

Risk Evaluation and Mitigation Strategy (REMS) Document

BLENREP™ (belantamab mafodotin) REMS Program

I. Administrative Information

Application Number: BLA 761158
Application Holder: GlaxoSmithKline
Initial REMS Approval: [08/2020]
Last modified/revised date: [09/2020]

II. REMS Goal

The goal of the BLENREP REMS is to manage the risk of ocular toxicity by:

1. Ensuring that healthcare providers are educated on the risk of ocular toxicity associated with the use of BLENREP
2. Ensuring that healthcare providers are educated and adhere to the following:
 - a. submit documentation that ophthalmic exams are being done at baseline and prior to each dose to identify ocular toxicity
 - b. counsel patients on the risk of ocular toxicity and the requirement for monitoring via ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms as described in the Prescribing Information
3. Ensuring safe use of BLENREP by:
 - a. Ensuring that BLENREP is infused in certified healthcare settings only after verification of ophthalmic exams
4. Ensuring that patients are informed about:
 - a. the risk of ocular toxicity associated with the use of BLENREP
 - b. the requirement for ophthalmic exams at baseline, prior to each dose and promptly for worsening symptoms, as described in the Prescribing Information

III. REMS Requirements

GlaxoSmithKline must ensure that healthcare providers, patients, healthcare settings, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe BLENREP must:

To become certified to prescribe

1. Review the drug's Prescribing Information.
2. Review the following: [Program Overview](#) and [Education Program for Prescribers](#).
3. Successfully complete the [Knowledge Assessment](#) and submit it to the REMS Program.
4. Enroll in the REMS by completing the [Prescriber Enrollment Form](#) and submitting it to the REMS Program.

Before treatment initiation (first dose)	<ol style="list-style-type: none"> 5. Counsel the patient on the risks associated with BLENREP, including the ocular toxicity and the requirement for monitoring via ophthalmic examinations (e.g., visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms using the Patient Guide. 6. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program. 7. Assess the patient’s ocular health by consulting an eye care professional to complete visual acuity and slit lamp examinations using the Eye Care Professional Consult Request Form. 8. Assess the patient’s ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the REMS Program using the Patient Status Form.
During treatment; before each infusion	<ol style="list-style-type: none"> 9. Assess the patient’s ocular health by consulting an eye care professional to complete visual acuity and slit lamp examinations using the Eye Care Professional Consult Request Form 10. Assess the patient’s ophthalmic consult results for appropriateness of continuing treatment. Document and submit to the REMS Program using the Patient Status Form.

2. Patients who are prescribed BLENREP:

Before treatment initiation	<ol style="list-style-type: none"> 1. Receive counseling from the prescriber using the Patient Guide. 2. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program. 3. Get an eye exam.
During treatment; before each infusion	<ol style="list-style-type: none"> 4. Get an eye exam.
At all times	<ol style="list-style-type: none"> 5. Inform the prescriber if you have signs or symptoms of worsening eyesight or eye health.

3. Healthcare Settings that dispense BLENREP must:

To become certified to dispense	<ol style="list-style-type: none"> 1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting. 2. Have the authorized representative review the Prescribing Information, Program Overview and Education Program for Health
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Care Settings.

3. Have the authorized representative enroll in the REMS Program by completing the [Healthcare Setting Enrollment Form](#) and submitting it to the REMS Program.
4. Train all relevant staff involved in dispensing BLENREP using the [Program Overview](#) and Education Program for [Health Care Settings](#).
5. Establish processes and procedures to verify the [REMS Checklist](#) is completed and submitted for each patient.

Before administering

6. Obtain authorization to dispense each dose by contacting the REMS Program to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug.
7. Complete the [REMS Checklist](#).

After administering, within 5 business days

8. Submit the [REMS Checklist](#) to the REMS Program.

To maintain certification to dispense

9. Have a new authorized representative enroll in the REMS Program by completing and submitting the [Healthcare Setting Enrollment Form](#) to the REMS program.

At all times

10. Not distribute, transfer, loan, or sell BLENREP.
11. Maintain records documenting staff's completion of REMS training.
12. Maintain records that all processes and procedures are in place and are being followed.
13. Comply with audits carried out by GlaxoSmithKline or third party acting on behalf of GlaxoSmithKline to ensure that all processes and procedures are in place and are being followed.

4. Wholesalers-distributors that distribute BLENREP must:

To be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings.
2. Train all relevant staff involved in distribution on the REMS requirements.

At all times

3. Distribute only to certified healthcare settings.
 4. Maintain records of all drug distribution.
 5. Comply with audits carried out by GlaxoSmithKline or a third party acting on behalf of GlaxoSmithKline to ensure that all processes and procedures are in place and are being followed.
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GlaxoSmithKline must provide training to healthcare providers who prescribe BLENREP.

The training includes the following educational materials: [Program Overview](#), [Education Program for Prescribers](#) and [Prescriber Knowledge Assessment](#). The training must be available online and in a hard copy format via mail or fax.

GlaxoSmithKline must provide training to healthcare settings that dispense BLENREP.

The training includes the following educational material: [Program Overview](#) and [Education Program for Healthcare Settings](#). The training must be available online and in a hard copy format via mail or fax.

