

**COVAX No Fault Compensation Program For AMC Eligible
Economies**

Vaccination Injury Table

April 27, 2023

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Introduction

The Vaccination Injury Table (the “Table”) for the COVAX No Fault Compensation Program for AMC Eligible Economies (the “Program”) was developed to provide information to individuals and Registered Healthcare Professionals in AMC Eligible Economies about possible serious injuries that may occur as a result of a COVID-19 Vaccine procured or distributed through the COVAX Facility, or the administration of such a Vaccine.

In order for an injury to be eligible for compensation under the Program, it must result in permanent total or partial impairment or death. More generally, the inclusion of an injury in the Table does not automatically mean that:

- an Application will be deemed receivable pursuant to section 4 of the Program’s Protocol; and/or that
- a Receivable Claim for such an injury will be found to be compensable under the Program. By way of example, based on the Application and/or Supporting Evidence provided, the Program’s Review Panel and as applicable, the Program’s Appeals Panel may find that the injury is more likely to have resulted from another cause, or that the disability resulting from the injury is not permanent.

For more information about eligibility for compensation under the Program, please see the Program’s Protocol [<https://covaxclaims.com/program-protocol/>] and FAQ [<https://covaxclaims.com/faqs/>]

The Table lists possible serious injuries that are documented by Stringent Regulatory Authorities ([Product-Eligibility COVAX-Facility Dec2020 0.pdf \(who.int\)](#)) in relevant vaccine information sheets.

The Table will be updated periodically as new information is documented by Stringent Regulatory Authorities in relevant vaccine information sheets about potential serious injuries that may occur as a result of a COVID-19 Vaccine procured or distributed through the COVAX Facility, or the administration of such a Vaccine.

If an injury is not listed in the Table, that does not necessarily mean that the injury is not eligible for compensation.

While all reasonable precautions have been taken to verify the information contained in the Table, no express or implied representations or warranties whatsoever are being provided. ESIS Inc., COVAX and its conveners, including WHO, Gavi and/or CEPI, as well as the members of the Program’s Scientific Advisory Committee hereby expressly disclaim any and all responsibility and liability for the Table’s content, presentation, completeness and/or accuracy (including its scientific merit) and shall not be held liable for any damages whatsoever as a result of its publication, use, interpretation, or application.

Capitalized terms used, but not defined, in this Introduction have the meaning ascribed to such terms in the Program’s Protocol.

ESIS Inc., as the Program independent claims administrator, would like to thank the members of the Scientific Advisory Committee and its advisors for their invaluable expertise and input in the development of this Table.

SUMMARY VACCINATION INJURY TABLE

Illness, disability, injury, or condition covered	Vaccine ¹ type	Time period for first onset of symptoms after vaccine administration
Acute Disseminated Encephalomyelitis	Viral Vector	Minutes to days
Anaphylaxis	All	≤24 hours
Brachial Neuritis/Brachial Plexus Injury	All	2 to 28 days
Capillary Leak Syndrome/Clarkson’s Disease	Messenger RNA Viral Vector	Within 4 days
Facial Nerve Palsy	Messenger RNA Viral Vector	Within 48 hours
Guillain Barre Syndrome	Viral Vector	Within 42 days
Myopericarditis	Messenger RNA Viral Vector	≤4 days
Shoulder Injury Related to Vaccine Administration	All	≤48 hours
Thrombosis with Thrombocytopenia Syndrome	Viral Vector	≤42 days
Transverse Myelitis	Viral Vector	15 hours to 6 weeks

COVID-19 viral vector Vaccines include:

- Janssen Covid-19 vaccine (Janssen–Cilag International NV)
- Astrazeneca Covid-19 vaccine (Vaxzevria)
- Serum Institute of India Covid-19 vaccine (Covishield)

COVID-19 messenger RNA Vaccines include:

- Moderna Biotech Covid-19 vaccine (Spikevax)
- BioNTech Covid-19 vaccine (Comirnaty)

Other COVID-19 Vaccines include:

- Sinopharm Beijing Institute Covid-19 vaccine (Covilo)
- Sinovac Life Sciences Covid-19 vaccine (CoronaVac)
- Serum Institute of India Covid-19 vaccine (Covovax)

¹ The term “Vaccine” as used herein is defined in Section 2(z) of, and exclusively includes the vaccines listed in Schedule 1 to, the Program’s Protocol see ([COVAX-Compensation-Program-Vaccine-List.pdf \(covaxclaims.com\)](https://covaxclaims.com/COVAX-Compensation-Program-Vaccine-List.pdf))

ACUTE DISSEMINATED ENCEPHALOMYELITIS (ADEM)

Definition:

A brief widespread attack of inflammation in the brain and spinal cord that damages myelin. ADEM occurs most commonly in children under the age of 10. Its incidence increases with increase in distance from the equator.

