

Risk Evaluation and Mitigation Strategy (REMS) Document

BLINCYTO® (blinatumomab) REMS Program

I. Administrative Information

Application Number: BLA 125557
Application Holder: Amgen, Inc.
Initial REMS Approval: 12/2014
Most Recent REMS Update: Month/2021

II. REMS Goals

The goals of the BLINCYTO REMS are to mitigate the risk of cytokine release syndrome which may be life-threatening or fatal; the risk of neurological toxicities which may be severe, life-threatening, or fatal; and the risk of preparation and administration errors associated with use of BLINCYTO by:

1. Informing healthcare providers about the risk of cytokine release syndrome which may be life-threatening or fatal
2. Informing healthcare providers about the risk of neurological toxicities which may be severe, life-threatening, or fatal
3. Informing pharmacists, who will prepare and dispense BLINCYTO, and nurses, who will administer BLINCYTO, about the risk of preparation and administration errors associated with use of BLINCYTO.

III. REMS Requirements

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

Target Audience	Communication Materials & Dissemination Plans
Healthcare providers including oncologists, oncology physician assistants, oncology nurse practitioners, hematologists, oncology nurses, home healthcare oncology nurses, and infusion nurses; healthcare providers who have prescribed BLINCYTO within the previous 12 months from the approval of this REMS modification; healthcare providers who are likely to prescribe or administer BLINCYTO	<p>REMS Letter: REMS Letter for Healthcare Provider or REMS Letter for Professional Societies with attachment Fact Sheet for Providers</p> <ol style="list-style-type: none">1. Email within 60 calendar days of approval of the REMS modification (Month/2021) 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. Make available via a link from the BLINCYTO REMS Program Website.3. Disseminate through field-based sales and medical representatives for 6 months from approval of the REMS modification (Month/2021).4. Disseminate to professional societies within 60 calendar days of the approval of the REMS modification (Month/2021), again 12 months later and request the letter or content be provided to their members.5. Disseminate at Professional Meetings for 6 months from approval of the REMS modification (Month/2021).

Target Audience**Communication Materials & Dissemination Plans**

Fact Sheet for Providers

1. Disseminate and prominently display at Professional Meetings where Amgen has a presence for 6 months from approval of the REMS modification (Month/2021).
2. Disseminate through field-based sales and medical representatives during the initial or follow-up discussion with healthcare providers for 6 months from approval of the REMS modification (Month/2021). Field-based sales or medical representatives to orally review the risk messages contained in the [Fact Sheet for Providers](#) during the visit with the healthcare provider.

Hospital-based pharmacists and home healthcare pharmacists

REMS Letter: [REMS Letter for Hospital and Home Healthcare Pharmacists](#) or [REMS Letter for Professional Societies](#) with attachment [Fact Sheet for Providers](#)

1. Email within 60 calendar days of the approval of the REMS modification (Month/2021) and again 12 months later.
 - a. Send by mail within 30 calendar days of the date the first email was sent if a pharmacist'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. Make available via a link from the BLINCYTO REMS Program Website.
3. Disseminate through field-based sales and medical representatives for 6 months from approval of the REMS modification (Month/2021).
4. Disseminate to professional societies within 60 calendar days of the approval of the REMS modification (Month/2021), again 12 months later, and request the letter or content be provided to their members.
5. Disseminate at Professional Meetings for 6 months from approval of the REMS modification (Month/2021).

Fact Sheet for Providers

1. Disseminate and prominently display at Professional Meetings where Amgen has a presence for 6 months from approval of the REMS modification (Month/2021).
2. Disseminate through field-based sales and medical representatives during the initial or follow-up discussion with healthcare providers for 6 months from approval of the REMS modification (Month/2021). Field-based sales or medical representatives to orally review the risk messages contained in the [Fact Sheet for Providers](#) during the visit with the healthcare provider.

REMS Program Website

1. Include all currently approved REMS materials, Prescribing Information, and Medication Guide.
2. Include a prominent REMS-specific link to the BLINCYTO REMS Program website. The BLINCYTO REMS Program website must not link back to the promotional product website.

Target Audience**Communication Materials & Dissemination Plans**

3. Continue for 3 years from approval of the REMS modification (Month/2021).
 4. Update all information within 60 calendar days from approval of the REMS modification (Month/2021).
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IV. REMS Assessment Timetable

Amgen must submit REMS Assessments at 18 months, 3 years, 5 years, and 7 years from the date of the initial REMS approval (12/03/2014). 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. Amgen 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 BLINCYTO REMS:

Communication Materials

1. [REMS Letter for Healthcare Provider](#)
2. [REMS Letter for Hospital and Home Healthcare Pharmacists](#)
3. [REMS Letter for Professional Societies](#)
4. [Fact Sheet for Providers](#)

Other Materials

5. [REMS Program Website](#)