

anaphylactic shock is, for purposes of the Table, as an acute, severe, and potentially lethal systemic allergic reaction to a component of the smallpox vaccine.

(ii) *Table requirements.* A Table injury for anaphylaxis or anaphylactic shock in a recipient requires sufficient evidence in the medical records of the occurrence of an acute anaphylaxis or anaphylactic shock. The anaphylaxis or anaphylactic shock must be of sufficient severity to require inpatient hospitalization. Anaphylaxis or anaphylactic shock is not a Table injury for contacts.

(11) *Vaccinial Myocarditis, Pericarditis, or Myopericarditis (MP)*—(i) *Definition.* MP is, for purposes of the Table, vaccinial myocarditis, pericarditis, or myopericarditis. Myocarditis is defined as an inflammation of the heart muscle (myocardium). Pericarditis is defined as an inflammation of the covering of the heart (pericardium). Myopericarditis is defined as an inflammation of both the heart muscle and its covering. The inflammation associated with MP may range in severity from very mild (subclinical) to life threatening. In many mild cases, myocarditis is diagnosed solely by transient electrocardiographic (EKG) abnormalities (e.g., ST segment and T wave changes), increased cardiac enzymes, or mild echocardiographic abnormalities. Arrhythmias, abnormal heart sounds, heart failure, and death may occur in more severe cases. Pericarditis generally manifests with chest pain, abnormal heart sounds (pericardial friction rub), EKG abnormalities (e.g., ST segment and T wave changes), and/or increased fluid accumulation around the heart.

(ii) *Table requirements.* A Table injury for MP in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute MP. The acute MP (or related complications) must be of sufficient severity to require inpatient hospitalization. A death resulting from MP requires sufficient microscopic (histopathologic) evidence of MP or its sequela in heart tissue.

(c) *Glossary for purposes of this section.*

(1) *Blister or vesicle* means a circumscribed, elevated skin or mucous

membrane lesion containing an accumulation of fluid.

(2) *Contact* means a person who developed a vaccinia lesion or infection through inoculation (and not vaccination).

(3) *Exposure period* means the span of time during which vaccinia virus can be transmitted from a vaccine recipient shedding vaccinia or through a contact case shedding vaccinia.

(4) *Inoculation* means transmission of and infection with the vaccinia virus through a means other than smallpox vaccination. Spread (inoculation) of vaccinia virus may occur in two ways: either self-inoculation in which the vaccinia virus is spread from the vaccinial lesion at the vaccination site to one or more areas on the same person or person-to-person inoculation when the vaccinia virus is spread to another person, a contact.

(5) *Inoculation site* means the skin or mucous membrane surface where the vaccinia virus entered the body through means other than vaccination.

(6) *Lesion* means a pathologic change.

(7) *Pustule* means a circumscribed, elevated skin or mucous membrane lesion containing an accumulation of white blood cells.

(8) *Recipient* means a person to whom the smallpox vaccine was administered.

(9) *Ulceration* means a specific skin or mucous membrane lesion characterized by erosion of the skin or mucous membrane surface.

(10) *Vaccination* means the administration and receipt of the smallpox (vaccinia) vaccine, and not through contact.

(11) *Vaccination site* means the skin surface where the vaccinia virus entered the body through vaccination.

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§§ 102.22–102.29 [Reserved]

Subpart D—Available Benefits

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.