



Pfizer Adverse Reaction Management User Guide

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Pfizer Adverse Reaction Management



Management of Cytokine Release Syndrome (CRS)

- Identify CRS based on clinical presentation. Evaluate and treat other causes of fever, hypoxia, and hypotension.
- If CRS is suspected, withhold ELREXFIO until CRS resolves. Clinical signs and symptoms of CRS may include but are not limited to, fever, hypoxia, chills, hypotension, tachycardia, headache, and elevated liver enzymes. At the first sign of CRS, evaluate patients immediately for hospitalization.
- Manage according to the recommendations in Table 1 below and consider further management per current practice guidelines. Withhold or permanently discontinue ELREXFIO based on severity. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS. Consider laboratory testing to monitor for disseminated intravascular coagulation (DIC), hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function.

Table 1: Recommendations for Management of CRS

Grade	Presenting Symptoms	Actions
Grade 1	Temperature ³ 100.4°F (38°C) ^b	<ul style="list-style-type: none">• Withhold ELREXFIO until CRS resolves.^c• Administer pretreatment medications before the next dose of ELREXFIO.

Grade 2	<ul style="list-style-type: none"> Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) with either: Hypotension responsive to fluid and not requiring vasopressors, and/or Oxygen requirement of low-flow nasal cannula or blow-by 	<ul style="list-style-type: none"> Withhold ELREXFIO until CRS resolves.^c Monitor patients daily for 48 hours following the next dose of ELREXFIO. Instruct patients to remain within proximity of a healthcare facility and consider hospitalization. Administer pretreatment medications before the next dose of ELREXFIO.
Grade 3 (First occurrence)	<ul style="list-style-type: none"> Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) with either: Hypotension requiring one vasopressor with or without vasopressin, and/or Oxygen requirement of high-flow nasal cannula, facemask, non-rebreather mask, or Venturi mask 	<ul style="list-style-type: none"> Withhold ELREXFIO until CRS resolves.^c Provide supportive therapy, which may include intensive care. Patients should be hospitalized for 48 hours following the next dose of ELREXFIO. Administer pretreatment medications before the next dose of ELREXFIO.
Grade 3 (Recurrent)	<ul style="list-style-type: none"> Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) with either: Hypotension requiring one vasopressor with or without vasopressin, and/or Oxygen requirement of high-flow nasal cannula, facemask, non-rebreather mask, or Venturi mask. 	<ul style="list-style-type: none"> Permanently discontinue therapy with ELREXFIO. Provide supportive therapy, which may include intensive care.
Grade 4	<ul style="list-style-type: none"> Temperature $\geq 100.4^{\circ}\text{F}$ (38°C) with either: Hypotension requiring multiple vasopressors (excluding vasopressin), and/or Oxygen requirement of positive pressure (e.g., continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, and mechanical ventilation) 	<ul style="list-style-type: none"> Permanently discontinue therapy with ELREXFIO. Provide supportive therapy, which may include intensive care.

1. Based on the American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for CRS.
2. Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anti-cytokine therapy.
3. See Table 2 in USPI for recommendations on restarting ELREXFIO after dose delays.
4. The low-flow nasal cannula is ≤ 6 L/min and the high-flow nasal cannula is >6 L/min.

Management of Neurologic Toxicity and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

- Manage neurologic toxicity and ICANS according to the recommendations in Tables 2 and 3 below and consider further management per current practice guidelines.

- At the first sign of neurologic toxicity, including ICANS, withhold ELREXFIO and consider neurology evaluation. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care, for severe or life-threatening neurologic toxicities including ICANS.

Table 2: Recommendations for Management of Neurologic Toxicity, excluding ICANS

Adverse Reaction	Severity	Actions
Neurologic Toxicity (excluding ICANS)	Grade 1	<ul style="list-style-type: none"> Withhold ELREXFIO until neurologic toxicity symptoms resolve or stabilize.
	Grade 2	<ul style="list-style-type: none"> Withhold ELREXFIO until neurologic toxicity symptoms improve to Grade 1 or less.
	Grade 3 (First occurrence)	<ul style="list-style-type: none"> Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	<ul style="list-style-type: none"> Permanently discontinue ELREXFIO. Provide supportive therapy, which may include intensive care.

