In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1437V

Filed: January 27, 2025

LISSETTE LIMONTA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Special Master Roth

Robert Hanreck, Esq., Robert J. Hanreck, P.A., Miami, FL, for petitioner.
Emilie Williams, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION DISMISSING CASE[1]

Roth, Special Master:

On September 20, 2018, Lissette Limonta ("Ms. Limonta," or "petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered "anaphylaxis, angioneurotic edema, [and] swelling of the face, tongue and lips" as a result of the October 6, 2015 influenza ("flu") vaccine and thereafter continued to suffer reoccurrences of her symptoms. *See* Petition, ECF. No. 1.

On December 7, 2022, petitioner's counsel filed a Motion for Ruling on the Six-Month Severity Requirement. Motion, ECF No. 70. Respondent filed his response to the motion on March 21, 2023. Response, ECF No. 72.

For the reasons detailed below and in consideration of all evidence in the record, I find that there is not preponderant evidence to conclude that petitioner's alleged vaccine reaction and the

[1] Because this Decision 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 Decision 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, the undersigned finds that the identified material fits within this definition, such material will be redacted 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 "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

effects thereof lasted for more than six months. Because petitioner has failed to satisfy a threshold requirement of the Vaccine Act, her petition must be dismissed.

I. Procedural History

The petition was filed on September 20, 2018 along with several medical records. Petitioner's Exhibits ("Pet. Ex.") 1-6, ECF No. 1.[3] The matter was initially assigned to the Special Processing Unit ("SPU"). ECF No. 4. Petitioner filed additional medical records designated as Pet. Ex. 7-26 on December 21, 2018, and a Statement of Completion on January 29, 2019. ECF. Nos. 11-12. In a status report filed on July 22, 201, respondent advised that he intended to defend this case and requested a deadline for his Rule 4(c) Report. ECF. No. 20.

Respondent filed his Rule 4(c) Report on September 27, 2019. Respondent's Report ("Resp. Rpt."), ECF No. 23. It is respondent's position that petitioner does not satisfy the requirements under the Act or the Qualifications and Aids to Interpretation ("QAI") for a Table claim of anaphylaxis, nor does she satisfy the six-month requirement. Resp. Rpt. at 4.

The matter was reassigned to the undersigned on April 3, 2020, following the filing of additional medical records requested in respondent's Rule 4(c) Report. Pet. Ex. 27-30, ECF Nos. 25-30. Additional medical records were filed on July 2, 2020. Pet. Ex. 31-34, ECF No. 32.

At a status conference held on September 30, 2020, the issues in this case were discussed in detail, specifically that petitioner did not meet the requirements for on-Table anaphylaxis as alleged and it did not appear that she satisfied the six-month severity requirement to sustain an off-Table claim. A detailed Order issued, and petitioner was provided sixty days within which to file a report from her treating physician, Dr. De La Cruz. ECF No. 35.

Petitioner filed additional medical records on February 26, 2021. Pet. Ex. 35, ECF No. 38. Another status conference was held on March 3, 2021, wherein petitioner's counsel advised that Dr. De La Cruz had unfortunately passed away. Petitioner was then ordered to file a report from her new treating allergist, Dr. Nunez, addressing episodes of angioedema she claimed occurred after the first episode, as well as the medication prescribed to treat petitioner's alleged anaphylaxis and/or angioedema. ECF No. 40.

On April 12, 2021, additional medical records were filed. Pet. Ex. 36-37, ECF No. 42. After the issuance of a subpoena, Dr. Nunez's opinion letter was filed on June 1, 2021. Pet. Ex. 38, ECF No. 47.

On July 1, 2021, respondent filed a status report, maintaining his position that this case was not compensable and asked that it proceed on a litigation track. ECF No. 48.

A status conference was held on August 12, 2021, after which respondent was ordered to

[3] Petitioner also submitted fourteen photographs when she filed her petition on September 20, 2018. Pet. Ex. 2. These photographs are undated and provide no further information or description. They appear to be self-captured and not prepared as part of medical records or any other official verified reports.

file a responsive expert report. ECF No. 49. Respondent filed a report from Dr. Fadugba on November 30, 2021. Respondent's Exhibit ("Resp. Ex.") A, ECF No. 54.

On December 30, 2021, petitioner filed a motion for interim attorneys' fees and costs. ECF No. 57. Petitioner then filed an expert report from Dr. Gershwin on February 10, 2022. Pet. Ex. 39-43, ECF No. 59. Respondent filed a response to petitioner's motion for interim fees on April 13, 2022, raising reasonable basis, and a responsive expert report on June 10, 2022. ECF No. 62; Resp. Ex. M, ECF No. 63. On June 16, 2022, an Order issued deferring ruling on the motion for interim fees as premature while the six-month severity requirement remained at issue and due to respondent raising a reasonable basis for the claim.

On July 13, 2022, an Order issued instructing petitioner to file a status report confirming that she had filed all the evidence she intends to file in support of the six-month severity requirement. Petitioner filed a status report on August 12, 2022, confirming that she had filed all documents available to her in support of the six-month severity requirement, arguing that she had satisfied the six-month severity requirement, and that the "Court's denial of Petitioner's interim fee request ties Petitioner's hands from obtaining further expert opinions." ECF No. 66.

In response to petitioner's status report, an Order issued on August 15, 2022, explaining that the six-month severity requirement is a "threshold factual question" that must be determined before reaching any issues related to causation or entitlement requiring expert opinion. Thus, petitioner was ordered to file any additional fact evidence in support of the six-month requirement or a status report confirming that no further evidence existed. ECF No. 67.

Petitioner filed a status report on September 29, 2022, stating that she "is not in the position to offer further evidence in support of her claims at this time." ECF No. 68.

Petitioner was then ordered to file a Motion for a Ruling on the Six-Month Severity Requirement. ECF No. 69. Petitioner filed her Motion for a Ruling on the Six-Month Severity Requirement on December 7, 2022. ECF No. 70. Respondent filed his response to the motion on March 21, 2023. Response, ECF No. 72. Petitioner filed a reply on March 28, 2023. Reply, ECF No. 73.

This matter is now ripe for ruling on the issue of the six-month severity requirement.

II. Evidence

A. Petitioner's Medical History

Petitioner has a past medical history of hypertension, type 2 diabetes with hyperglycemia[4] and leg swelling, irritated seborrheic keratosis,[5] degenerative joint disease,

[4] Hyperglycemia is defined as "abnormally increased glucose in the blood." Hyperglycemia, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 878 (33rd ed. 2020) [hereinafter DORLAND'S].

[5] Seborrheic keratosis is defined as "a common, usually benign type of skin lesion composed of basaloid cells; it usually first appears after age 30 and presents as a soft, friable plaque with variable pigmentation. The most common sites are the face, trunk, and limbs." Seborrheic keratosis, DORLAND'S 970.

osteoarthritis, and frequent episodes of back pain associated with stiffness improved with Tramadol. Pet. Ex. 9 at 12-13, 15, 16; Pet. Ex. 12; Pet. Ex. 13 at 3; Pet. Ex. 15 at 2.

Petitioner is a nurse. She received the subject flu vaccine while at work on October 6, 2015 at around 6:30am. Pet. Ex. 1; Pet. Ex. 36 at 1.

