Using Oracle Health Capabilities

BLENREP
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To Include BLENREP in Treatment Plans, 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).**

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

About This Guide

This electronic health record (EHR) guide is intended to help healthcare providers (HCPs) use Oracle Health (formerly Cerner Millennium) capabilities to facilitate accurate prescribing for BLENREP. It includes steps and examples for adding BLENREP to PowerPlans, 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 Oracle Health. Locations, 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 Oracle Health. GSK does not endorse or recommend any EHR system.

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INDICATION

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Updating a PowerPlan to Include BLENREP

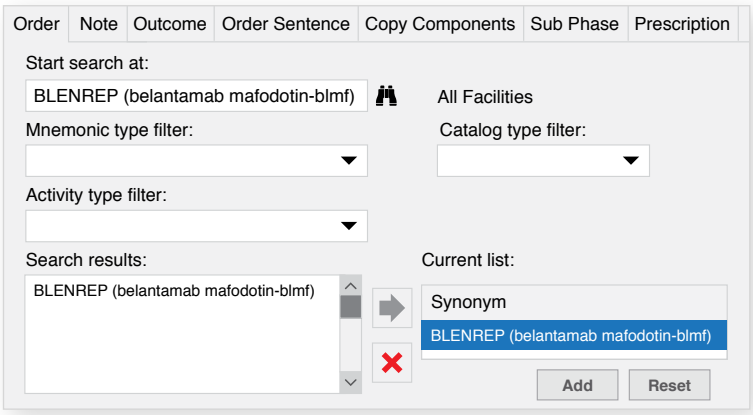
When new information or data become available, oncology practices may update or create PowerPlans that include administration instructions as well as necessary tests such as ophthalmic exams and REMS requirements (i.e., completed and submitted Patient Status Form before each dose of BLENREP and obtaining authorization to dispense for all doses). PowerPlans 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 has an existing PowerPlan for multiple myeloma and is certified in the BLENREP REMS, BLENREP can be added as a treatment option.

NOTE: *The specific PowerPlan components listed below are for illustrative purposes only.*

Steps for Updating an Existing PowerPlan

1. Log in to **DCPTOOLS.exe** using the correct credentials.
2. Navigate to the **PowerPlan Tool**.
3. Click the **Open Existing Plan** icon.
4. Search for and select existing **PowerPlan** that BLENREP and other orders for BLENREP treatment should be added to.
5. Select **OK** to load the PowerPlan to be updated.
6. Select the **Chemotherapy Phase**, then the **Order** tab.
7. **Search** for and select **BLENREP**.
8. Right-click the **Order Sentence** tab.



Illustrative example of Order Search (recreated from Oracle Health)

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%).

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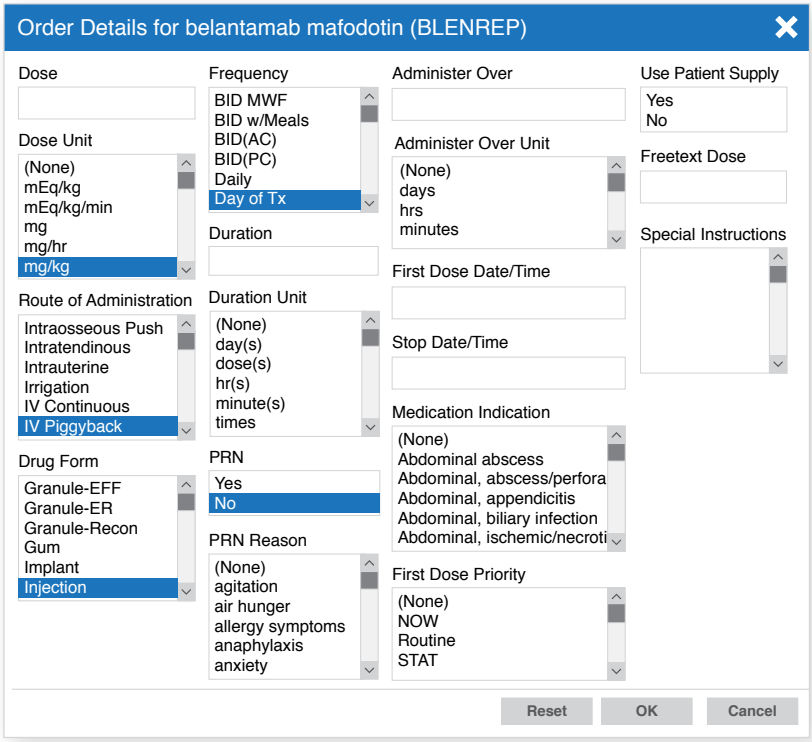
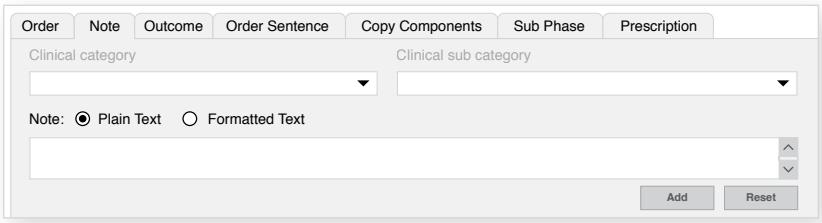
Updating a PowerPlan to Include BLENREP (cont.)

Steps for Updating an Existing PowerPlan (cont.)

9. Set the **Order Sentence** as appropriate.
10. Select the **Note** tab.
11. Enter monitoring information.
12. Select **Add**.
13. Select the **Treatment** phase and set BLENREP to be included on the appropriate days.
14. Review the **Lab** phase and add **Lab Orders** as appropriate.
15. Create a **Note** to remind ordering providers to select labs as appropriate.



Illustrative example of Order Sentence setup (recreated from Oracle Health)



Illustrative example of adding monitoring information (recreated from Oracle Health)

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.

