



Compensation Programs for Potential COVID-19 Vaccine Injuries

March 22, 2021

Following the Food and Drug Administration’s (FDA) emergency authorization of the [Pfizer/BioNTech](#), [Moderna](#), and [Janssen Biotech/Johnson & Johnson](#) vaccines against COVID-19, [millions of Americans](#) have received at least one dose of a COVID-19 vaccine regimen. Based on months-long clinical trials (including safety monitoring) of each vaccine candidate involving tens of thousands of participants, FDA [did not](#) identify [any](#) safety concerns for these vaccines that would preclude FDA emergency use authorization. As with most vaccines, however, a very small percentage of inoculated individuals experienced adverse reactions to a COVID-19 vaccine. [Anecdotal reports](#) from early in the COVID-19 vaccination campaign include several cases of anaphylaxis—a severe and potentially life-threatening allergic reaction—following vaccination.

According to a [joint study](#) by scientists at the Centers for Disease Control and Prevention (CDC) and FDA, there were 21 reported cases of anaphylaxis from the first 1.9 million Pfizer/BioNTech vaccinations. [Nearly all](#) of these individuals (19 of 21) received epinephrine as treatment. Although some of these individuals were hospitalized, all have recovered and were discharged; no deaths were reported. The most recent evidence available [indicates](#) serious allergic reactions to COVID-19 vaccines occur in approximately two to five people per million doses administered. Although these serious adverse events are rare, the CDC [recommends](#) that all individuals be monitored for at least 15 minutes following their vaccinations, and that all vaccination sites have epinephrine available for treatment of anaphylaxis.

Federal law has two distinct vaccination compensation regimes that may compensate individuals harmed by adverse reactions. In general, the [National Vaccine Injury Compensation Program](#) (VICP) may provide compensation for injuries or deaths associated with [most vaccines](#) routinely administered in the United States (such as pediatric and seasonal influenza vaccines). During certain public health emergencies, the [Countermeasures Injury Compensation Program](#) (CICP) may provide compensation for injuries and deaths resulting from the administration of “covered countermeasures” under the [Public Readiness and Emergency Preparedness Act](#) (PREP Act), which may include vaccines.

Under the Secretary of Health and Human Services’s (HHS) [PREP Act Declaration](#) for COVID-19 (and its [amendments](#)), COVID-19 vaccines are considered covered countermeasures within the PREP Act’s scope. As a result, CICP—and [not](#) VICP—will apply to injuries resulting from COVID-19 vaccinations while the public health emergency persists and the Declaration remains in force. Compensation through

Congressional Research Service

<https://crsreports.congress.gov>

LSB10584

CICP is generally somewhat [more limited](#) than through VICP. This Sidebar will review and compare the compensation regimes available for vaccine-related injuries under CICP and VICP, and describe the procedures for injured individuals to obtain compensation under each program.

The Countermeasures Injury Compensation Program

To encourage expeditious development and deployment of medical countermeasures during a public health emergency, the [PREP Act](#) authorizes the Secretary of HHS (the Secretary) to limit legal liability for losses resulting from the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020 ([the PREP Act Declaration](#)), the Secretary invoked the PREP Act and declared COVID-19 to be a public health emergency warranting liability protections for covered countermeasures. Pursuant to the PREP Act Declaration and its [subsequent amendments](#), manufacturers, distributors, and health care providers are generally [immune](#) from legal liability (i.e., they cannot be sued for money damages in court) for losses related to the administration or use of covered countermeasures against COVID-19. (For a detailed discussion of the scope of liability immunity under the PREP Act, see [this CRS Sidebar](#).)

In addition to providing immunity from liability, the PREP Act established [CICP](#), a compensation program for individuals seriously injured or killed as a direct result of the administration or use of a covered countermeasure. CICP is a [regulatory process](#) administered by HHS’s Health Resources and Services Administration ([HRSA](#)). [HRSA regulations](#) govern CICP’s procedures and eligibility determinations.

Covered Vaccines and Injuries

Under the PREP Act and the [amended Declaration](#), covered countermeasures for COVID-19 [may include](#) drugs, biological products, and medical devices that the FDA approves, licenses, or authorizes for emergency use “to diagnose, mitigate, prevent, treat, or cure” COVID-19, or used “to limit the harm [the COVID-19 pandemic] might otherwise cause.” For example, personal protective equipment (PPE) (e.g., respirators), ventilators, therapeutic drugs (e.g., remdesivir), and monoclonal antibody treatments [authorized by FDA](#) to treat or prevent COVID-19 are covered countermeasures under the PREP Act. Notably, FDA-authorized COVID-19 vaccines—such as those produced by Pfizer, Moderna, and Johnson & Johnson—are covered countermeasures under the PREP Act Declaration.

