BLENREP REMS (Risk Evaluation and Mitigation Strategy)

The BLENREP REMS is a safety program that manages the risk of ocular toxicity from BLENREP. The BLENREP REMS is required by the Food and Drug Administration (FDA) to ensure the potential benefits of BLENREP outweigh its risks. BLENREP is only available through the BLENREP REMS, a restricted distribution program.

PRESCRIBERS

Prescribers must become certified in the BLENREP REMS to prescribe BLENREP.

LEARN ABOUT PRESCRIBER CERTIFICATION.

LEARN MORE

HEALTHCARE SETTINGS

Healthcare settings must become certified in the BLENREP REMS to order and dispense BLENREP.

LEARN ABOUT HEALTHCARE SETTING CERTIFICATION.

LEARN MORE

PATIENTS

Patients who are prescribed BLENREP must be enrolled in the BLENREP REMS.

LEARN ABOUT PATIENT ENROLLMENT.

LEARN MORE

To learn more about the risks associated with BLENREP please refer to the **Prescribing Information**, including Boxed Warning, and the **Medication Guide**.

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This site is intended for US residents only.
BLENREP REMS: 1-855-209-9188 Monday-Friday, 8:00am - 8:00pm ET

BLENREP
belantamab
mafodotin-blmf
for injection 100 mg

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To report side effects please contact GlaxoSmithKline at 1-888-825-5249 or FDA at www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088).

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Prescribers

BLENREP is only available through the BLENREP REMS. In order for a prescriber to prescribe BLENREP, they must become certified.

To Become Certified in the BLENREP REMS, Prescribers Must:

1. Complete the training program, which includes reviewing the following educational materials:
   - *Prescribing Information*
   - *Program Overview*
   - *Education Program for Prescribers*
2. Successfully complete and submit the *Knowledge Assessment*
   - Online
   - By fax at 1-888-635-1044
3. Enroll in the program by completing the *Prescriber Enrollment Form* and submitting it to the BLENREP REMS
   - Online
   - By fax at 1-888-635-1044
4. The Healthcare Setting where BLENREP will be administered to the patient also needs to be enrolled in the REMS. If this is at your clinic, please refer to the Healthcare Setting Instructions within the *Program Overview*. If this is not at your clinic, then reach out to the Healthcare Setting to inform them that they need to enroll in the REMS.

The BLENREP REMS will send confirmation of a prescriber's enrollment within 2 business days, including the prescriber's assigned BLENREP REMS identification number. You will not be able to prescribe BLENREP without completing your certification in the BLENREP REMS. If you fail to comply with the BLENREP REMS requirements, you will no longer be able to participate in the BLENREP REMS.

How Do I Enroll a Patient in the BLENREP REMS Program?

1. **Counsel** your patient using the *Patient Guide* about:
   - the risk of ocular toxicity and
   - the requirement for monitoring via ophthalmic exams (visual acuity and slit lamp):
     - at baseline
     - prior to each dose and
     - promptly for worsening symptoms
2. **Complete and submit** the *Patient Enrollment Form*:
   - Online
   - By fax at 1-888-635-1044

The BLENREP REMS will send confirmation of a patient's enrollment within 2 business days, including the patient's assigned BLENREP REMS identification number. Patients who are prescribed BLENREP must be enrolled in the BLENREP REMS.

Patient Management:

Before Treatment

- **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* or equivalent.
- **Assess** the patient's ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the BLENREP REMS using the *Patient Status Form*.

During Treatment

- **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* or equivalent
- **Assess** the patient's ophthalmic consult results for corneal adverse reactions, which are based on both corneal examination findings and changes in best-corrected visual acuity (BCVA).
- **Manage** corneal adverse reactions per **Table 1. Dosage Modifications for Corneal Adverse Reactions per the Keratopathy and Visual Acuity (KVA) Scale** in the *Prescribing Information* with dose reductions or withhold BLENREP until improvement or permanently discontinue based on severity
- If continuation of therapy is appropriate, document and submit the *Patient Status Form* to the BLENREP REMS
  - Online
  - By fax at 1-888-635-1044

Notifiy the BLENREP REMS if an enrolled patient who has received BLENREP is no longer under your care or has discontinued treatment.

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Healthcare Settings

BLENREP is only available through the BLENREP REMS. In order for a Healthcare Setting to order and dispense BLENREP, they must become certified. Certified Healthcare Settings may access BLENREP through BLENREP-authorized Specialty Distributors contracted with GlaxoSmithKline.