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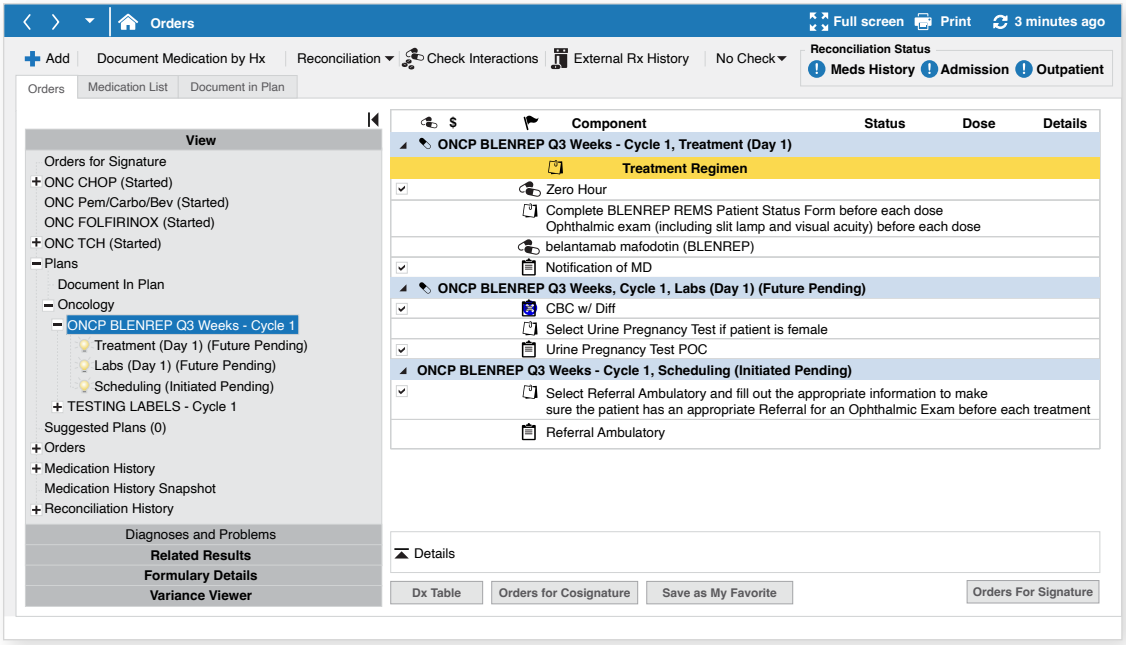
Updating a PowerPlan to Include BLENREP (cont.)

Steps for Updating an Existing PowerPlan (cont.)

16. Set the **Treatment Schedule** attribute as appropriate.
17. Select the **Scheduling** phase and add the appropriate orders, such as **Referral Ambulatory**.
18. Create a note to remind ordering provider to select the **Referral Ambulatory** order, ensure the prescriber and healthcare setting are certified in the REMS, ensure that the patient is enrolled in the REMS, ensure that authorization to dispense is obtained, ensure that prescribers 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, instruct care team staff to follow up with Eye Care Professionals if the BLENREP REMS Eye Care Professional Exam Form is still pending before infusion appointment, and include notes to Pharmacy that a Patient Status Form has been completed before each dose of BLENREP.
19. Select **Save Plan** to complete the build steps for updating an existing PowerPlan with appropriate BLENREP and related orders.
20. Repeat these steps for all the PowerPlans that have been identified that should include BLENREP as part of treatment.



Illustrative example of PowerPlan updated to include BLENREP Q3W (recreated from Oracle Health)

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.

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Creating a PowerPlan to Include BLENREP

PowerPlans 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 PowerPlan to include BLENREP.

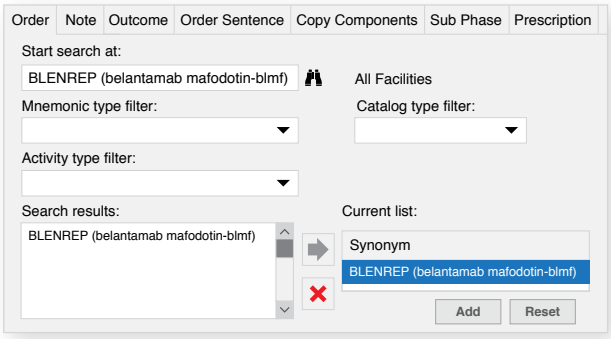
Steps for Creating a New PowerPlan

1. Log in to **DCPTOOLS.exe** using the correct credentials.
2. Navigate to the **PowerPlan** tool.
3. Click the **Create New Plan** icon:
    a. Enter a **Plan Name** following the organization's naming convention
    b. Select **Multiple Phase**
    c. Select the appropriate **Plan Type**
    d. Select **Sequenced** for Display Method
    e. Add the appropriate **Phases** based on the organization's Day of Treatment PowerPlan layouts
    f. Select **OK** to display PowerPlan shell in the background
4. Select the **PowerPlan Level Attributes** and align them to the organization's standards.
5. Set attributes:
    a. Check: **Cross Encounter**
    b. Check: **Allow Diagnosis Propagation**
    c. Set **Cycle Settings** as appropriate
    d. Check: **Prompt for Ordering Physician**
    e. Check: **Copy Forward**
    f. Set Plan Ordering Defaults as appropriate
    g. Check: **Do Not Allow Proposal**
    h. Check: **Do Not Allow as Plan Favorite**

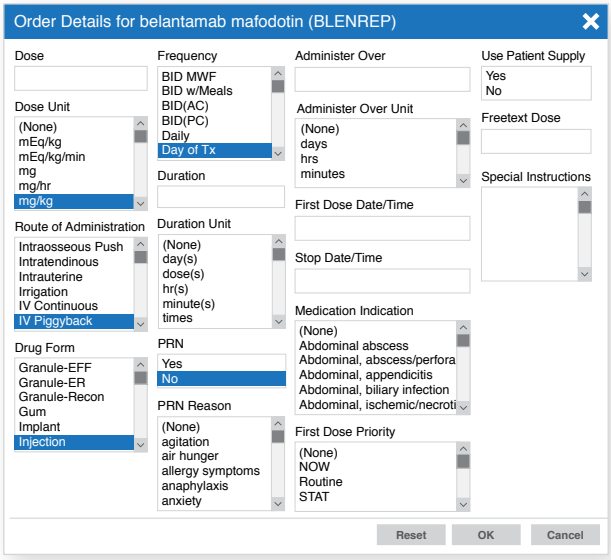
Creating a PowerPlan to Include BLENREP (cont.)

Steps for Creating a New PowerPlan (cont.)

6. Select the **Treatment Phase** and set the **Phase Level** attributes according to the organization's standards.
7. Select the **Labs Phase** and set the **Phase Level** attributes according to the organization's standards.
8. Select the **Scheduling Phase** and set the Phase Level attributes according to the organization's standards.
9. Select the **Treatment Phase** and navigate to the **Copy Components** tab.
10. Select **Copy Phase/components** and search for a build template or existing PowerPlan that is aligned with the organization's standards.
11. Select **Copy/Import** and select the items that should be included in this Treatment Phase, such as ensuring the prescriber and healthcare setting are certified in the REMS, ensuring that the patient is enrolled in the REMS, ensuring that authorization to dispense is obtained, ensuring that prescribers counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic examinations, and providing patients with the BLENREP REMS Patient Guide, instructing care team staff to follow up with Eye Care Professionals if BLENREP REMS Eye Care Professional Exam Form is still pending before infusion appointment, and ensuring that a Patient Status Form has been completed before each dose of BLENREP.
12. Select **Copy**.
13. Select the **Order** tab and search for BLENREP.