Under the PREP Act, CICP remedies “[shall be exclusive of any other civil action or proceeding](#)” for injuries directly caused by administering covered countermeasures, with limited exceptions. Thus, while the current PREP Act Declaration and public health emergency remain in effect, CICP is the [exclusive](#) remedy for injuries resulting from COVID-19 vaccinations. (As discussed in detail below, VICP may eventually apply to COVID-19-vaccine injuries after the public health emergency terminates, contingent on certain statutory and regulatory changes.)

CICP compensation is limited to [eligible individuals](#), such as persons injured by countermeasures or their survivors. CICP only provides compensation for death or “[serious physical injuries](#),” that is, injuries that warrant hospitalization or lead to a significant loss of function or disability. Thus, individuals who experience only minor [side effects](#) from a COVID-19 vaccine—such as soreness, headache, or fatigue—would not be eligible for CICP compensation.

Procedure for Obtaining Compensation

To apply for CICP compensation, a claimant must file a [request for benefits](#) within [one year](#) of the date the countermeasure was administered. In addition to the request form, claimants [may need to submit](#) medical records and other evidence to establish eligibility. If determined to be eligible, claimants may

submit additional [documentation](#) to demonstrate the compensation amount. Eligibility and compensation determinations [are made by](#) CICIP, as the delegate of the Secretary. Claimants may seek [reconsideration](#) of an adverse eligibility decision by CICIP, but the ultimate decisionmaking authority lies with the Secretary. The PREP Act [precludes judicial review](#) of the Secretary's eligibility and compensation decisions.

CICIP claimants can prove eligibility for compensation in one of [two ways](#). The first only applies to injuries listed on the Countermeasure Injury Table, which the Secretary [must establish](#) by regulation when compelling medical and scientific evidence shows that administration or use of a covered countermeasure directly causes particular injuries. (The table established for the H1N1 [pandemic influenza vaccine](#) is one example; no such table has yet been promulgated for COVID-19 vaccines.) For injuries listed on a Countermeasure Injury Table, if the claimant can [show](#) that the countermeasure recipient's injury is listed on the table and was sustained within the relevant time interval (and meets any other requirements set forth in the table), CICIP will presume the injury was a direct result of the covered countermeasure. For injuries *not* on a Countermeasure Injury Table (or outside its scope), the claimant [must prove](#) the non-table injury was the "direct result" of the countermeasure's administration based on "compelling, reliable, valid, medical and scientific evidence" beyond mere temporal association.

Available Compensation

Compensation under CICIP is [limited to](#) (1) reasonable medical expenses (e.g., unreimbursed hospitalization costs); (2) loss of employment income (e.g., income lost from inability to work due to disability); and (3) a set death benefit where the death is a direct result of the administration or use of a covered countermeasure. Attorneys' fees and pain-and-suffering damages are [not available](#). CICIP awards are also subject to various annual and lifetime limits. For example, annual lost employment income awards are [capped](#) at \$50,000 per year, and the standard [maximum](#) death benefit is the same as that under the [Public Safety Officers' Benefits](#) program (currently \$370,376).

Given the limited number and scope of past [PREP Act declarations](#), CICIP has been used relatively [infrequently](#) since the PREP Act's 2005 enactment. The [majority](#) of these claims were related to the H1N1 influenza vaccine. According to [HRSA](#), CICIP has received 551 claim filings, of which 450 were determined to be ineligible for compensation; only 29 claims to date have been [paid out](#) by CICIP, amounting to \$6 million in awards.

Congress funds CICIP awards through emergency appropriations to the Covered Countermeasure Process Fund (CCP Fund). Both the Coronavirus Aid, Relief, and Economic Security Act ([CARES Act](#)) and the [Coronavirus Preparedness and Response Supplemental Appropriations Act](#) appropriate funding that HHS may transfer to the CCP Fund to use for CICIP awards.

The National Vaccine Injury Compensation Program

After the Secretary terminates the PREP Act Declaration for the COVID-19 pandemic, any injuries or death from COVID-19 vaccines would be addressed in court under tort law unless the COVID-19 vaccines are added to the [National Vaccine Injury Compensation Program](#) (VICP). VICP provides compensation for injuries and deaths caused by certain vaccines listed on the [Vaccine Injury Table](#).

