42 C.F.R. § 110.100

Injury Tables.

(a) *Pandemic influenza countermeasures injury table.*

Covered countermeasures under Secretarial declarations	Serious physical injury (illness, disability, injury, or condition) [1]	Time interval (for first symptom or manifestation of onset of injury after administration or use of covered countermeasure, unless otherwise specified)
I. Pandemic influenza vaccines administered by needle into or through the skin	A. Anaphylaxis B. Deltoid Bursitis C. Vasovagal Syncope	A. 0–4 hours. B. 0–48 hours. C. 0–1 hour.
II. Pandemic influenza intranasal vaccines	A. Anaphylaxis	A. 0–4 hours.
III. Pandemic influenza 2009 H1N1 vaccine	A. Guillain-Barré Syndrome	A. 3–42 days (not less than 72 hours and not more than 42 days).
IV. Oseltamivir Phosphate (Tamiflu) when administered or used for pandemic influenza	A. Anaphylaxis	A. 0–4 hours.
V. Zanamivir (Relenza) when administered or used for pandemic influenza	A. Anaphylaxis	A. 0–4 hours.
VI. Peramivir when administered or used for 2009 H1N1 influenza	A. Anaphylaxis	A. 0–4 hours.
VII. Pandemic influenza personal respiratory protection devices	A. No condition covered [2]	A. Not applicable.
VIII. Pandemic influenza respiratory support devices	A. Postintubation Tracheal Stenosis	A. 2–42 days (not less than 48 hours and not more than 42 days) after extubation (removal of a tracheostomy or endotracheal tube).
	B. Ventilator-Associated Pneumonia and Ventilator-Associated Tracheobronchitis	B. More than 48 hours after intubation (placement of an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).

	C. Ventilator-Induced Lung Injury	C. Throughout the time of intubation (breathing through an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).
IX. Pandemic influenza respiratory support device: Extra-corporeal membrane oxygenation (ECMO)	A. Bleeding Events	A. Throughout the time of anticoagulation treatment for ECMO therapy, including the time needed to clear the effect of the anti-coagulant treatment from the body.
X. Pandemic influenza diagnostic testing devices	A. No condition covered	A. Not applicable.

[1] Serious physical injury as defined in 42 CFR 110.3(z). Only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability will be considered serious physical injuries.

[2] The use of "No condition covered" in the Table reflects that the Secretary at this time does not find compelling, reliable, valid, medical and scientific evidence to support that any serious injury is presumed to be caused by the associated covered countermeasure. For injuries alleged to be due to covered countermeasures for which there is no associated Table injury, requesters must demonstrate that the injury occurred as the direct result of the administration or use of the covered countermeasure. *See* 42 CFR 110.20(b), (c).

(b) *Qualifications and aids to interpretation (table definitions and requirements).* The following definitions and requirements shall apply to the Table set forth in paragraph (a) of this section and only apply for purposes of this subpart.

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without *sequelae.* Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Deltoid bursitis.* Deltoid bursitis is an inflammation of the bursa that lies beneath the deltoid muscle and between the acromion process and the rotator cuff. Subdeltoid bursitis manifests with pain in the lateral aspect of the shoulder similar to rotator cuff tendonitis. The presence of tenderness on direct palpation beneath the acromion process distinguishes this bursitis from rotator cuff tendonitis. Similar to tendonitis, isolated bursitis will have full passive range of motion. Other causes of bursitis such as trauma (other than from vaccination), metabolic disorders, and systemic diseases such as rheumatoid arthritis, dialysis, and infection will not be considered Table injuries. This list is not exhaustive. The deltoid bursitis must occur in the same shoulder that received the pandemic influenza vaccine.

(3) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and loss of postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected countermeasure. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant *sequelae.* Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously. Loss of consciousness resulting from the following conditions will not be considered vasovagal

syncope: Organic heart disease; cardiac arrhythmias; transient ischemic attacks; hyperventilation; metabolic conditions; neurological conditions; psychiatric conditions; seizures; trauma; and situational as can occur with urination, defecation, or cough. This list is not complete. Episodes of recurrent syncope occurring after the applicable time period are not considered to be *sequelae* of an episode of syncope meeting the Table requirements.

(4) *Guillain-Barré Syndrome (GBS).* (i) GBS is an acute monophasic peripheral neuropathy that currently is known to encompass a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time frame would not be consistent with GBS.