Illustrative Example of Order Search (recreated from Oracle Health)



Illustrative example of Order Sentence setup for BLENREP (recreated from Oracle Health)

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.

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Creating a PowerPlan to Include BLENREP (cont.)

Steps for Creating a New PowerPlan (cont.)

14. Select the **BLENREP** order and right-click to open **Order Details** to set **Order Sentence/Expectation**.
15. Set the **Order Sentence** as appropriate for BLENREP.
16. Select the **Note** tab, enter monitoring information, and select **Add**.
17. Select the **Treatment Phase** and set the **Treatment Schedule** attribute according to organization's standards.
18. Select the **Labs Phase** and the **Copy Components** tab and search for a similar PowerPlan or Build Template PowerPlan to copy the lab orders that are appropriate for BLENREP treatment.
19. Select the appropriate **Labs** for this PowerPlan.
20. While the **Labs** phase is selected, navigate to the **Order** tab, search for and select the appropriate pregnancy test, and select **Add**.
21. Create a **Note** to remind ordering providers to select this pregnancy test if the patient is female.
22. Set the **Treatment Schedule** attribute as appropriate.
23. Select the **Scheduling Phase** and the **Copy Components** tab and search for a similar PowerPlan or Build Template PowerPlan.
24. Copy the **Scheduling Order** as appropriate.
25. Select the **Scheduling Order** and select the **Scheduled Phases** attribute.
26. Set the **Scheduled Phases** with **Treatment – Day 1** to link this order to the Day of Treatment associated with the Treatment Phase.
27. Add the appropriate **Referral Order** for an ophthalmic exam.
28. Create a **Note** to help guide when to select the **Referral Ambulatory** order and to ensure the patient completes an ophthalmic exam before each treatment.
29. Select **Save Plan** to complete the build steps for adding a new BLENREP PowerPlan.

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.

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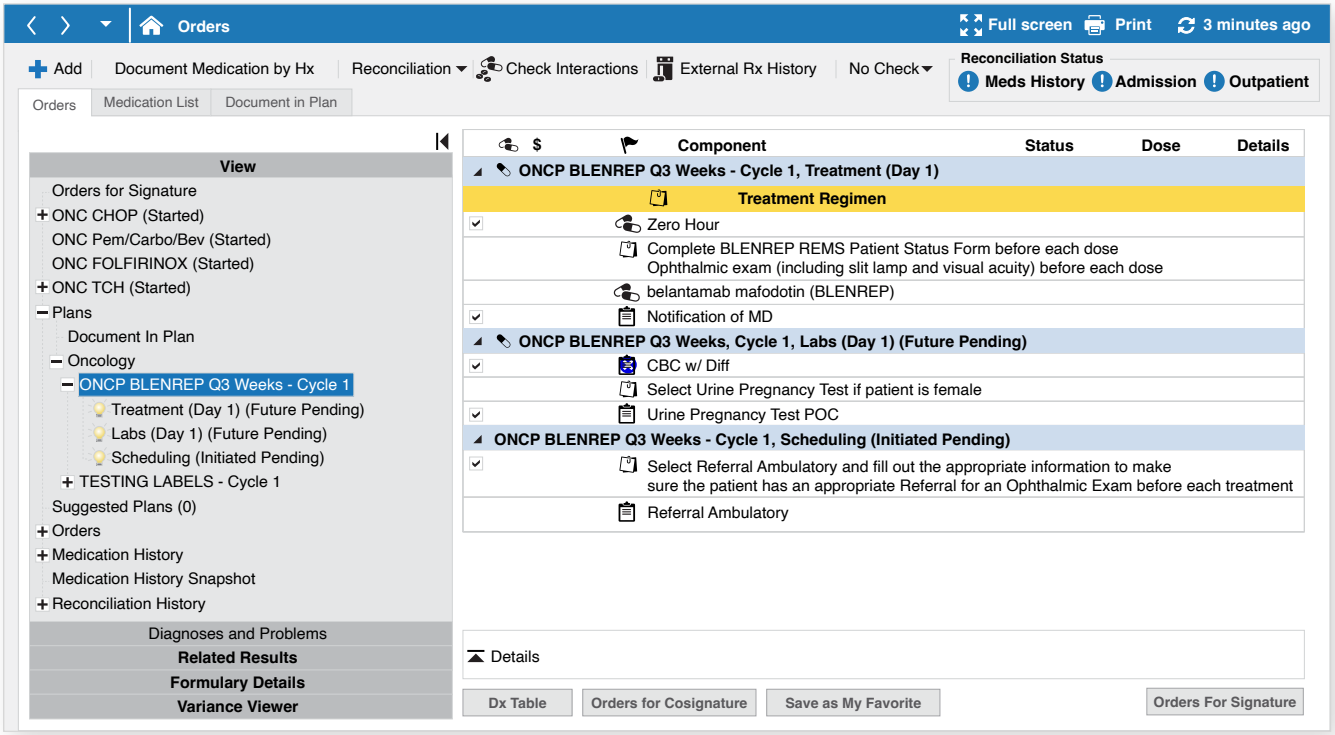
Creating a PowerPlan to Include BLENREP (cont.)



Illustrative example of PowerPlan updated to include BLENREP Q3W (recreated from Oracle Health)

Include the BLENREP REMS Eye Care Professional Exam Form available at **www.BLENREPREMS.com** as part of the BLENREP PowerPlan. 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.)

BLENREP Risk Evaluation and Mitigation Strategy (REMS)

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Creating Automated Patient Reminders

This workflow allows HCPs to draft and set up Patient Reminders that are delivered to the patient via the patient portal. By adding Patient Reminders to a BLENREP PowerPlan, patients who are prescribed BLENREP will automatically receive a patient portal message with a reminder 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.