Diagnostic Criteria:

For all cases, the following must be present:

- Onset of symptoms in minutes to hours or days (acute) or days to weeks (subacute) after vaccine administration.
- No other explanation for symptoms or abnormal diagnostic test results.

Symptoms:

Presentation can be similar to other demyelinating diseases, such as multiple sclerosis. Symptoms include:

- Fever
- Headache
- Stiff neck
- Weakness, numbness or tingling of arms and legs
- Difficulty with balance
- Drowsiness
- Optic neuritis leading to blurred or double vision
- Difficulty with swallowing and speaking
- Confusion
- Bowel or bladder dysfunction
- Seizures or coma

Diagnostic Testing:

- There is no specific diagnostic test for this condition. Brain MRI or CT, brain biopsy, lumbar puncture, electromyography (EMG) and nerve conduction studies may be helpful but are not required.
- Complete neurologic examination is necessary, including use of Glasgow Coma Scale, Pediatric Coma Scale, Mini-Mental State Exam, Barthel Index and Modified Rankin Functional Score as needed.

Recovery and Prognosis:

The prognosis is favorable, and most studies report a full recovery in 50%–75% of patients over a period of 1–6 months after the illness. The most common sequelae are focal motor deficits, which could range from mild ataxia to hemiparesis. The degree of impairment is determined by the duration and severity of inflammation in brain and spinal cord. A hyperacute onset, severe neurologic deficits as a result of aggressive disease, and unresponsiveness to steroids are poor prognostic indicators.

Recurrence of symptoms 3 months or longer after initial attack suggests an alternative diagnosis.

Types of Vaccines Involved:

- Viral Vector

ANAPHYLAXIS

Definition:

A life-threatening, severe, and progressive multisystemic allergic reaction of rapid onset, within 24 hours of vaccine administration. Characterized by involvement of the skin, respiratory, gastrointestinal, and cardiovascular systems.

Diagnostic Criteria:

For all cases, the following must be present:

- Sudden onset of symptoms leading to a marked change in condition within 24 hours of vaccine administration.
- Rapid progression of symptoms.
- Involvement of multiple systems – skin, respiratory, gastrointestinal, and cardiovascular – with involvement of at least two organ systems within 24 hours.
- No other explanation for symptoms or abnormal diagnostic test results.

Symptoms:

- Skin or mucosa
 - Generalized urticaria (hives) or erythema
 - Angioedema that may be generalized or local
 - Generalized pruritis with or without rash
 - Generalized prickle sensation
 - Urticaria (hives) localized at injection site
 - Red and itchy eyes
- Cardiovascular
 - Tachycardia
 - Capillary refill time greater than 3 seconds with or without hypotension
 - Reduced central pulse volume
 - Decrease in or loss of consciousness
- Respiratory
 - Bilateral wheeze (bronchospasm)
 - Stridor
 - Obvious upper respiratory swelling involving the tongue, throat, uvula, or larynx
 - Signs of respiratory distress – tachypnea, increased use of respiratory accessory muscles, recession, cyanosis, grunting
 - Persistent dry cough
 - Hoarseness
 - Difficulty breathing with or without wheezing or stridor
 - Sensation of throat closure
 - Sneezing
 - Rhinorrhea (runny nose)
- Gastrointestinal
 - New onset of diarrhea
 - Abdominal pain

- New onset of nausea and vomiting

Diagnostic Testing:

There is no specific diagnostic testing for anaphylaxis. Serum mast cell tryptase elevation may be helpful but is not required. (This occurs within 6 hours of symptoms.)

Recovery and Prognosis:

With immediate treatment, most patient recover fully. However, delayed intervention resulting in prolonged lack of circulation or oxygenation may lead to significant injury and impairment and even death.

Types of Vaccines Involved:

- All²

² All refers to all vaccines listed in Schedule 1 to, the Program's Protocol see ([COVAX-Compensation-Program-Vaccine-List.pdf \(covaxclaims.com\)](https://covaxclaims.com/COVAX-Compensation-Program-Vaccine-List.pdf))

BRACHIAL NEURITIS/BRACHIAL PLEXUS INJURY

Definition:

A dysfunction of the upper extremity nerve plexus characterized by deep, steady, and often severe aching pain in the shoulder and upper arm. There may also be weakness of the affected upper arm.

