vaccinia inoculation (during the effective period of the Declaration or within 30 days after the end of such period) in relation to a covered injury must also be met.

(b) *Minor injuries.* Any injuries that the Secretary deems minor will not be considered covered injuries. Minor injuries include expected and routine responses to the smallpox vaccine, other covered countermeasures, or accidental vaccinia inoculation that are not severe (e.g., minor scarring or minor local reactions, for instance a mild systemic illness with a generalized maculopapular rash that resolves quickly).

(c) *Table injuries.* A requester may establish that a covered injury occurred by demonstrating that a smallpox vaccine recipient or vaccinia contact sustained an injury listed on the Smallpox (Vaccinia) Vaccine Injury Table, set forth in §120.21, within the time interval listed on the Table and as defined by the Table's Definitions and Requirements, set forth in §120.21(b). In such circumstances, the requester need not demonstrate the cause of the injury because the Secretary will presume, only for purposes of making determinations under this subpart, that the injury was the direct result of the administration of a smallpox vaccine or exposure to vaccinia. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based upon his review of the evidence, that a source other than the smallpox vaccine or exposure to vaccinia more likely than not caused the injury. In such circumstances, the Table presumption will be rebutted.

(d) *Injuries for which causation must be proven.* If an injury is not included on the Table or if a requester is unable to meet all of the Table requirements with respect to an injury included on the Table (e.g., the first symptom or manifestation of onset of the injury within the time interval included on the Table), a requester may establish a covered injury by proving causation. To establish that a covered countermeasure or accidental vaccinia inoculation caused an injury, the requester must demonstrate, by a preponderance of the evidence (more likely than not), that:

(1) In the case of a smallpox vaccine recipient, he or she sustained an injury as the direct result of the administration of a covered countermeasure (including the smallpox vaccine) during the effective period of the Declaration; or

(2) In the case of a vaccinia contact, he or she sustained an injury as the direct result of vaccinia contracted through accidental vaccinia inoculation from a person described in §102.3(bb)(2) (a person meeting the definition of a smallpox vaccine recipient, except that the person need not sustain a covered injury, or the contact of such a person), and not as the result of receiving a smallpox vaccine. Such vaccinia must have been contracted during the effective period of the Declaration (or within 30 days after the end of such period). The Secretary will consider an injury that resulted from the administration of a covered countermeasure (other than the smallpox vaccine) to be the direct result of vaccinia contracted through accidental vaccinia inoculation if the covered countermeasure was administered as a result of such vaccinia.

[68 FR 70093, Dec. 16, 2003, as amended at 71 FR 29810, May 26, 2006]

§102.21 Smallpox (Vaccinia) Vaccine Injury Table.

(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE

Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C). Please note that these time intervals do not refer to time periods for the date of diagnosis of the injury.
1. Significant Local Skin Reaction	R or C: 1–21 days.
2. Stevens-Johnson Syndrome	R or C: 1–21 days.
3. Inadvertent Inoculation	R or C: 1–21 days.
4. Generalized Vaccinia	R or C: 1–21 days.

(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE—Continued

Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C). Please note that these time intervals do not refer to time periods for the date of diagnosis of the injury.
5. Eczema Vaccinatum	R or C: 1–21 days.
6. Progressive Vaccinia	R or C: 1–21 days.
7. Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis.	R or C: 1–21 days.
8. Fetal Vaccinia	Maternal R or C: any time in gestation until 7 days after birth.
9. Secondary Infection	R or C: 0–30 days.
10. Anaphylaxis or Anaphylactic Shock	R: 0–4 hours. C: Not Covered.
11. Vaccinial Myocarditis, Pericarditis, or Myopericarditis.	R or C: 1–21 days.
12. Death resulting from an injury referred to above in which the injury arose within the time interval referred to above (except as specifically provided in specified paragraph (b) of this section).	R or C: No time interval specified.

(b) *Table definitions and requirements.* The Table Definitions that follow shall apply to, define and describe the scope of, and be read in conjunction with paragraph (a) of this section.