Approximately 10 hours later, at 4:41 pm, petitioner presented to the emergency room with swelling of her lips and right side of her face. She reported receipt of a flu vaccine at 7am that morning. Pet. Ex. 21 at 3, 5, 6, 42. The hospital record documents that petitioner was able to speak in full sentences and did not have shortness of breath or swelling of the tongue. *Id*. at 4, 39. She was taking Metformin for type 2 diabetes and Losartan for hypertension. *Id*. at 35, 42. Petitioner was diagnosed with angioedema[6] without airway obstruction, "probably secondary to influenza vaccine," and prescribed prednisone, Pepcid/famotidine,[7] Zyrtec/cetirizine,[8] and an EpiPen and told to follow up with her PCP. *Id.* at 24, 42-43; *see also* Pet. Ex. 3. No urticarial lesions[9] or rash was noted.

Over a month later, on November 9, 2015, petitioner presented to the emergency room reporting facial and lip swelling since last night. Pet. Ex. 4 at 1, 9. No respiratory involvement was noted. *Id*. at 9. Being a diabetic and due to an expected rise in blood sugar from steroid administration, petitioner was admitted to the hospital for IV steroids and antihistamines. *Id*. at 12. The diagnosis upon admission was "angioneurotic edema". *Id*. at 29. She was discharged on November 11, 2015. *Id*. at 27. The record documents no itching or rash. *Id*. at 22. It further documents that no lesions were noted. *Id*. at 4. Her medication for hypertension was changed to amlodipine besylate.[10] *Id.* at 27. There was no record of any "urticarial lesions." The record did not include her taking any of the medications she was prescribed at her last hospital visit (Pepcid and cetirizine). *See id*.

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[6] Angioedema is defined as "a vascular reaction involving the deep dermis or subcutaneous or submucosal tissues, representing localized edema caused by dilatation and increased permeability of capillaries, with development of giant wheals." Angioedema, DORLAND'S 83. A wheal is "the typical lesion of urticaria, the dermal evidence of allergy . . . a smooth, slightly elevated, discolored area on the body surface, often accompanied by severe itching." Wheals are also known as hives. Wheal, DORLAND'S 2049.

[7] Pepcid is a trademark for preparations of famotidine. Pepcid, DORLAND'S 1387. Famotidine is "a histamine H2 receptor antagonist; it inhibits gastric acid secretion and is used in the prophylaxis and treatment of peptic ulcer, the relief of symptoms associated with hyperacidity, and the treatment of gastroesophageal reflux disease". Famotidine, DORLAND'S 671.

[8] Zyrtec is the trademark for cetirizine hydrochloride. Zyrtec, DORLAND'S 2066. Cetirizine hydrochloride is defined as "a nonsedating antihistamine that is a metabolite of hydroxyzine, used in treatment of allergic rhinitis and chronic idiopathic urticaria, and as a treatment adjunct in asthma; administered orally." Cetirizine, DORLAND'S 329.

[9] Urticaria is defined as "a vascular reaction in the upper dermis, usually transient, consisting of localized edema caused by dilatation and increased capillary permeability with wheals. Most types are named for the causative stimulus or mechanism, such as *physical urticaria* and *contact urticaria*. *Angioedema* is the same physiologic response in the deep dermis or subcutaneous or submucosal tissues. Also called *hives*." Urticaria, DORLAND'S 1981.

[10] Amlodipine is defined as "a calcium channel blocking agent used in the treatment of hypertension and chronic stable and vasospastic angina; administered orally." Amlodipine, DORLAND'S 63.

On November 19, 2015, petitioner presented to her primary care physician, Dr. Valdespino for eosinophilia[11] with high levels of IgE.[12] Pet. Ex. 5 at 1-2. There were no other notes related to this encounter.

Petitioner presented to her allergist, Dr. De La Cruz on November 23, 2015, for "follow up of allergic reaction" with no new symptoms. Pet. Ex. 28 at 1. Dr. De La Cruz planned for an allergy panel to evaluate for possible allergy and to test for IgE level. *Id*. at 2; Pet. Ex. 6 at 1. Dr. De La Cruz's diagnosis was allergic reaction and angioedema. She was instructed to continue taking amlodipine, cetirizine, Pepcid, hydroxyzine pamoate,[13] and Metformin. Pet. Ex. 28 at 2. Allergy testing performed showed among other things no sensitivity to egg whites.[14] Pet. Ex. 5 at 3-9.

Petitioner returned to Dr. De La Cruz on December 15, 2015. Examination was normal with no acute lesions or rash noted. She was to continue with her previously prescribed medications. Pet. Ex. 6 at 3-4; *see also* Pet. Ex. 28 at 3-4. No complaints of any additional incidents of angioedema or urticarial lesions were reported in the record.

Petitioner presented to Dr. Valdespino on February 10, 2016 reporting a hospitalization for "acute angioedema (facial, tongue)". Pet. Ex. 9 at 10.[15] Her diagnosis on that date was hypertension and diabetes. *Id*. There were no complaints of any additional episodes of angioedema, rash, or urticarial lesions reported at that visit. *Id*.

Petitioner returned to Dr. Valdespino on February 20, 2016 for her annual physical and lab work, which showed high glucose, low HDL, and high IgE. *See generally* Pet. Ex. 26; Pet. Ex. 27 at 28-38.

There were no further records filed that mention any additional episodes of angioedema, rash, or injuries associated with the flu vaccine and no record documenting follow up or monitoring of the prescribed medications. No records document "urticarial lesions." The remainder of petitioner's medical visits in 2016 involved care unrelated to this claim and included a positive tuberculosis test, routine gynecological care, imaging for scoliosis following a car accident, and continued care for hypertension and diabetes. *See* Pet. Ex. 9 at 2-11. At her November 3, 2016 visit for lab work the record includes the following "active medications":

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[11] Eosinophilia is the "formation and accumulation of an abnormally large number of eosinophils in the blood". Eosinophils are a granular leukocyte with a nucleus that usually has two lobes connected by a slender thread of chromatin, and cytoplasm containing coarse, round granules that are uniform in size. Eosinophilia, DORLAND'S 622; Eosinophils, DORLAND'S 622.

[12] IgE (immunoglobulin) has the unique function of mediating immediate hypersensitivity reactions; it binds to specific receptors on basophils and mast cells and triggers the release of mediators on contact with antigen. IgE, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=24894.

[13] Hydroxyzine pamoate is "the pamoate salt of hydroxyzine, having the actions and uses of the hydrochloride salt", which is "used as an antianxiety agent and antiemetic, in urticaria and other manifestations of allergic dermatoses". Hydroxyzine, DORLAND'S 873.

[14] Certain commonly used vaccines contain small amounts of egg protein from the manufacturing process, with typically higher concentrations in vaccines cultured on embryonated chicken eggs like the influenza vaccine. Michael M. McNeil, MD, MPH & Frank DeStefano, MD, MPH, *Vaccine-associated Hypersensitivity*, 141 CLINICAL REV. IN ALLERGY AND IMMUNOLOGY 463, 465 (2018), filed as "Pet. Ex. 40".

[15] The majority of the records in this file are handwritten and are largely illegible. *See* Pet. Ex. 9.

Active Medications

MEDICATION	SIG	START/STOP	ASSOCIATED DX
amLODIPine (AmLODIPine Besylate) 10 mg oral tablet	once a day	07/17/14 -	-
Cetirizine HCl 10 MG Oral Tablet	TAKE ONE TABLET BY MOUTH ONCE DAILY	-	-
GlipIZIDE 5 MG Oral Tablet	Take 1 tablet (5 mg) by mouth daily	06/23/16 -	-
HydrOXYzine HCl 25 MG Oral Tablet	TAKE ONE TABLET BY MOUTH ONCE DAILY	-	-
Losartan Potassium & Hydrochlorothiazide (Losartan Potassium-HCTZ) 100-12.5 MG Oral Tablet	1 tablet orally daily	05/19/15 -	-
MetFORMIN HCl 850 MG Oral Tablet	Take 1 tablet (850 mg) by mouth 2 times per day with meals	03/02/15 -	-

ASA: 81 mg daily

Pet. Ex. 9 at 4. The record does not include any "start" or "stop" date for cetirizine or hydroxyzine.