To Become Certified in the BLENREP REMS, Healthcare Settings Must:

1. Designate an Authorized Representative.
2. Review the *Prescribing Information*, *Program Overview* and the *Education Program for Healthcare Settings*.
3. Complete and submit the *Healthcare Setting Enrollment Form*.
   - Online
   - By fax at 1-888-635-1044

The BLENREP REMS will send confirmation of a Healthcare Setting's enrollment within 2 business days, including the Healthcare Setting's assigned BLENREP REMS identification number. The Healthcare Setting will not be able to order or dispense BLENREP without completing certification in the BLENREP REMS. If the Healthcare Setting fails to comply with the BLENREP REMS requirements, the Healthcare Setting will no longer be able to participate in the BLENREP REMS.

Instructions for Healthcare Settings:

Before administering:

1. Train all relevant staff involved in dispensing and administering BLENREP using:
   - *Program Overview*
   - *Education Progam for Healthcare Settings*
2. Establish processes and procedures to verify the REMS Checklist is completed and submitted for each patient.
3. Obtain authorization to administer each dose by logging into the BLENREP REMS portal to verify*:
   - prescriber is certified
   - patient is enrolled and authorized to receive BLENREP

After administering, within 5 business days:

1. Capture the dose and date of infusion in the online *REMS Checklist* and submit it to the REMS within 5 business days of the infusion.
   - Online
   - By fax at 1-888-635-1044

To maintain certification to administer:

1. Have a new authorized representative enroll in the REMS Program by completing the *Healthcare Setting Enrollment Form* and submitting it to the REMS program if the authorized representative changes.

At all times:

1. Do not distribute, transfer, loan, or sell BLENREP.
2. Maintain records documenting staff's completion of REMS training.
3. Maintain records to demonstrate all processes and procedures are in place and being followed
4. Comply with audits carried out by GlaxoSmithKline or third parties acting on behalf of GlaxoSmithKline to ensure all processes and procedures are in place and are being followed.

***Alternatively, you may contact the BLENREP REMS Coordinating Center at 1-855-209-9188 to verify this information and obtain the authorization to dispense BLENREP.**

Who Can Be an Authorized Representative?

An Authorized Representative at the Healthcare Setting can be a:

- Pharmacist
- Physician
- Director of Healthcare Setting
- Nurse
- Nurse Practioner
- Physician Assistant
- Or any responsible individual in the Healthcare Setting

Please check with your manager to ensure the appropriate person represents the Healthcare Setting and attests to the enrollment requirements as stated on the *Healthcare Setting Enrollment Form*.

One representative needs to enroll per Healthcare Setting (the "authorized representative"). One authorized representative can manage more than one Healthcare Setting and has the ability to add additional users to the online portal.

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Patients

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS.

BLENREP has a REMS because of the risk of eye problems. The BLENREP REMS educates patients and doctors about the risks associated with BLENREP. You must be enrolled in the BLENREP REMS to get BLENREP.

How Do I Enroll in the BLENREP REMS and What Is Required of Me?

1

Your healthcare provider will go over this *Patient Guide* with you to ensure that you understand:

- Eye problems are common with BLENREP.
- The risk of eye problems while you are on treatment with BLENREP, which can cause changes to the surface of your eye that can lead to dry eyes, blurred vision, worsening vision, severe vision loss, and corneal ulcer.
- The need to see an eye specialist to check your eyes:
  - before starting treatment with BLENREP
  - prior to each dose of BLENREP
  - if you have worsening symptoms of eye problems
- Even if your vision seems fine, it is important that you get your eyes checked during treatment with BLENREP because some changes can happen without symptoms and may only be seen on an eye exam.
- You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.
- You should use caution when driving or operating machinery as BLENREP may affect your vision.
- Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye specialist.

2

Your healthcare provider will help you complete and sign the *Patient Enrollment Form* to enroll you in the BLENREP REMS.

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Certified Participant Locator

This may not be an all-inclusive list. Please discuss with your Healthcare Provider.

Please enter a street address, city, state, or ZIP Code you would like to search for.