Steps for Creating Reminders for Patients Prescribed BLENREP

NOTE: *This workflow associates the Patient Reminder with the reason for visit (e.g., BLENREP treatment). When practice staff schedule a patient visit, the ophthalmic exam reminder can be added into Patient Instructions via Auto Text.*

1. Log in to **DCPTOOLS.exe Order Management PowerPlan Tool**.
2. Search for and select the **BLENREP PowerPlan**.
3. Select **OK**.
4. Select the **Infusion 30 Minutes** order in the **Scheduling Phase**.
5. Right-click on **Order Sentence/Expectation** and select **Modify**.
6. Fill in the **Reason for Exam** as appropriate.
7. Repeat these steps for all the Scheduling Orders for this PowerPlan and select the **Save Plan** icon.
8. Navigate to **Discerndev.exe**.
9. Click the **New Rule** icon and select **Expert Knowledge Module**.
10. In the **Maintenance** section, fill in each field as appropriate.
11. Select the **Knowledge** tab at the bottom.
12. Select **Evoke Events** and select **ADDTOSCRATCHPAD**.
13. Right-click and **Insert Template**.
14. Select **EKS_ORDER_ACTION_DETAIL_E** and fill in the details as appropriate.
15. Right-click in the **Logic** Section and choose **EKS_ORDER_INCOMING_DETAIL_L**, then click **Finish**.
16. Fill in the details using the same data as the Evoke template.
17. Right-click on the **Action** Section, then choose **Insert Template After** and select the **EKS_MESSENGER_A**.

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).

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

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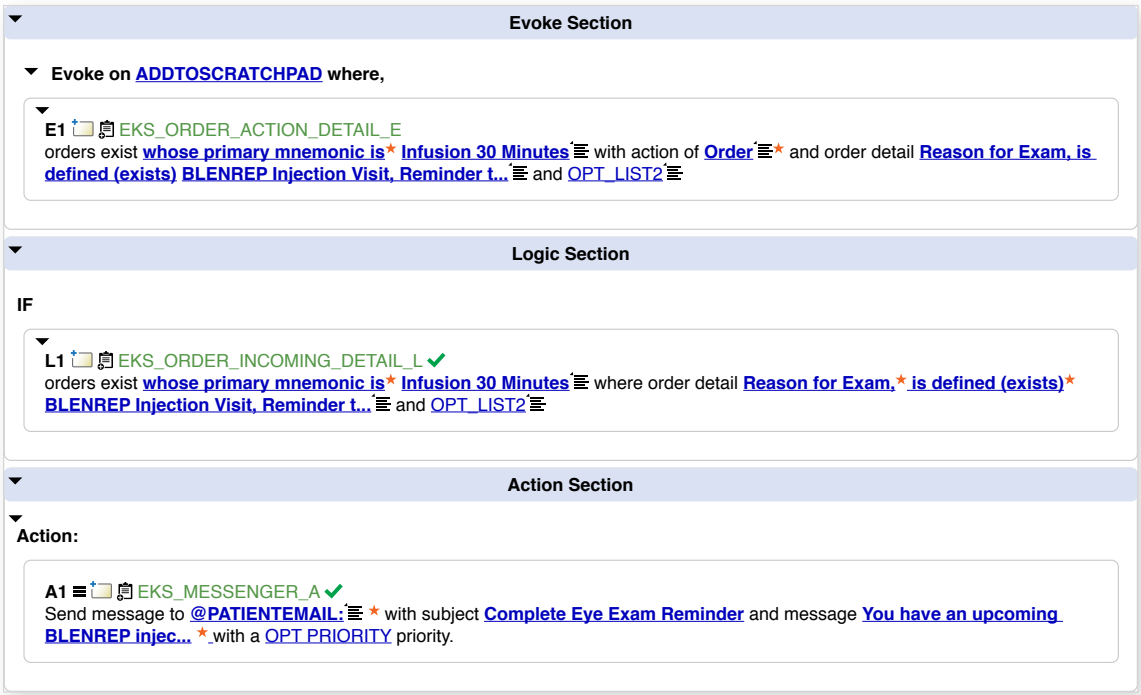
Creating Automated Patient Reminders (cont.)

Steps for Creating Reminders for Patients Prescribed BLENREP (cont.)

18. Fill in the **Action Template**, with the language you want to include in the Automated Patient Reminder:
    a. *Illustrative example: "You have an upcoming appointment for your BLENREP infusion. Before you can start BLENREP, you must receive the BLENREP REMS Patient Guide from your prescriber, receive counseling from your prescriber on the risk of eye problems and the need for eye exams using the Patient Guide. You must enroll in the REMS by completing the Patient Enrollment Form with your prescriber to document that you were counseled on the REMS requirements and agree to get eye exams before starting BLENREP, before each dose, promptly for any new or worsening eye symptoms, and as clinically indicated, as described in the BLENREP REMS Patient Guide. Remember to ask your oncology healthcare team if there are lab tests you might need prior to your BLENREP infusion or if you have any questions related to your infusion."*
        i. If functionality allows, this language may be customized.
19. Click the **Save** icon.
20. Name the **Module** based on your organizational standards.
21. Click **OK** to save.



Illustrative example of complete Discern rule (recreated from Oracle Health)

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.

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Creating Automated HCP Inbox Messages

Oracle Health allows HCPs to draft and set up silent notifications called Inbox Messages. These Inbox Messages 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 their required ophthalmic exams and CBC tests. Additionally, an Inbox Message may be used to remind HCPs about ordering labs or checking REMS requirements such as prescriber certification, patient enrollment, dispensing healthcare setting certification, completed and submitted Patient Status Form, authorization code prior to dispensing, etc.

Steps for Creating an Inbox Message

1. Launch **DiscernDev** and log in as a Database Administrator (DBA).
2. Navigate to **File New Expert Knowledge Module**.
3. Create a new rule entering appropriate parameters.
4. Select the **Knowledge** tab and click **Select Evoke Event**.
5. Search for **ORDEREVENT**, select it, and click **OK**.
6. Right-click in the **Evoke** section and select **Insert Template**.
7. Select **EKS_ORDER_LIST_E** and click **Finish**.
8. Set the **ORD_METHOD** parameter to that was ordered as, then click **Finish**.
9. Set the **OPT_ODERS** parameter to the orders desired to trigger the messages to the ordering provider.
10. Right-click in the **Evoke** section and select **Insert Template After**.
11. From the list, choose **EKS_DEBUGEKM_E**, then click **Finish**.
12. Select **DEBUG_STATUS** to **To FullAudit for this module only**, then click **Finish**.
13. Right-click on the **Logic** section and choose **Insert Template**.
14. Select **EKS_ORDER_LIST_INCOMING_L**.
15. Set the **ORD_METHOD** parameter to "that was ordered as", and click **Finish**.
16. Set the **OPT_ORDERS** parameter with the first order to trigger a message to the ordering provider.
17. Select the **OPT_ORDER_STATUS** parameter and choose **Ordered**, then **Finish**.
18. Right-click **L1 Template** and select **Copy**.
19. Right-click **L1** and select **Paste**.
20. Repeat this step so you have a total of 3 Logic Templates: **L1**, **L2**, and **L3**.
21. Change the **OPT_ORDERS** parameter on **L2** to the second order to trigger a message to the ordering provider.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Embryo-fetal Toxicity (cont.)

