

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0350V

TERRI SAMUELS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 26, 2024

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Madelyn Weeks, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 8, 2021, Terri Samuels filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) resulting from an influenza (“flu”) vaccine received on September 9, 2020. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find that record evidence preponderantly establishes that the onset of Petitioner's shoulder pain began within 48 hours of vaccination, and that she has satisfied the remaining requirements for entitlement.

I. Relevant Procedural History

This case was activated on November 18, 2021 (ECF No. 13). When Respondent had not determined his position over a year later, Petitioner filed a motion for a ruling on the record (ECF No. 25). In response, Respondent argued that Petitioner's motion was premature because the Department of Health and Human Services had not yet completed its review and provided a medical analysis due to a backlog (ECF No. 26). Petitioner replied, arguing that she had established entitlement to compensation and the processing of her case had taken too long (ECF No. 27). Thereafter, Respondent was directed to file a supplemental response to Petitioner's motion or to provide his position. Scheduling Order (NON PDF), issued Feb. 8, 2023.

On March 10, 2023, Respondent filed a status report stating that he was amenable to informal resolution, and the parties negotiated (ECF Nos. 28-39). However, they were unable to reach an agreement (ECF No. 40). On March 15, 2024, Respondent filed his Rule 4(c) Report and supplemental response to Petitioner's motion (ECF No. 42). The issue of Petitioner's entitlement to compensation is now ripe for resolution.

II. Factual Findings and Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his or her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is “consistent, clear, cogent, and compelling.” *Sanchez v. Sec’y of Health & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

In addition to requirements concerning the vaccination received and the lack of other award or settlement,³ a petitioner must establish that he or she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he or she received. Section 11(c)(1)(C). The Vaccine Act further includes a “severity requirement,” pursuant to which a petitioner demonstrate that they:

- (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

“[T]he fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury.” *Morine v. Sec’y of Health & Human Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); *see also Herren v. Sec’y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (“a discharge from medical care does not necessarily indicate there are no residual effects”). “A treatment gap . . . does not automatically mean severity cannot be established.” *Law v. Sec’y of Health & Human Servs.*, No. 21-0699V, 2023 WL 2641502, at *5 (Fed. Cl. Spec. Mstr. Feb. 23, 2023) (finding severity requirement met where the petitioner sought care for under three months and had met physical therapy goals but still lacked full range of motion and experienced difficulty with certain activities, then returned to care nearly five months later reporting stiffness and continuing restrictions in motion); *see also Peebles v. Sec’y of Health & Human Servs.*, No. 20-0634V, 2022 WL 2387749 (Fed. Cl. Spec.

³ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception and has not filed a civil suit or collected an award or settlement for his or her injury. Section 11(c)(1)(A)(B)(E).

Mstr. May 26, 2022) (finding severity requirement met where the petitioner sought care for four months, followed by fifteen month gap); *Silvestri v. Sec'y of Health & Human Servs.*, No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021) (finding severity requirement satisfied where the petitioner did not seek additional treatment after the five month mark.

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation (“QAI”) are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

B. Relevant Factual History

This ruling contains only a brief overview of facts most relevant to the parties’ dispute.

1. Medical Records

Petitioner received the flu vaccine at issue in this case in her left deltoid on September 9, 2020, at Kaiser Permanente. Ex. 1 at 2. Nineteen days later (September 28th), she messaged Dr. Catherine Twimasi of Kaiser about a possible urinary tract infection. Ex. 2 at 930. She did not mention shoulder pain. *Id.* On October 7, 2020, she messaged her oncologist about her menstrual cycle, with no mention of her shoulder. *Id.* at 932.

On October 15, 2020, Petitioner messaged Dr. Twimasi complaining of left arm pain. Ex. 2 at 934. She requested an x-ray, explaining that she could not raise her left arm past her breast level and that the pain woke her at night. *Id.* A left shoulder x-ray two days later was negative. *Id.* at 1240. Six days after the x-ray, Petitioner messaged Dr. Twimasi about “major pain” in her left shoulder. *Id.* at 937. Petitioner stated that she had read about SIRVA online and that she had “all the signs of this – pain, limited mobility and cannot raise my arm to brush my teeth without pain.” *Id.* She added that the pain had “gone on for too long and it’s becoming unbearable.” *Id.* Dr. Twimasi referred her to an orthopedist. *Id.*

On October 26, 2020 (now 47 days after vaccination), Petitioner was seen by orthopedic physician assistant (“PA”) Alfred Phelps for left shoulder pain. Ex. 2 at 938. The date of injury section of the record notes “onset after flu shot ~ 1 week[s] ago.” *Id.* at 939. The history section of the record indicates that her left shoulder had been painful for “~1 month[s]” and that Petitioner “recalls getting a flu shot prior to onset.” *Id.* She reported being concerned about SIRVA. *Id.* She typically had a little shoulder soreness after injections, but this was “far worse.” *Id.* She rated her pain ten out of ten at rest and with activity. *Id.* at 939-40. On examination, she had positive signs on the Neer, cross-arm, lift-off, belly press, and empty can tests. *Id.* at 942. Forward flexion and abduction were approximately 90 degrees, and external rotation was approximately 40 degrees. *Id.* PA Phelps prescribed a prednisone taper and referred Petitioner for physical therapy. *Id.* at 943.

