

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 vaccinia 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 vaccinia 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 vaccinia 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 vaccinia vaccination or inoculation, with the occurrence of vaccinia 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-vaccinia bacterial, fungal, or viral infection at the site of a vaccinia skin or mucous membrane lesion. SI occurs because the blister formation or ulceration that is part of the normal progression of a vaccinia skin or mucous membrane lesion disrupts the surface of the skin or mucous membrane, allowing potential germs to invade and infect the vaccinia skin or mucous membrane lesion leading to significant illness requiring hospitalization.

(ii) *Table requirements*. A Table injury for SI in a recipient or contact