(1) *Significant local skin reaction*—(i) *Definition.* Significant local skin reaction is, for purposes of the Table, an unexpected and extreme response at the vaccination or inoculation site that results in a significant scar that is serious enough to require surgical intervention. The onset of this injury is the initial skin lesion at the vaccination or inoculation site that generally occurs with smallpox vaccinations or inoculations. Minor scarring or minor local reactions do not constitute a Table injury. Even a robust take, defined as an area of redness at the vaccination site that exceeds 7.5 cm in diameter with associated swelling, warmth and pain, in general is considered an expected response to the vaccination or inoculation. A robust take does not in itself constitute a Table injury, even when the redness and swelling involves the entire upper arm with associated enlargement and tenderness of the glands (lymph nodes) in the underarm (axilla).

(ii) *Table requirements.* A Table injury for a significant local skin reaction in a recipient or contact requires sufficient evidence in the medical records of the occurrence of a significant local skin reaction at the vaccination or inoculation site and a permanent, disfiguring scar that resulted from the significant local skin reaction. The scar must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records.

(2) *Stevens-Johnson Syndrome (SJS)*—(i) *Definition.* SJS (sometimes called erythema multiforme major) is an acute hypersensitivity reaction that affects skin, mucous membranes, and sometimes internal organs (systemic toxicity). For purposes of the Table, both skin and mucous membrane rash or lesions must be present and the rash or lesions may not cover less than ten percent of body surface area. In SJS, mucosal involvement generally predominates. Mucosal lesions generally occur at more than one location and manifest as painful lesions in sites such as the mouth or eyes. Skin rash or lesions in SJS usually consist of red raised areas (erythematous macules), blisters, and ulcerations.

(ii) *Table requirements.* A Table injury for SJS in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SJS. The SJS, or related complications, must be of sufficient severity to require inpatient hospitalization.

(3) *Inadvertent Inoculation (II)*—(i) *Definition.* II is the spread of vaccinia virus from an existing vaccination or inoculation site to a second location usually by scratching the vaccination or inoculation site and subsequently spreading the virus, which produces a

new vaccinial lesion on the same person. Alternatively, II is the spread of vaccinia virus from an existing vaccination or inoculation site to another person usually by scratching an existing vaccination or inoculation site and subsequently spreading the virus, resulting in a contact case.

(ii) *Table requirements.* A Table injury for II in a recipient or contact requires sufficient evidence in the medical records of the occurrence of II and the occurrence of one of the following:

(A) Eye lesions, e.g., vaccinial keratitis or vaccinial blepharitis, that resulted from II and that led to a permanent sequela, e.g., decrease in visual acuity;

(B) Permanent and disfiguring scar(s) that resulted from II. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(C) Acute II or related complications of sufficient severity to require inpatient hospitalization.

(4) *Generalized Vaccinia (GV)*—(i) *Definition.* GV is a vaccinial infection that occurs from the spread of vaccinia from an existing vaccination or inoculation site to otherwise normal skin, resulting in multiple new areas of vaccinial rash or lesions. The vaccinia is believed to be spread through the blood. The rash or lesions are characterized by multiple blisters (vesicles or pustules) that generally evolve in a similar sequence or manner as the original vaccination or inoculation site.

(ii) *Table requirements.* A Table injury for GV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of GV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from GV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute GV or related complications of sufficient severity to require inpatient hospitalization.

(5) *Eczema Vaccinatum (EV)*—(i) *Definition.* EV is the transmission or the spread of vaccinia virus from a vaccination or inoculation site to skin that has been affected by, or is currently affected with, eczema or atopic dermatitis. EV is characterized by lesions that include multiple blisters (vesicles or pustules), which generally evolve in a similar sequence or manner as the original vaccination or inoculation site. The lesions may come together to form larger lesions. Lesions may also spread to patches of skin that have never been involved with eczema or atopic dermatitis. A person with EV may be quite ill with signs and symptoms that involve the whole body (systemic illness), such as fever, malaise, or enlarged glands (lymph nodes).