Diagnostic Criteria:

For all cases, the following must be present:

- Deep, steady, and often severe aching pain in the shoulder and upper arm.
- Onset of pain occurs within 2-28 days of administration of vaccine in the affected arm.
- No other risk factors such as HIV, Lyme disease, head or neck tumor, neurological disorder, endocrine disorder, drug toxicity or inherited or congenital disorder.
- No other explanation for abnormal diagnostic testing.

Symptoms:

In addition to the above, the following may also occur:

- Sensory loss in the affected arm.
- Muscle weakness in the affected arm.
- Muscle atrophy in the affected arm.
- Peripheral neuritis may occur in the affected and/or opposite arm.

Diagnostic Testing:

If available, nerve conduction study or EMG should be obtained if muscle weakness is limited to muscles supplied by one peripheral nerve. If nerve conduction studies or EMG were not done or not available, weakness in muscles of the affected arm supplied by more than one peripheral nerve is sufficient to establish diagnosis.

Recovery and Prognosis:

Recovery occurs after 3 months, with complete resolution in 89% of cases, but it may result in permanent weakness.

Types of Vaccines Involved:

- All³

³ All refers to all vaccines listed in Schedule 1 to, the Program's Protocol see ([COVAX-Compensation-Program-Vaccine-List.pdf \(covaxclaims.com\)](#))

CAPILLARY LEAK SYNDROME/CLARKSON'S DISEASE

Definition:

A rare and serious condition characterized by escape of blood plasma through capillary walls from the circulatory system to surrounding tissues, muscle compartments, organs, or body cavities. Attacks are severe, acute and recurrent and are accompanied by rapid fall in blood pressure.

Diagnostic Criteria:

For all cases, the following must be present:

- Sudden and acute onset.
- Swelling of the arms and legs.
- Hypotension.
- Thickening of the blood, elevated hematocrit.
- Low albumin.
- No other risk factors such as HIV, Lyme disease, head or neck tumor, neurological disorder, endocrine disorder, drug toxicity or inherited or congenital disorder.
- No other explanation for abnormal diagnostic testing.

Symptoms:

Initial onset occurs within 4 days following vaccine administration. One to two days prior to attack, patients may experience one or more of the following:

- Abdominal and muscle pain
- Anasarca
- Fatigue
- Weakness
- Thirst
- Irritability
- Nausea
- Sudden weight gain
- Viral or upper respiratory tract infection

Diagnostic Testing:

The following diagnostic testing may be helpful in confirming the diagnosis *but is not required*:

- Hemoglobin and hematocrit levels
- Serum albumin level
- Serum M protein (monoclonal gammopathy)

Recovery and Prognosis:

There is no cure for this disorder. Survival requires prompt diagnosis and treatment of each episode.

Types of Vaccines Involved:

- Messenger RNA
- Viral Vector

FACIAL NERVE PALSY

Definition:

A lower motor neuron neuropathy resulting the inability to wrinkle the forehead or raise the eyebrows on the affected side.

Diagnostic Criteria:

For all cases, the following must be present:

- Sudden onset and rapid progression of symptoms within 48 hours of vaccine, with some or complete resolution.
- Inability to wrinkle the forehead or raise the eyebrows.
- No other risk factors such as HIV, Lyme disease, head or neck tumor, neurological disorder, endocrine disorder, drug toxicity or inherited or congenital disorder.
- No other explanation for abnormal findings.

Symptoms:

- Mild weakness to total paralysis of one side of the face.
- Difficulty with facial expressions such as closing of the eye, smiling.
- Drooling.
- Numbness or heavy feeling in the face.
- Pain around the jaw or behind the ear.
- Increased sensitivity to sound on the affected side.
- Headache.

Diagnostic Testing:

None needed.

Recovery and Prognosis:

Clinical evidence of improvement occurs spontaneously within three weeks in 85% of cases, and most individuals eventually recover normal facial function.

Types of Vaccines Involved:

- Messenger RNA
- Viral Vector

GUILLAIN-BARRE SYNDROME

Definition:

A rare neurological disorder in which the body's immune system attacks the peripheral nervous system.

Diagnostic Criteria:

For all cases, the following must be present:

- Flaccid and bilateral weakness
- Decreased or absent deep tendon reflexes in limbs that are weak
- Symptoms are progressive over hours to weeks following vaccine administration
- No other risk factors such as recent infectious illness
- No other explanation for abnormal findings

Symptoms:

- Onset of symptoms within 42 days following vaccine administration.
- Weakness and tingling of the legs and hands, usually progressing in ascending or descending fashion
- Sensation of heat, pain, or inability to feel textures in the limbs
- Spread of weakness and abnormal sensations to the upper body
- Inability to walk or climb stairs
- Loss of knee jerk reflex
- Difficulty controlling bowel and bladder function

Diagnostic Testing:

Nerve conduction studies and cerebrospinal fluid analysis may be helpful but are not required for diagnosis.

