# Using NextGen® Capabilities



## To Include BLENREP in Order Sets, Send Ophthalmic Exam Notifications, and Monitor Patients' Results

BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

Notable requirements of the BLENREP REMS include the following:

Prescribers must be certified in the BLENREP REMS by enrolling and completing training. Prescribers must counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic exams before each dose, and provide patients with the BLENREP REMS Patient Guide. Patients must be enrolled in the BLENREP REMS and adhere to monitoring. Healthcare settings that dispense BLENREP must be certified in the BLENREP REMS by enrolling and must obtain authorization prior to dispensing. Wholesalers and distributors must distribute BLENREP only to certified healthcare settings.

Further information is available at www.BLENREPREMS.com and 1-855-690-9572.

#### **INDICATION**

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

#### IMPORTANT SAFETY INFORMATION

### **WARNING: OCULAR TOXICITY**

- BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.
- Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.
- Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).

### **About This Guide**

This electronic health record (EHR) guide is intended to help healthcare providers (HCPs) use NextGen® capabilities to facilitate accurate prescribing for BLENREP. It includes steps and examples for adding BLENREP to My Plan Order Sets, automating notifications for HCPs and patients about REMS requirements, the need for ophthalmic exams and complete blood count (CBC) tests as directed in the USPI, and customizing Flowsheets to capture and monitor patients' overall ophthalmic exam results grading which can be used to inform BLENREP treatment decisions in line with the USPI.

This guide does not constitute guidance for treatment or medical advice. It is the HCP's responsibility to select a treatment based on their independent medical judgment and the needs of each individual patient.

The examples and instructions listed in this guide are based on the most recent version of NextGen. Location, illustrations, and terminology are subject to change with system updates. This guide is meant to serve as an overview only and should not replace detailed instructions provided to you by your internal or external EHR support resources. GSK makes no claims or warranties about the applicability or appropriateness of this information. This guide has not been reviewed or endorsed by NextGen. GSK does not endorse or recommend any EHR system.

Use the links in the table of contents below or the tabs on each page to navigate this guide.

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## **Updating an Order Set to Include BLENREP**

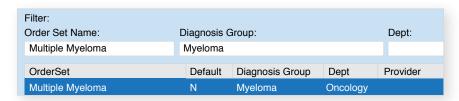
When new information or data become available, oncology practices may update or create My Plan Order Sets that include administration instructions as well as necessary tests such as ophthalmic exams and REMS requirements (i.e., completed and submitted Patient Status Form before each dose of BLENREP and obtaining authorization to dispense for all doses). My Plan Order Sets help care teams facilitate care by grouping together clinical actions that will be administered to a patient during multiple encounters over a specific time frame.

Prescribers must be certified in the BLENREP REMS by enrolling and completing training at www.BLENREPREMS.com. Healthcare settings that dispense BLENREP must be certified in the BLENREP REMS by enrolling at www.BLENREPREMS.com and must obtain authorization prior to dispensing BLENREP. If the practice is certified in the BLENREP REMS, uses general My Plan Order Sets across many disease types, and many treatment options are available for selection, BLENREP can be added as a treatment option.

NOTE: The specific Order Set components listed below are for illustrative purposes only.

### Steps for Updating an Existing My Plan Order Set

- 1. From the File menu, select System/Practice Template.
- 2. From the **Practice** Tab, select **Ngkbm Data Sets**.
- From the Configuration menu, select My Plan/Order Sets.
- 4. In the Order Set Configuration window, filter to locate and select the **Multiple Myeloma Order Set** to be modified.
- 5. Select the Class MED. In the Order field, select BLENREP.



