

**Initial REMS approval: 12/2014**

**Most recent modification: 08/2016**

**BLA 125557**  
**BLINCYTO® (blinatumomab)**  
**Bispecific CD19-directed CD3 T-cell engager**

Amgen, Inc.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799  
1-805-447-1000

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL(S):**

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:

- Informing healthcare providers about the risk of cytokine release syndrome which may be life-threatening or fatal
- Informing healthcare providers about the risk of neurological toxicities which may be severe, life-threatening, or fatal
- 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

**II. REMS ELEMENTS**

**A. Communication Plan**

Amgen must implement the following communication plan to healthcare providers likely to prescribe and pharmacists likely to dispense BLINCYTO. The communication plan must include:

**1. REMS Letters**

- Amgen must send a *REMS Letter for Healthcare Providers*, a *REMS Letter for Hospital and Home Healthcare Pharmacists*, and a *REMS Letter for Professional Societies* within 60 calendar days from the date of approval of this REMS modification (August 2016). Amgen must send a second emailing 12 months from the date of approval of this REMS modification. The REMS Letters must address 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. Email must be the

primary method to disseminate the REMS Letters. If an email is marked as unopened, a second email must be sent within 30 calendar days of the date the first email was sent. If the second email is marked as unopened, the REMS Letters must be mailed within 30 calendar days of the date the second email was sent. If a healthcare provider's, pharmacist's or professional society's email address is not available or if the email is undeliverable, the REMS Letters must be mailed within 30 calendar days of the date the first sets of emails were sent. A copy of or link to the Prescribing Information (PI) and *REMS Fact Sheet* must accompany each REMS Letter. Amgen must make the *REMS Letter for Healthcare Providers* and *REMS Letter for Hospital and Home Healthcare Pharmacists* available via a link from the *BLINCYTO REMS Program Website* and through Amgen field based sales and medical representatives upon request for 12 months after the approval of this REMS modification.

- **REMS Letter for Healthcare Providers:** The intended audience for the *REMS Letter for Healthcare Providers* must be oncologists, oncology physician assistants, oncology nurse practitioners, hematologists, oncology nurses, home healthcare oncology nurses, and infusion nurses. This includes healthcare providers who have prescribed BLINCYTO within the previous 12 months from the approval of this REMS modification and healthcare providers likely to prescribe or administer BLINCYTO.
- **REMS Letter for Hospital and Home Healthcare Pharmacists:** The intended audience for the *REMS Letter for Hospital and Home Healthcare Pharmacists* must be hospital-based pharmacists and home healthcare pharmacists.
- **REMS Letter for Professional Societies:** The intended audience for the *REMS Letter for Professional Societies* must be the following professional societies and organizations. Amgen must request the letter or content be provided to the societies' members:
  - American Society of Clinical Oncology (ASCO)
  - American Society of Hematology (ASH)
  - Oncology Nursing Society (ONS)
  - National Comprehensive Cancer Network (NCCN)
  - Hematology Oncology Pharmacy Association (HOPA)
  - American Pharmacists Association (APhA)
  - American Society of Health System Pharmacists (ASHP)
  - Home Health Nurses Association (HHA)
  - National Association for Home Care & Hospice (NAHCH)
  - Advanced Practitioner Society for Hematology and Oncology (APSHO)
  - American Society of Pediatric Hematology/Oncology (ASPHO)
  - Association of Pediatric Hematology/Oncology Nurses (ASPHON)

2. **REMS Fact Sheet:** A *BLINCYTO REMS Fact Sheet for Providers* must be made available for healthcare providers and disseminated through Amgen's field based sales or medical representatives during the initial or follow-up discussion with healthcare providers within the first 12 months after the approval of this REMS modification (August 2016). Amgen's field based sales or medical representatives must orally review the risk messages contained in the *BLINCYTO REMS Fact Sheet for Providers* during the visit with the healthcare provider.
3. **Dissemination of REMS information at Scientific Meetings:** The BLINCYTO REMS materials must be prominently displayed and disseminated together with responses to medical information requests at all relevant scientific meetings where Amgen has a presence (e.g., exhibit booth) for 12 months following the approval of this REMS modification (August 2016).
4. **REMS Program Website:** The *BLINCYTO REMS Program Website* ([www.blincytoREMS.com](http://www.blincytoREMS.com)) must continue for 3 years from the date of initial approval of the REMS (12/03/2014). The *BLINCYTO REMS Program Website* must include the option to print the currently approved PI, Medication Guide, *REMS Letter for Healthcare Providers*, *REMS Letter for Hospital and Home Healthcare Pharmacists*, and *REMS Factsheet*. The BLINCYTO product website must include a prominent REMS-specific link to the *BLINCYTO REMS Program Website*. All website information must be updated within 60 calendar days from the date of approval of this REMS modification (August 2016).

The following are part of the BLINCYTO REMS and are appended:

- *REMS Letter for Healthcare Providers* (email and print versions)
- *REMS Letter for Hospital and Home Healthcare Pharmacists* (email and print versions)
- *REMS Letter for Professional Societies* (email and print versions)
- *BLINCYTO REMS Fact Sheet for Providers*
- *BLINCYTO REMS Program Website*

### III. Timetable for Submission of Assessments

Amgen must submit REMS Assessments to the FDA at 18 months, 3 years, and 7 years from the date of the initial approval of the REMS (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.