VICP was created by the [National Childhood Vaccine Injury Act of 1986](#) (NCVIA) amid concerns that lawsuits against vaccine manufacturers and health care providers alleging vaccine injuries could lead to vaccine shortages and lower immunization rates. Under a typical state [tort law](#) framework, the injured person must generally prove that a vaccine caused the injury and that either the vaccine manufacturer is at fault (e.g., negligent, failed to warn adequately) or, under products liability doctrines, that the vaccine was defective. If the person cannot prove one of these elements—for example, if the manufacturer adequately warned of side effects or it is unclear whether the vaccine caused the injury—the claimant receives no

compensation. If the vaccine manufacturer is found liable, however, it may be responsible for compensatory damages and potentially punitive damages as determined by a jury. Regardless of the outcome, both sides generally would be responsible for litigation costs.

The NCVIA created a no-fault alternative compensation program for deaths and injuries caused by certain vaccines. The program shields vaccine manufacturers from most liability for vaccine-related injuries and deaths, while providing compensation for those injured by vaccines. By limiting liability exposure for vaccine manufacturers, expanding the availability of compensation for injured parties, and lowering the burden of proof, the program reduces uncertainty for both injured persons and vaccine manufacturers. From implementation of the program in 1988 through March 1, 2021, more than [23,902 petitions](#) for compensation have been filed, of which 19,609 have been adjudicated, and 7,874 determined to merit compensation. The program has paid out approximately [\\$4.5 billion](#) in compensation since its inception.

Covered Vaccines and Injuries

To receive compensation, an injured party must show he or she received a “covered vaccine.” Not every FDA-approved vaccine is covered by the VICP. The NCVIA included an [initial Vaccine Injury Table](#) listing vaccines covered by the program. The statute requires the Secretary to [amend](#) the Vaccine Injury Table to add all vaccines recommended by the CDC for routine administration to children or pregnant women within two years of such a recommendation. To receive compensation through the VICP, the person must have received a vaccine that is (1) recommended by the CDC for routine administration to children or pregnant women, (2) subject to an [excise tax](#), and (3) listed by the Secretary on the [Vaccine Injury Table](#). The types of vaccines subject to the excise tax are [specified in statute](#) and therefore can only be amended by an act of Congress.

In addition to having received a covered vaccine, the injured party must [show](#) either that (1) he or she experienced an injury listed for the vaccine in the [Vaccine Injury Table](#) and the first symptom of the onset or significant aggravation of the injury occurred within the timeframe specified in the table, or (2) the vaccine caused the injury. The Vaccine Injury Table accordingly allows injured persons to avoid having to prove a vaccine caused their injuries by allowing them instead to show they received an injury that has been associated with the vaccine soon after receiving the vaccine. Nonetheless, injured persons still have the option of directly proving that a vaccine caused their injuries if they experience a less common injury or the onset or aggravation of the injury is delayed.

Procedure for Obtaining Compensation

To receive compensation through VICP for a vaccine-related injury or death, the injured person (or the estate in the case of a death) files a petition with the U.S. Court of Federal Claims (Claims Court). The [petition](#) must generally contain an affidavit and supporting documentation, including relevant medical records, showing the person:

- received a vaccine listed in the Vaccine Injury Table;
- sustained an illness, disability, injury, or condition set forth in the Vaccine Injury Table for the particular vaccine, and
 - the first symptom or manifestation occurred within the required time period; or
 - the vaccine caused the injury;
- suffered residual effects or complications that lasted for more than 6 months or required inpatient hospitalization and surgery, or died; and
- has not collected another award or settlement for the injury or death.

Petitions for vaccine-related injuries must generally be filed within [three years](#) of the first symptom or significant aggravation of the injury. Petitions for vaccine-related deaths must be filed within [two years](#) of the death and within four years of the first symptom or significant aggravation of the injury from which the death resulted. If the Vaccine Injury Table is amended such that a person qualifies for compensation who previously did not, that person has [two years](#) from when the table is revised to seek compensation for injuries or deaths that occurred up to eight years before the table was revised.

When a person files a petition with the Claims Court, the clerk of the court [forwards](#) the petition to the [chief special master](#) to assign the petition to one of eight special masters. The special master conducts a [proceeding](#) to evaluate whether the petition merits compensation under the VICP and, if so, how much. The proceedings resemble trials in allowing the presentation of evidence and submission of testimony, but they operate under more flexible, informal [procedures](#) to allow for expeditious resolution. Once a petition is filed, the special master has [240 days](#) to issue a decision that includes factual findings and legal conclusions, though the parties may suspend the proceedings by motion for up to 150 days if necessary.

