

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-314V

TRACEY ERVIN-SPENCER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: December 8, 2023

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

Ronalda Elnetta Kosh, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 8, 2021, Tracey Erwin-Spencer 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 a Table injury - that she suffered a shoulder injury related to vaccine administration (“SIRVA”) after receiving an influenza (“flu”) vaccine on

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 (2012).

October 2, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

After a full review of the evidence, I find that Petitioner has satisfied all Table requirements for a SIRVA Table injury and is otherwise entitled to compensation for her injury.

I. Relevant Procedural History

On May 13, 2022, Petitioner filed a Motion for a Ruling on the Record (hereinafter “Motion”), at my invitation after Respondent failed to provide his position in this case for more than following the claim’s assignment to SPU. ECF No. 23. In her Motion, Petitioner argues that she has satisfied all requirements under the Vaccine Act and established entitlement to compensation for a Table SIRVA injury. *Id.* Respondent reacted to Petitioner’s Motion (hereinafter “Response”) on July 27, 2022, recommending that entitlement to compensation be denied under the terms of the Vaccine Act. ECF No. 27.³ Specifically, Respondent argues that the evidence preponderates against a finding that the onset of Petitioner’s shoulder pain occurred within 48 hours of her vaccination. ECF No. 27 at 8-9. Additionally (and although this argument is not fully developed), Respondent *appears* to assert that Petitioner’s pain is not limited to the shoulder in which she was vaccinated. *Id.* at 9.

On August 10, 2022, Petitioner filed a Reply brief addressing Respondent’s objections to compensation and arguing that she has established a SIRVA Table case. ECF No. 28. This matter is ripe for my resolution.

II. Authority

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 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*

³ During the interim between the filing of Petitioner’s Motion and Respondent’s Response the parties engaged in discussions to informally resolve this case. ECF Nos. 22, 25 -26. I offered to stay the briefing deadlines at the parties’ joint request, if further time to engage in settlement discussions would be fruitful, but no request was made. Scheduling Order (Non-PDF) filed June 7, 2022.

of Health & Hum. 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). Contemporaneous medical records are presumed to be accurate. See *Cucuras v. Sec’y of Health & Hum. 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 & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement,⁴ a petitioner must establish that 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 she received. Section 11(c)(1)(C).

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 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:

⁴ 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; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

(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).

III. Relevant Factual Evidence

I have fully reviewed the evidence, including all medical records and affidavits, and the parties' briefing. I find most relevant the following:

A. Records

- Prior to her vaccination, Petitioner suffered some significant non-contributory comorbidities, including myelodysplastic syndrome ("MDS") with sideroblastic anemia which necessitated frequent blood transfusions, aortic regurgitation, and common variable immunodeficiency. See *generally* Ex. 2.
- On October 2, 2019, Petitioner received the flu vaccine in her left deltoid. Ex. 1 at 1.
- On October 21, 2019, Petitioner made a telephone call to her primary care provider's ("PCP") office, the Polyclinic, in regard to an MRI order for brain imaging that took place later that same day. Ex. 4 at 30; 57-59.
- On October 23, 2019, Petitioner underwent a blood transfusion at Seattle Cancer Care Alliance ("SCCA"). Ex. 2 at 264.

- On October 31, 2019, Petitioner was seen by her cardiologist for a follow-up appointment. Ex. 5 at 43-49.
- On November 14, 2019, Petitioner underwent another blood transfusion at SCCA. Ex. 2 at 266. A nursing note states that Petitioner reported “new” left deltoid pain “post flu shot.” *Id.* Petitioner’s pain score was 2/10, and up to 7/10 with movement. *Id.*
- On November 21, 2019, Petitioner was evaluated by hematologist Janice L. Abkowitz, M.D., at SCCA. Ex. 2 at 397. Dr. Abkowitz’s record memorializes that Petitioner’s “only complaint in [a] complete review of systems,” except as noted in her history, was that “after her flu vaccination, she has had some nerve pain in her left arm. She does not want physical therapy or other intervention for this. Rather she has been doing stretching and has been placing heat on it at home.” *Id.*
- On December 3, 2019, Petitioner was seen by her PCP, Dr. Cynthia Smyth, with a “complain[t] of a 2-month history of worsening left shoulder pain.” Ex. 4 at 33. Petitioner reported to Dr. Smyth that “[s]he feels as though her symptoms started after getting a flu shot in the left upper arm. She has been giving it time but her symptoms have not improved but have worsened.” *Id.* Petitioner also informed Dr. Smyth that she “had not had a fall or any trauma to the area,” and that she had a “mass near her left elbow which [has] gotten bigger which she would like evaluated,” that she continued to receive blood transfusions every three weeks for her MDS and that she had not suffered any recent infections. *Id.*

