CDC Case Report Form: Serious Adverse Events Following Ceftriaxone Injection in Healthcare Settings

Form Approved

OMB Control No. 0920-1011 Expiration Date: 12/31/2025

This form is intended to be completed by a healthcare provider or a healthcare facility staff member, coroner, medical examiner, or public health professional in conjunction with a healthcare provider. The purpose of this form is to report a serious adverse event after administration of ceftriaxone injection. If you are a patient and want to report an adverse event related to ceftriaxone injection, please speak with your medical provider.

A serious adverse event is defined by the Food and Drug Administration as any undesirable experience associated with the use of a medical product in a patient, including:

- Death
- Life-threatening outcome
- Hospitalization (initial or prolonged)
- Outcomes which required intervention to prevent permanent impairment or damage
- Other serious events (including allergic bronchospasm or serious problems with breathing)

For additional information from the Food and Drug Administration on the definition of serious adverse events, please view: https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

Please note that completing this form does not replace reporting adverse events to FDA's MedWatch or to the manufacturer directly. The online form to file a MedWatch report can be found here: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Reporter Information	
Reporter name	
Reporter phone number	
Reporter email	
Reporter fax number	
Name of reporter's workplace	
Reporter work address	

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30333; ATTN: PRA 0920-1011

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Reporter city	
Reporter zip code	
Reporter county	



Reporter state	○ Alabama
	Alaska
	Arizona
	○ Arkansas
	○ California○ Colorado
	○ Connecticut
	O Delaware
	Florida
	○ Georgia
	○ Hawaii
	◯ Idaho
	○ Illinois
	○ Indiana
	Olowa
	Kansas
	○ Kentucky
	Louisiana
	○ Maine○ Maryland
	○ Massachusetts
	Michigan
	Minnesota
	Mississippi
	Missouri
	○ Nebraska
	○ Nevada
	New Hampshire
	New Jersey
	New Mexico
	○ New York○ North Carolina
	North Dakota
	Ohio
	Oklahoma
	Oregon
	Pennsylvania
	○ Rhode Island
	○ South Carolina
	○ South Dakota
	Tennessee
	Texas
	O Utah
	○ Vermont
	○ Virginia○ Washington
	○ West Virginia
	Wisconsin
	Wyoming
Reporter type	○ Coroner
•	○ Hospital
	Outpatient facility
	Health department
	Other
If other, please specify	
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Patient Demographics		
Patient age		
Patient sex	○ Male○ Female	
Patient county of residence		
		



Patient state of residence	○ Alabama
	Alaska
	○ Arizona
	○ Arkansas
	○ California
	○ Colorado
	○ Connecticut
	O Delaware
	○ Florida
	GeorgiaHawaii
	○ Idaho
	Illinois
	○ Indiana
	Olowa
	○ Kansas
	○ Kentucky
	○ Louisiana
	○ Maine
	Maryland
	○ Massachusetts
	○ Michigan
	○ Minnesota
	○ Mississippi
	○ Missouri
	○ Montana
	Nebraska
	○ Nevada
	New Hampshire
	○ New Jersey
	New Mexico
	○ New York
	○ North Carolina
	○ North Dakota
	○ Ohio
	○ Oklahoma
	○ Oregon
	Pennsylvania
	Rhode Island
	O South Carolina
	South Dakota
	Tennessee
	○ Texas
	○ Utah
	○ Vermont
	○ Virginia
	○ Washington
	○ West Virginia○ Wisconsin
	○ Wyoming
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- Death: Check if the patient died after receiving the medical product.
- Life-threatening outcome: Check if you suspect that the patient was at substantial risk of dying at the time of the adverse event, or if continued use of the medical product might have resulted in the death of the patient.
- Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
- Outcomes which required intervention to prevent permanent impairment or damage: Check if you believe that medical or surgical intervention was delivered to prevent permanent impairment of a body function or prevent permanent damage to a body structure due to the use of a medical product.
- Other serious or important medical events: Check when the event does not fit the other outcomes, but the event could have jeopardized the patient and could have required medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room.