The next day (October 27th), Petitioner underwent a video physical therapy evaluation for her left shoulder. Ex. 2 at 973. She complained of pain, swelling, and limited range of motion. *Id.* at 974. Her pain began “1 month[s] ago . . . after getting the flu shot and the pain remained.” *Id.* She rated her pain as zero out of ten, increasing to seven out of ten when moving. *Id.* On examination, her left shoulder active range of motion was 90 degrees in flexion and 70 degrees in abduction. *Id.* at 975.

On November 18, 2020, Petitioner was seen by orthopedic PA Allison Parver, who administered a steroid injection in her left shoulder. Ex. 2 at 998. Over the next several months, she continued to send messages about her shoulder pain. *Id.* at 1015, 1020-21, 1038, 1048-49, 1082-83. She saw PA Phelps on March 8, 2021 for another steroid injection. *Id.* at 1090.

Petitioner had a left shoulder MRI on March 16, 2021, which showed a tiny partial thickness supraspinatus tear, minimal infraspinatus tendinopathy, mild intra-articular biceps tendinopathy, findings suspicious for a small labral tear, trace subacromial/subdeltoid bursitis, and low-grad deltoid muscle strain. Ex. 4 at 72. Ten days later (March 26, 2021) she saw PA Phelps and received a third steroid injection in her left shoulder. *Id.* at 28.

2. Declarations

Petitioner submitted two declarations⁴ in support of her claim. Exs. 3, 7. She explains that when she received the flu vaccine in September 2020, she felt “immediate pain in my shoulder.” Ex. 3 at ¶ 2. Normally after vaccines the pain and soreness go away after two or three days, but this time “the pain never went away.” *Id.* The day after vaccination, her shoulder was so painful that she began taking Tylenol, Excedrin Back & Body, and Goody’s. *Id.* at ¶ 3. When the pain persisted, she reached out to her primary care physician about it. *Id.* Ultimately, she was referred to an orthopedist. *Id.*

C. The Parties’ Arguments

Petitioner argues that her medical records make clear that the onset of her pain was within 48 hours of vaccination. Petitioner’s Motion for Ruling on the Record, filed Nov. 21, 2022, at *7 (ECF No. 25) (“Mot”). When seeking care for her shoulder pain, she consistently related her pain to her flu shot. Mot. at *7-8. She also filed a declaration reporting that her severe pain began immediately after vaccination and “never went away.” *Id.* at *8 (*citing* Ex. 3 at 1). Her “medical records and her [declaration] evidence work in tandem to provide preponderant evidence of onset within 48 hours of her September 9, 2020 vaccination.” *Id.* at *8-9.

⁴ Although Petitioner labeled these documents as affidavits, they are not notarized. Nonetheless, they are acceptable as declarations because they comply with the requirements of 28 U.S.C. §1746.

Respondent argues that the medical records do not establish that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination. Rule 4(c) Report and Supplemental Response, filed March 15, 2024, at *9 (ECF No. 42) ("Supp. Resp."). Respondent emphasizes that Petitioner's first post-vaccination complaint of shoulder pain occurred 36 days after vaccination, at which time she did not specify when the pain had begun or connect the onset to her vaccination. Resp. at *9. She also contacted physicians twice between the September 9th vaccination and her first report of shoulder pain on October 15th, for issues that Respondent believes appear to be non-emergent. *Id.* at *9-10. Petitioner frequently used the Kaiser messaging system to communicate with her providers, reflecting an established pattern of seeking medical care in an accessible and affordable way when needed. *Id.* at *10. Respondent adds that Petitioner understood that her post-vaccination pain usually resolved within two to three days, and thus questions why Petitioner did not promptly message her physicians when this had not occurred. *Id.*

Respondent adds that Petitioner's first two reports of shoulder pain do not indicate when the pain began or relate her pain to her vaccination. Resp. at *10. She did not associate her shoulder pain with vaccination until her October 26th appointment, after she had learned about SIRVA. *Id.* At that time, she reported pain that began about a month earlier – which would place onset around September 26th, more than two weeks after vaccination. *Id.* At her physical therapy evaluation, she stated only that her pain began "after" vaccination. *Id.* (*citing* Ex. 2 at 974). Respondent argues that the contemporaneous records reflect "vague statements that are insufficient to support a finding" that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination. *Id.* Respondent also urges that I consider that she did not connect the onset of her left shoulder pain with her flu vaccination until she learned about SIRVA. *Id.* at *11 (*citing* *Vashro v. Sec'y of Health & Human Servs.*, No. 20-1849V, 2023 WL 6643108, at *3 (Fed. Cl. Spec. Mstr. Sept. 5, 2023)).