Following the decision, the petitioner has [30 days](#) to appeal a special master's decision to the Claims Court for review. The court then has 120 days to uphold the decision, issue its own decision, or remand to the special master for further proceedings. Once the court issues its judgment, either because the petitioner does not appeal the special master's decision within 30 days or the court issues a decision after review, the petitioner has 60 days to appeal the judgment to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). If the petitioner chooses not to appeal the decision, the judgment becomes final.

After a final judgment, the petitioner has [90 days](#) to inform the Claims Court whether the petitioner accepts the judgment or will file a civil action for damages in court. A petitioner may also [withdraw](#) its petition and file a civil action if the special master fails to act within 240 days or the Claims Court fails to enter the judgment within 420 days, both timeframes excluding any suspended time. (Petitioners may [opt](#) not to withdraw their petitions if they do not want to risk proceeding in civil court.) Petitioners who neither rejected a judgment nor withdrew their petition due to the court's failure to act in time are [barred](#) from filing civil claims.

In addition to limiting the availability of civil actions to parties who have gone through the petition process, the VICP imposes [certain limitations](#) on vaccine manufacturers' liability. For example, vaccine manufacturers are not liable for injuries or deaths due to unavoidable side effects from properly prepared vaccines accompanied by proper directions and warnings. Any action that proceeds against a vaccine manufacturer is tried in [three stages](#): (1) liability, (2) general damages, and (3) punitive damages. Trifurcating the trial in this manner limits the evidence presented to the jury in the first and second stages to the evidence relevant to each stage of the trial.

Available Compensation

The VICP allows individuals to receive [compensation](#) for:

- actual and reasonably projectable unreimbursable expenses directly related to the vaccine-related injury, including the cost of diagnosis, medical care, rehabilitation, counseling, and vocational training, among others;
- actual and anticipated loss of earnings;
- actual and projected pain and suffering and emotional distress, capped at \$250,000;
- vaccine-related death, in the amount of \$250,000; and
- reasonable attorneys' fees and other costs associated with proceeding on the petition.

The NCVIA [authorized appropriations](#) to compensate individuals injured by vaccines administered before October 1, 1988. Compensation for injuries for vaccines administered after October 1, 1988, is paid out of

the [Vaccine Injury Compensation Trust Fund](#) (Trust Fund). Vaccine manufacturers pay into the Trust Fund through [excise taxes](#) imposed on covered vaccines. The Trust Fund may [only be used](#) to pay for vaccine-related injuries from vaccines subject to the excise tax at the time of payment, and for certain government administrative expenses incurred when administering the program.

Considerations for Congress

There are many unknowns about the future of the COVID-19 pandemic, the impact of SARS-CoV-2 variants, and the vaccines authorized to prevent COVID-19. It remains to be seen, for example, how long immunity lasts after individuals receive authorized vaccines, and whether additional inoculations will be needed for vaccinated individuals as the virus evolves. In addition, in the United States, COVID-19 vaccines are currently only authorized for individuals older than 16 or 18 years old, depending on the vaccine. Accordingly, it is unknown whether COVID-19 vaccines will become routinely administered, and whether the CDC would recommend any such vaccine for administration to children or pregnant women. If so, Congress may consider whether to add COVID-19 vaccines to the excise tax list, which would include them in the VICP. Alternatively, Congress might consider a broader amendment to the excise tax statute to allow any vaccine recommended for routine administration to children or pregnant women to be automatically subject to the excise tax and therefore eligible for the VICP. Or, if Congress decides that COVID-19 injuries should be compensated through VICP even while the public health emergency persists, Congress could amend the PREP Act and NCVIA accordingly.

Congress could also implement an entirely new program specifically addressing compensation for COVID-19 vaccine-related injuries or deaths should it so choose. Or, Congress could opt to leave COVID-19 vaccines out of the VICP and allow the traditional tort system to address any vaccine-related injuries, either now or after the public health emergency ends and CICIP no longer applies. In evaluating these options, Congress may consider the prevalence and severity of adverse effects related to COVID-19 vaccines, which will become more apparent as vaccine manufacturers and CDC collect additional data about vaccine recipients.