Please choose the type of serious adverse event (Note: Please choose the most serious adverse event type applicable)	 Death Life-threatening outcome Hospitalization (initial or prolonged) Outcomes which required intervention to prevent permanent impairment or damage Other serious or important medical events
DATE of most recent dose of ceftriaxone received?	
TIME of most recent dose of ceftriaxone if known (please enter in 24-hour time format) Note: For outpatient facilities, if the timing of administration is not documented, please record estimated time of ceftriaxone administration from the treating provider.	
Healthcare facility type where ceftriaxone was administered	 Outpatient clinic (including primary care clinics) Urgent care clinic Ambulatory surgery center Emergency department Acute care hospital, excluding emergency department and ICU Acute care hospital ICU Long term acute care hospital Skilled nursing facility Assisted living facility Rehab facility Other
If other, please specify	
DATE of adverse event onset (Note: Please specify date when new or worsening symptoms occurred after ceftriaxone administration)	

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TIME of adverse event onset (Note: please enter in 24-hour time format) (Note: Please specify time when new or worsening symptoms occurred after ceftriaxone administration)	
Did the onset of the serious adverse event within 6 hours of receiving ceftriaxone?	YesNoUnknown
In which setting did the adverse event occur?	 Community setting (ex: home, store, restaurant, etc.) Outpatient clinic (including primary care clinics) Urgent care clinic Ambulatory surgery center Emergency department Acute care hospital, excluding emergency department and ICU Acute care hospital ICU Long term acute care hospital Skilled nursing facility Assisted living facility Rehab facility Other
If other setting of adverse event, please specify	
Did EMS evaluate the patient?	○ Yes○ No○ Unknown
Was the patient transferred to a higher level of care as a result of this severe adverse event? (If "No" or "Unknown", please skip to question about signs and symptoms of serious adverse event)	○ Yes○ No○ Unknown
If patient transferred to a higher level of care, what was the highest level of care the patient received for management of the adverse event?	 Treatment in urgent care or outpatient clinic Treatment in emergency department (for cases where patient was not admitted to hospital after emergency department evaluation) Treatment in acute care hospital (excluding emergency department or ICU) Treatment in ICU Other (specify)
If "other" selected for highest level of care, please specify	
If the patient was evaluated in an outpatient setting or in emergency department, what was the disposition after care?	Discharged homeTransferred to another facilityDeathOther
If "other" selected for question above, please specify	

If the patient was hospitalized or if "other" selected for higher level of care, what was the disposition after care?	 Discharged home Discharged or transferred to another facility Still receiving care inpatient Death Other
If "other" selected for question above, please specify	
Signs and symptoms of serious adverse event (select all that apply)	Facial swelling Urticaria (hives) Low blood pressure Bradycardia Tachycardia Palpitations Nausea Shortness of breath Vomiting Tingling Flushing Diaphoresis Abdominal pain Diarrhea Loss of consciousness Chills Fever Difficulty swallowing Wheezing Found unresponsive Throat closing Tongue itching Cough Hypoxia Headache Chest pain Strange taste Other
If other sign or symptom of serious adverse event, please list here	
Was the adverse event suspected to be an allergic (immunologically-mediated) reaction? (Select yes if an allergic reaction is suspected OR if event clinically managed as an allergic reaction)	
Did the patient receive cardiopulmonary resuscitation (CPR) as a result of the serious adverse event?	○ Yes ○ No
Note: For the purpose of this form, CPR is defined as cardiopulmonary resuscitation defined as the use of chest compressions and mechanical ventilation or provision of rescue breaths to maintain circulatory flow and oxygenation during cardiac arrest.	
If CPR selected, enter DATE CPR was initiated	
If CPR selected, enter TIME CPR was initiated (Note: please enter in 24-hour time format)	



Does the treating provider attribute the adverse event to a cause OTHER than ceftriaxone administration?	 Adverse event attributed to a cause other than ceftriaxone administration (such as known infection, other underlying medical condition, or exposure to a medication or medical product other than ceftriaxone) Adverse event NOT attributed to a cause other than ceftriaxone administration
Does the treating provider attribute the adverse event to ceftriaxone administration?	○ Yes○ No○ Provider not sure
If the adverse event is suspected to be from ceftriaxone, is it a known adverse effect of ceftriaxone?	○ Yes○ No○ Adverse event not suspected to be from ceftriaxone
Note: Major known adverse effects of ceftriaxone are listed below. For other known adverse events of ceftriaxone, please refer to the ceftriaxone product label corresponding to the NDC number and manufacturer administered to this patient here: https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=ceftriaxone	

Major known adverse effects of ceftriaxone include:

- Local reactions: Pain, induration and tenderness was 1% overall. Phlebitis was reported in < 1% after IV administration.
- Hypersensitivity: Rash (1.7%). Less frequently reported (< 1%) were pruritus, fever or chills.
- Infections and infestations: Genital fungal infection (0.1%).
- Hematologic: Eosinophilia (6%), thrombocytosis (5.1%) and leukopenia (2.1%). Less frequently reported (< 1%) were anemia, hemolytic anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.
- Blood and lymphatic disorders: Granulocytopenia (0.9%), coagulopathy (0.4%).
- Gastrointestinal: Diarrhea/loose stools (2.7%). Less frequently reported (<1%) were nausea or vomiting, and dysgeusia. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment.
- Hepatic: Elevations of aspartate aminotransferase (AST) (3.1%) or alanine aminotransferase (ALT) (3.3%). Less frequently reported (< 1%) were elevations of alkaline phosphatase and bilirubin.
- Renal: Elevations of the BUN (1.2%). Less frequently reported (< 1%) were elevations of creatinine and the presence of casts in the urine.
- Central nervous system: Headache or dizziness were reported occasionally (< 1%).
- Genitourinary: Moniliasis or vaginitis were reported occasionally (< 1%).
- Miscellaneous: Diaphoresis and flushing were reported occasionally (< 1%).
- Investigations: Blood creatinine increased (0.6%).

Post-market adverse experiences reported:

- Gastrointestinal: Pancreatitis, stomatitis and glossitis.
- Genitourinary: Oliguria, ureteric obstruction, post-renal acute renal failure.
- Dermatologic: Exanthema, allergic dermatitis, urticaria, edema; acute generalized exanthematous pustulosis (AGEP) and isolated cases of severe cutaneous adverse reactions (erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis) have been reported.
- Hematological changes: Isolated cases of agranulocytosis (< 500/mm) have been reported, most of them after 10 days of treatment and following total doses of 20 g or more.
- Nervous system disorders: Convulsion
- Other: Symptomatic precipitation of ceftriaxone calcium salt in the gallbladder, kernicterus, oliguria, and anaphylactic or anaphylactoid reactions. Source:

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8351aa37-552d-471d-b293-c564dcb6ec29

Other:

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- The combination of lansoprazole and ceftriaxone has been associated with prologed corrected QT (QTc) intervals. Citations: Bai AD, Wilkinson A, Almufleh A, et al. Ceftriaxone and the Risk of Ventricular Arrhythmia, Cardiac Arrest, and Death Among Patients Receiving Lansoprazole. JAMA Netw Open. 2023;6(10):e2339893. doi:10.1001/jamanetworkopen.2023.39893;

Lorberbaum T, Sampson KJ, Chang JB, Iyer V, Woosley RL, Kass RS, Tatonetti NP. Coupling Data Mining and Laboratory Experiments to Discover Drug Interactions Causing QT Prolongation. J Am Coll Cardiol. 2016 Oct 18;68(16):1756-1764. doi: 10.1016/j.jacc.2016.07.761. PMID: 27737742; PMCID: PMC5082283.

If the adverse event was attributed to a cause other than ceftriaxone administration, what was the suspected cause of the adverse event?	 Adverse event secondary to another medication other than ceftriaxone (please specify below) Active infection (please specify below) Other medical diagnosis (please specify below)
If the primary cause of the adverse event is suspected to be a medication other than ceftriaxone, please specify that medication here	
If the primary cause of the adverse event is suspected to be an active infection, please specify the infection here	
If the primary cause of the adverse event is suspected to be another medical diagnosis, please specify the medical diagnosis here	
Is patient deceased? (If no, please skip to next section on EKG information)	○ Yes ○ No
DATE of death	
TIME of death if known (Note: please enter in 24-hour time format)	
Recorded cause of death in medical record or death certificate	
Per treating provider or clinician, was this death in an apparently healthy patient or patient whose disease is not so severe that a fatal outcome would be expected?	○ Yes ○ No
Was autopsy performed?	○ Yes
Please note that autopsy findings are critical to evaluate unexpected deaths which are suspected to be related to a medical product exposure. Please reach out to CDC at haioutbreak@cdc.gov with any questions regarding autopsy.	○ No ○ Unknown
If autopsy was performed, what were significant findings?	
Was a toxicology screen performed?	○ Yes○ No○ Unknown

If toxicology screen was performed, what were significant findings?		
Vital Signs Information		
What were the patient's vital signs BEFORE the onset of the aconce before adverse event, please report those recorded mos		
Heart rate (beats per minute) Respiratory rate (breaths per minute) Systolic blood pressure (mmHg) Diastolic blood pressure (mmHg) Oxygen saturation (%) Temperature (degrees Fahrenheit)		
What were the patient's vital signs AFTER the onset of the advonce after adverse event, please report those recorded most in		
Heart rate (beats per minute) Respiratory rate (breaths per minute) Systolic blood pressure (mmHg) Diastolic blood pressure (mmHg) Oxygen saturation (%) Temperature (degrees Fahrenheit)		
EKG, Rhythm Strip, or Defibrillator Recording Info	rmation	
Was an EKG, rhythm strip, or defibrillator recording collected during the severe adverse event? (If "No" or "Unknown", please skip to next section on patient medical information)	YesNoUnknown	
What was the heart rate?		
If computerized reading available, what was the PR interval?		
If computerized reading available, what was the QRS duration?		
If computerized reading available, what was the QT interval?		
If computerized reading available, what was the QTc interval?		