Petitioner's next visit to Dr. De La Cruz was on September 21, 2017. No episodes of angioedema or other concerns associated with her October 6, 2015 flu vaccine since her last visit were documented as reported. Examination was normal with no rash or skin lesions noted; she was to continue with her medications. Pet. Ex. 6 at 5-6; Pet. Ex. 28 at 5-6.

On October 10, 2017, petitioner presented with herpes zoster and was prescribed valacyclovir. Pet. Ex. 6 at 7-8. Her following visits were for unrelated medical follow up care on March 8, 2018; August 23, 2018; December 4, 2018; April 4, 2019; April 23, 2019; June 11, 2019; September 10, 2019; October 8, 2019; November 7, 2019; and February 6, 2020. The record does not contain any reports or findings of any additional incidents of angioedema, rash, swelling or urticarial lesions at any of these visits. *See generally* Pet. Ex. 28. At all times, petitioner's medication lists included cetirizine, Pepcid, and hydroxyzine pamoate.

Over five years after the receipt of the subject flu vaccination, on November 17, 2020, petitioner presented to a new allergist, Dr. Nunez at Asthma and Allergy Associates of Florida, for evaluation and management of her "nasal symptoms". Pet. Ex. 35 at 1. Dr. Nunez's record included "mild" allergy to flu vaccine. *Id*. at 2. Petitioner provided a history of allergic rhinitis,[16] asthma, and angioedema/hives. Petitioner reported that she suffered lip angioedema following flu vaccine in 2015 with three recurrent episodes over the next several months. She was prescribed cetirizine, hydroxyzine, and famotidine and "has been compliant with the above regimen since 2015" despite

[16] Allergic rhinitis is "a general term used to denote any allergic reaction of the nasal mucosa." Allergic rhinitis, DORLAND'S 1613.

being asymptomatic for more than one year. *Id.* Upon examination, she had no rashes and no edema. *Id*. at 3. Skin testing performed was positive to dust mites. *Id*. at 5. Dr. Nunez diagnosed petitioner with allergic rhinitis due to perennial allergens and seasonal pollen. The record further documented moderate asthma, idiopathic angioedema, and flu vaccine "causing almost immediate angioedema in 2015." *Id*. She was prescribed medication for her asthma and seasonal allergies. *Id*. at 6. She reported being asymptomatic for angioedema for over one year, so the hydroxyzine and famotidine were discontinued. *Id*. At her follow up visit on December 15, 2020, she reported doing well. *Id.* at 15. She had no rash, swelling, or itching and no documented recurrence of angioedema or urticaria since discontinuing the hydroxyzine and famotidine. *Id*. at 15-17.

No further medical records were filed.

B. Petitioner's Affidavit

In an affidavit dated October 18, 2020, petitioner affirmed being a nurse and receiving a flu vaccine at work on October 6, 2015 at approximately 6:30am. Pet. Ex. 36 at 1. She "had always taken a flu vaccine" and never had any prior allergic reactions. *Id.*

She affirmed that when she got home the day of the vaccine, her face and lips were inflamed and swollen. She was diagnosed with angioedema caused by an allergic reaction to the flu vaccine at Palm Spring General Hospital. Pet. Ex. 36 at 1. According to petitioner, the nurse in charge of epidemiology sent a report to the vaccine manufacturer advising of her reaction, but she was unable to obtain a copy of the report from her employer. *Id.* at 1-2.

Petitioner affirmed having suffered several other episodes of angioedema[17] in the month following October 6, 2015. Pet. Ex. 36 at 2. She presented to the ER on November 9, 2015 for one episode and admitted "due to [her] life being in danger." *Id*.

According to petitioner, she continues to "receive treatments to relieve the episodes of angioedema resulting from [her] allergic reaction to the flu vaccine". Pet. Ex. 36 at 2. There is no mention in the affidavit of urticaria, lesions or any other symptoms. *See generally id.*

C. Dr. Nunez's Opinion

In May of 2021, Dr. Nunez authored a letter documenting that at petitioner's first visit with him on November 17, 2020, she reported a "history of chronic urticarial lesions with angioedema" after a flu vaccine. Pet. Ex. 38 at 1. "Patient stated multiple episodes of angioedema with concurrent urticarial lesions for 'several months.' Patient also reported that urticarial lesions persisted, although at the time of our initial consultation patient had been free of urticarial lesions for >1 year." *Id*.

[17] *Supra* note 6.

Dr. Nunez described petitioner's treatment with cetirizine[18], hydroxyzine[19], and famotidine[20] following her allergic reaction "as the minimum treatment which controlled symptoms with infrequent breakthrough urticarial lesions." Pet. Ex. 38 at 2. He added that the duration of treatment with these medications was "not inconsistent with management of chronic urticaria with angioedema". *Id*. at 2. He included a flow chart for treatment of angioedema, which included that "step down" of the medications is appropriate when control of urticaria/angioedema is achieved, meaning no breakthrough lesions for a period of at least 6-12 weeks. *Id*. Dr. Nunez explained that urticaria and angioedema are driven by activation of mast cells which, when activated, release inflammatory mediators, including histamine, heparin, leukotriene C4, and prostaglandin D2, which cause dilation of venules in the skin and enhance venule permeability, resulting in tissue swelling. *Id*. at 3. Dr. Nunez noted that that urticaria and angioedema are "pathologically identical processes", with urticaria being a superficial dermal process while angioedema takes place in the deeper levels of the skin and subcutaneous tissues, most often involving the face or mouth. Given the almost identical nature of both processes, patients are customarily maintained on treatment until well-controlled and ready to wean off medication, whether angioedema is reported or not. *Id*.

In his letter, Dr. Nunez concluded that given petitioner's reports of breakthrough urticarial lesions while compliant with medication, it was medically prudent to continue or even step-up therapy until she reported control without breakthrough lesions, at which time weaning would be appropriate. "The presence or lack of angioedema is not considered with regards to the duration of treatment as we are only focused on the continued presence of the process (i.e. Mast cell activation) not its presentation (Urticaria/Angioedema)." Pet. Ex. 38 at 3.

Dr. Nunez did not cite to or present any literature in support of his opinion. More importantly, he did not cite to any medical record documenting episodes of angioedema with urticarial lesions or urticarial lesions persisting until a year prior to her first visit with him on November 17, 2020. Rather, he documented petitioner's reported history: "Patient stated multiple episodes of angioedema with concurrent urticarial lesions for 'several months.' Patient also reported that urticarial lesions persisted, although at the time of our initial consultation patient had been free of urticarial lesions for >1 year." *Id*.

D. Dr. Gershwin's Opinion

Petitioner retained an expert, Dr. Gershwin who issued an opinion letter dated February 6, 2022 stating that angioedema following flu vaccine is well documented in medical literature and that the mechanism of all angioedema, including vaccine-induced angioedema, is "enigmatic". Pet. Ex. 39 at 2. He further wrote that in virtually all cases of angioedema, Zyrtec/cetirizine would be prescribed to be taken on a daily basis to prevent acute episodes of angioedema. *Id.* Without citing to any medical records, Dr. Gershwin opined that this appears to be the case with petitioner and that the periods of time in which her angioedema was in remission would be consistent with the "natural and unpredictable nature of angioedema" and also with the continued use of Zyrtec/cetirizine. *Id.*

[18] *Supra* note 8.
[19] *Supra* note 13.
[20] *Supra* note 7.