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.

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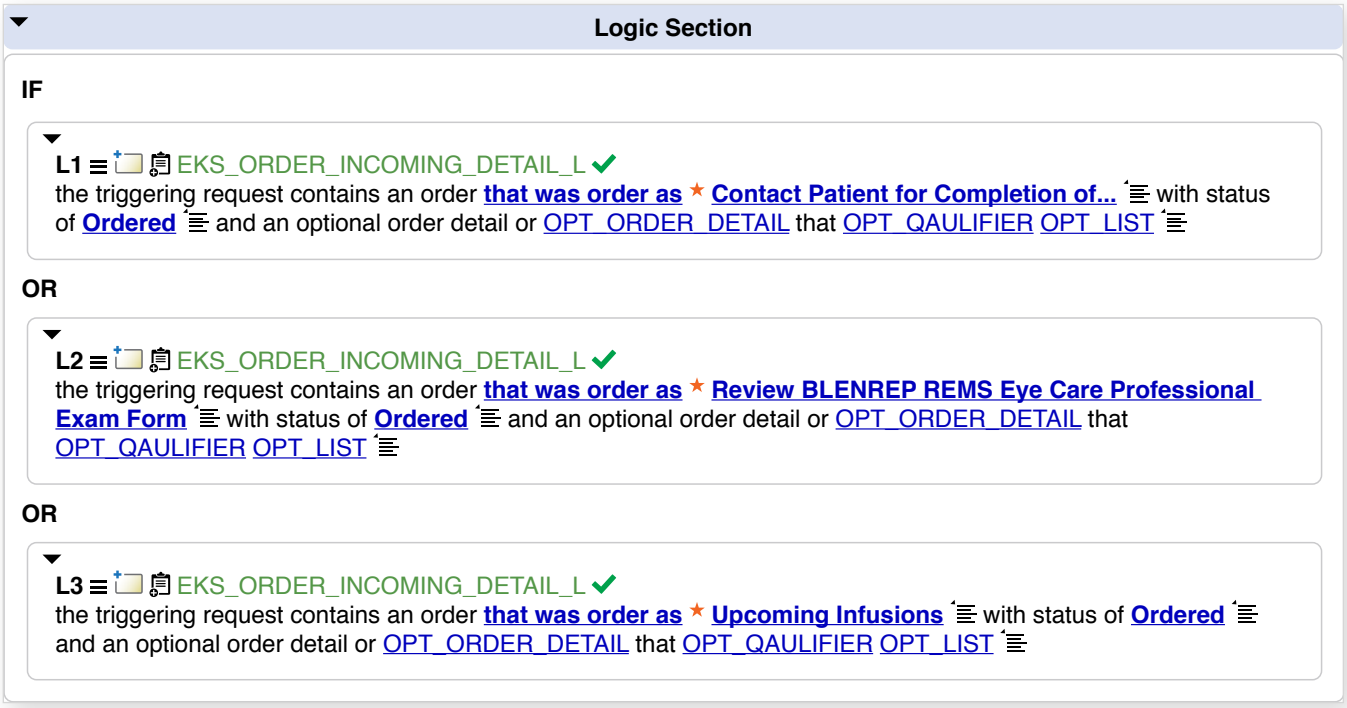
Creating Automated HCP Inbox Messages (cont.)

Steps for Creating an Inbox Message (cont.)

22. Change the **OPT_ORDERS** parameter on **L3** to the third order to trigger a message to the ordering provider.
23. Update the And separators to Or by right-clicking on the **And**, and selecting **Change to OR**.



Illustrative example of completed Logic Section (recreated from Oracle Health)

24. Right-click in the **Action** section and choose **Insert Template**.
25. Select **EKS_MESSENGER_ESC_A**.
26. Set **OPT_RECIPIENT** to **Order Physician**.
27. Click **Inbox** > **Order Relation** > **Select this line** and press **[<<Next>>]** to continue or **(Cancel)** to quit to open **Order Physician**.
28. Select **OPT_SUBJECT** and enter the message subject.

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.

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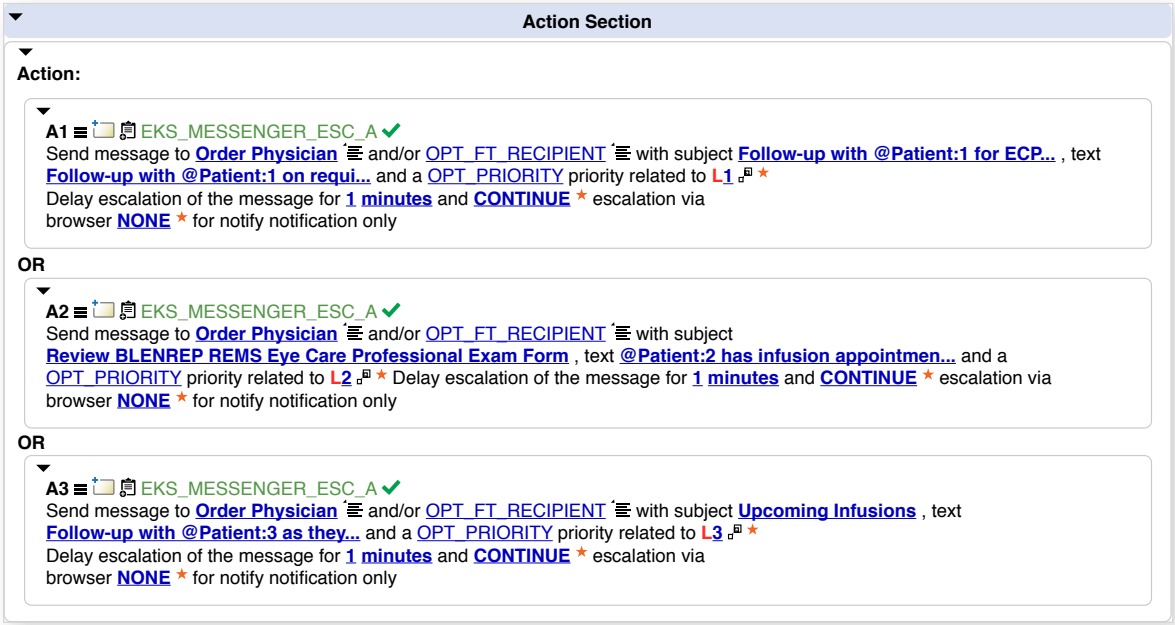
Creating Automated HCP Inbox Messages (cont.)