Please select any EKG, rhythm strip, or defibrillator recording findings that apply	 Normal sinus rhythm Sinus tachycardia Sinus bradycardia Atrial fibrillation Atrial flutter Supraventricular tachycardia Ventricular fibrillation Ventricular tachycardia ST elevation Right bundle branch block Left bundle branch block QT prolongation Other
If other EKG findings (or to elaborate on previous selected findings), please list here	<u> </u>
Patient Medical Information	
Patient's medical history (select all that apply)	□ COPD/emphysema/chronic lung disease □ Asthma □ Diabetes □ Coronary arterial disease (including history of myocardial infarction, coronary stents, or coronary artery bypass graft [CABG] surgery) □ Chronic renal insufficiency (CRI/CKD) or end-stage renal disease (ESRD) □ Cirrhosis/liver disease □ History of stroke/CVA □ Dementia □ HIV/AIDS □ Cancer (specify in next question) □ Allergy to penicillin □ Hypothyroidism □ Psychiatric illness □ Hypertension □ Hyperlipidemia □ Tobacco use □ Alcohol use disorder □ Hyperthyroidism □ Arrhythmia (ex: atrial fibrillation) □ Gastroesophageal reflux disease (GERD □ Other
If other medical history, please list here:	
List all the medications that the patient was taking at the time of the serious adverse event. Please use generic names of medications. Please separate medications by a semi-colon (ex: aspirin; atorvastatin; metoprolol). If no other medications, please state "none".	

Certriaxone information	
Manufacturer of most recent dose of ceftriaxone received	<u></u>
NDC (National Drug Code) number of ceftriaxone received	
Note: This is a 10-digit number found on the medication vial.	
Lot number of most recent dose of ceftriaxone received	
Was this lot number documented as administered to the patient or present in the facility at the time of ceftriaxone administration (but not documented in the medical record as administered to patient)?	Documented as administered to the patientPresent in facility at time of administrationOther
If other selected for above question, please specify	
If lot number was present in the facility at time of administration (but not documented in the medical record as administered to patient), please list any other manufacturers and lot numbers of ceftriaxone present in the facility at the time of administration	
Expiration date of most recent dose of ceftriaxone received	
Dose of most recent ceftriaxone injection	○ 1 g○ 2 g○ Other (please specify)
For other dose of ceftriaxone, please specify	
Route of administration of ceftriaxone	○ Intramuscular (IM)○ Intravenous (IV) infusion○ Intravenous (IV) push○ Unknown



Which diluent was used to prepare the ceftriaxone injection?	 Sterile water 0.9% Sodium chloride 1% Lidocaine solution without epinephrine Bacteriostatic water + 0.9% benzyl alcohol 5% Dextrose 10% Dextrose 5% Dextrose + 0.9% Sodium Chloride Solution 5% Dextrose + 0.45% Sodium Chloride Solution Sodium lactate 10% Invert sugar 5% Sodium bicarbonate Freamine III Normosol-M in 5% dextrose Ionosol-B in 5% dextrose 5% Mannitol 10% Mannitol No other diluent used Unknown Other (specify)
If other diluent used, please specify	
Reason for ceftriaxone treatment	 Pneumonia COPD exacerbation Other respiratory illness (please specify) Urinary tract infection Sexually transmitted infection Skin and soft tissue infection Bloodstream infection Intra-abdominal infection Other (please specify)
If "other respiratory illness" or "other" chosen for reason for ceftriaxone treatment, please specify	
List any other medications and route of administration provided at the same time as ceftriaxone (ex: dexamethasone intramuscular, etc.).	
Has this patient received ceftriaxone before this incident?	YesNoUnknown
If this patient has received ceftriaxone prior to current administration, did the patient experience any adverse events with previous receipt of ceftriaxone?	YesNoUnknown
Respiratory Testing Information	
Please answer the following questions if the reason for ceftriaxo (pneumonia, COPD exacerbation, or other respiratory illness). If chosen, please skip to the next section on microbiology test info	another reason for treatment with ceftriaxone was
Did the patient have a flu test performed?	YesNoUnknown