On exam, Petitioner exhibited reduced range of motion of her left arm, strength in her left upper extremity of 4/5, and “tenderness over her biceps and supraspinatus tendon.” *Id.* at 34. Dr. Smyth also recorded Petitioner had a “2 x 2 centimeter raised palpable mass” on her left elbow. *Id.* Dr. Smyth ordered an MRI’s of Petitioner’s left shoulder and elbow, and referred her to orthopedics. *Id.*

- On December 9, 2019, Petitioner underwent an MRI of her left shoulder, and the findings included: an “abnormal low T1 signal throughout the proximal humerus extending from the head to the metadiaphysis” with “similar changes” in the acromion and the clavicle; a “[t]race amount of bursal inflammation and fluid;” a “[q]uestion [of] mild inflammation of the anterior band of the inferior glenohumeral ligament and thickening of the coracoid humeral ligament;” “[m]inor marrow edema and cyst formation;” a “partial footprint attachment tear of the far anterior supraspinatus” that “probably has bursal extension;” an “[a]bnormal signal in the biceps anchor;” and an “irregularity of the posterosuperior labral contour.” Ex. 4 at

60. An MRI was also conducted that same day of Petitioner's left elbow. *Id.* at 61-62.

- Petitioner was seen by orthopedist Dr. Daniel G. Schwartz on December 13, 2019. Ex. 6 at 4. Petitioner reported to Dr. Schwartz that her "symptoms have been ongoing [since] 10/2/19. She states that there was a flu shot injury – states that she felt them hit a nerve." Ex. 6 at 4. Dr. Schwarz diagnosed Petitioner with impingement syndrome of the left shoulder and a traumatic incomplete tear of the left rotator cuff. *Id.* at 3.
- On December 20, 2019, Petitioner began physical therapy. Ex. 3 at 245. Petitioner's initial evaluation history records "Date of Injury: date symptoms began: 10/2/19." *Id.* The history further provides "61 year old female who present[s] to therapy with L[eft] sided shoulder pain that resulted after a flu shot was injected into the subacromial bursa." *Id.*
- Subsequently, Petitioner continued to treat with Dr. Schwartz and undergo physical therapy for her left shoulder pain. In April of 2020, Petitioner reported at a physical therapy session, that she could not get her "arm up any higher." Ex. 3 at 180. She stated that the "inside of the shoulder feels pinching and sharp nerve pain that goes down the arm and across her chest," she elaborated that "if she tries to use the arm too much then she gets radiating pain." *Id.* At another physical therapy session a few days later, she reported that the previous day she had received a blood transfusion and "from the wrist up into the shoulder was miserable but is much better today." *Id.* at 178.
- After undergoing physical therapy for approximately 17 months, Petitioner was discharged on May 18, 2021. Ex. 8 at 1. She was described as "90% better with some ROM loss still and minor pain in bicep but otherwise doing well functionally." *Id.* at 6.

B. Declaration

Petitioner executed a signed and sworn declaration on January 25, 2021 addressing her October 2, 2019 vaccination and alleged shoulder injury. Ex. 7. In regard to the administration of her vaccination, Petitioner states she received the vaccination at SCCA on October 2, 2019 following her receipt of a blood transfusion. *Id.*, ¶ 1. Petitioner recounts that when the vaccine needle was inserted into her left shoulder that her "left shoulder and [her] left arm flew straight up to the ceiling and fell back down." *Id.* She recalls the "pain I felt was immediate." *Id.* The nurse requested that she "relax and

completed the injection.” *Id.* She advised the nurse that she thought he “hit a nerve.” *Id.* Petitioner states that night she had a fever and called the after-hours line at SCCA to speak with a nurse – Petitioner was not sure if the fever was due to her vaccination or her transfusion. *Id.*, ¶ 2. Petitioner reported her arm pain and fever to the nurse and it was “decided” both were due to her injection as she had a fever the prior year after her vaccination. *Id.* The next morning Petitioner states that she could not “move [her] arm without extreme pain” and required assistance from her husband showering and dressing. *Id.*

Petitioner states that her pain persisted, and she required continued assistance from her husband. *Id.*, ¶ 3. Petitioner avers that she had another blood transfusion on October 24, 2019⁵ and when asked if she was currently in any pain she reported that her left arm had “been extremely painful since [her] flu shot.” *Id.*, ¶ 4. Petitioner states that thereafter she subsequently reported her pain at every blood transfusion visit. *Id.*

Petitioner provides in her affidavit that after the pain persisted for several weeks, she began to think it was not normal pain and that she had nerve damage. *Id.*, ¶ 5. She states that by mid-November after “getting no relief from extreme pain” she scheduled an appointment with her primary care provider, Dr. Smyth, and that the first appointment available was in early December. *Id.* Petitioner states Dr. Smyth thought she had a left rotator cuff tear and referred her to orthopedics. *Id.*

Petitioner’s affidavit describes her subsequent treatment, and the limitations that she suffered in her daily activities due to her shoulder pain.