Steps for Creating an Inbox Message (cont.)

29. Set **OPT_MSG** with appropriate text and substitution values that should be included in the message to the order physician.
    a. *illustrative example: "You have an upcoming appointment for your BLENREP infusion. Before you can start BLENREP, you must receive the BLENREP REMS Patient Guide from your prescriber, receive counseling from your prescriber on the risk of eye problems and the need for eye exams using the Patient Guide. You must enroll in the REMS by completing the Patient Enrollment Form with your prescriber to document that you were counseled on the REMS requirements and agree to get eye exams before starting BLENREP, before each dose, promptly for any new or worsening eye symptoms, and as clinically indicated, as described in the BLENREP REMS Patient Guide. Remember to ask your oncology healthcare team if there are other tests you might need prior to your BLENREP infusion or if you have any questions related to your infusion."*
30. Set **ESC_LINK** to **L1**.
31. Set **TIME_INTERVAL** to **1** and **TIME_UNIT** to **minutes**.
32. Repeat steps 27-29, linking each to L2 and L3 to generate messages for the other orders.



Illustrative example of completed Action section, with 3 rules (recreated from Oracle Health)

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.

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

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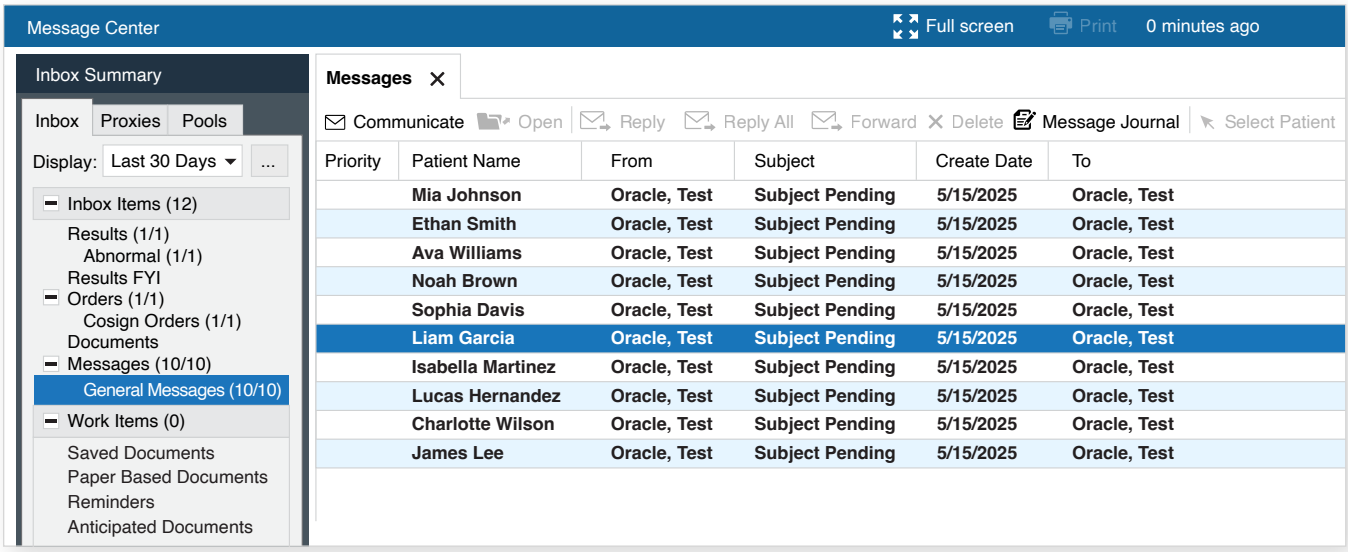
Creating Automated HCP Inbox Messages (cont.)

Steps for Creating an Inbox Message (cont.)

33. Select the **Save** icon. In the **Save Module As** window, enter module name.



Illustrative example of Message Center messages regarding BLENREP follow-up (recreated from Oracle Health)

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).**

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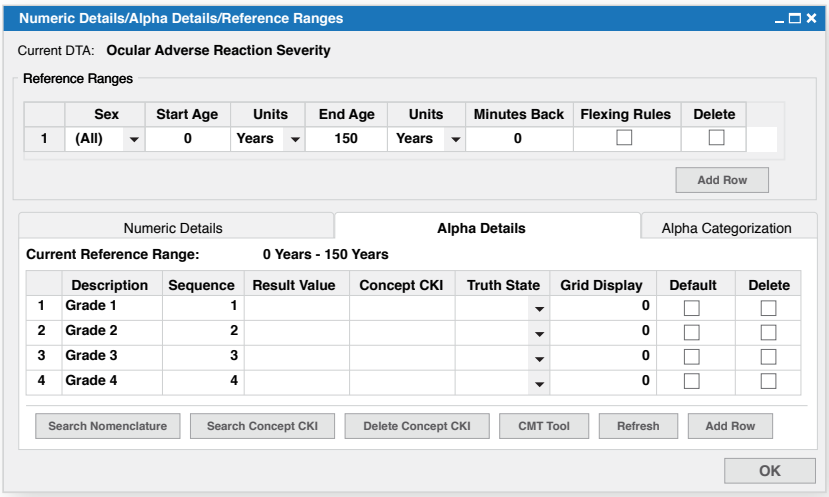
Creating a Flowsheet to Document Ocular Adverse Reaction Severity Grade

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. Login into **DCPTOOLS.exe** to create a new Discrete Task Array (DTA).
2. Select **Documentation Management DTA Wizard**.
3. Select **Clear** to open the fields to create new DTAs.
4. Add **Unique Mnemonic** for the first DTA.
5. Copy and paste the same text into the **Description** field.
6. Select **Patient Care** as the **Activity Type**.
7. Select **Alpha** as the **Result Type**.
8. Select the **Alpha Details** button.
9. Select the **Add Row** button 4 times for each grade.



Illustrative example of setting Description and Sequence (recreated from Oracle Health)

10. Enter **Grade 1, 2, 3, 4** in **Description** and **1, 2, 3, 4** in **Sequence**, respectively, then select **OK**.
    a. Ensure the Grades listed correspond to the listed severity grades for Ophthalmic Examination Findings as outlined in the Prescribing Information.
11. Select the binoculars for the **Associate Event Code To** field.
12. Select **Create** and add an **Event Code** using the same naming convention as the Mnemonic.
13. Select **OK**, then **OK** again to fill in **Associate Event Code To** with the new Event Code.
14. Select **Apply**.