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If the patient had a flu test performed result?	, what was the	Flu A positiveFlu B positiveFlu negative	
Did the patient have a covid test perf	ormed?	YesNoUnknown	
If the patient had a covid test perform the results?	ned, what were	Covid test positiveCovid test negative	
Note: The following four questions are	e to be completed for p	patients diagnosed with pneur	monia.
CURB-65 Pneumonia Severity Score Q	uestions		
The following four questions are deriv			ol which helps stratify risk for
Citation: Lim WS, van der Eerden MM, community acquired pneumonia seve study. Thorax. 2003 May;58(5):377-8	rity on presentation to	hospital: an international der	rivation and validation
	Yes	No	Unknown
Was the patient confused (e.g., disoriented to time, place, or person) prior to receiving ceftriaxone? (Note: if inpatient, this question applies to the 24 hours prior to receiving ceftriaxone)			
Was the patient's blood urea nitrogen (BUN) level 20 mg/dL or higher prior to receiving ceftriaxone? (Note: if inpatient, this question applies to the 24 hours prior to receiving ceftriaxone)	0		
Was the patient's respiratory rate 30 breaths per minute or higher prior to receiving ceftriaxone? (Note: if inpatient, this question applies to the 24 hours prior to receiving ceftriaxone)	0		0



Was the patient's systolic blood pressure less than 90 mmHg, or diastolic blood pressure less than 60 mmHg prior to receiving ceftriaxone? (Note: if inpatient, this question applies to the 24 hours prior to receiving ceftriaxone)			
Microbiology Test Information			
Please answer the following questions ab	out any positive i	microbiology results within 2 days of	the adverse event.
If there are no microbiology results to rep	oort, please skip t	o the next section on picture upload.	
Microbiology test #1 name (ex: respirato panel, stool culture, etc.)	ry viral		
Microbiology test #1 specimen source		Nasal or oropharyngealSputumBloodUrineStoolWoundOther	
If other specimen for microbiology test # specify	1, please		
Microbiology test #1 type		CultureGram stainNAAT (including PCR)Other	
If other test type for microbiology test #3 specify	l, please		
Microbiology test #1 result			
Microbiology test #2 name (ex: respirato panel, stool culture, etc.)	ry viral		
Microbiology test #2 specimen source		Nasal or oropharyngealSputumBloodUrineStoolWoundOther	
If other specimen for microbiology test # specify	2, please		



Microbiology test #2 type	○ Culture○ Gram stain○ NAAT (including PCR)○ Other
If other test type for microbiology test #2, please specify	
Microbiology test #2 result	
Microbiology test #3 name (ex: respiratory viral panel, stool culture, etc.)	
Microbiology test #3 specimen source	 Nasal or oropharyngeal Sputum Blood Urine Stool Wound Other
If other specimen for microbiology test #3, please specify	
Microbiology test #3 type	○ Culture○ Gram stain○ NAAT (including PCR)○ Other
If other test type for microbiology test #3, please specify	
Microbiology test #3 result	
If additional microbiology tests, please list with name, specimen source, test type, and result	
Picture Upload	
Upload pictures of ceftriaxone vial of most recent dose if availal number.	ole. Ideally include front label of bottle and lot
Ceftriaxone vial picture #1	
Ceftriaxone vial picture #2	
Ceftriaxone vial picture #3	
Upload picture of medication vials/containers coadministered with ceftriaxone if available (ex: lidocaine, saline). Ideally include front label and lot number.	
Other medical vials/containers picture #1	
Other medical vials/containers picture #2	

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Other medical vials/containers picture #3		
Healthcare Facility Information		
Healthcare facility name where ceftriaxone was administered		-
Street address of healthcare facility where ceftriaxone was administered		
City of healthcare facility where ceftriaxone was administered		



State of healthcare facility where ceftriaxone was administered	 Alabama Alaska Arizona Arkansas California Colorado Connecticut Delaware Florida Georgia Hawaii Idaho Illinois Indiana Iowa Kansas Kentucky Louisiana Maine Maryland Massachusetts Michigan Minnesota Mississippi Missouri Montana Nebraska Nevada New Hampshire New Jersey
	 ○ North Dakota ○ Ohio ○ Oklahoma ○ Oregon ○ Pennsylvania ○ Rhode Island ○ South Carolina
	 ○ South Dakota ○ Tennessee ○ Texas ○ Utah ○ Vermont ○ Virginia ○ Washington ○ West Virginia
Zip code of healthcare facility where ceftriaxone was	○ Wisconsin ○ Wyoming
administered	