Recovery and Prognosis:

Full recovery occurs in 70% of people with GBS. With careful intensive care and successful treatment of autonomic dysfunction and other medical complications, even those individuals with respiratory failure usually survive.

Types of Vaccines Involved:

- Viral Vector

MYOPERICARDITIS

Definition:

An immunocomplex mediated inflammation of the myocardium (heart muscle) *and* pericardium (exterior covering of the heart). Most often affects adolescent and young adult males after COVID-19 vaccine. This term is also used for analysis and reporting purposes when either myocarditis or pericarditis is present.

Myocarditis

Diagnostic Criteria:

- At least one of the following ECG findings:
 - ST-segment or T-wave abnormalities
 - Paroxysmal or sustained atrial, supraventricular, or ventricular arrhythmias
 - AV nodal conduction delays
- Laboratory findings, if available, may include:
 - Elevated erythrocyte sedimentation rate ESR
 - Elevated C-reactive protein
 - Elevated brain natriuretic peptide (BNP)
- No other identified cause for symptoms.

Symptoms:

- Onset 0-4 days following vaccine administration
- May present as or develop into congestive heart failure
- Chest pain, pressure, discomfort
- Shortness of breath
- Palpitations
- Swelling of legs, ankles, feet
- Flu-like symptoms – headache, body aches, joint pain, fever, sore throat

Diagnostic Testing:

- Elevated erythrocyte sedimentation rate ESR, if available
- Elevated CK and/or troponin, if available
- Elevated C-reactive protein, if available
- Elevated brain natriuretic peptide (BNP), if available
- MRI or CT scan, if available
- No other identified cause for symptoms

Recovery and Prognosis:

The disease is self-limited and full recovery is likely.

Types of Vaccines Involved:

- Messenger RNA
- Viral Vector

Pericarditis

Diagnostic Criteria:

- At least one of the following findings:
 - Elevated troponin T, troponin I, or creatine kinase-myocardial band
 - Abnormal echocardiogram, if available, showing thickened pericardium
 - ECG abnormalities such as paroxysmal or sustained atrial, supraventricular, ventricular arrhythmias, or AV nodal conduction delays
- Other laboratory findings, if available, may include:
 - Elevated C-reactive protein
 - Elevated erythrocyte sedimentation rate (ESR)
 - Elevated D-dimer
- Cardiac friction rub, Kussmaul’s sign, pericardial knock, muffled heart sounds, pulsus paradoxus, and transudate pericardial effusion may be present
- No other identified cause for symptoms.

Symptoms:

- Onset 0-4 days following vaccine administration.
- Pleuritic chest pain relieved by leaning forward
- Difficulty breathing (dyspnea)
- Fatigue or lightheadedness
- Swelling in the abdomen or legs
- Low-grade fever

Diagnostic Testing:

- ECG, if available, demonstrating:
 - PR depression
 - ST elevation – diffuse, non-localizing
 - Atrial arrhythmias
 - Ventricular arrhythmias
 - Electrical alternans
- Laboratory findings, if available, may include:
 - Elevated ESR
 - Elevated C-reactive protein
- Imaging:
 - CT or MRI, if available, showing thickened pericardium

Recovery and Prognosis:

- Self-limited – full recovery likely

Types of Vaccines Involved:

- Messenger RNA

- Viral Vector

Effusive Pericarditis

Diagnostic Criteria:

- Abnormal echocardiogram showing pericardial effusion must be present
- ECG abnormalities, if available, such as paroxysmal or sustained atrial, supraventricular, ventricular arrhythmias, or AV nodal conduction delays
- Other laboratory findings, if available, may include:
 - Elevated C-reactive protein
 - Elevated erythrocyte sedimentation rate (ESR)
 - Elevated D-dimer
 - Elevated troponin T, troponin I, or creatine kinase-myocardial band
- Cardiac friction rub, Kussmaul’s sign, pericardial knock, muffled heart sounds, paradoxus, and transudate pericardial effusion may be present
- No other identified cause for symptoms.

