nemluvio™
(nemolizumab-ilto) for injection
30 mg

Electronic Health Record (EHR)

Instructions to Create a PowerPlan for Atopic Dermatitis (AD) With NEMLUVIO® in the Oracle Cerner® EHR System

IMPORTANT SAFETY INFORMATION

INDICATION: NEMLUVIO® (nemolizumab-ilto) is an interleukin-31 receptor alpha antagonist indicated for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

CONTRAINDICATION: NEMLUVIO is contraindicated in patients with known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO.

Please see Important Safety Information on page 8 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Background, Instructions, and Limitations

Indication

NEMLUVIO is indicated for the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.[1]

Limitations of Use

These instructions were created specifically to update a PowerPlan in the Oracle Cerner EHR system and will not work in other EHR systems. These instructions are designed to be used for NEMLUVIO for the treatment of AD and should not be used for other conditions, treatments, or therapeutic areas.

The processes outlined in this piece are variable and not all steps will apply to every health system. Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

A health system may choose to optimize existing EHR order sets or to create a new order set for NEMLUVIO. Order sets consolidate notes, referrals, imaging studies, lab orders and bundles, medications, patient education, coding and billing information, and other orderable items used to manage a condition or problem. Order sets can improve the user experience and help reduce practice variation. These instructions detail specifically how to add the initiation and maintenance dosing of NEMLUVIO to an order set.

AD, atopic dermatitis; EHR, electronic health record.

Please see Important Safety Information on page 8 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Recommended Dosage of NEMLUVIO for AD[1]:

- Concomitant topical therapies:
  - Use NEMLUVIO with topical corticosteroids and/or topical calcineurin inhibitors. When the disease has sufficiently improved, discontinue use of topical therapies[1]

Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with NEMLUVIO [*see Warnings and Precautions (5.2)*].[1]

Review the NEMLUVIO Prescribing Information for additional information, including important administration instructions, preparation for use of NEMLUVIO, missed dose information, and additional information.

Mechanism of Action

- NEMLUVIO is a humanized monoclonal antibody of the IgG2 subclass that inhibits IL-31 signaling by binding selectively to IL-31RA[1]
- IL-31 is a naturally occurring cytokine that is involved in pruritis, inflammation, epidermal dysregulation, and fibrosis[1]
- NEMLUVIO inhibited IL-31-induced responses including the release of proinflammatory cytokines and chemokines[1]

AD, atopic dermatitis; IgG, immunoglobulin G; IL-31RA, interleukin-31 receptor alpha; Q8W, every 8 weeks.

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Oracle Cerner Instructions

Updating PowerPlans requires minimal time but must be implemented at the system level. Check for existing PowerPlans before creating new PowerPlans to avoid duplication.

1. Select ***DCP*** tools from the list of available Millennium applications
2. Click the ***+ (plus) sign*** next to Order Management to expand the available options
3. Click the ***PowerPlan*** tool to open the ***DB PowerPlan*** tool
4. Check to see if an existing PowerPlan may be modified. Click ***Task > Open Plan*** and use the search query in the ***Start Search at: field***. Consider using search terms such as "moderate-to-severe atopic dermatitis" or "atopic dermatitis" to narrow the query to find appropriate PowerPlans (this may vary based on the naming conventions of the organization)
5. Once the PowerPlan(s) has/have been found, double-click the PowerPlan to display its contents. If no existing plans are available, click ***Task > New Plan*** to create a new plan
6. Update the ***Plan Name***, ***Phase***, ***Type***, and ***Display Method*** if needed. Set the status to ***Testing***
7. In the ***Reference*** section, enter:
"NEMLUVIO is indicated for the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors, whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable"[1]
8. Select the ***Medications*** section of the PowerPlan

Instructions continued on the next page.

DB, database; DCP, dynamic care planning.