IV. Findings of Fact

A. Onset

The primary disputed factor in this case is whether Petitioner’s first post-vaccination symptom or manifestation of onset (specifically pain) of her shoulder injury occurred within 48 hours of her flu vaccination as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation (“QAI”) for a Table SIRVA. 42 C.F.R. § 100.3(a)(XIV)(B) (seasonal influenza vaccines); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI); ECF No. 27 at 8-9. Based upon a review of the entire record, and for the reasons set forth below, I find that it more likely than not did.

⁵ This appears to be a typographical error as Petitioner’s blood transfusion occurred on October 23, 2019, not October 24, 2019. Ex. 2 at 264.

In this case, as correctly pointed out by Respondent, the records corresponding to Petitioner's first several encounters with medical providers following her October 2, 2019 vaccination contain no reference to Petitioner's shoulder pain at all. These encounters consist of a phone call on October 21, 2019 to her PCP in regard to an unrelated MRI scheduled for later that day, Petitioner's actual MRI imaging visit that same day, an appointment on October 23, 2019 at SCCA for a blood transfusion, and a cardiology appointment on October 31, 2019. ECF No. 27 at 8 (citing Ex. 2 at 264; Ex. Ex. 4 at 30, 58; Ex. 5 at 43-49).

Petitioner, however, asserts in her declaration that she called an after-hours line at SCCA the night she received her vaccination and reported her shoulder pain and a fever. Ex. 7, ¶ 2. Petitioner also states that she reported her shoulder pain at her October 23, 2019 SCCA appointment for a blood transfusion. Ex. 7, ¶ 4. I cannot conclude *per se* that Petitioner reported her shoulder pain to SCCA on the evening of October 2, 2019, or at her October 23, 2019 appointment. However, as I have observed in other cases, it would not be uncommon for either a patient to fail to report, or for a provider to fail to document, symptoms outside the primary purpose of a medical visit – as would be the case for Petitioner's medical encounters regarding her October 21, 2019 MRI, October 23, 2019 SCCA blood transfusion, and cardiology appointment on October 31, 2019.

The fact that references to onset are not precise in terms of time or date does not prevent a favorable finding. As I have previously observed, “the Vaccine Act clearly does *not* require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe.” *Niemi v. Sec'y of Health & Hum. Servs.*, No. 19-1535V, 2021 WL 4146940, at *4 (Fed. Cl. Aug. 10, 2021) (citing Section 13) (emphasis in original). Neither does the Act require that the medical records document an exact date that the onset of a petitioner's shoulder pain began. A special master may thus 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).

In this case, Petitioner's allegation that her shoulder pain occurred within 48 hours of her vaccination is supported by *many* contemporaneous treatment records close-in-time to her vaccination – even if the medical records most contemporaneous to her October 2, 2019 vaccination do not. In particular, the records corresponding to Petitioner's November 13, 2019 appointment for a blood transfusion at SCCA – which occurred only 42 days after her vaccination (and only a few weeks after her first post-vaccination medical encounter) - specifically document that Petitioner suffered “new pain” in her left shoulder “post flu shot.” Ex. 2 at 266.

Thereafter, Petitioner consistently reported to her providers at numerous appointments that she experienced the onset of her shoulder pain contemporaneous with her October 2, 2019 flu vaccination. See, e.g., Ex. 2 at 397 (November 21, 2019 complaint to Dr. Abkowitz that “after her flu vaccination, she has had some nerve pain in her left arm. She does not want physical therapy or other intervention for this. Rather she has been doing stretching and has been placing heat on it at home.”); Ex. 4 at 33 (December 3, 2019 PCP record a documenting a “complain[t] of a 2-month history of worsening left shoulder pain” and report that “[s]he feels as though her symptoms started after getting a flu shot in the left upper arm. She has been giving it time but her symptoms have not improved but have worsened.”); Ex. 6 at 4 (December 13, 2019 complaint to orthopedist Dr. Schwartz that her “symptoms have been ongoing [since] 10/2/2019. She states that there was a flu shot injury – states that she felt them hit a nerve.”); Ex. 3 at 25 (Petitioner’s initial physical therapy evaluation history states, “Date of Injury: date symptoms began: 10/2/19” and provides “L[eft] sided shoulder pain after a flu shot was injected into the subacromial bursa.”).