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%).

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

Steps for Configuring a PowerForm as Flowsheet

1. Log in to **DCPTOOLS.exe**.
2. Select **Documentation Management PowerForms**.
3. Click **Section** and choose **New**.
4. Name the **Section** as appropriate and select **OK**.
5. Select the **Label** button on the toolbar.
6. Drag, drop, and resize **FormLabel1** as the header for this section.
7. Right-click the label and select **Label Properties**.
8. Add appropriate text to the Label in line with corresponding dose modification instructions as presented in the USPI.
9. Select **Font** and update as appropriate.
10. Select **Back Color**, choose standard **Blue**, then click **OK**.
11. Add another Label from the toolbox, right-click properties, repeat steps 5-10. Label this section **Ocular Adverse Reaction Severity**.
12. From the toolbar, select the **Alpha List** button.
13. Drag, drop, and resize that box to be in line with the Label boxes.
14. Right-click the **Alpha List** box and choose **Properties**.
15. Click the **Select DTA** button.
16. **Search** for the newly created **DTA** from previous steps, select it, then click **OK**.

Recommended Dosage Modifications for Ocular Toxicity based on Ophthalmic Exam Findings[1]	
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 **Prescribing Information**.

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.

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

Steps for Configuring a PowerForm as Flowsheet (cont.)

17. Select **OK** again to associate the **Ocular Adverse Reaction Severity DTA** to this box and section.
18. Repeat steps 5-17 to add 3 more Label Boxes, adding appropriate text for each.
19. Select **Section,** then **Save**.
20. Select the **Form** button, then **New**.
21. Name the PowerForm and select **OK**.
22. Select **Add New Section**.
23. Search for and select **Ocular Adverse Reaction Severity** and select **OK**.
24. Click the **Form** button, then **Save**.
25. Select **Form**, then **Customize**.
26. Fill in the applicable details based on the organization's standards for PowerForms.
27. Click **OK** to save.
28. While still logged into DCPTOOLS.exe and under **Documentation Management**, launch **Order Task Tool**.
29. Select **Tasks**.
30. Select **Create a New Task**.
31. Fill in the fields as appropriate and click **Apply**.
32. Select the **Form/Task Link** button.
33. Select **Form View**.
34. Select **Charting Agent**.
35. Search for and select **powerform**.
36. Search for and select the **Ocular Adverse Reaction Severity PowerForm** and **Task**.
37. Move both to **Related Tasks** and select **Apply**.

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.

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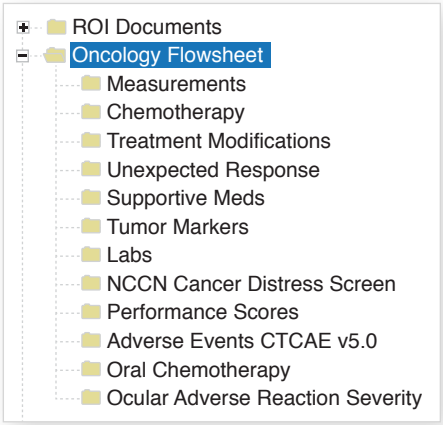
Creating a Flowsheet to Document Ocular Adverse Reaction Severity Grade (cont.)

Step for Configuring an Event Set Hierarchy (ESH) for Flowsheet

1. Log in to **coreeventmanager.exe**.
2. Click the white box next to **Registered**.
3. The **Event Set Hierarchy (ESH)** will unload.
4. Once complete, the white box has a checkmark inside it.
5. Based on organizational standards, search for the appropriate place to store the newly created **Event Code** in the ESH, select it, then click **Find**.
6. The Event Set loads.
7. Right-click and choose **Add Event Set**.
8. Name the new **Event Set** as appropriate and select **OK**.
9. Select the **Find** button.
10. Change the dropdown to **Event Codes by Display**, and search for the previously created event code.
11. Select the appropriate **Event Code** and click **Find**.
12. The event code path loads.
13. Select **...** on the far right to associate this event code to the newly created event set.
14. Search for and select the **Event Set**, click **OK**.
15. Click **Apply**.
16. In the **Oncologic** folder, right-click **Ocular Adverse Reaction Severity** Event Set, and choose **Cut/Copy Event Set**.
17. Search for and select an existing **Flowsheet** and click **Find**.
18. Right-click the **Oncology Flowsheet** Event Set and select **Paste Event Set**.
19. Unregister the ESH.



Illustrative example of an Event Set associated with the Oncology Flowsheet (recreated from Oracle Health)

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.

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

Steps for Configuring Smart Templates for Mpage Flowsheet

1. Log in to **Bedrock.exe**.
2. Select **Quality Reporting and Mpage Setup**.
3. Select **Mpage**, then **View Builder**.
4. Select **Begin**.
5. Select **Add**.
6. Select **Smart Template** from the **Layout Types** dropdown menu.
7. Name the **Smart Template**.
8. Pull across **Clinical Events** and select **Save**, then **Finish**.
9. Select **Mpage Setup**.
10. Search for the newly created Smart Template type **Mpage** and select **Next**.
11. Select **Define Mpage Layout**.
12. Select **Ok**.
13. Select **Clinical Events** and **Begin**.
14. Select **Time Range Options**, fill in as appropriate, then click **Save**.
15. Select **Result Trending Options** and set it to **5**, then click **Save**.
16. Select **Result Sorting Options** and set it to **2**, then click **Save**.
17. Select **Clinical Event Display Format** and set it to **2**, then click **Save**.
18. Select **Date Time Format** and set it to **2**, then click **Save**.

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.