Dr. Gershwin concluded that petitioner's "acute angioedema was caused by influenza vaccination" but as to the six months issue, he "cannot comment on the[] gaps within the medical record when [petitioner] was not seen by a physician." Pet. Ex. 39 at 2.

E. Dr. Fadugba's Opinion

Respondent's expert, Dr. Fadugba issued two reports in this case. Resp. Ex. A; Resp. Ex. M. His opinion, like Dr. Gershwin's, is largely focused on causation rather than the issue of six months; however, he did touch on the six-month issue. He opined that petitioner's clinical presentation was consistent with chronic spontaneous idiopathic urticaria and angioedema ("CSU"). Resp. Ex. A at 7. He stated that "[e]ven if the petitioner had a diagnosis of CSU based on having angioedema and hives for > 6 weeks, it could have self-resolved within less than 6 months. One cannot determine with full certainty, how long the petitioner's condition lasted because she was maintained on chronic suppressive antihistamines for several years." *Id*. at 7-8, 10. Dr. Fadugba further noted that there is no evidence that petitioner's symptoms of angioedema with urticarial lesions persisted beyond six months. *Id*. at 9, 10. He explained that a patient should follow up with a doctor regularly to determine if they are still having recurrence of CSU but that "[t]here is no specific time frame for when chronic antihistamines should be discontinued". *Id*. at 11. Here, the issue is that petitioner did not follow up with medical providers to determine whether continued medication was necessary until she met with Dr. Nunez in 2020. *Id*.

F. Photographs

Petitioner filed several photographs which did not include a time/date stamp, so it is unclear when the photographs were taken. *See generally* Pet. Ex. 2.

III. The Parties' Arguments

A. Petitioner's Submission

In her Motion for Ruling on the severity requirement, petitioner claims that "[e]vidence of record clearly establishes that Petitioner suffered the required residual effects and complications for well over 6 months post vaccination; that symptoms were suppressed because of medication; and that the Petitioner's treating doctors continued to medicate Petitioner for the vaccine injury for years post vaccination." Motion at 2, ECF No. 70.

Petitioner argues that there is no requirement that "symptoms be present or that they be severe" submitting that petitioner's symptoms were suppressed by the medication she was taking. Motion at 3. Additionally, "[p]ursuant to the applicable law, the focus should be on the injury and its residual effects and complications, and not on the Petitioner not having sought further medical attention. . .". *Id*. at 2. Further, '"residual effects or complications' and 'symptomatic' are not synonymous; one can suffer from a disease without exhibiting any clinical signs thereof. . . the ongoing need for medication to prevent symptoms and/or relapse of the alleged vaccine-caused illness constitutes a residual effect or complication of that illness." Motion at 2-3, quoting *Faup v.*

Sec'y of Health & Human Servs., 12-87V, 2015 WL443802, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2015).

Petitioner alleges that she suffered symptoms repeatedly, was medicated to prevent recurrence of symptoms, and was medicated for much longer than six months. She experienced "several other episodes of angioedema" during the month following administration of the flu vaccine and was admitted to the hospital less than a month later on November 9, 2015 with facial and lip swelling. Motion at 2, 3.

On November 23, 2015 at a follow-up visit with Dr. De La Cruz, petitioner was diagnosed with allergic reaction and angioedema and instructed to continue taking cetirizine, Pepcid, and hydroxyzine. Motion at 4. In February of 2016, she was seen by her primary Dr. Valdespino for follow up of her November hospitalization for angioedema. *Id.*

Petitioner submitted that Dr. De La Cruz passed away during the pendency of this action and was unable to provide an opinion but had "voiced to her that the vaccine caused [her] injury, that the injury and necessity of medication for it lasted long in excess of 6 months, and was still present at the date of filing." Motion at 4.

Petitioner further argues that the opinion letters from Dr. Nunez and Dr. Gershwin support that petitioner suffered a vaccine injury in excess of six months. Motion at 4-5, 7-8. Dr. Nunez's letter supports that she was prescribed and took medication, including cetirizine, hydroxyzine, and famotidine to prevent reoccurrence of symptoms for "6 months or more post vaccination", thus satisfying the severity requirement. Motion at 5.

Petitioner alleges that the Court has "criticized and discounted" the opinions of Dr. Nunez because he has not reviewed petitioner's medical records "yet the Court has not approved payment for the work he has already performed at its request" nor did the Court ask that Dr. Nunez review all of petitioner's medical records. Motion at 5. "[T]he Court seems to impose a requirement that he had reviewed all of Petitioner's medical records to consider his opinion as a treating doctor." *Id.*

Petitioner further argues that the Court noted that Dr. Nunez's opinions refer to urticarial lesions despite there being no evidence of them in the medical records. Motion at 5. However, "Dr. Nunez. . . explained that urticaria and angioedema are pathologically identical processes". *Id*. at 5. Further, respondent's expert agreed the photographs she filed showed the presence of urticarian lesions in addition to angioedema. *Id*. at 6, citing Resp. Ex. A. As such, petitioner argues that "[t]here is no legitimate basis to have discounted [Dr. Nunez's] opinions," stating "Dr. Nunez is correct, and the medical record (sic) are obviously not complete in not having made reference to uticarian (sic) lesions". Motion at 6.

Petitioner further states that Dr. Gershwin's report "establishes that Petitioner continues to suffer from residual effects and complications of her vaccine injuries for more than 6 months" and that "while her angioedema may ultimately resolve, more likely than not Petitioner will continue to experience intermittent episodes throughout her life." Motion at 7. Dr. Gershwin opined that the

periods where her angioedema was in remission is consistent with the "natural and unpredictable nature" of angioedema and treatment with Zyrtec/Cetirizine for prevention of acute episodes. *Id.*

B. Respondent's Submission

In his response, respondent argues that petitioner has failed to meet the threshold issue of six-month severity because the medical records are "devoid of any objective evidence that petitioner suffered the residual effects of her alleged injury for at least six months." Response at 6, ECF No. 72.

Respondent submits that the medical records show two occasions of documented objective signs of angioedema: one on the date of vaccination and another one month after vaccination. Response at 6. There is no further objective medical documentation of angioedema that exists in the medical records, and no medical record documenting the presence of urticaria at any time. *Id.*

Respondent argues that petitioner's testimony is insufficient to satisfy the severity requirement without any corroborating evidence, citing § 13(a)(1) which states that a special master may not find in favor of petitioner "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Response at 6. Thus, her affidavit on its own is insufficient to meet the severity requirement. Respondent further argued that the photographs submitted by petitioner are insufficient to meet the severity requirement because they are undated. *Id*., note 4. After November 2015—one month after vaccination—there are no medical records that document angioedema. *Id.*

Further, respondent argues that petitioner's use of medication does not satisfy the severity requirement because "[m]ere precautionary measures based on injury history and/or patient apprehension, taken in absence of recurrent injury or actual injury-related symptoms, do not constitute 'residual effects,' even if they persist for greater than six months." Response at 6, citing ECF No. 49 and *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999 (Fed. Cir. 2022).

C. Petitioner's Reply

Petitioner's reply repeats the arguments contained in her initial brief. Reply, ECF No. 73; *see* Motion. Petitioner submits that her use of medication for over six months suppressed any symptoms, thus satisfying the severity requirement. Reply at 2.