D. Factual Finding Regarding QAI Criteria for Table SIRVA

1. Onset

After a review of the entire record, I find that onset of Petitioner's shoulder pain most likely began within 48 hours of vaccine administration.

Petitioner complained of left arm pain 36 days after vaccination. Ex. 2 at 934. She was first seen by a healthcare provider for shoulder pain 47 days after vaccination, at which time she related her pain to her vaccination. *Id.* at 938. I acknowledge that the record indicates she reported the onset of her pain either approximately one week or one month earlier. However, when she was seen the next day for physical therapy, she again related her pain to her flu vaccination. *Id.* at 974. And Petitioner's witness statements also maintain that her pain began immediately after vaccination. Ex. 3 at ¶ 2.

It is not unusual for a SIRVA petitioner to delay care, expecting the pain to resolve on its own. See *Amor v. Sec’y of Health & Human Servs.*, No. 20-0978V, 2024 WL 1071877, at *6 (Fed. Cl. Spec. Mstr. Feb. 8, 2024) (“[w]hile evidence of a medical visit for shoulder pain within two days of vaccination would be highly relevant to the question of onset, in my experience it is much more common for petitioners in SIRVA cases to delay seeking care for weeks, or even months, in hopes that the pain will resolve without treatment”); *Winkle v. Sec’y of Health & Human Servs.*, No. 20-0485V, 2021 WL 2808993, at *4 (Fed. Cl. Spec. Mstr. June 3, 2021) (“[i]t is common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own” and finding onset was within 48 hours when the petitioner did not seek care until five months after vaccination). Thus, the fact that Petitioner did not report her pain until 36 days after vaccination, and was not seen until 47 days after vaccination, does not by itself cast doubt on her claim.

Respondent’s objection centers around the fact that Petitioner’s health care provider has a messaging system that is accessible and affordable, and that Petitioner uses frequently – but not in this case. Petitioner credibly explained, however, that she self-treated with over-the-counter medications, and sought medical advice when the pain persisted. Ex. 3 at ¶ 3. In light of the limited extent of the delay in seeking treatment, the medical records linking her shoulder pain to her vaccination, and Petitioner’s explanation – which is consistent with her medical records – a preponderance of the evidence leads to the conclusion that her shoulder pain began within 48 hours of vaccination.

Vashro is not on point. That petitioner was found not to meet *two* of the SIRVA QAI criteria: she had pre-vaccination shoulder pain, and when she initially sought care for shoulder pain, she did not attribute it to her vaccination. *Vashro*, 2023 WL 6643108, at *3. In addition, months later – *four months* after vaccination – she reported that the onset of her pain occurred one week after vaccination. *Id.* It was not until over a week later that she reported that her shoulder pain began on the date of vaccination. *Id.* I found reason to give less weight to her reported onset on the day of vaccination because it occurred after she “followed up with a group that may help provide support for folks that have had symptoms from the flu shot.” *Id.* (citing ECF No. 20 at 9; Ex. 3 at 16). This was “good grounds for giving less weight to the specific cites of onset consistent with the Table, versus the longer onset reported before those other references.” *Id.*

While Ms. Samuels described the onset of her shoulder pain imprecisely, she consistently linked it to her vaccination. And she sought care within a reasonable time after vaccination, further supporting her claim. The fact that a petitioner knows about the *existence* of a SIRVA claim does not, by itself, impair the credibility of their statements to treaters.

2. Other SIRVA QAI Criteria and Claim Elements

The remaining SIRVA QAI criteria are not contested, and I find that they are satisfied. There is no evidence that Petitioner had a pre-vaccination left shoulder

condition, or another condition or abnormality, that would explain her symptoms after vaccination. Ex. 2. And her symptoms were limited to her left shoulder, where she received the flu vaccine. Exs. 2, 4. In addition, the record establishes that Petitioner received a covered vaccine in the United States. Ex. 1 at 2. She experienced the residual effects of her condition for more than six months. Ex. 2 at 1090, Ex. 4 at 28. And she states that she has never received an award or settlement, or filed a civil action, for her vaccine-related injuries. Ex. 7 at ¶ 9.

Conclusion

Based on my review of the record as a whole, I find that it is more likely than not that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccine administration, and that all other SIRVA Table requirements, as well as all statutory requirements, are met. Therefore, Petitioner's motion for a ruling on the record that she is entitled to compensation is **GRANTED**.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master