BLENREP
belantamab
mafodotin-blmf
for injection 70 mg

How to Be REMS Audit Ready

Risk Evaluation and Mitigation Strategy (REMS) audits are designed to verify that healthcare settings are following **REMS requirements**. As part of the healthcare setting's certification process in the BLENREP REMS, the Authorized Representative (AR) has agreed that the healthcare setting **must comply with audits** to ensure that all **training, processes and procedures are in place and are being followed**. A healthcare setting **becomes eligible for a BLENREP REMS audit upon generation of the first Authorization Code**, indicating the healthcare setting's **first dispense** of BLENREP. If an AR is affiliated with more than one healthcare setting, they may be involved in more than one audit in any given year. **Information in this handout will help the AR be audit ready at all times**.

How can a healthcare setting be audit ready?

- ☑ Confirm the Authorized Representative (AR) information is up-to-date. **If the AR has changed,** the new AR must re-submit a Healthcare Setting Enrollment Form to the REMS.
- ☑ Maintain training documentation of relevant staff* who have completed training with the BLENREP REMS **Program Overview** and the **Education Program for Healthcare Settings**.
- ☑ Ensure staff obtain **REMS authorization to dispense (i.e., Authorization Code)**, to verify the prescriber is certified, the healthcare setting is certified, and the patient is enrolled and authorized to receive treatment, before dispensing each BLENREP dose.
- ☑ Maintain **internal documentation of noncompliance** when REMS requirements were not followed, even if already reported to the BLENREP REMS.

* Relevant staff are staff involved in dispensing BLENREP who are responsible for obtaining REMS authorization to dispense (i.e., Authorization Code).

Always, at all times:

Healthcare setting staff must obtain **REMS authorization to dispense (i.e., Authorization Code)** to dispense each dose of BLENREP to verify the prescriber is certified, the healthcare setting is certified, and the patient is enrolled and authorized to receive treatment.

Do not distribute, transfer, loan, or sell BLENREP, **except to REMS-certified healthcare settings**.

Maintain records documenting staff's completion of training:

Recommended option: **Use the online REMS portal for training documentation**. When granting staff access to the online REMS portal, the Authorized Representative will attest the staff member(s) has been trained and enter the training date. *This is adequate documentation, as long as the Authorized Representative is actively maintaining staff access.*

Alternative options: Maintain a physical training log or records from your internal training system.

Maintain internal documentation of noncompliance incidents:

How the Authorized Representative maintains documentation of noncompliance incident(s), when REMS requirements were not followed, is dependent on the site's operations.

This documentation helps the auditor confirm the **Authorized Representative has sufficient oversight** of the BLENREP REMS at their site.

When your healthcare setting is selected for a BLENREP REMS audit:

The Authorized Representative will receive an **Audit Questionnaire** for the applicable audit time period. Completion of the questionnaire is required **within 30 calendar days** of receipt.

- Include copies of your training documentation (unless you are using the REMS portal as training documentation).
- Identify any noncompliance incidents that occurred during the audit time period, and describe what corrective actions were taken.

Information on what to expect during a BLENREP REMS audit is provided on the next page.

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What to Expect if Your Healthcare Setting Is Selected for an Audit

The Audit Questionnaire must be completed by the Authorized Representative (AR) for the certified healthcare setting within 30 calendar days. Compliance with the audit is a requirement for continued participation in the BLENREP REMS. **Failure to complete the Audit Questionnaire and the audit process could result in decertification of your healthcare setting, and affect your healthcare setting's eligibility to order and dispense BLENREP.**

STEP 1 Authorized Representative (AR) receives notification of audit.

- Day 1 (Audit Questionnaire assigned): Audit notification emailed to AR by REMS Auditor.
- Day 5 (business): Reminder call from REMS Auditor if questionnaire not completed.
- Day 14 (calendar): Automatic reminder notification from REMS Auditor if questionnaire not completed.
- Day 25 (calendar): Automatic reminder notification from REMS Auditor if questionnaire not completed.
- Day 30 (calendar) – Due Date: Final notification from REMS Auditor if questionnaire not completed.

STEP 2 AR completes questionnaire with associated documentation via online REMS portal.

- Within 30 calendar days of receipt of audit notification: AR must complete the audit questionnaire and submits completed form plus associated documentation to REMS Auditor.
- After receipt: Notification emailed by REMS Auditor confirming receipt.

If AR does not submit completed audit questionnaire and associated documentation to REMS Auditor by Day 30 (calendar), GSK will be notified to determine appropriate action.

STEP 3 REMS Auditor completes review of questionnaire and associated documentation within 10 business days of receipt.

FURTHER ACTION IS REQUIRED

REMS Auditor requests additional information.

AR sends requested information within 5 business days.

NON-COMPLIANT OR **COMPLIANT**

REMS Auditor reviews additional information and determines site to be non-compliant.

After GSK review, REMS Auditor sends notification email with **audit deficiencies identified,** and informs the AR if a **Corrective and Preventive Action (CAPA)** is needed.

If a CAPA is needed, **AR completes CAPA form within 30 calendar days**, provides clear actions to ensure REMS compliance**, and provides evidence** to demonstrate action(s) have been taken.

REMS Auditor will follow up with AR on corrective action(s) / CAPA implementations.

NON-COMPLIANT OR **COMPLIANT**

If CAPA is not submitted or is inadequate, the REMS Auditor will notify GSK.

GSK will review to determine appropriate action.
Failure to comply with BLENREP REMS requirements could result in decertification of the healthcare setting.

OR

COMPLIANT

REMS Auditor determines no further clarification required and site is determined to be compliant

REMS Auditor sends audit complete notification with "no audit findings" to the AR

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GSK

For additional information on the BLENREP REMS, visit www.BLENREPREMS.com or call 1-855-690-9572 (Mon-Fri, 8AM - 8PM ET).

For additional BLENREP REMS audit resources provided by GSK, visit www.BLENREPREMSEducation.com.