Further, petitioner argues that respondent incorrectly analogized her case to the facts before the Federal Circuit in *Wright*. Reply at 1. In *Wright*, petitioner submitted that the evidence supported that the injury had resolved within six months of vaccination; "there was no reoccurrence, just ongoing testing for a resolved condition." *Id*. Here, the evidence supports that petitioner continued to suffer from her vaccine injury for years post vaccination and she underwent continuing treatment in the form of medication to manage her condition. *Id*. at 1-2.

IV. Legal Framework

A. Overall Fact-Finding Framework

In the Vaccine Program, the fact-finding process begins with an analysis of the medical records filed with the petition. §11(c)(2). A special master's finding of fact is to be upheld when her evaluation is evidence-based and not wholly implausible. *See Colon v. Sec'y of Health & Human Servs.*, 156 Fed. Cl. 534, 538-39 (2021). "[R]eversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Hines v. Secretary of Health & Human Servs.,* 940 F.2d 1518, 1528 (Fed. Cir. 1991).

B. Severity Requirement

To receive compensation, a petitioner must also show that the injured person

> (i) suffered the residual effects or complications of his illness, disability, injury, or condition for more than six 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[.]

§ 11(c)(1)(D)(i)–(iii). Cases may appropriately be dismissed for failure to substantiate the severity requirement. *See, e.g.*, *Hinnefeld v. Sec'y of Health & Human Servs.,* No. 11-328V, 2012 WL 1608839, at *4–5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's Guillain–Barré Syndrome resolved less than two months after onset). Petitioner has not alleged, and the record does not support, that she suffered an injury resulting in inpatient hospitalization and surgical intervention or that she died as a result of the vaccination. Thus, petitioner must establish that she "suffered the residual effects or complications of [her] illness, disability, injury, or condition for more than six months after the administration of the vaccine[.]" *See* § 11(c)(1)(D)(i).

It is petitioner's burden to prove her case, including the six-month requirement, by a preponderance of the evidence. *See* § 13(a)(1)(A). To satisfy the six-month requirement, "[a] potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute." *Faup,* No. 12-87V, 2015 WL 443802, at *3 (quoting *Black v. Sec'y of Health & Human Servs.,* 33 Fed. Cl. 546, 550 (1995), *aff'd*, 93 F.3d 784, 792 (Fed. Cir. 1996)). A petitioner cannot establish the length or ongoing nature of an injury merely through their own statements, but rather is required to "submit supporting documentation which reasonably demonstrates that the alleged injury or its sequelae lasted more than six months . . . .". *Black*, 33 Fed. Cl. at 550 (internal quotations omitted); *see also Lett v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 259, 260–61 (1997) ("Section 300–aa13(a)(1) provides that a special master may not award compensation 'based on the claims of [a] petitioner alone, unsubstantiated by medical records or by medical opinion'").

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005)); *Cucuras v. Sec'y of Health & Human Servs.*, 993

F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs*., 997 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Curcuras* does not stand for the proposition that medical records are presumptively accurate and complete as to all the patient's physical conditions). Generally, while not presumptively complete and accurate, medical records created while seeking treatment are afforded more weight than statements made by petitioner after-the-fact or letters prepared for litigation purposes. *See Milik v. Sec'y of Health & Human Servs*., No. 01-64V, 2014 WL 6488735 at *12 (Fed. Cl. Spec. Mstr. Oct. 29, 2014) (giving more weight to contemporaneously recorded medical evidence than facts recorded in later medical histories or physician records created for purposes of litigation) *mot. for rev. denied*, 121 Fed. Cl. 68 (2015), *aff'd*, 822 F.3d 1367 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 2206 (2017); *Gerami v. Sec'y of Health & Human Servs*., No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (same), *mot for rev. denied*, 127 Fed. Cl. 299 (2014).

However, neither the opinions of treating physicians nor contemporaneous medical records are binding on the special master. § 13(b)(1); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346–49 (Fed. Cir. 2010) (affirming the special master's finding that the petitioner suffered from one disease even though the petitioner's treating doctor had diagnosed the petitioner with a different disease). When there are inconsistencies between witness testimony and medical records, such testimony may be given more weight if it is consistent, clear, cogent, and compelling. *See Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825 at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (vacated on other grounds, *Sanchez by & through Sanchez v. Sec'y of Health & Human Servs*., No. 2019-1753, 2020 WL 1685554 (Fed. Cir. Apr. 7, 2020), *review denied, Sanchez by & through Sanchez v. Sec'y of Health & Human Servs.*, 152 Fed. Cl. 782 (2021)) (quoting *Blustein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In sum, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . .". § 13(b)(1).

There are several cases addressing the sufficiency of evidence provided to satisfy the six-month severity requirement. For example, in *Kirby*, the special master's finding that Ms. Kirby's injury lasted for more than six months was upheld by the Circuit. 997 F.3d at 1378. The special master determined that the petitioner satisfied the severity requirement based on her testimony, corroborating documentation, and expert testimony, and despite medical records documenting that the petitioner reported "feeling fine". *Id*. at 1381. The Circuit distinguished the petitioner's case from *Cucuras* "where the petitioners said one thing to their physician and another thing to the special master." *Id*. at 1383, citing 993 F.2d at 1527-28. The Circuit held that a reasonable fact finder could find that petitioner's testimony of ongoing pain did not conflict with the records, as the records were also silent about the "*non*existence" of such symptoms, meaning that the records did not specifically document the absence of certain symptoms. *Kirby*, 997 F.3d at 1383. The petitioner's testimony that her symptoms persisted for over a year was supported by medical records showing discharge from in-person physical therapy with instruction to continue with home exercises in addition to the home exercise instruction sheets that she produced at trial. *Id*. at 1380, 1381.

Special masters have found that continuing a course of medication that is actively treating a condition for over six months can meet the severity requirement; however, taking medication prophylactically to evade recurrence cannot. *Prepejchal v. Sec'y of Health & Human Servs.*, No. 15-1302V, 2018 WL 5782865 at *16 (Fed. Cl. Spec. Mstr. Oct. 5, 2018); *Watts v. Sec'y of Health & Human Servs.*, No. 17-1494V, 2019 WL 4741748 at *7 (Fed. Cl. Aug. 13, 2019). There is a distinction between taking medication without evidence of symptoms versus taking medication to prevent symptoms and/or relapse, the latter of which can meet the severity requirement. *See also Faup*, No. 12-87V, 2015 WL 443802 at *4 (finding that the ongoing need for medication to prevent symptoms and/or relapse of the alleged vaccine-caused illness constitutes a residual effect or complication of that illness).

However, the severity requirement may not be met merely by speculation that if a petitioner was not taking a medication, they would experience further symptoms related to the vaccine injury. *Toebe v. Sec'y of Health & Human Servs*, No. 91-1623V, 1992 WL 101638 at *3 (Fed. Cl. Spec. Mstr. Apr. 23, 1992). In *Toebe*, the petitioner's neurologist prescribed medication for greater than six months for a "seizure disorder." *Id.* However, the petitioner did not experience any seizures the day after she was vaccinated, and when the medication was discontinued, she had no further seizures. *Id.* Petitioner failed to meet the severity requirement because a determination that she would have suffered additional seizures if she had not been taking medication was based on speculation. Further, any argument that the seizure medication was masking further seizures was weakened by the fact that petitioner's seizures did not recur after stopping medication. *Id.* Thus, the special master found no basis for concluding that the residual effects continued for more than six months. *Id.*; *but see Hernandez v. Sec'y of Health & Human Servs.,* No. 17-0143V, 2023 WL 9186318, at *21 (Fed. Cl. Spec. Mstr. Dec. 15, 2023) (holding the severity requirement was met with continued use of anti-seizure medication despite no manifestation of symptoms in part because the decision to wean off medication is a case-by-case clinical judgment made in light of the "risk of recurrence and in order to give the brain time to become less excitable"; distinguishing the case from *Toebe* by crediting the experts' explanation that a child is considered to be in "remission" of epilepsy only *after* they have been successfully weaned from medication).

