At-home administration

Getting patients started

Nucala (mepolizumab) Injection 100 mg/mL

GSK is committed to supporting the continued care of patients during these challenging times. 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 benefit 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 benefit investigation for the Autoinjector at **844-4-NUCALA** (844-468-2252).

If your patient is NOT enrolled in Gateway to NUCALA, please complete the relevant enrollment form (**EGPA** or **Severe Eosinophilic Asthma**) linked here and 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 "GSK Sign" 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.

Overall response times with payers and specialty pharmacies may be longer due to the ongoing impact of COVID-19.Please check with them for updates.

INDICATIONS

NUCALA is indicated for the add-on maintenance treatment of patients 6 years and older with severe asthma with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

NUCALA is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

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*

- Patient-specific benefits investigations
- Re-verification of benefits for annual health plan changes
- Coding and billing details
- Prescription referral triage to an in-network specialty pharmacy
- Prior authorization research tracking assistance
- Claims appeals tracking assistance
- Estimate of insurance coverage and cost-share information
- Eligibility determinations for the NUCALA Co-pay Program and the Patient Assistance Program for Uninsured Patients
- Alternative coverage research

*Gateway services are not a guarantee of coverage or reimbursement. The payer will make individual coverage determinations based upon the specific circumstances of the patient. Providers should contact third-party payers for specific information on coding, coverage, or reimbursement.

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). If a hypersensitivity reaction occurs, discontinue NUCALA.

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: SEVERE ASTHMA

The most common adverse reactions (≥3% and more common than placebo) reported in the first 24 weeks of 2 clinical trials with 100 mg of NUCALA were: headache, injection site reaction, back pain, fatigue, influenza, urinary tract infection, abdominal pain upper, pruritus, eczema, and muscle spasms.

Systemic Reactions, including Hypersensitivity Reactions: In 3 clinical trials, the percentages of subjects who experienced systemic (allergic and nonallergic) reactions were 3% for 100 mg of NUCALA and 5% for placebo. Manifestations included rash, flushing, pruritus, headache, and myalgia. A majority of the systemic reactions were experienced on the day of dosing.

Injection site reactions (eg, pain, erythema, swelling, itching, burning sensation) occurred in 8% of subjects treated with 100 mg of NUCALA versus 3% treated with placebo.

ADVERSE REACTIONS: EGPA

In a 52-week clinical trial in patients with EGPA receiving 300 mg of NUCALA, no additional adverse reactions were identified to those reported in severe asthma clinical trials.

Systemic Reactions, including Hypersensitivity Reactions: Percentages of subjects who experienced systemic (allergic and nonallergic) reactions were 6% for subjects receiving 300 mg of NUCALA and 1% for placebo. Manifestations of systemic allergic reactions included rash, pruritus, flushing, fatigue, hypertension, warm sensation in trunk and neck, cold extremities, dyspnea, and stridor. The reported manifestation of systemic nonallergic reactions was angioedema. Two of the four (50%) systemic reactions in subjects receiving 300 mg of NUCALA were experienced on the day of dosing.

Injection site reactions (eg, pain, erythema, swelling) occurred in 15% of subjects treated with 300 mg of NUCALA versus 13% treated with placebo.

USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy. To enroll call 1-877-311-8972 or visit **www.mothertobaby.org/asthma**.

The data on pregnancy exposures from the clinical trials 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)