Symptoms:

- Onset 0-4 days following vaccine administration.
- Pleuritic chest pain relieved by leaning forward may or may not be present
- Difficulty breathing (dyspnea)
- Fatigue or lightheadedness
- Swelling in the abdomen or legs
- Low-grade fever

Diagnostic Testing:

- ECG, if available, demonstrating:
 - PR depression
 - ST elevation – diffuse, non-localizing
 - Atrial arrhythmias
 - Ventricular arrhythmias
 - Electrical alternans
- Laboratory findings, if available, may include:
 - Elevated ESR
 - Elevated C-reactive protein
- Imaging:
 - CT or MRI, if available, showing thickened pericardium

Recovery and Prognosis:

Self-limited – full recovery likely

Types of Vaccines Involved:

- Messenger RNA
- Viral Vector

SHOULDER INJURY RELATED TO VACCINE ADMINISTRATION (SIRVA)

Definition:

Shoulder pain and decreased range of motion following intramuscular injection in the upper arm. The condition usually resolves within weeks.

Diagnostic Criteria:

For all cases, the following must be present:

- Pain onset within 48 hours of vaccine administration.
- Pain and decreased range of motion in the vaccinated shoulder.
- No prior history of pain or dysfunction in the affected arm or shoulder.
- No other explanation for abnormal findings or symptoms.

Symptoms:

- Significant pain in the vaccinated shoulder.
- Decreased range of motion in the vaccinated shoulder.
- Difficulty moving shoulder in the vaccinated arm.

Diagnostic Testing:

None required though MRI may be done to determine extent of injury.

Recovery and Prognosis:

Recovery can take up to 6 months. SIRVA can lead to permanent impairment.

Types of Vaccines Involved:

- All⁴

⁴ All refers to all vaccines listed in Schedule 1 to, the Program's Protocol see ([COVAX-Compensation-Program-Vaccine-List.pdf \(covaxclaims.com\)](https://covaxclaims.com/COVAX-Compensation-Program-Vaccine-List.pdf))

THROMBOSIS & THROMBOCYTOPENIA SYNDROME (TTS)

Definition:

An acute onset of venous or arterial thrombosis with thrombocytopenia.

Diagnostic Criteria:

For all cases, the following must be present:

- Onset of symptoms within 42 days following vaccine administration.
- Thrombocytopenia with platelet count less than $150 \times 10^9/L$ with no history of heparin therapy within 100 days.
- No history of prior thrombosis or thrombocytopenia.
- No other explanation for abnormal findings or symptoms.

Symptoms:

- Shortness of breath
- Chest pain
- Swelling in the legs
- Persistent pain in the abdomen
- Severe or persistent headaches
- Blurred vision
- Easy bruising

Diagnostic Testing:

- MRI or CT likely necessary to determine cause of symptoms.
- Platelet count (blood test).
- PF4 heparin induced thrombocytopenia ELISA test if available.

Recovery and Prognosis:

Patients who develop TTS after vaccination require hospitalization. While treatment protocols have improved survival rate, long term prognosis remains uncertain.

Types of Vaccines Involved:

- Viral Vector

TRANSVERSE MYELITIS

Definition:

Inflammation of both sides of one section of the spinal cord, causing weakened muscles and reflexes.

Diagnostic Criteria:

- Pain, usually in the torso, lower back, or legs, affecting both sides.
- Weakness in the legs and possibly arms, affecting both sides.
- A clearly defined sensory level, at and below which pain and other symptoms are present.
- Motor, sensory, or autonomic dysfunction attributable to spinal cord.
- No recent history of viral, bacterial, parasitic, or fungal infection.
- No history of immune disorders.
- No history of vascular disorders such as arteriovenous malformation, dural arterio-venous fistula, intraspinal cavernous malformations or disk embolism.
- No history of spinal cord irradiation within the past 10 years.
- No history of connective tissue disease such as sarcoidosis, Behcet's disease, Sjogren's syndrome or systemic lupus erythematosus.
- No history of optic neuritis.
- No other explanation for abnormal findings or symptoms.

Symptoms:

- Onset of symptoms ranges from 15 hours to 6 weeks following vaccine administration.
- Paresthesias (burning, tingling, numbness, cold, tickling, pricking sensation).
- Muscle spasms
- Bowel and bladder dysfunction – increased urinary frequency, incontinence, constipation.
- Headaches, fever, loss of appetite.

Diagnostic Testing:

Patients with this condition require hospitalization. Testing such as lumbar puncture, D-DIMER test, CT scan and MRI may be done (if available) to confirm the diagnosis and rule out other causes of symptoms as well as to determine treatment.

Recovery and Prognosis:

Most patients recover with treatment.

Types of Vaccines Involved:

- Viral Vector