Long gaps in the medical records with no mention of ongoing symptoms may weaken the probative value of medical records created in anticipation of litigation stating that petitioner's symptoms lasted for longer than six months. *See, e.g., Watts*, No. 17-1494V, 2019 WL 4741748 at *7 (finding six-month severity requirement was not met where medical records were silent for over two years of any symptoms of GBS, but petitioner later sought treatment right before initiating her claim, alleging she experienced persistent symptoms throughout the interim period). When making severity requirement determinations, it is a sound exercise of the special master's discretion to afford more weight to contemporaneous medical records over medical opinion letters which make conclusory assertions without citation to the medical records. *Gerami v. Sec'y of Health & Human Servs*., 127 Fed. Cl. 299, 306 (2014) (affirming special master's finding that severity requirement was not met where medical records showed no complaints of symptoms in excess of six months, but a physician letter in response to an attorney request stated symptoms lingered for six months without referencing contemporaneous medical records).

The Federal Circuit addressed the six-month severity requirement in *Wright*. 22 F.4th 999. The Circuit held that a petitioner failed to satisfy the six-month requirement when her child's

platelet count normalized less than three months post ITP onset because "relatively non-invasive ongoing [platelet] monitoring" was not a "residual effect" pursuant to § 11(c)(1)(D)(i). *Id.* at 1001, 1003, 1006–07. The Circuit noted that the child experienced later bruising that was not related to his vaccine injury and that his ongoing testing "did not reveal, constitute, or cause any somatic change". *Id.* at 1001. Defining the language in § 11(c)(1)(D)(i), the Federal Circuit determined that "[t]he term 'residual effects[]' . . . requires a change within the patient that is caused by the vaccine injury." *Id.* at 1004. It continued that "'[r]esidual' suggests something remaining or left behind from a vaccine injury . . . . Because vaccine injuries are somatic conditions defined by their signs and symptoms within the patient, . . . their residues are similarly defined." *Id.* at 1005–06. The Federal Circuit stated that the use of the words "suffered" and "complication" in association with "residual effects" in § 11(c)(1)(D)(i) "suggest[s] that Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms." *Id.* at 1006. It concluded that "[r]ead together, 'residual effects' and 'complications' appear to both refer to conditions within the patient, with 'residual effects' focused on lingering signs, symptoms, or sequelae characteristic of the course of the original vaccine injury, and 'complications' encompassing conditions that may not be 'essential part[s] of the disease' or may be outside the ordinary progression of the vaccine injury." *Id*.

The Federal Circuit in *Wright* noted that "it is sufficient that the vaccine injury be both a but-for cause of the residual effect and a substantial factor in bringing about the residual effect, even if it is not the predominant factor." 22 F.4th at 1005 (citing *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). However, it noted that "even if legally caused by his thrombocytopenic purpura, [the child's] testing was not a 'residual effect'". 22 F.4th at 1005. This is because the "[t]he tests revealed [that the child] had no lingering symptoms or recurrence of thrombocytopenic purpura[;]" and because "there [was] no showing or argument that [the testing] was detrimental to [the child's] health such that it might qualify under § 300aa–11(c)(1)(D)(i) as a 'residual effect' or a 'complication' of thrombocytopenic purpura." *Id.* at 1006. The Federal Circuit concluded that the ongoing monitoring was "neither an 'ongoing disability' nor indicative that he 'suffered' or was 'seriously injured' within Congress's intended meaning of the severity requirement." *Id.* at 1007 (internal citations omitted).

The Federal Circuit clarified that its decision in *Wright* "do[es] not disturb existing case law holding that a course of treatment lasting longer than six months can be a 'residual effect.'" 22 F.4th 1007. The Circuit cited *H.S. v. Sec'y of Health & Human Servs.*, No. 14-1057V, 2015 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015), in which the special master determined that restrictions on physical activity, including restrictions from participating in gym class, recess, and sports, following a concussion constituted a "residual effect" because the restriction was medically necessary to prevent aggravation of the injury. *Id.*; *H.S.*, No. 14-1057V, 2015 WL 1588366, at *3. The Circuit also cited *Faup*, wherein the special master held that the petitioner fulfilled the six-month requirement because her child needed medication for her arthritis for more than six months. *Wright*, 22 F.4th at 1007; *Faup*, 12-87V, 2015 WL 443802, at *4. The Federal Circuit noted that "[d]uring a long course of treatment, the patient generally has some lingering condition such that symptoms will likely recur if the treatment were stopped. Otherwise, the long course of treatment would not be necessary." *Wright*, 22 F.4th at 1007. The Circuit also clarified that *Wright* "do[es] not decide [ ] whether a course of testing or monitoring that is part of the management or treatment of a condition, necessary even in the absence of possible symptoms, could be a 'residual effect'"

as monitoring may be considered an ongoing part of treatment if "the patient's somatic condition increases the risk of recurrence." *Id.*

V. Discussion

Whether the flu vaccine petitioner received on October 6, 2015 caused and/or contributed to petitioner's two documented episodes of angioedema is not at issue, relevant, or the focus of this decision. The only issue addressed here is whether petitioner has satisfied the statutory six months severity requirement as required by the Vaccine Act. § 11 for the case to continue.

Following review of all the evidence filed and the parties' arguments, and as set forth below, I find that there is insufficient evidence to demonstrate petitioner has satisfied the six months requirement.

A. There is not preponderant evidence that petitioner's symptoms of angioedema lasted beyond six months.

The evidence filed in this case can be summarized as follows:

- Petitioner received the subject flu vaccine on October 6, 2015 at approximately 6:30am. Pet. Ex. 1.

- Ten hours later, at 4:41pm, she presented to the ER with swelling of her lips and the right side of her face. Pet. Ex. 21 at 3, 5, 6, 42. She was diagnosed with angioedema "probably secondary to influenza vaccine" and prescribed prednisone, Pepcid/famotidine, Zyrtec/cetirizine, and an EpiPen. *Id.* at 24, 42-43; *see also* Pet. Ex. 3.

- A month later on November 9, 2015, petitioner presented to the ER reporting facial and lip swelling since the night before. Pet. Ex. 4 at 1, 9. Her diagnosis was angioneurotic edema. *Id*. at 29. There were no reports of angioedema or urticarial lesions between the two events documented.

- Petitioner presented to Dr. Valdespino for eosinophilia[21] on November 19, 2015. The record does not contain any reference to angioedema or lesions. Pet. Ex. 5 at 1-2.

- Petitioner presented to her allergist, Dr. De La Cruz on November 23, 2015, for "follow up of allergic reaction" with no new symptoms. Pet. Ex. 28 at 1. Dr. De La Cruz's diagnosis was allergic reaction and angioedema. She was instructed to continue taking the antihistamines (cetirizine and Pepcid). *Id*. at 2.

- Petitioner returned to Dr. De La Cruz on December 15, 2015. Examination on that day was normal specifically documenting no acute lesions or rash. She was to

[21] *Supra* note 11.

continue with her previously prescribed medications. Pet. Ex. 6 at 3-4; *see also* Pet. Ex. 28 at 3-4. Petitioner did not see Dr. De La Cruz again until September 2017, 21 months later.

- Petitioner presented to Dr. Valdespino on February 10, 2016 reporting a history of hospitalization for "acute angioedema (facial, tongue)". Pet. Ex. 9 at 10. No additional episodes of angioedema, rash, or urticarial lesions were reported or documented. *Id*.