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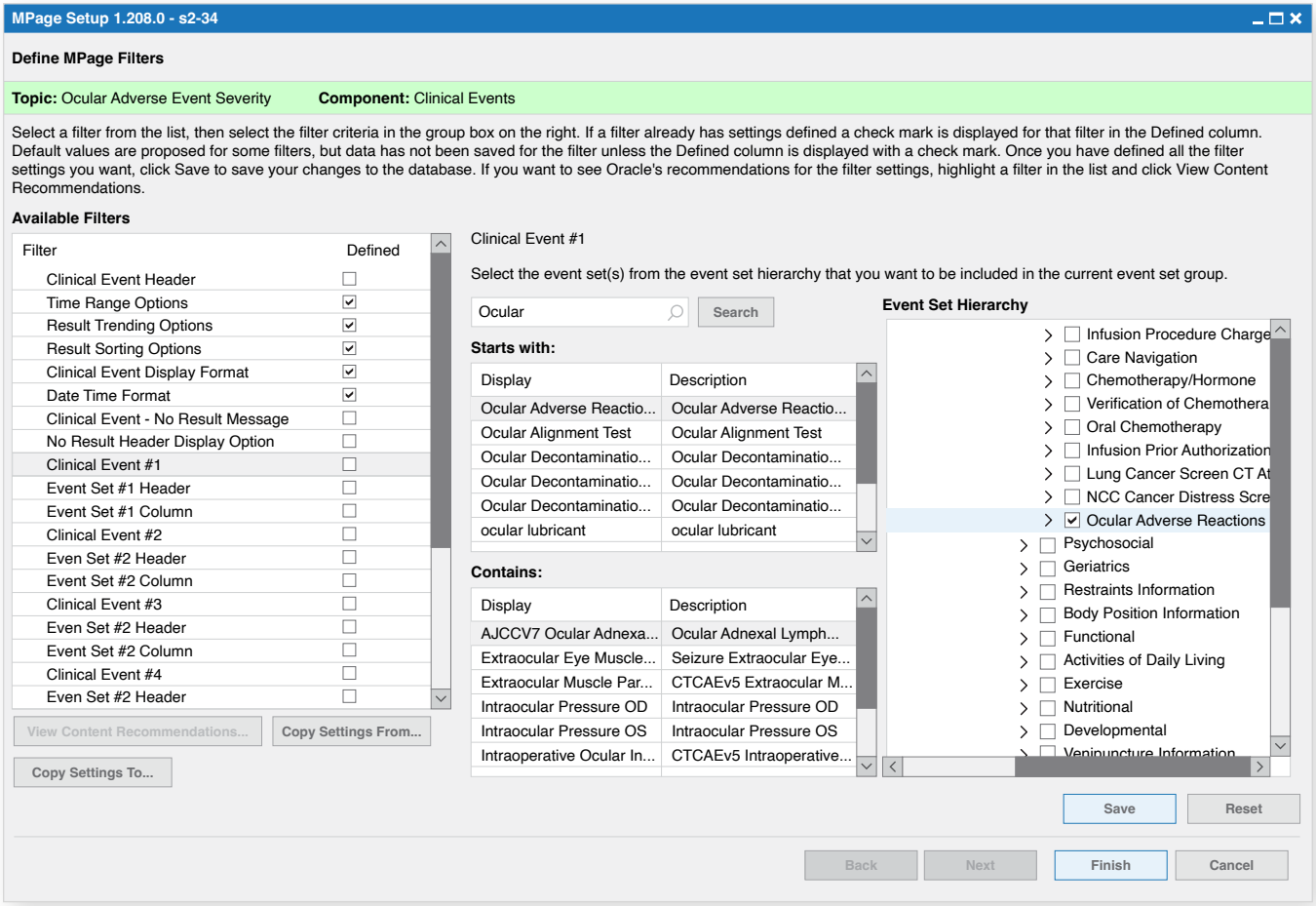
Creating a Flowsheet to Document Ocular Adverse Reaction Severity Grade (cont.)

Steps for Configuring Smart Templates for Mpage Flowsheet (cont.)

19. Select **Clinical Event #1**.
20. Search for and select **Ocular Adverse Reaction Severity Event Set**, then click **Save**.
21. Click **Finish**.



Illustrative example of Clinical Event #1 search and selection (recreated from Oracle Health)

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.

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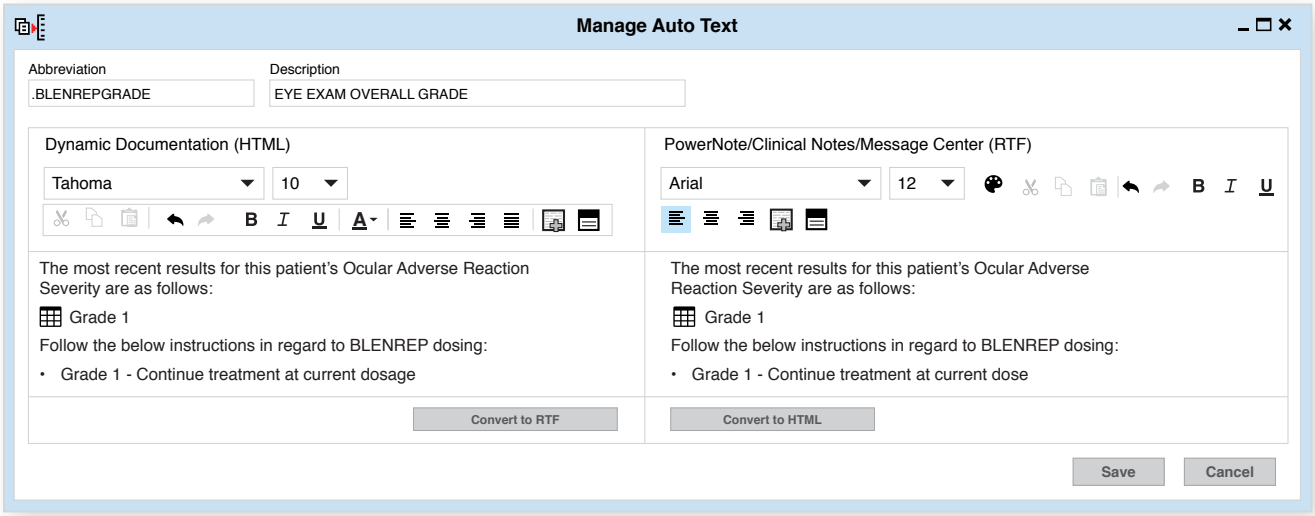
Creating an Auto Text to View or Document Ocular Adverse Reaction Severity Grade

An Auto Text phrase can be created to insert documented grading based on ophthalmic exam results into visit notes. Auto Text are shortcuts that insert predefined text into patient notes, discharge instructions, or other documentation using an abbreviated phrase. By typing a period (.) followed by the phrase, the predefined text associated with that phrase is automatically inserted.

Steps for Creating a New Auto Text

1. Log in to **scdke.exe**.
2. Select **Tools** then **Manage Auto Text**.
3. Select the ✚ to create a **New Auto Text**.
4. Type in the **Abbreviation** and **Description** that will be utilized by end users.
5. Fill in the text details as appropriate. Select the **Insert Templates/Tokens** button.
6. Search for the **Smart Template** that will pull in the Grade(s) results and select **Insert**.
7. Finalize the text for this Auto Text, select **Convert to RTF**, then click **Save**.
8. Ensure that **.BLENREPGRADE** is searchable in the **Public Phrases** library.



Illustrative example of completed Auto Text (recreated from Oracle Health)

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).

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

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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.

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.

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.

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

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