Illustrative example of the Order Set filter (recreated from NextGen)

### **IMPORTANT SAFETY INFORMATION (cont.)**

#### WARNINGS AND PRECAUTIONS

#### **Ocular Toxicity**

BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

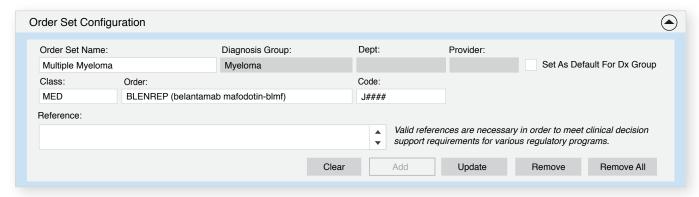
In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).



## Updating an Order Set to Include BLENREP (cont.)

### Steps for Updating an Existing My Plan Order Set (cont.)

- 6. Select Update to add BLENREP to the Order Set.
- 7. Repeat this process to add other orders associated with BLENREP, including:
  - a. Before treatment
    - i. Prescriber RFMS certification
    - ii. Patient REMS enrollment and counseling
    - iii. Patient Status Form submitted before each dose of BLENREP
    - iv. REMS authorization to administer before each dose of BLENREP
    - v. Ophthalmic exam (including slit lamp and visual acuity)
    - vi. Complete Blood Count (CBC)
    - vii. Pregnancy testing for females of reproductive potential
    - viii. Patient weight
  - b. During treatment
    - i. Complete Blood Count (CBC)
    - ii. Ophthalmic exam (including slit lamp and visual acuity)
    - iii. Patient weight



Illustrative example of the Order Set Configuration window (recreated from NextGen)

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

### Ocular Toxicity (cont.)

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 25% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.



## Creating an Order Set to Include BLENREP

My Plan Order Sets help care teams facilitate care by grouping together clinical actions that will be administered to a patient during multiple encounters over a specific time frame.

The following steps provide an overview of the process for creating a new multiple myeloma My Plan Order Set to include BLENREP. NextGen® supports treatment regimens using My Plan Order Sets targeting each regimen's milestones.

### Steps for Creating a New My Plan Order Set

- From the File menu, select System/Practice Template.
- 2. From the **Practice** Tab, select **Ngkbm Data Sets**.
- 3. From the Configuration menu, select My Plan/Order Sets.
- 4. In Order Set Configuration, clear the Order Set Name field and enter the new Order Set name, such as "Multiple Myeloma with BLENREP".
- Select Diagnosis Group and Dept.
- 6. In the Order field, select Multiple Myeloma with BLENREP.
- 7. Select Add to create the Order Set including the first item.

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

Ocular Toxicity (cont.)

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.



## Creating an Order Set to Include BLENREP (cont.)

### Steps for Creating a New My Plan Order Set (cont.)

- 8. Repeat this process to add other orders associated with BLENREP, selecting **Update** after each item including:
  - a. Before treatment
    - i. Prescriber REMS certification
    - ii. Patient REMS enrollment and counseling
    - iii. Patient Status Form submitted before each dose of BLENREP
    - iv. REMS authorization to administer before each dose of BLENREP
    - v. Ophthalmic exam (including slit lamp and visual acuity)
    - vi. Complete Blood Count (CBC)
    - vii. Pregnancy testing for females of reproductive potential
    - viii. Patient weight
  - b. During treatment
    - i. Complete Blood Count (CBC)
    - ii. Ophthalmic exam (including slit lamp and visual acuity)
    - iii. Patient weight

Order Set Configuration							(
Filter: Order Set Name:			Diagnosis Group:		Dept:	Provider:	
Multiple Myeloma with BLENREP (belantamab mafor	lotin-blmf)		Myeloma				Clear
OrderSet	Default	Diagnosis Group	Dept	Order Type	Order		
Multiple Myeloma with BLENREP PreTreatment	N	Myeloma	Oncology	Referral/Procedure	Ophthalmic exam (	including slit lamp a	nd visual acuity)
Multiple Myeloma with BLENREP During Treatment	N	Myeloma	Oncology	Administration	[Belamaf-belantamab mafodotin]		
Multiple Myeloma with BLENREP During Treatment	N	Myeloma	Oncology	Referral/Procedure	[ECP for Ophthalmic Exam]		
Multiple Myeloma with BLENREP During Treatment	N	Myeloma	Oncology	Referral/Procedure	[Ophthalmic exam (including slit lamp and visual acuity)]		
Multiple Myeloma with BLENREP During Treatment	N	Myeloma	Oncology	Prescription	Preservative-free Artificial Tears		

