

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 18, 2023

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GEORGE SWAISS,	*	UNPUBLISHED
	*	
Petitioner,	*	No. 15-286V
	*	
v.	*	Special Master Gowen
	*	
SECRETARY OF HEALTH	*	Ruling on Damages; Medically
AND HUMAN SERVICES,	*	Necessary Treatment.
	*	
Respondent.	*	
* * * * *		

Joseph Pepper, Conway, Homer, P.C., Boston, MA, for petitioner.
Mark K. Hellie, U.S. Depart. of Justice, Washington, D.C., for respondent.

RULING ON DAMAGES¹

On March 19, 2015, George Swaiss (“petitioner”) filed a petition in the National Vaccine Injury Vaccine Program² (“Vaccine Program”), alleging that the influenza (“flu”) vaccine he received on June 1, 2012 caused his small fiber neuropathy (“SFN”). On November 4, 2019, I issued a Ruling on Entitlement, finding that the flu vaccine was the cause of petitioner’s SFN and he was entitled to compensation. Ruling on Entitlement (ECF No. 101); *Swaiss v. Sec’y of Health & Human Servs.*, No. 15-286, 2019 WL 6520791 (Fed. Cl. Spec. Mstr. Nov. 4, 2019). The case has been in damages since the entitlement ruling was filed.

After hearing oral arguments from each party on the issue of whether IVIG treatment is a medically necessary treatment of petitioner’s vaccine-induced SFN, I find that ongoing and

¹ Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services), because this decision contains a reasoned explanation for the action in this case, I am required to post it to a publicly available website. This decision will appear at <https://www.govinfo.gov/app/collection/uscourts/national/cofc> or on the Court of Federal Claims website. **This means the decision will be available to anyone with access to the Internet.** Before the decision is posted on the court’s website, each party has 14 days to file a motion requesting redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). “An objecting party must provide the court with a proposed redacted version of the decision.” *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court’s website without any changes.** *Id.*

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter “Vaccine Act” or “the Act”). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

continuous IVIG treatment is medically necessary as treatment for petitioner's SFN. This ruling is consistent with my ruling made during the status conference.

I. Relevant procedural history

After the parties worked together to resolve most elements of damages in this case, the parties have been unable to resolve the issue of future IVIG expenses for the treatment of petitioner's vaccine-induced SFN. The parties requested that the Court issue a ruling on this matter.

I held a status conference on this issue on May 1, 2023, where each party presented their arguments about whether IVIG is a medically necessary treatment for petitioner's SFN and whether it should be paid for as an element of damages.

II. Arguments by the parties

Petitioner argued that he had been receiving monthly IVIG infusions for treatment of his small fiber neuropathy at the Stanford Neuroscience Health Center since 2018, that these treatments are medically necessary, and they are compensable under § 300aa-15(a)(1)(A).

Respondent argued that the IVIg was not medically necessary, without submitting any documentation from medical expert. Respondent, in agreement with the petitioner, requested that the Court determine whether the IVIg is medically necessary and should be compensable under the Vaccine Act.

III. Discussion and conclusion

On January 4, 2018, petitioner's treating neurologist, Srikanth Muppidi M.D. at the Stanford Neuroscience Health Center explained that petitioner wanted to try IVIg treatment for his neuropathic pain related to his small fiber neuropathy. Petitioner's Exhibit ("Pet. Ex") 24 at 17. Dr. Muppidi wrote that petitioner had "significant neuropathic pain in his lower limbs" and that he had previously tried Lyrica and Cymbalta, which did not work. *Id.* at 24. Petitioner had some relief of symptoms with Gabapentin. In general, the petitioner did not get significant relief from other medications and Dr. Muppidi agreed to try IVIG. Petitioner began receiving IVIG in 2018 at the Stanford Infusion Center. Petitioner began receiving IVIg doses every two weeks, s. He continued to receive IVIg every three weeks. Pet. Ex. 28 at 281. *Id.*

As petitioner's treatment with IVIg infusions began, Stanford billed Medicare for the drug services provided. Pet. Ex. 36 at 5. As outlined in a letter dated April 4, 2019, from the Medicare Federal Services (a contractor to Medicare to review appeals), Noridian Administration Services (the Medicare contract administrator of the region), "determined that the services failed to meet Medicare criteria for coverage [for IVIg]." *Id.* at 2. Specifically, the reason for denial was, "The submitted documentation failed to support a covered diagnosis per the applicable Local Coverage Determination or a covered labeled or off-labeled utilization of Gammagard per the Medicare approved compendia." *Id.* at 7.