(ii) *Table requirements.* A Table injury for EV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of EV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from EV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute EV or related complications of sufficient severity to require inpatient hospitalization.

(6) *Progressive Vaccinia (PV)*—(i) *Definition.* PV is the failure to initiate the healing process in an initial vaccination or inoculation site by 21 days after exposure to vaccinia with progressive ulceration or necrosis at the vaccination or inoculation site leading to a large destructive ulcer. PV is seen in people with an impaired immune system (immunocompromised) and is characterized by a complete or near complete lack of inflammation or absence of inflammatory cells in the dermis of the skin at the vaccination or inoculation site. The diagnosis of PV may be made before 21 days after exposure, especially in a known immunocompromised individual who

develops a lesion at the vaccination or inoculation site. PV may spread through the blood to any location in the body. Any person who initiates a significant healing process of the vaccination or inoculation site by 21 days after receipt of the smallpox vaccine or exposure to vaccinia does not have PV.

(ii) *Table requirements.* A Table injury for PV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of PV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from PV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute PV or related complications of sufficient severity to require inpatient hospitalization.

(7) *Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis (PVEM)*—(i) *Definition.* PVEM is, for the purposes of the Table, an autoimmune central nervous system injury. In rare cases, the vaccinia virus is isolated from the central nervous system. Manifestations usually occur abruptly and may include fever, vomiting, loss of appetite (anorexia), headache, general malaise, impaired consciousness, confusion, disorientation, delirium, drowsiness, seizures, language difficulties (aphasia), coma, muscular incoordination (ataxia), urinary incontinence, urinary retention, and clinical signs consistent with inflammation of the spinal cord (myelitis) such as paralysis or meningismus. Long term central nervous system impairments such as paralysis, seizure disorders, or developmental delays are known to occur as sequelae of the acute PVEM. No clinical criteria, radiographic findings, or laboratory tests are specific for the diagnosis of PVEM.

(ii) *Table requirements.* A Table injury for PVEM in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute PVEM. The acute PVEM or related complications must be of sufficient severity to require inpatient hospitalization.

(8) *Fetal Vaccinia (FV)*—(i) *Definition.* FV is an intrauterine vaccinial infection subsequent to vaccinia vaccination or inoculation of the mother that results from the placental transmission of the vaccinia virus during any time in the pregnancy. FV manifests as multiple skin lesions or organ involvement and may result in significant scarring or death. FV skin lesions are similar to those seen in GV or PV and the lesions may come together to form larger lesions. Congenital malformations, other than those described above, are not Table injuries.

(ii) *Table requirements.* A Table injury for FV requires sufficient evidence in the medical records of the occurrence of the FV. The occurrence of the FV or related complications must be of sufficient severity to require inpatient hospitalization or result in permanent and disfiguring scar(s). In addition, a Table injury for FV requires one of the following:

(A) A maternal history of vaccinial vaccination or inoculation, with the occurrence of vaccinial skin or mucous membrane lesions within the incubation period for vaccinia during the pregnancy in a maternal recipient or contact; or

(B) Isolation of vaccinia from intrauterine or neonatal tissue.

(9) *Secondary Infection (SI)*—(i) *Definition.* SI is, for purposes of the Table, a non-vaccinial bacterial, fungal, or viral infection at the site of a vaccinial skin or mucous membrane lesion. SI occurs because the blister formation or ulceration that is part of the normal progression of a vaccinial skin or mucous membrane lesion disrupts the surface of the skin or mucous membrane, allowing potential germs to invade and infect the vaccinial skin or mucous membrane lesion leading to significant illness requiring hospitalization.

(ii) *Table requirements.* A Table injury for SI in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SI. The acute SI or related complications must be of sufficient severity to require inpatient hospitalization.

(10) *Anaphylaxis or Anaphylactic shock*—(i) *Definition.* Anaphylaxis or

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 vaccinial 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.

[68 FR 70093, Dec. 16, 2003, as amended at 71 FR 29808, May 24, 2006]

§§ 102.22–102.29 [Reserved]

Subpart D—Available Benefits

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