



Risk Evaluation and Mitigation Strategy (REMS)

Boxed Warning

CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving BREYANZI[®]. Do not administer BREYANZI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.
- BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS.

Access BREYANZI online REMS training and Knowledge Assessment:

[HEALTHCARE FACILITY STAFF >](#)

Access BREYANZI REMS online resources:

[AUTHORIZED REPRESENTATIVES >](#)

CONTACT

For more information about BREYANZI REMS, call
1-888-423-5436.

RESOURCES

- ± [BREYANZI Prescribing Information](#)
- ± [BREYANZI Medication Guide](#)
- ± [BREYANZI REMS Knowledge Assessment](#)
- ± [BREYANZI REMS Live Training Program](#)
- ± [BREYANZI REMS Patient Wallet Card](#)

About BREYANZI REMS

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the United States (US) Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. BREYANZI is available only under a restricted program called BREYANZI REMS because of the serious risks of CRS and neurologic toxicities.

The goals of BREYANZI REMS are to mitigate the risks of CRS and neurologic toxicities by:

1. Ensuring that hospitals and associated clinics that dispense BREYANZI are specially certified and have on-site immediate access to tocilizumab.
2. Ensuring that those who prescribe, dispense, or administer BREYANZI are aware of how to manage the risks of CRS and neurologic toxicities.

BREYANZI REMS Requirements

All hospitals and their associated clinics must be certified and enrolled in the BREYANZI REMS to be able to infuse BREYANZI.

All relevant staff involved in the prescribing, dispensing, or administering of BREYANZI are trained on BREYANZI REMS requirements, and must successfully complete the BREYANZI REMS Knowledge Assessment.

Hospital and Associated Clinic Enrollment Instructions

To become certified to infuse BREYANZI, hospitals and associated clinics must designate an authorized representative (AR) to complete REMS requirements and enroll in BREYANZI REMS. The AR must:

1. Complete the BREYANZI REMS Live Training (live in-person or via webcast).
2. Successfully complete and submit a BREYANZI REMS Knowledge Assessment.
3. Oversee the implementation of and compliance with BREYANZI REMS to:
 - Ensure all relevant staff involved in prescribing, dispensing, or administering of BREYANZI are trained on the REMS requirements and successfully complete the BREYANZI REMS Knowledge Assessment, and maintain records of staff training.
 - Put processes and procedures in place to ensure that staff involved in the prescribing, dispensing, or administering of BREYANZI are retrained on BREYANZI REMS if BREYANZI has not been dispensed at least once annually from the date of certification in the BREYANZI REMS.
 - Dispense BREYANZI only after verifying a minimum of 2 doses of tocilizumab are available on-site for each patient and ready for immediate administration (within 2 hours).
 - Prior to infusion, provide patients/caregivers with the Patient Wallet Card and instruct patients to remain within 2 hours of the certified hospital and its associated clinics for at least 4 weeks following BREYANZI infusion.
 - Ensure that, if the hospital and its associated clinics designate a replacement AR, the replacement AR must take the BREYANZI REMS Live Training Program (in-person or via live webcast), complete the BREYANZI REMS Knowledge Assessment, and complete/submit a new BREYANZI REMS Enrollment Form.
4. Submit a completed BREYANZI REMS Enrollment Form online.

Report suspected adverse reactions to Bristol Myers Squibb at www.bms.com or **1-888-805-4555** or to the FDA at www.fda.gov/medwatch or by calling **1-800-FDA-1088**.

Indication

BREYANZI is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma, after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Limitation of Use: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.



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- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concomitantly with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.
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1. Ensuring that hospitals and associated clinics that dispense BREYANZI are specially certified and have on-site immediate access to tocilizumab.
2. Ensuring that those who prescribe, dispense, or administer BREYANZI are aware of how to manage the risks of CRS and neurologic toxicities.

BREYANZI REMS Requirements

All hospitals and their associated clinics must be certified and enrolled in the BREYANZI REMS to be able to infuse BREYANZI.

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1. Complete the BREYANZI REMS Live Training (in-person or via webcast).
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 3. Oversee the implementation of and compliance with BREYANZI REMS to:
 - Ensure all relevant staff involved in prescribing, dispensing, or administering of BREYANZI are trained on the REMS requirements and successfully complete the BREYANZI REMS Knowledge Assessment, and maintain records of staff training.
 - Put processes and procedures in place to ensure that staff involved in the prescribing, dispensing, or administering of BREYANZI are trained on BREYANZI REMS if BREYANZI has not been dispensed at least once annually from the date of certification in the BREYANZI REMS.
 - Dispense BREYANZI only after verifying a minimum of 2 doses of tocilizumab are available on-site for each patient and ready for immediate administration (within 2 hours).
 - Prior to infusion, provide patients/caregivers with the Patient Relief Card and instruct patients to remain within 2 hours of the certified hospital and its associated clinics for at least 4 weeks following BREYANZI infusion.
 - Ensure that, if the hospital and its associated clinic designate a replacement AR, the replacement AR must take the BREYANZI REMS Live Training Program (in-person or via live webcast), complete the BREYANZI REMS Knowledge Assessment, and complete/submit a new BREYANZI REMS Enrollment Form.
 4. Submit a completed BREYANZI REMS Enrollment Form online.
- Report successful enrollment reactions to Bristol Myers Squibb at www.bms.com or **1-800-805-4535** or to the FDA at www.fda.gov/medwatch or by calling **1-800-FDA-1088**.

Indication

BREYANZI is a CD19-directed genetically modified subpopulation T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from t(14q24) translocation), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 2B.

Limitation of Use: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.

Access BREYANZI online REMS training and Knowledge Assessment:

[MULTICARE FACILITY \(MFP\)](#)

Access BREYANZI REMS online resources:

[CUSTOMER SUPPORT CENTER](#)

CONTACT

For more information about BREYANZI REMS, call **1-800-423-5434**.

RESOURCES

- [BREYANZI Prescribing Information](#)
- [BREYANZI Product Information](#)
- [BREYANZI REMS Knowledge Assessment](#)
- [BREYANZI REMS Live Training Program](#)
- [BREYANZI REMS Patient Relief Card](#)

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Terms of Use



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Online REMS Training and Knowledge Assessment

For Healthcare Facility Staff

*Required

REMS Site ID *

No REMS Site ID? Please contact your DREYANZI REMS Authorized Representative.

NEXT

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Authorized Representative Access

Email Address *

[Send Code](#)

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