Illustrative example of the Order Set Configuration tool with BLENREP Order Sets and associated therapy items (recreated from NextGen)

Include the BLENREP REMS Eye Care Professional Exam Form available at www.BLENREPREMS.com as part of the BLENREP Order Set. The form should be completed by the patient's optometrist or ophthalmologist and sent (via eFax, Fax, EMR, or by the patient) to the oncologist at the close of the patient's eye exam to give the oncologist time to determine appropriate treatment dosing prior to administration of BLENREP. If supported, work with your EHR IT team to add the form as a custom document.

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

### Ocular Toxicity (cont.)

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.



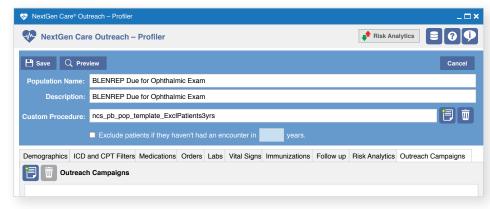
This workflow allows HCPs to draft and set up Patient Reminders that are delivered to the patient via their preferred communication contact method. The ability to create automated patient outreach outlined in this section is available in **NextGen Care Outreach**, which is included in **NextGen Population Health Suite**. This is add-on software that requires separate licensing from NextGen®. Heath systems using NextGen Care Outreach may create a campaign that sends patient reminders to complete requirements prior to administration of BLENREP, including patient enrollment in the BLENREP REMS to document that they were counseled and agree to adhere to ophthalmic monitoring, required ophthalmic exams, completed BLENREP REMS Eye Care Professional Exam Form, etc.

Set-up and configuration of outreach campaigns is typically managed by an EHR specialist. EHR user access to NextGen Care Outreach must be set up in the System Administration application.

### Steps for Creating Campaigns for Patients Prescribed BLENREP

To create Campaigns in **NextGen Care Outreach** for REMS enrollment, counselling, ophthalmic exam and other testing due prior to BLENREP infusion, navigate to server where **NextGen Care Outreach** is installed:

- 1. Select NextGen Care Outreach Profiler icon.
  - a. The profiler application opens
- 2. Select New.
- Complete the following fields:
  - a. Population Name
  - b. **Description**
  - c. Custom Procedure
- Select the Demographics tab and add new.
- 5. Select the **Save** button.



Illustrative example of the Outreach - Profiler configuration (recreated from NextGen)

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

#### Ocular Toxicity (cont.)

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.



## Steps for Creating Campaigns for Patients Prescribed BLENREP (cont.)

- 6. Select the Outreach Campaigns tab.
- 7. Select Add new.
- 3. Complete the fields:
  - a. Outreach Campaign Name (potential illustrative example name: "BLENREP Pre-Infusion Requirements")
  - b. Alerts Text
  - c. **Description**
  - d. Custom Procedure: Several SQL Stored Procedures come "out of the box"
    - i. Practice also has the option to create their own SQL Custom Stored Procedures
- 9. Select the **Appointment Exclusions** tab.
- 10. Select all of the **Appointment Events to EXCLUDE** from outreach.
- 11. Select the **Preview** button to see the list of patients.
- 12. Close the window and select **Save** to save the **Campaign**.
- 13. Close the NextGen Care Outreach Application.