- Petitioner returned to Dr. Valdespino on February 20, 2016 for an annual exam. No reports of angioedema, lesions, or rash were documented. *See generally* Pet. Ex. 26; Pet. Ex. 27 at 28-38.

- On May 25, 2016, petitioner had a positive tuberculosis test. Pet. Ex. 9 at 7.

- Petitioner was seen following an auto accident on September 15, 2016. Pet. Ex. 9 at 5-6. She visited Dr. Valdespino on October 14, 2016 with complaints related to the car accident. The results of an MRI were discussed. *Id*. at 9. There was no mention of angioedema, lesions, or rash in the record. *Id*.

- Petitioner presented for blood work up on November 3, 2016. Pet. Ex. 9 at 2-4. The record includes active medications of amlodipine, cetirizine, glipizide, hydroxyzine, losartan, and Metformin; the entries for cetirizine and hydroxyzine did not have start or stop dates like the other medications listed. *Id*. at 4. There were no complaints of angioedema, lesions, or rash documented. *See id*.

- On November 21, 2016, petitioner had a follow up with Dr. Valdespino. Her diagnosis included hypertension and diabetes mellitus. There were no complaints or findings of angioedema, lesions, swelling, or rash documented. Pet. Ex. 9 at 8.

- There were no records filed for the timeframe between November 2016 through September 2017.

- Petitioner returned to Dr. De La Cruz on September 21, 2017, 21 months since she was last seen. Examination was normal; she was to continue with the same medications. Pet. Ex. 6 at 5-6; Pet. Ex. 28 at 5-6. There was no complaint or documentation of any episodes of angioedema since her last visit on December 15, 2015, at which time the record contained, "no rash" and "no skin lesion". *See* Pet. Ex. 6 at 3-4.

- On October 10, 2017, petitioner presented with herpes zoster. She was prescribed valacyclovir. The record documented "no skin lesion". Pet. Ex. 6 at 7-8.

- Petitioner presented on March 8, 2018; August 23, 2018; December 4, 2018; April 4, 2019; April 23, 2019; June 11, 2019; September 10, 2019; October 8, 2019;

November 7, 2019; and February 6, 2020. Each visit documents "no skin lesion" and "no acute lesion." *See* Pet. Ex. 28 at 9-34.

- No medical records were filed between February 2020 and November 2020.

- A status conference was held on September 30, 2020 to discuss the evidence filed, that petitioner's claim did not meet the criteria for on-Table anaphylaxis as alleged, and that her off-Table claim of angioedema would likely fail the six-month severity requirement. *See* ECF No. 35.

- Roughly a month and half after that status conference and an Order detailing the discussion, petitioner presented to Dr. Nunez as a new patient on November 17, 2020. Pet. Ex. 35 at 1. The record reflects that petitioner provided her history which included lip angioedema following a flu vaccine in 2015 with three recurrent episodes over the next several months. She was prescribed cetirizine, hydroxyzine, and famotidine and "has been compliant with the above regimen since 2015" despite being asymptomatic for more than one year. *Id.* at 2. Examination by Dr. Nunez showed no rashes and no edema. *Id*. at 3. Dr. Nunez documented that she had been asymptomatic for over one year, so he discontinued the medications. *Id*. at 6.

- At her follow-up visit with Dr. Nunez on December 15, 2020, petitioner reported doing well with no symptoms of angioedema since discontinuing the medication. Pet. Ex. 35 at 15-17.

To summarize, petitioner had an episode of angioedema 10 hours after her flu vaccination and a second episode of angioedema one month later. Pet. Ex. 21 at 1, 3, 5-6, 23-24, 42-43; Pet. Ex. 4 at 1, 9. There are no documented reports of any episodes of angioedema between the October 6, 2015 and November 9, 2015 event or any further episodes of angioedema reported in any medical record until November 17, 2020—roughly five years later when petitioner presented to Dr. Nunez and reported a history of angioedema and urticaria (never mentioned in any prior record) after a flu vaccine with three recurrent episodes of angioedema "during the next several months". Pet. Ex. 35 at 2; *See* Pet. Ex. 9 at 2-10; Pet. Ex. 26; Pet. Ex. 27 at 28-38; Pet. Ex. 28 at 3-4.

No medical records were filed for the timeframe November 2016 through September 2017. Petitioner provided no explanation for the gap in her medical records or why, if she had suffered any breakthrough events of angioedema or urticarial lesions, she did not seek treatment or report these events to any medical provider until she saw Dr. Nunez five years later. Therefore, there is a lack of objective evidence to support petitioners' claims that she suffered breakthrough episodes of angioedema and urticarial lesions during this timeframe. *See Kirby*, 997 F.3d at 1380, 1381 (finding the six-month requirement met when the petitioner was discharged from PT to continue at-home exercises and produced the instruction sheets for the at-home exercises, despite the lack of formal medical treatment).

Petitioner's records after September 2017 also do not support any ongoing or breakthrough episodes of angioedema or urticarial lesions. On September 21, 2017, when petitioner returned to

Dr. De La Cruz, after not being seen for 21 months, Dr. De La Cruz documented that there was an "*episode* of angioneurotic edema with vaccine flu" with "no rash. . . no skin lesion" upon presentation that day. Pet. Ex. 28 at 5 (emphasis added). Petitioner returned to Dr. De La Cruz on October 10, 2017, for herpes zoster. She was again noted to have no lesions or skin lesions. *Id*. at 7-8. Petitioner presented to Dr. De La Cruz for unrelated complaints on March 8, 2018, August 23, 2018, December 4, 2018, April 4, 2019, April 23, 2019, June 11, 2019, September 10, 2019, October 8, 2019, November 7, 2019 and February 6, 2020; the visit notes from each of these appointments specifically document "no skin lesion". *Id*. at 9-32.

Petitioner submitted photographs showing facial/lip swelling. The photographs contained no corresponding time/date stamp making it unclear when the photographs were taken. Even when questioned by respondent, no clarification or proof of when the photographs were taken was provided. *See generally* Pet. Ex. 2. The photographs therefore lend no support to satisfy the six-month severity requirement.

The contemporaneous medical records support petitioner suffering two episodes of angioedema: one 10 hours after a flu vaccine and one a month later. Pet. Ex. 21 at 3, 42; Pet. Ex. 4 at 1, 9. There is no further support in the contemporaneous medical records or otherwise other than petitioner's word to corroborate any additional angioedema events or that petitioner ever suffered from urticarial lesions. The records do, however, document that no lesions or rashes were noted at any visit. Dr. Nunez's medical record for petitioner's first visit in November of 2020 documents that petitioner reported three episodes of angioedema "during the next several months" after vaccination. The term "several" generally means more than two but not many and does not reflect six or more months.[22] Pet. Ex. 35 at 1-2. Further, the word of petitioner alone is insufficient to satisfy her burden in proving that her symptoms lasted for more than six months. § 13(a)(1). It is notable that this visit occurred following a status conference in which the content of petitioner's medical records was discussed, and counsel was advised that the records were insufficient to prove that her symptoms lasted more than six months. The timing of the visit, petitioner's reported history, and Dr. Nunez's medical record and letter are unpersuasive in proving the severity requirement. ECF No. 35. Notably, the history petitioner provided to Dr. Nunez is also inconsistent with her affidavit in which she affirmed that "[d]uring the *month*" following the flu vaccine she experienced several other episodes of angioedema. Pet. Ex. 36 at 2 (emphasis added). Regardless of whether it was one month with several episodes of angioedema or three episodes of angioedema over several months as she reported to Dr. Nunez, neither preponderantly demonstrates that petitioner suffered any residual effects to satisfy the six-month severity requirement.