To inform healthcare providers about the REMS Program and the risks and safe use of BLENREP, GlaxoSmithKline must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials-& Dissemination Plans
Healthcare providers likely to prescribe BLENREP, oncology nurses, and pharmacists	<p>REMS Letter: Healthcare Provider REMS Letter, REMS Letter for Professional Societies with attachment: REMS Factsheet</p> <ol style="list-style-type: none">1. Email within 30 calendar days of the date BLENREP is first commercially distributed and again 12 months later.<ol style="list-style-type: none">a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable.b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.2. Disseminate through field-based sales and medical representatives.3. Disseminate through the following professional societies and request the letter or content be provided to their members.<ol style="list-style-type: none">a. American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), Advanced Practitioner Society for Hematology and Oncology (APSHO), Oncology Nursing Society (ONS), National Comprehensive Cancer Network (NCCN), Society of Hematologic Oncology (SOHO), Hematology Oncology Pharmacy Association (HOPA)4. Disseminate at Professional Meetings for 12 months from the date BLENREP is first commercially distributed. <p>Fact Sheet</p> <ol style="list-style-type: none">1. Disseminate through field-based sales and medical representatives during the initial discussion with healthcare providers for 12 months after BLENREP is first commercially distributed. Field-based sales and/or medical representatives will discuss ocular toxicity and associated management messages contained in the REMS Factsheet during the visit with the health care provider.

To support REMS Program operations, GlaxoSmithKline must:

1. Authorize dispensing for each patient based on receipt of the [Patient Enrollment Form](#) and [Patient Status Form](#) on the following schedule: Authorize the first dispensing upon receipt of the [Patient Enrollment Form](#) and [Patient Status Form](#). If a completed [Patient Enrollment Form](#) and [Patient Status Form](#) are not received, the patient is not authorized to receive the drug. For subsequent dispensing, authorize dispensing based on receipt of the [Patient Status Form](#). The authorization is valid for 14 calendar days from receipt of the [Patient Status Form](#).

2. Establish and maintain a REMS Program website, www.BLENREPREMS.com. The REMS Program website must include the capability to complete prescriber and healthcare setting certification and enrollment online, the capability to enroll and manage patients online, the capability to review patient enrollment status and prescriber and healthcare facility certification status, the capability to search for a REMS certified prescriber or healthcare facility, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
3. Make the REMS Program website fully operational and all REMS materials available through www.BLENREPREMS.com and the REMS Program call center.
4. Establish and maintain a REMS Program call center for REMS participants at [1-855-209-9188].
5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the BLENREP REMS Program.
6. Ensure prescribers and healthcare settings are able to complete the certification process online and by fax.
7. Ensure prescribers are able to use the Eye Care Professional Consult Request Form by fax and to adapt it as a template to use within healthcare information technology system software
8. Ensure healthcare settings are able to obtain authorization to dispense BLENREP by phone and online.
9. Ensure healthcare settings are able to complete and submit the [REMS Checklist](#) online or by fax.
10. Provide [Prescriber Enrollment Form](#), [Patient Enrollment Form](#), [Healthcare Setting Enrollment Form](#), [Program Overview](#), [Education Program for Prescribers](#), [Eye Care Professional Consult Request Form](#), [Patient Status Form](#), [REMS Checklist](#), [Education Program for Healthcare Settings](#), [Patient Guide](#) and the Prescribing Information to prescribers or healthcare settings who want to prescribe/dispense BLENREP but are not yet certified.
11. Notify prescribers and healthcare settings within 2 business days after they become certified in the REMS Program.
12. Provide certified prescribers access to the database of certified healthcare settings and their enrolled patients.
13. Provide certified healthcare settings access to the database of certified prescribers and enrolled patients.
14. Provide authorized wholesalers-distributors access to the database of certified healthcare settings.

To ensure REMS participants' compliance with the REMS Program, GlaxoSmithKline must:

15. Verify annually that the designated authorized representative for the healthcare setting is the same. If different, the healthcare setting must re-certify with a new authorized representative.
16. Notify healthcare settings if a completed REMS Checklist has not been received by the REMS.
17. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: drug distribution and administration; certification of prescribers and healthcare settings; enrolled patients; and audits of health care settings and wholesalers-distributors. These records must be readily available for FDA inspections.
18. Establish a plan for addressing noncompliance with REMS Program requirements.
19. Monitor prescribers and healthcare settings on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
20. Audit certified health care settings no later than 180 calendar days after they have dispensed BLENREP, and once every 3 years thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.

21. Audit wholesalers-distributors that have distributed BLENREP no later than 90 calendar days after they become authorized to distribute the drug and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
22. Take reasonable steps to improve implementation of and compliance with the requirements in the BLENREP REMS Program based on monitoring and evaluation of the BLENREP REMS Program.

IV. REMS Assessment Timetable

GlaxoSmithKline must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. GlaxoSmithKline must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the BLENREP REMS:

Enrollment Forms

Prescriber:

1. [Prescriber Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Healthcare Setting:

3. [Healthcare Setting Enrollment Form](#)

Patient Care Forms

4. [Patient Status Form](#)
5. [REMS Checklist](#)
6. [Eye Care Professional Consult Request Form](#)

Training and Educational Materials

Prescriber:

7. [Program Overview](#)
8. [Education Program for Prescribers](#)
9. [Prescriber Knowledge Assessment](#)

Patient:

10. [Patient Guide](#)

Healthcare Setting:

11. [Program Overview](#)
12. [Education Program for Health Care Settings](#)

Communication Materials

13. [Healthcare Provider REMS Letter](#)

14. [REMS Fact Sheet](#)
15. [REMS Letter for Professional Societies](#)

Other Materials

16. [Program website](#)