on the previous page. Please see accompanying full Prescribing Information, including Patient Information, for NUCALA or visit NucalaHCP.com.

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Nucala (mepolizumab)