## IMPORTANT SAFETY INFORMATION (cont.)

### WARNINGS AND PRECAUTIONS (cont.)

BLENREP Risk Evaluation and Mitigation Strategy (REMS)

BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

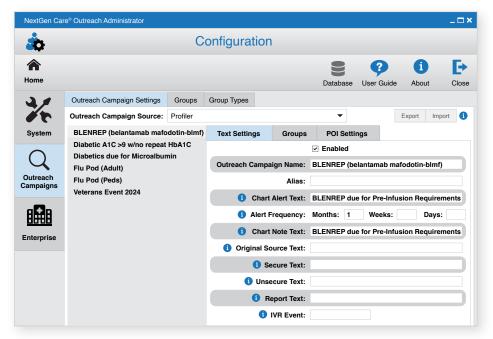
Further information is available at www.BLENREPREMS.com and 1-855-690-9572.



### Steps for Creating Campaigns for Patients Prescribed BLENREP (cont.)

To Build Outreach Campaigns Messages:

- 1. Navigate to NextGen® Care Administrator icon.
- 2. Select Configuration button.
- 3. Complete the **System Settings** based on Practice requirements.
- 4. Select the **Outreach Campaigns** button and select the **Outreach Campaign Name: BLENREP Pre-Infusion Requirements**.
- 5. Select the **Enabled** checkbox and complete the **Text Settings** specific to the practice requirements for outreach.



Illustrative example of the Outreach Campaign Settings (recreated from NextGen)

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

#### **Thrombocytopenia**

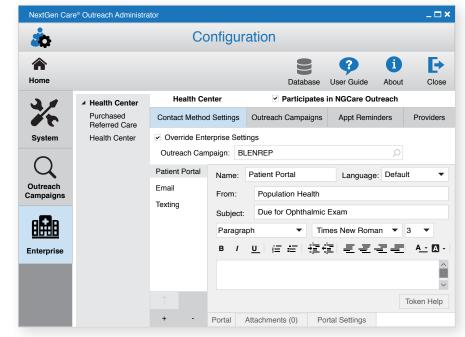
Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).



### Steps for Creating Campaigns for Patients Prescribed BLENREP (cont.)

- 6. Select the Enterprise button and Contact Method Settings.
- 7. Select the name of the Campaign.
- 8. Select the Contact Types:
  - a. Text
  - b. **Email**
  - c. Patient Portal
  - d. Recall Plan
  - e. Voice Reminder
- Configure the message that will be sent for each Contact Type.
  - a. Texting has a120-character limit
  - There is no character limit on the other Contact Types



Illustrative example of the Contact Method Settings tab (recreated from NextGen)

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

Thrombocytopenia (cont.)

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.



## NextGen® Care Outreach Configuration for Population Management Hub Outreach

For outreach from the Hub, navigate to the Nextgen Care Outreach Administrator Application.

- 1. Navigate to the **Outreach Campaigns** button.
- 2. Select the Outreach Campaign Source > Population Management Hub.
- 3. Select Create New Hub Campaign at the bottom of the left panel.
- 4. Add the Name of the outreach.
- 5. Navigate to the **Enterprise** button.
- 6. Select the Outreach Campaign Name just added: Population Management Hub > BLENREP Pre-Testing.
- 7. Follow the previous steps to add outreach types as mentioned already (e.g., text, email, patient portal, recall plan, or voice reminder) and attach patient education including the BLENREP REMS Patient Guide.
  - a. Prescribers must counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic examinations, and provide patients with the BLENREP REMS Patient Guide

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

#### **Embryo-fetal Toxicity**

Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose.



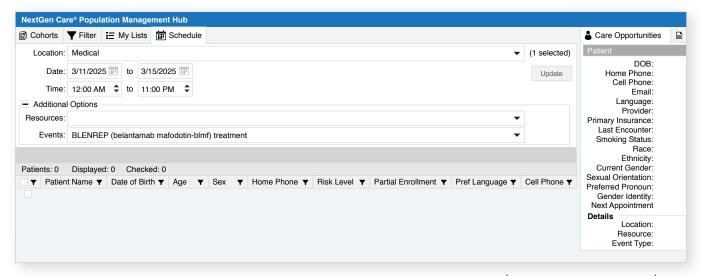
## Creating Bulk Tasks for HCPs (If Available)