Table 3: Recommendations for Management of ICANS

Grade	Presenting Symptoms	Actions
Grade 1	<p>ICE score 7-9^c</p> <p>Or depressed level of consciousness: awakens spontaneously.</p>	<ul style="list-style-type: none"> Withhold ELREXFIO until ICANS resolves.^e Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis.
Grade 2	<p>ICE score 3-6^c</p> <p>or depressed level of consciousness: awakens to voice.</p>	<ul style="list-style-type: none"> Withhold ELREXFIO until ICANS resolves. Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. Monitor patients daily for 48 hours following the next dose of ELREXFIO. Instruct patients to remain within proximity of a healthcare facility, and consider hospitalization.

Grade	Presenting Symptoms	Actions
Grade 3 (First occurrence)	<p>ICE score 0-2^c</p> <p>or depressed level of consciousness: awakens only to tactile stimulus,</p> <p>or seizures, either:</p> <ul style="list-style-type: none"> any clinical seizure, focal or generalized, that resolves rapidly, or non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, <p>or raised intracranial pressure: focal/local edema on neuroimaging</p> 	<ul style="list-style-type: none"> Withhold ELREXFIO until ICANS resolves.^e Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. Provide supportive therapy, which may include intensive care. Patients should be hospitalized for 48 hours following the next dose of ELREXFIO.
Grade 3 (recurrent)	<p>ICE score 0-2^c</p> <p>or depressed level of consciousness: awakens only to tactile stimulus,</p> <p>or seizures, either:</p> <ul style="list-style-type: none"> any clinical seizure, focal or generalized, that resolves rapidly, or non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, <p>or raised intracranial pressure: focal/local edema on neuroimaging</p> 	<ul style="list-style-type: none"> Permanently discontinue ELREXFIO. Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. Monitor neurologic symptoms and consider neurology consultation and other specialists for further evaluation and management. Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. Provide supportive therapy, which may include intensive care.

Grade	Presenting Symptoms	Actions
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Grade 4	<p>ICE score 0^c</p> <p>or, depressed level of consciousness either:</p> <ul style="list-style-type: none"> · patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or · stupor or coma, or seizures, either: · life-threatening prolonged seizure (>5 minutes), or · repetitive clinical or electrical seizures without return to baseline in between, <p>or motor findings:</p> <ul style="list-style-type: none"> · deep focal motor weakness such as hemiparesis or paraparesis, <p>Or raised intracranial pressure / cerebral edema, with signs/symptoms such as:</p> <ul style="list-style-type: none"> · diffuse cerebral edema on neuroimaging, or · decerebrate or decorticate posturing, or · cranial nerve VI palsy, or · papilledema, or · Cushing's triad 	<ul style="list-style-type: none"> · Permanently discontinue ELREXFIO. · Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. · Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously for 3 days. · Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. · Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. · Provide supportive therapy, which may include intensive care.
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1. Based on the American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
2. Management is determined by the most severe event, not attributable to any other cause.
3. If the patient is arousable and able to perform an Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: Orientation (oriented to year, month, city, hospital = 4 points); Naming (name 3 objects, e.g., point to clock, pen, button = 3 points); Following Commands (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); Writing (ability to write a standard sentence = 1 point; and Attention (count backward from 100 by ten = 1 point). If the patient is unarousable and unable to perform ICE Assessment

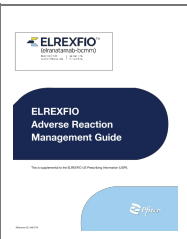
(Grade 4 ICANS) = 0 points.

4. Not attributable to any other cause.
5. See Table 2 in USPI for recommendations on restarting ELREXFIO after dose delays.
6. All references to dexamethasone administration are dexamethasone or equivalent medications.


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- www.ELREXFIOREMS.com
- **PHONE:** 1-[844-923-7845](tel:844-923-7845)
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Documents / Resources

	Pfizer Adverse Reaction Management [pdf] User Guide Adverse Reaction Management, Reaction Management, Management
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References

-  [ELREXFIO REMS | elranatamab-bcmm](#)
- [User Manual](#)

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