B. Petitioner's use of medication does not satisfy the six-month severity requirement.

Petitioner argued that the medications she was prescribed (cetirizine, hydroxyzine, and famotidine) and continued to take prevented reoccurrence of symptoms for "6 months or more post vaccination." Motion at 5. Further, that her experts' opinions along with her medical records support that she suffered from persistent angioedema that was controlled by the use of medication, which is sufficient to satisfy the Act's severity requirement. *See generally* Motion; Reply.

[22] Several, *Merriam-Webster Dictionary*, https://www.merriam-webster.com/dictionary/several.

As an initial matter, petitioner's arguments regarding the use of medication are mutually exclusive. On the one hand, she argued that taking the medication prevented breakthrough symptoms. On the other hand, she apparently reported to Dr. Nunez that she continued to experience breakthrough symptoms despite using the medication up to a year prior to their first visit in 2020. *See generally* Pet. Ex. 38. Both cannot be true.

Nevertheless, the Federal Circuit has emphasized that a continued course of treatment may meet the severity requirement, but whether or not it does depends on its medical necessity. The Circuit has explained that "[d]uring a long course of treatment, the patient generally has some lingering condition such that symptoms will likely recur if the treatment were stopped. Otherwise, the long course of treatment would not be necessary." *Wright*, 22 F.4th at 1007. Here, there is no evidence submitted to support that petitioner's angioedema would have recurred without the use of medication. Dr. Gershwin described the typical course of angioedema as "unpredictable", thus not rising to the level of "likely [to] recur if the treatment were stopped." Pet. Ex. 39 at 2; *Wright*, 22 F.4th at 1007. Further, Dr. Gershwin made clear that his opinion related to whether a flu vaccine can cause angioedema; as to the six months issue, he "cannot comment on the[] gaps within the medical record when [petitioner] was not seen by a physician." Pet. Ex. 39 at 2.

Simply because petitioner continued taking medications prescribed following two separate events of angioedema for more than six months is insufficient to meet the severity requirement. Motion at 2-3. Petitioner relies on *Faup*, arguing that taking medication for over six months to control the symptoms of her angioedema meets the severity requirement. However, petitioner failed to demonstrate that the medication was medically necessary to control ongoing symptoms or that it was necessary to prevent further progression of her angioedema or permanent damage. *See Faup*, 12-87V, 2015 WL443802, at *4 (finding the severity requirement satisfied when experts testified that continued medication was medically necessary because if the disease relapsed, future recurrences may fail to respond to previously effective treatments, there was a risk of "evolving to severe erosive disease" in the absence of treatment, and treatment with medication would prevent the development of permanent joint damage); *see also H.S.*, No. 14-1057V, 2015 WL 1588366 (holding that restriction on physical activity after a concussion was medically necessary to prevent further health consequences and was a residual effect); *Prepejchal*, No. 15-1302V, 2018 WL 5782865 at *16 (finding that the severity requirement was not met where petitioner's DVT had resolved within three months of vaccination, but petitioner continued to take medication to prevent further possible clotting not to treat an existing DVT).

The lack of any medical records filed for the timeframe between November 2016 and September 2017 suggests that there was no monitoring of her medications and no support for the medical necessity of petitioner continuing to take the antihistamine medications prescribed after two events of angioedema, one in October and one in November 2015. When petitioner presented to Dr. Nunez five years later, he discontinued the medications and petitioner reported "doing well" with no complaints, demonstrating that the medications were not masking angioedema symptoms, rashes, or urticaria. Pet. Ex. 35 at 6, 15; Pet. Ex. 38 at 2; *see Toebe*, No. 91-1623V, 1992 WL 101638, at *3 ("had [the petitioner] experienced additional seizures after she was taken off the phenobarbital, then there would be a basis for concluding that the residual effects continued for more than six months and were masked by the medication, but she has been seizure free since being taken off the medication.").

Here, neither Dr. Nunez or Dr. Gershwin indicated that petitioner's angioedema could or would progress without the medication, that relapses would reduce the effectiveness of antihistamine use, or that failing to medicate her would lead to permanent physical injury. More likely because angioedema or hives is not a progressive, chronic disease. Despite medical records to the contrary, Dr. Nunez accepted petitioner's "reported history of continuing breakthrough urticarial lesions while compliant" with medication in rendering his opinion that "it was medically prudent to continue [medication] or even consider stepping up therapy" until petitioner reported that her symptoms were controlled. Pet. Ex. 38 at 3. As detailed above, none of petitioner's medical records support her having had any ongoing or breakthrough symptoms. Therefore, I do not find Dr. Nunez's opinion regarding the continued use of medication to be persuasive in proving that petitioner's symptoms lasted more than six months. *Gerami*, 127 Fed. Cl. at 306 (affirming special master's finding that severity requirement was not met where medical records showed no complaints of symptoms in excess of six months, but a physician letter in response to an attorney request stated symptoms lingered for six months without referencing contemporaneous medical records); *see also Burns by Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (upholding the special master's rejection of expert testimony where the expert based his opinions on facts not supported by the record). While Dr. Nunez wrote that "[t]he presence or lack of angioedema is *not considered with regards to the duration of treatment* as we are only focused on the continued presence of the process (ie. Mast cell activation) not its presentation (Urticaria/Angioedema)", he gave no explanation as to how to assess the "continued presence of the process", much less that this process can persist in excess of six months. Pet. Ex. 38 at 3 (emphasis added).

Dr. Nunez further explained that step down in medication is appropriate after 6-12 weeks of being symptom free. Pet. Ex. 38 at 2. Given that the records show petitioner's last symptoms of angioedema occurred in November 2015 and according to Dr. Nunez's opinion, continued medication became unnecessary around February 2016—less than 4 months post-vaccine.

Dr. Gershwin submitted that medication is used in virtually all cases of angioedema to prevent "acute" episodes. Pet. Ex. 39 at 2. It is worth noting that Dr. Gershwin only opined on whether a flu vaccine can cause "acute angioedema"—not whether continuing medication was necessary because he "obviously cannot comment on these gaps within the medical record when [petitioner] was not seen by a physician." *Id*. As Dr. Gershwin aptly pointed out that the medical records show that there was a lack of follow up regarding the medication by any treating provider to assess whether continued use of medication was appropriate or necessary. *See also* Resp. Ex. A at 11 (Dr. Fadugba stating that the issue is that petitioner did not follow up with medical providers to determine whether continued medication was necessary until she met with Dr. Nunez in 2020). Thus, there is no evidence that the use of medication was medically necessary to prevent disease progression or permanent damage or to treat any allegedly ongoing symptoms in petitioner's case. The simple fact that she continued to take medication with no medical oversight does not meet the severity requirement.

Finally, petitioner's argument that taking the medication suppressed any symptoms of her angioedema is based entirely on speculation. Motion at 2; Reply at 2; *see Toebe*, No. 91-1623V, 1992 WL 101638 at *3 (severity requirement is not met by mere speculation that if a petitioner

was not taking a medication, they would experience further symptoms related to the alleged vaccine injury). After discontinuing the medications, petitioner had no symptoms of angioedema or urticaria, which weighs against petitioner's argument that she had ongoing symptoms that were suppressed by medication. Pet. Ex. 35 at 6, 15-17.

VI. Conclusion

Upon careful review of the record and assigning all evidence its appropriate weight, petitioner has failed to satisfy the severity requirement by preponderant evidence. Therefore, the petition must be **DISMISSED.**

The Clerk of Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master