*Find a Certified Participant near:

*Search Radius:

Within 25 miles

SEARCH

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CERTIFIED PRESCRIBERS | CERTIFIED HEALTCHARE SETTINGS

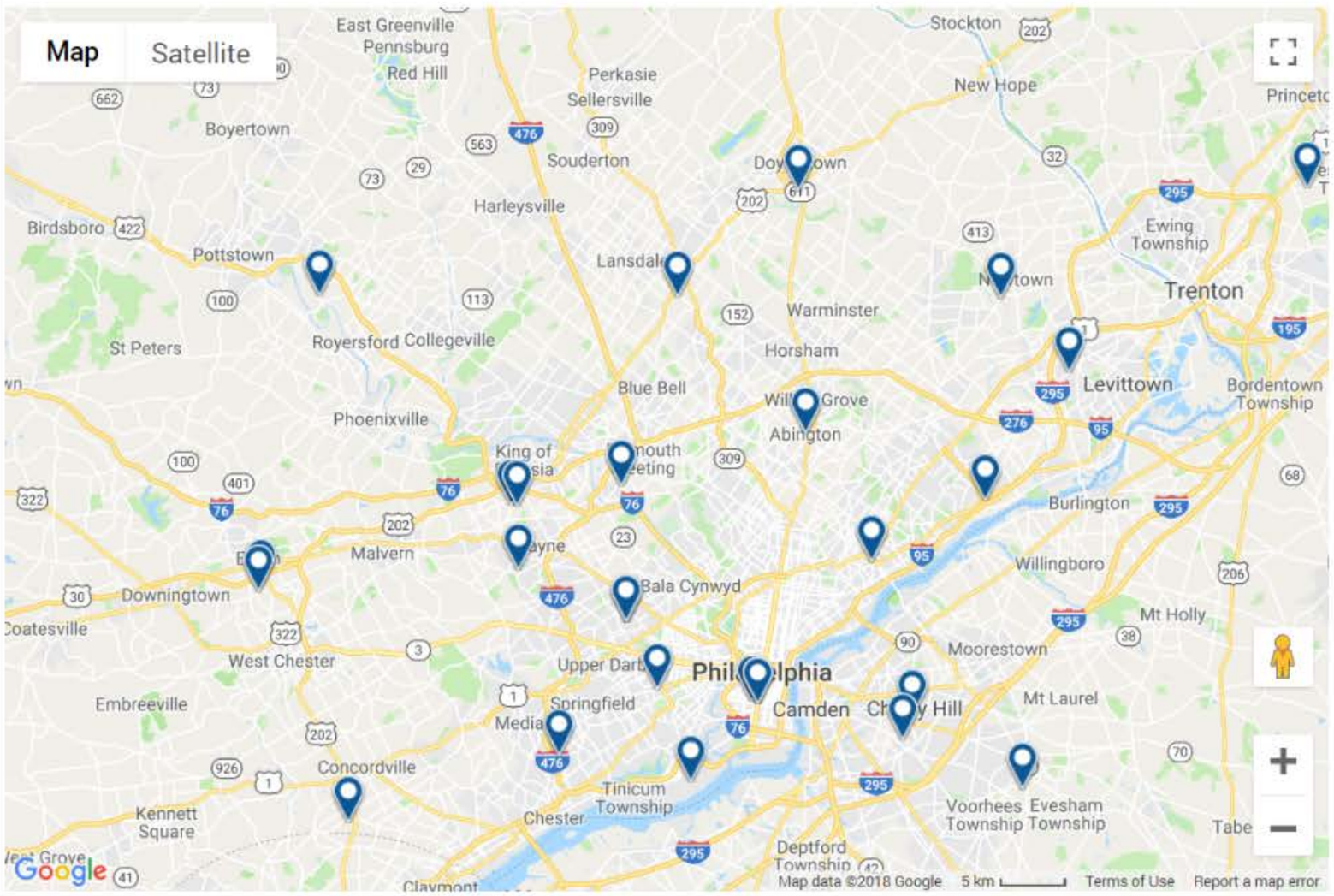
*Find a Certified Participant near:

12345

*Search Radius:

Within 25 miles

SEARCH



PRESCRIBER NAME 75.1 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

PRESCRIBER NAME 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

PRESCRIBER NAME 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

PRESCRIBER NAME 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

PRESCRIBER NAME 76.2 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

PRESCRIBER NAME 76.6 miles
100 Main St
DIRECTIONS

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CERTIFIED PRESCRIBERS | **CERTIFIED HEALTCHARE SETTINGS**

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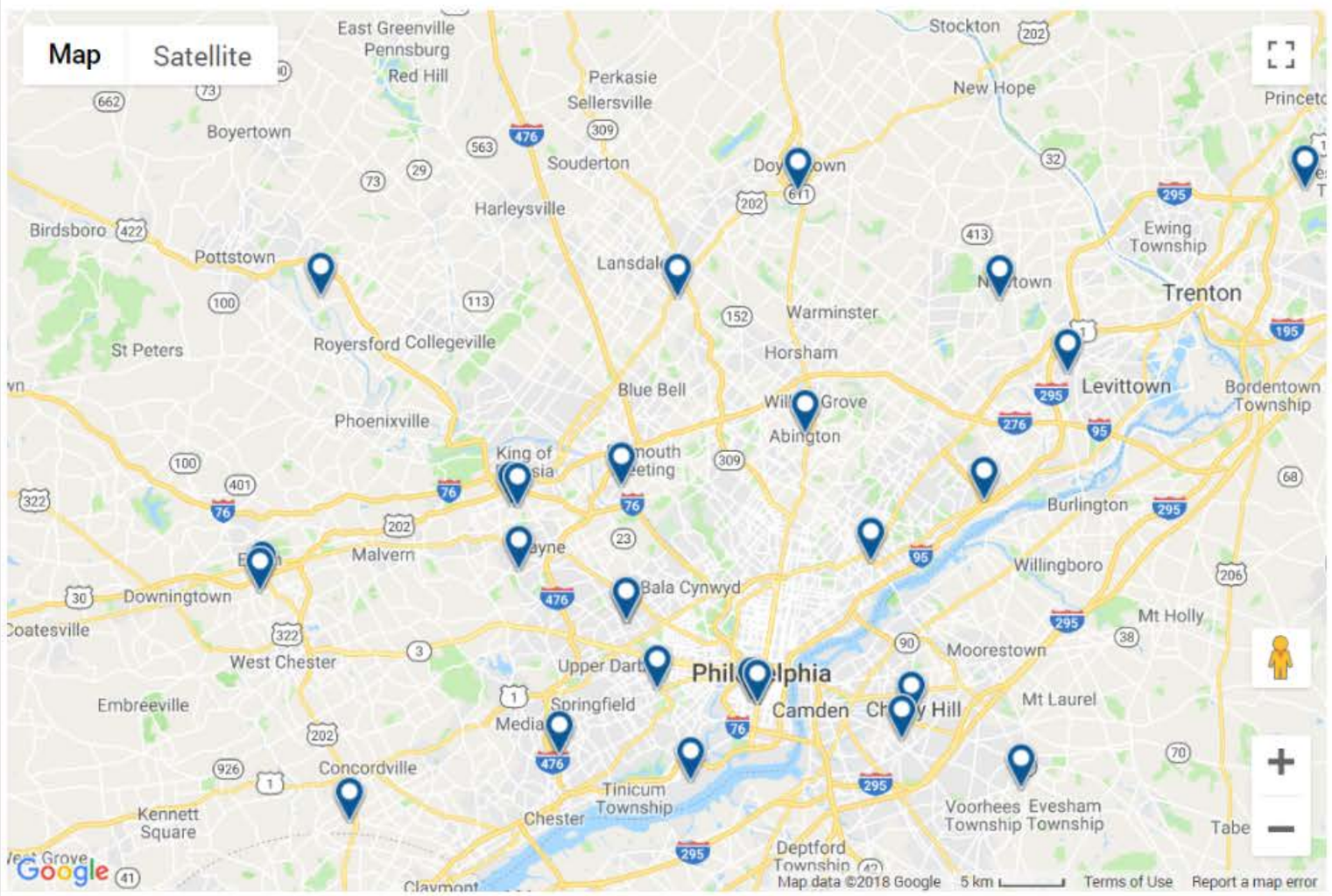
12345

*Search Radius:

Within 25 miles

SEARCH



HCS NAME 75.1 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

HCS NAME 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
DIRECTIONS

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HCS NAME 76.6 miles
100 Main St
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Resources

PRESCRIBERS

- Program Overview
- Education Program for Prescribers
- Knowledge Assessment
- Prescriber Enrollment Form
- Patient Status Form
- Eye Care Professional Consult Request Form
- Healthcare Provider Letter
- Professional Society Letter
- BLENREP REMS Fact Sheet

HEALTHCARE SETTINGS

- Program Overview
- Education Program for Healthcare Settings
- Healthcare Setting Enrollment Form
- REMS Checklist

PATIENTS

- Medication Guide
- Patient Guide
- Patient Enrollment Form

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Contact Us

PHONE

1-855-209-9188

FAX

1-888-635-1044

HOURS OF OPERATION

Monday - Friday
8:00 AM - 8:00 PM
Eastern Time

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BLENREP
belantamab mafodotin-blmf
for injection 100 mg

Login

Login / Register

Login is available to certified prescribers, healthcare settings, and other users authorized by the REMS Coordinating Center.

User Name

LOGIN

Forgot Username

OR

Don't have an online account?

Register

To create your web account for the BLENREP REMS, please select whether you are registering as a Prescriber or Healthcare Setting.

* I want to register as a:
○ Prescriber ○ Healthcare Setting

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DORIS A AUTH
11/13/2020 11:18:17 AM

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