BLENREP REMS Audit Webinar
For Certified HealthCare Settings
Let's Review

1. HealthCare Setting (HCS) REMS requirements
2. How to be Audit Ready
3. How should I complete the Audit Questionnaire?
4. What does the HCS Auditor look for?
5. What happens next once I submit the completed questionnaire?
6. Will my HCS be decertified?

September 9, 2021
HealthCare Setting (HCS) REMS requirements

BEFORE ADMINISTRATION OF BLENREP

- **Train** all relevant staff involved in dispensing and administering BLENREP using:
  - Program Overview
  - Education Program for Healthcare Settings
- **Establish processes and procedures** to verify the REMS Checklist is completed and submitted for each patient
- Obtain **authorization prior to each infusion** by logging into the BLENREP REMS portal or calling the REMS Coordinating Center to verify: 1) prescriber is certified 2) patient is enrolled and authorized to receive BLENREP
- Capture required information in the **REMS Checklist** and submit it to the REMS program within 5 business days of the infusion

AT ALL TIMES

- Do not distribute, transfer, loan, or sell BLENREP (1) outside of your Healthcare Setting or (2) within your health network to a Healthcare Setting that is not REMS certified.
- Maintain records documenting staff’s completion of REMS training
- Maintain records to demonstrate all processes and procedures are in place and being followed
- Comply with audits carried out by GSK or third parties acting on behalf of GSK to ensure all processes and procedures are in place and are being followed

September 9, 2021
How to be Audit Ready

Ensure the current designated AR has completed and signed the Healthcare Setting Enrollment Form

Maintain a list of staff involved and trained in the REMS and ensure REMS training is current

Ensure all internal documents are in the most current version and describe current REMS processes and procedures adequately
What to expect if selected for audit

Day 0 – Audit questionnaire sent

Reminders (email/phone at Day 5 business, 14 calendar, @ Day 25-27 calendar and Day 30)

Day 30 – Completed questionnaire + supporting documentation due
How should I complete the Audit Questionnaire?

The questionnaire comes pre-populated with site details – confirm those are accurate.

Answer each Yes/No question as appropriate.

Provide evidence of procedures and training when you send the response back.

Don’t forget to sign and date!
What does the HCS Auditor look for

**HCS specific BLENREP REMS written procedures**
- Does it cover who performs the roles, that a REMS authorization code is obtained prior to each infusion and REMS Checklist submitted within 5 business days of infusion.

**BLENREP REMS Training**
- Was training provided to relevant staff BEFORE administration of BLENREP on the BLENREP requirements as well as the HCS written procedure?
- Evidence to support that training was done, e.g., a training log, sign-in sheet, LMS (Learning Management System) printout, etc showing names, date training taken and what staff were trained on

**Noncompliance details**
- Provide information on ALL non-compliances to the REMS at your HCS during the audit period (even if you already notified the REMS CC)

September 9, 2021
Audit Questionnaire excerpt

2. Does the HCS have processes and procedures in place to ensure the following:

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. All <strong>relevant staff</strong> involved in dispensing and/or administering BLENREP are <strong>trained</strong></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b. During treatment, and before dispensing, it is verified that the <strong>prescriber is certified</strong> in the REMS</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c. Before dispensing, it is verified that the <strong>patient is enrolled</strong> in the REMS and <strong>authorized</strong> to receive the dose of BLENREP</td>
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<tr>
<td>d. The <strong>REMS Checklist</strong> is completed and <strong>submitted</strong> for each patient <strong>within five (5) business days</strong> of infusion</td>
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<td>☐</td>
</tr>
<tr>
<td>e. BLENREP is <strong>not distributed, transferred, loaned or sold</strong> outside of their HCS</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

*Please provide documentation or summary of the processes and procedures that are in place and that they are being followed with this completed questionnaire.*
What happens next once I submit the completed questionnaire?

- Confirmation of receipt of your audit responses
- Feedback from the auditor if additional clarification is needed (look out for emails)
- QA auditor determines if site is compliant
  - Confirmation of compliance sent – see you in 3 years!
  - Non-compliance identified and sent to site with request for additional actions
Will my HCS be decertified?

Decertification is the very last step in the process (if applicable)

Only used as a last resort when:

- Stakeholders have persistent/significant non-compliance that impact patient safety (e.g., consistently bypass REMS authorization process)
- Stakeholders have significant non-compliance and refuse to implement corrective actions to address deficiencies
- Stakeholders are nonresponsive to audits and do not respond back to the QA Auditor or GSK after multiple attempts
Thank You

For more information, please contact the REMS Coordinating Center between the hours of 8am and 8pm Eastern Time, Monday through Friday, at 1-855-209-9188