Based on the record as a whole, I find that Petitioner has established the onset of her injury occurred within 48 hours of her vaccination. Of course, Petitioner’s short delay in seeking medical treatment specific to her shoulder pain demonstrates that she was able to tolerate the pain initially and is indicative of a somewhat less severe SIRVA – a factor I will consider in awarding damages for pain and suffering in this case.

B. Injury Limited to Shoulder

The second disputed issue is whether Petitioner’s “[p]ain and reduced range of motion are limited to the [left] shoulder in which the intramuscular vaccine was administered.” 42 C.F.R. § 100.3(c)(10)(iii).

Preliminarily, Respondent has not explicitly contested that Petitioner has failed to satisfy this SIRVA Table requirement – or any SIRVA Table requirement aside from onset. Nonetheless, Respondent seemingly calls the third SIRVA QAI factor into question in his Response. Thus, Respondent has generally maintained that “[P]etitioner’s complaints indicate that she was also experiencing radiating pain that she described as ‘nerve pain in her left arm,’ wrist pain, ‘a mass near her left elbow which [had] gotten bigger,’ and her left shoulder MRI showed a minor marrow edema and cyst formation.” ECF No. 27 at 9 (citing Ex. 2 at 397; Ex. 3 at 178, 180; Pet. Ex. 4 at 33, 60).

Respondent fails to further develop this argument, however. And Petitioner correctly points out that her “treatment records have consistently confirmed a left shoulder

injury,” and that after thorough examinations of both her complete left shoulder and arm, the subsequent assessment of her injury and focus of her treatment was on her left shoulder. ECF No. 28 7-8 (citing Ex. 3 at 185, 245; Ex. 4 at 33; Ex. 6 at 3, 8). While Petitioner on several occasions described her left shoulder and arm pain as nerve pain collectively, and stated when her vaccination was administered that she thought a nerve had been hit, these appear to be Petitioner’s *subjective* descriptions of her injury and pain as a lay person (and there is no evidence in the record that Petitioner suffered any neurological injury from her vaccination).

Additionally, some of the symptoms and findings cited by Respondent do not actually appear to be related to Petitioner’s shoulder injury or vaccination, but instead appear to constitute, or be reflective of, comorbidities – for example her elbow mass (Ex. 4 at 33). To be clear, a petitioner must establish pain and reduced ROM were “limited to the shoulder in which the intramuscular vaccine was administered” in order to demonstrate a Table SIRVA. 42 C.F.R. § 100.3(c)(10)(iii). However, this requirement “does not prevent a petitioner with simultaneous areas of pain due to unrelated conditions from also meeting the Table SIRVA definition.” *Rodgers v. Sec’y of Health & Hum. Servs.*, No. 18-0559V, 2021 WL 4772097, at *8 (Fed. Cl. Spec. Mstr. Sept. 9, 2021).

To the extent that any pain did radiate from Petitioner’s shoulder to other part of her body, I have previously found that claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body, since the essence of the claim is that a vaccine administered to the shoulder primarily caused pain there. *Cross v. Sec’y of Health & Hum. Servs.*, No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023). This reading is consistent with the determinations of other special masters. *Grossmann v. Sec’y of Health & Hum. Servs.*, No. 18-0013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (explaining that the criterion is intended to “guard against compensating claims involving patterns of pain or reduced range of motion indicative of a *contributing etiology* beyond the confines of a musculoskeletal injury to the affected shoulder”) (emphasis added). Here, despite *some* notations of pain extending beyond the shoulder, Petitioner’s injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology.

V. Other Table Requirements and Entitlement

Petitioner has established all other requirements for a Table SIRVA claim. 42 C.F.R. § 100.3(c)(10). There is no history of shoulder pain, inflammation, or dysfunction that would explain the post-vaccination injury. 42 C.F.R. § 100.3(c)(10)(i). And there is not preponderant evidence of another condition that would explain the symptoms. 42

C.F.R. § 100.3(c)(10)(iv).⁶ However, even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, residual effects of injury lasting six months, *etc.* See *generally* Section 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed in this claim. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran

Chief Special Master

⁶ To the extent that Respondent may have argued that Petitioner suffered any other condition that would explain her condition/SIRVA, I explicitly find, as discussed above, that Petitioner did not. See *supra* section IV B.