With the reconsideration denied, Stanford appealed that decision to the Office of Medicare Hearings and Appeals. Pet. Ex. 46. The Office of Medicare Hearings and Appeals, of the Department of Health and Human Services, once again denied Stanford Health Care's claim for payment of Gammagard for the petitioner. *Id.* at 1. Administrative Law Judge Earnhart explained that "coverage rules" for intravenous IVIg includes the treatment for certain primary immune deficiency diseases and the corresponding diagnostic codes. *Id.* at 4. Further, the decision explains that there are acceptable "off-label" uses for IVIg "in rare patient populations or in rare individual patient clinical scenarios," which include neurological disorders. *Id.* at 4-5. The initial claim submitted by Stanford included the ICD-10 diagnosis code of G62.9, small fiber neuropathy. *Id.* at 5. Stanford attempted to change the billing code to G60.3, idiopathic progressive neuropathy, which is covered. However, the contract administrator for the region, denied Stanford's request to file an amended claim with the diagnosis code of G60.3. *Id.* at 6. After a hearing, Administrative Law Judge Earnhart wrote:

While the beneficiary's record confirmed a diagnosis narration of small fiber neuropathy, with treatment that included the use of IVIg, the G62.9 diagnosis code was the associated treatment diagnosis and not an approved diagnosis for the IVIg services per LCD L34314. Although the record contained a referral from January 4, 2018 by Dr. Muppidi to the Infusion Center with a diagnosis code G60.3 for idiopathic progressive neuropathy, the diagnosis was not supported in the medical record. The medical record confirmed only that a diagnosis of small fiber neuropathy was ever established and that the same diagnosis, G62.9 was used for the immune globulin infusions.

Pet. Ex. 46 at 7. The conclusion of the ALJ was that "The Immune Globulin (Gammagard Liquid), services provided to the beneficiary on the dates of service did not meet Medicare coverage criteria." *Id.* at 7.

As petitioner's treating neurologist, Dr. Muppidi explained when he evaluated the petitioner, there is a "lack of treatment options for post-vaccination neuropathy." Pet. Ex. 24 at 19. Petitioner had experienced burning pain in his feet and severe muscle pains because of his small fiber neuropathy for five years. *Id.* at 18. Dr. Muppidi also explained that certain treatment for neuropathic pain, such as Lyrica and Cymbalta were not helping the petitioner and Gabapentin provides some relief. *Id.* Thus, given the length of time that petitioner was experiencing his neuropathic pain and symptoms, he prescribed IVIg treatment. *Id.* at 19. At a follow-up appointment on March 12, 2021, petitioner reported that he felt like the IVIg was working. Dr. Muppidi stated that the optimal management of petitioner's neuropathic pain was to continue IVIg. Thus, petitioner's treating physician continued IVIg as an appropriate treatment for SFN. Petitioner's life care plan proposed continued IVIg at least every three weeks and respondent's life care planner agreed with this recommendation.

Respondent did not submit a medical expert report indicating that the IVIg was medically unnecessary. Respondent's reluctance to include funding for IVIg treatments seems to stem from the possibility that petitioner's IVIg may be covered by Medicare at some point in the future. However, given the outcome of Stanford's appeals to date, it appears that CMS would have to amend its criteria for the use of IVIg to include small fiber neuropathy. While this could occur at some time in the future as the effectiveness of IVIg for small fiber neuropathy becomes

better established, it is not clear that it will, and it is unreasonable to place the risk that coverage will not be extended on the petitioner.

There is an established record over a period of years that the regular IVIg infusions provide relief for petitioner's neuropathic pain and there is no certain or even likely prospect of insurance coverage for the treatment, I find that the cost of IVIg is a compensable expense to be covered by a Vaccine Program award.

Accordingly, I find that IVIg treatment is reasonable and necessary for petitioner's small fiber neuropathy and is compensable under § 300aa-15(a)(1)(A)(iii)(I). The parties may fund the IVIg as they see necessary to carry out the finding of this Ruling. Payment for IVIg shall begin as of the date of judgment in this case. Thus, the following is hereby **ORDERED**:

- 1) Within fifteen (15) days, Friday, June 2, 2023**, respondent shall file a proffer consistent with this ruling resolving all damages in this matter.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master