The ability to create Bulk Tasks for HCPs outlined in this section is available in **NextGen Care Outreach**, which is included in **NextGen Population Health Suite**. This is add-on software that requires separate licensing from NextGen®. If available, Bulk Tasks could include a reminder to verify prescriber REMS certification and patient REMS enrollment, complete a BLENREP REMS Eye Care Professional Exam Form, submit a Patient Status Form before each dose of BLENREP, obtain authorization to dispense, or to follow up with patients prior to upcoming infusions to ensure that they have completed requirements prior to administration of BLENREP, including patient enrollment in the BLENREP REMS to document that they were counseled and agree to adhere to ophthalmic monitoring, required ophthalmic exams, completed BLENREP REMS Eye Care Professional Exam Form, etc.

### Steps for Creating HCP Reminders as Bulk Tasks

To access the NextGen Care Population Health Management Hub in NextGen Enterprise EHR:

- 1. Open EHR and navigate to File > View > NextGen Care Population Management Hub.
- 2. Select the **Schedule** tab and complete the fields:
  - a. Date range to search for upcoming appointments
  - b. **Events:** BLENREP treatment
  - c. Select Update to run the report



Illustrative example of NextGen Care Population Management Hub Schedule tab (recreated from NextGen)

### IMPORTANT SAFETY INFORMATION (cont.)

#### **ADVERSE REACTIONS**

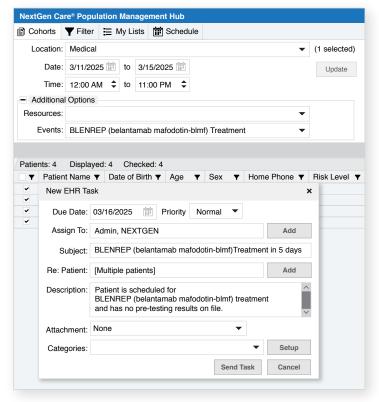
The most common adverse reactions (≥20%) with BLENREP in combination with bortezomib and dexamethasone are reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract and COVID-19.



## Creating Bulk Tasks for HCPs (If Available) (cont.)

### Steps for Creating HCP Reminders as Bulk Tasks (cont.)

- 3. The list of patients who are scheduled for BLENREP treatment is displayed.
- 4. Review each patient chart for **Ophthalmic Exam Documentation AND/OR Completed Ophthalmic Exam Referral with Interpretation**.
- 5. If no documentation exists, select the checkmark next to the patient's name or select multiple patients.
- 6. Select the Task > EHR task button at the bottom of the window.
- 7. The **New EHR task window** will open.
- 8. Complete the following fields:
  - a. Due Date
  - b. **Priority**
  - c. Assign To
  - d. Subject
  - e. The Re: Patient field will default to
     Multiple patients if multiple patients
     are selected in step 5
  - f. **Description** of the task
- Select **Send Task** to send the task to the recipient.



Illustrative example of a Care Population Management Hub New EHR Task (recreated from NextGen)

## IMPORTANT SAFETY INFORMATION (cont.) ADVERSE REACTIONS (cont.)

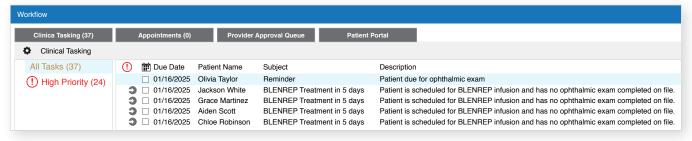
The most common Grade 3 or 4 (≥10%) laboratory abnormalities are decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.



## Creating Bulk Tasks for HCPs (If Available) (cont.)

## Steps for Creating HCP Reminders as Bulk Tasks (cont.)

- 10. The task will display in the recipient's Clinical Tasking inbox.
- 11. Recipients can select each patient and document in their EHR the contact information in accordance with practice documentation workflow process.



