

Medical Countermeasure Option Available from the Strategic National Stockpile for Treatment of Mpox (formerly known as monkeypox): TEMBEXA® (brincidofovir)

The Strategic National Stockpile (SNS) holds TEMBEXA® (brincidofovir) in inventory as a therapeutic option available for patients with human mpox disease who meet specific eligibility criteria.

- TEMBEXA® is an oral antiviral medication approved by the U.S. Food and Drug Administration (FDA) in tablet and oral suspension formulation for the treatment of human smallpox disease in adult and pediatric patients.
- **TEMBEXA® is not FDA-approved to treat mpox in humans.** Currently, there is no treatment approved specifically for mpox. Refer to [CDC interim guidance](#) on available treatment options for mpox. TEMBEXA® can be considered for use under a single patient emergency use Investigational New Drug (EIND) protocol for treatment of mpox disease in adults and pediatric patients with severe illness who meet specific eligibility criteria.
- TEMBEXA® is made available from the SNS for the treatment of mpox to clinicians who request and obtain an FDA-authorized single-patient emergency use IND (EIND).



Accessing TEMBEXA®

Requests for SNS-held TEMBEXA® must go directly to the FDA for approval. **An EIND request to FDA can be submitted in multiple ways:**

- Access FDA's [web-based application for single-patient emergency use IND requests for TEMBEXA®](#)
- Call or email FDA during normal business hours (Monday – Friday, 8 a.m. to 4:30 p.m. ET):
 - Phone: (855) 543-3784 or (301) 796-3400
 - Email: DDI.EIND@fda.hhs.gov
- Contact the FDA Emergency Coordinator or CDER Emergency Coordinator after normal business hours and all day on weekends/holidays:
 - FDA Emergency Coordinator:
 - Phone: (866) 300-4374 or (301) 796-8240
 - CDER Emergency Coordinator:
 - Phone: (301) 796-9900
 - Email: CDER-EIND@fda.hhs.gov

Additional Information About TEMBEXA® Supplied by the SNS

- FDA authorization is on an individual basis, single-patient EIND. FDA will send an EIND authorization email to the requesting provider and SNS with the TEMBEXA® formulation, quantity, delivery information and point of contact. SNS will treat all FDA-authorized TEMBEXA® EINDs as urgent (within 24 hours).
- TEMBEXA® treatment course is covered by one bottle of suspension or one card of four tablets.
- TEMBEXA® is stored and shipped at controlled room temperature.
- TEMBEXA® supplied by the SNS does not have an expiration date printed on its label. Product lot numbers and expiration dates are posted on the [SNS Products: Vaccines and Treatment Available for Use in the Mpox Response webpage](#).
- For additional information on the federal response to the 2022 U.S. Mpox Outbreak:
 - [HHS website](#)
 - [ASPR website](#)
 - [FDA website](#)
 - [CDC website](#)