Table I. Comparison of Vaccine-Injury Compensation Programs: CICIP v. VICP

	Countermeasures Injury Compensation Program (CICIP)	Vaccine Injury Compensation Program (VICP)
Scope of Coverage	“Covered countermeasures” under the PREP Act, such as pandemic and epidemic products used to treat, mitigate, prevent, or cure COVID-19 (e.g., vaccines, PPE, treatments)	“Covered Vaccines” are those recommended by CDC for routine administration to children, subject to a federal excise tax, and added to the Vaccine Injury Table
Covered Injuries	Death or serious physical injury that (1) warrants hospitalization or (2) led to a significant loss of function or disability	Death or an illness, injury, or condition that lasted more than 6 months or required inpatient hospitalization and surgical intervention and was associated with one or more vaccines in the Vaccine Injury Table, unless the cause was an adulterant or contaminant that was intentionally added to the vaccine
Process for Obtaining Compensation	Administrative Process: file request form and supporting documentation with CICIP to prove eligibility and compensation amounts	Judicial Process (“vaccine court”): file a petition in the U.S. Court of Federal Claims

	Countermeasures Injury Compensation Program (CICP)	Vaccine Injury Compensation Program (VICP)
Available Benefits	Reasonable medical expenses, lost employment income, and death benefits	Non-reimbursed expenses related to the injury for the diagnosis, medical care, and various rehabilitation and recovery services; lost employment income; pain, suffering, and emotional distress damages; death benefits; attorney's fees
Unavailable Benefits	Attorneys' fees, pain-and-suffering damages, punitive damages	Punitive or exemplary damages
Benefit Caps	\$50,000/year for lost employment income (lifetime cap is generally \$379,000); standard death benefit of \$370,376 for FY2021	\$250,000 for death; \$250,000 for pain and suffering and emotional distress
Filing Deadlines	Within 1 year of the administration of the covered countermeasure	For injuries, within 3 years of the first symptom; for deaths, within 2 years of the death and 4 years of the first symptom
Standard of Proof	Must show the injury (1) meets the requirements on a Covered Countermeasures Injury Table; or (2) was a direct result of the administration or use of a covered countermeasure	Must show the person (1) received a vaccine in the Vaccine Injury Table; (2) sustained or significantly aggravated an illness, disability, injury, or condition, or died; (3) the illness, disability, injury, condition, or death is either listed in the Vaccine Injury Table in association with the vaccine and occurred within a set time period or was caused by the vaccine; (4) suffered the effects for more than 6 months or required inpatient hospitalization and surgery or died; and (5) has not previously collected an award for the injury or death
Initial Decisionmaker	CICP (as delegate of the Secretary of HHS)	U.S. Court of Federal Claims special master
Appeals & Judicial Review	Claimant may seek reconsideration of CICP decision to a qualified independent panel within 60 days; no further judicial or administrative review	Claimant may seek review of special master decision by U.S. Court of Federal Claims within 30 days of decision; claimant may seek review by the U.S. Court of Appeals for the Federal Circuit within 60 days of final judgment; claimant may accept the judgment or reject it and file a tort claim
Funding Source	Emergency appropriations to Covered Countermeasure Process Fund	Vaccine Injury Compensation Trust Fund based on excise tax of \$0.75 per dose on "taxable vaccines"
Number of Claims Processed	551 claims as of 3/1/2021, of which 450 were determined ineligible and 29 compensated (6%)	23,902 petitions as of 3/1/2021, of which 19,609 have been adjudicated, 11,735 were determined ineligible, and 7,874 compensated (40%)
Process for Adding New Vaccines	Scope of "covered countermeasures" is determined by Secretary of HHS's PREP Act declarations	Secretary of HHS may add vaccines to the Vaccine Injury Table that are (1) subject to the excise tax; and (2) recommended by the CDC for routine administration to children or pregnant women

Source: HRSA; CRS; 42 U.S.C. §§ 300aa-10 – 300aa-34; 42 U.S.C. § 247d-6d to -6e; 42 C.F.R. pt. 110.

Author Information

Kevin J. Hickey
Legislative Attorney

Erin H. Ward
Legislative Attorney

Disclaimer

This document was prepared by the Congressional Research Service (CRS). CRS serves as nonpartisan shared staff to congressional committees and Members of Congress. It operates solely at the behest of and under the direction of Congress. Information in a CRS Report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to Members of Congress in connection with CRS's institutional role. CRS Reports, as a work of the United States Government, are not subject to copyright protection in the United States. Any CRS Report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS Report may include copyrighted images or material from a third party, you may need to obtain the permission of the copyright holder if you wish to copy or otherwise use copyrighted material.