Oracle Cerner Instructions (cont'd)

9 In the lower right panel, ***enter*** "NEMLUVIO" using the search functionality. ***Select and add*** the NEMLUVIO initiation and maintenance dosing formulations:

For the NEMLUVIO initiation dosing, complete the medication details below[1]:

Consider adjusting the Order Composer as per the health system's governing SmartGroup conventions

- The recommended initiation dosage of NEMLUVIO in patients aged 12 years and older is
  - An initial dose of 60 mg (two 30 mg injections)
- **Concomitant topical therapies:**
  - Use NEMLUVIO with topical corticosteroids and/or topical calcineurin inhibitors. When the disease has sufficiently improved, discontinue use of topical therapies. *Click the **right arrow** to add order to the current selection. Click **Add** when done*

For the NEMLUVIO maintenance dosing, complete the medication details below[1]:*

- The recommended maintenance dosage of NEMLUVIO in patients aged 12 years and older is
  - A maintenance dosing of 30 mg given every 4 weeks (Q4W)
  - After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a dosage of 30 mg Q4W or every 8 weeks (Q8W) is recommended
- **Concomitant topical therapies:**
  - Use NEMLUVIO with topical corticosteroids and/or topical calcineurin inhibitors. When the disease has sufficiently improved, discontinue use of topical therapies. Click the ***right arrow*** to add order to the current selection. Click ***Add*** when done

Instructions continued on the next page.

*Maintenance dosing starts 4 weeks after initial dose.[1]

Oracle Cerner Instructions (cont'd)

10 In the ***Medications*** section, consider adding a Note for NEMLUVIO by selecting the Note tab in the lower right panel. Consider adding:

The hyperlink to the current NEMLUVIO PI (which includes the NEMLUVIO recommended vaccinations prior to treatment initiation, dosage and administration, warnings and precautions, and adverse reactions): https://www.galderma.com/sites/default/files/2024-12/Nemluvio_Dual%20PI%20for%20website%2013Dec24.pdf	The hyperlink and QR code accessing the NEMLUVIO enrollment form. Note: the patient enrollment form has 2 prescriptions on the bottom of the form (for quick start and regular prescription): https://www.nemluviohcp.com/pdf/enrollment-form.pdf	The hyperlink to the NEMLUVIO patient savings card for Commercial patients: https://www.GaldermaHCPPortal.com	NEMLUVIO has a limited distribution network and is available at: https://www.nemluviohcp.com/pdf/specialty-pharmacy-facts.pdf

11 Click ***Task > Save Plan*** once satisfied with the changes

12 Release the PowerPlan to the production environment after satisfactory testing has been completed

PI, Prescribing Information.

Please see Important Safety Information on page 8 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Notes

The customers (i.e., physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system.

Capabilities, functionality, and setup (customization) for each EHR system may vary. Galderma shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Galderma.

While Galderma tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and Galderma shall have no liability thereto.

While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a provider in consultation with the patient after a review of the patient's records to determine eligibility, and Galderma shall have no liability thereto.

The instructions have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement.

EHR, electronic health record.

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CONTRAINDICATION: NEMLUVIO is contraindicated in patients with known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO.

WARNINGS AND PRECAUTIONS:
Hypersensitivity reactions have been reported with NEMLUVIO use. If clinically significant hypersensitivity reaction occurs, immediately institute appropriate therapy, and discontinue NEMLUVIO. Avoid use of live vaccines during treatment with NEMLUVIO.

ADVERSE REACTIONS:
Most common adverse reactions (incidence ≥1%) are headache (including migraine), arthralgia, urticaria, and myalgia.

USE IN SPECIFIC POPULATIONS:
Pregnancy: There are no adequate and well-controlled studies on NEMLUVIO in pregnant women. The limited available information on NEMLUVIO use during pregnancy is not sufficient to inform a drug- associated risk of major birth defects or miscarriage in humans. Human IgG antibodies are known to cross the placental barrier; therefore, NEMLUVIO may be transmitted from the mother to the developing fetus.

Lactation: There are no data on the presence or transfer of NEMLUVIO in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. The effects of local gastrointestinal and limited systemic exposure to NEMLUVIO on the breastfed infant are unknown. NEMLUVIO has not been administered to nursing/lactating women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEMLUVIO and any potential adverse effects on the breastfed child from NEMLUVIO or from the underlying maternal condition.

Pediatric Use: The safety and effectiveness of NEMLUVIO has not been established in pediatric patients younger than 12 years of age for the treatment of moderate-to-severe atopic dermatitis.

Please see accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Reference: 1. NEMLUVIO. Prescribing Information. Galderma Laboratories, L.P.