Illustrative example of a Task List (recreated from NextGen)

#### INDICATION

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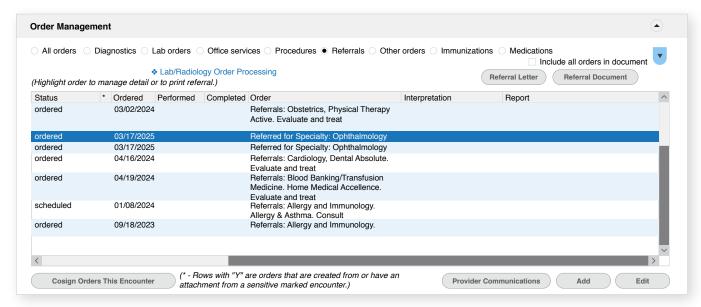


## Creating a Flowsheet to Document Ocular Adverse Reaction Severity Grade

Flowsheets are templates used for documentation and can be customized to capture the patient's ophthalmic exam results (conducted by either optometrists or ophthalmologists) before administration of BLENREP. Storing exam results within a Flowsheet can provide clinicians with an aggregated view of a patient's eye health and any vision changes over time.

### Steps for Creating an Ophthalmic Exam Flowsheet

- 1. Navigate to the patient's chart from PAQ or search for the patient.
- 2. Select the Order Management template.
  - a. The Order Management grid will contain all Orders for patients including Referrals
  - b. Select the Referrals radio button to see only Ordered and Completed Referrals
- 3. Select the Referral for the Eye Care Professional Consult and select the Edit button



Illustrative example of an Order Management Referrals grid (recreated from NextGen®)

### IMPORTANT SAFETY INFORMATION (cont.)

#### WARNINGS AND PRECAUTIONS

#### **Ocular Toxicity**

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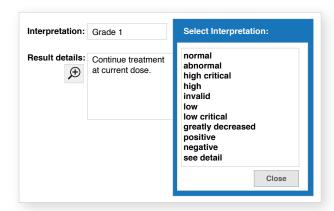
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## Creating a Flowsheet to Document Ocular Adverse Reaction Severity Grade (cont.)

### Steps for Creating an Ophthalmic Exam Flowsheet (cont.)

- 4. Document results/interpretation from the Eye Care Professional Request Form Exam.
- Select Received > Completed > Interpretation and Result Details.
  - a. Interpretation is a pick list that can be configured by EHR Analyst/information technology (IT) staff
- 6. Add appropriate text to the Label in line with corresponding dose modification instructions as presented in the USPI (see table below).
- 7. Select **Save and Close** button.



Illustrative example of a pick list for interpretation documentation (recreated from NextGen)

Recommended Dosage Modifications for Ocular Toxicity based on Ophthalmic Exam Findings <sup>1</sup>						
Grade 1	Continue treatment at current dosage.					
Grade 2	Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. Resume treatment at Reduced Dosage Level 1 as per Table 1. If recurrent Grade 2 or 3 ocular toxicity is experienced, resume treatment at Reduced Dosage Level 2.					
Grade 3	Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. Resume treatment at Reduced Dosage Level 1 as per Table 1. If recurrent Grade 2 or 3 ocular toxicity is experienced, resume treatment at Reduced Dosage Level 2.					
Grade 4	Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. For patients previously on 2.5 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 1 as per Table 1. For patients previously on 1.9 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 2. If recurrent Grade 4 ocular toxicity is experienced, permanently discontinue BLENREP.					

For more information on grading definitions and dose modifications for ocular toxicity and non-ocular adverse reactions, please see the full <u>Prescribing Information</u>.

## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

### Ocular Toxicity (cont.)

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.



## IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

### Ocular Toxicity (cont.)

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

#### BLENREP Risk Evaluation and Mitigation Strategy (REMS)

BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

Further information is available at www.BLENREPREMS.com and 1-855-690-9572.

### **Thrombocytopenia**

Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.

Reference: 1. BLENREP. Prescribing Information. GSK; 2025.

Please see additional Important Safety Information throughout and <u>click here for full Prescribing Information</u> including Boxed Warning for BLENREP.

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