



8/20/2021

## **MEMORANDUM**

TO: Monoclonal Antibody Therapy Provider Sites in Illinois  
Hospital and Infusion Site Administrators  
Hospital and Infusion site Pharmacists  
Regional Hospital Coordinating Centers  
Local Health Departments

FROM: Ashley Thoele, MSN, MBA, RN  
Division Chief, EMS and Highway Safety  
Office of Preparedness and Response

RE: **FDA Authorizes Shelf-life extension of bamlanivimab**

The Assistant Secretary for Preparedness and Response and the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services are committed to transparent communication regarding the COVID-19 monoclonal antibody treatments currently authorized for emergency use in certain patients with COVID-19.

FDA and ASPR are announcing the authorization of an extension to the shelf-life from 12 months to 18 months for the refrigerated Eli Lilly monoclonal antibody, bamlanivimab, which is currently authorized for emergency use only when administered together with etesevimab. As a result of this extension, unopened vials of bamlanivimab, injection, 700 mg/20 mL, should be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F), and may be stored for an additional 6 months from the labeled date of expiry (See Table 1 below). FDA granted this extension following a thorough review of data submitted by Eli Lilly. This extension applies to all unopened vials of bamlanivimab that have been held in accordance with storage conditions detailed in the authorized [Fact Sheet for Health Care Providers](#) and the [Letter of Authorization for Emergency Use Authorization \(EUA\) 094 for bamlanivimab and etesevimab](#), administered together.

**The national pause on distribution of bamlanivimab and etesevimab remains in effect. We recommend that providers use alternative authorized monoclonal antibody therapies until further notice.**

The bamlanivimab authorized to be administered together with etesevimab under the EUA has fixed expiration dates on the label of each vial and carton. The date identified on the vial and carton reflects the original shelf-life expiry of 12 months and does not reflect the extended 18-month shelf-life expiry. The table below provides the updated expiry, by batch, for distributed bamlanivimab.

**Table 1: Extended Expiry Dating for Bamlanivimab Authorized under EUA 94 (Bamlanivimab and Etesevimab Administered together)**

Batch	Labeled Expiry Date	Extended Expiry Date
D308778A	2021-09-09	2022-03-09
D310126A	2021-09-27	2022-03-27
D318845A	2021-10-16	2022-04-16
D318846A	2021-10-23	2022-04-23
D2000176	2021-09-30	2022-03-30
D2000178	2021-10-31	2022-04-30
D2000180	2021-10-31	2022-04-30
D2000179	2021-10-31	2022-04-30
D308777C	2021-09-05	2022-03-05
D336348C	2021-11-01	2022-05-01
D340792A	2021-12-01	2022-06-01
D2000181	2021-10-31	2022-04-30
D332491A	2021-11-16	2022-05-16

D310125C	2021-09-22	2022-03-22
D2000193	2021-11-30	2022-05-30
D332490A	2021-11-21	2022-05-21
D347561A	2021-11-29	2022-05-29
D2000184	2021-11-30	2022-05-30
D332489A	2021-11-08	2022-05-08
D336908A	2021-11-19	2022-05-19
D2000183	2021-10-31	2022-04-30
D344776A	2021-11-22	2022-05-22
S20N002A	2021-12-14	2022-06-14
S20N001A	2021-12-02	2022-06-02
D336907A	2021-11-17	2022-05-17
S20N003A	2021-12-20	2022-06-20
D2000187	2021-11-30	2022-05-30
D2100021	2021-12-31	2022-06-30
D2000192	2021-12-31	2022-06-30
D2000186	2021-11-30	2022-05-30
D2000185	2021-11-30	2022-05-30

D2100022	2021-12-31	2022-06-30
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**Additional contacts:**

IDPH technical assistance contact for monoclonal antibody therapy [ashley.thoele@illinois.gov](mailto:ashley.thoele@illinois.gov).

Therapeutic Questions: Please contact [COVID19Therapeutics@hhs.gov](mailto:COVID19Therapeutics@hhs.gov).

AmeriSource Bergen: [C19therapies@amerisourcebergen.com](mailto:C19therapies@amerisourcebergen.com)

REGEN-COV Direct Ordering Process [link](#)

[Sotrovimab Direct Ordering Process via GlaxoSmithKline's website](#)

**Are you registered in SIREN?**

SIREN is the state's Health Alert Network that provides tools and capacity for rapid, reliable, and secure web-based alerting. SIREN is the emergency planning, alerting, and notification system for IDPH.

Please use this link to guide you to the correct registration instructions for your public health related classification: <http://www.dph.illinois.gov/siren>