In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 11, 2026

SUSAN HUBBARD,	*	PUBLISHED
Petitioner,	*	No. 23-917V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Influenza ("Flu") Vaccine; Transverse Myelitis ("TM").
Respondent.	*	

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.
Naseem Kourosh, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On June 16, 2023, Susan Hubbard ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018).[2] Petitioner alleges that as a result of receiving an influenza ("flu") vaccine on October 11, 2021,[3] she developed transverse myelitis ("TM"). Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating that this "case does not

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it 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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[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 (2018). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

[3] Petitioner also received a Covid-19 vaccination on October 11, 2021, which is a non-covered vaccine. Petitioner's Exhibit ("Pet. Ex.") 1 at 2-4; Pet. Ex. 13 at ¶ 1; 42 C.F.R. § 100.3(a).

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meet the criteria for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 1 (ECF No. 24).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards,[4] the undersigned finds that Petitioner has provided preponderant evidence that her flu vaccine caused her TM, satisfying Petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

I. ISSUES TO BE DECIDED

The parties agree that Petitioner, at 72 years of age, received a flu vaccination on October 11, 2021 in the United States and that this vaccine is listed on the Vaccine Injury Table. Joint Prehearing Submissions ("Joint Sub."), filed Jan. 21, 2025, at 1 (ECF No. 50).

The parties dispute "[w]hether [P]etitioner had pre-existing chronic inflammatory demyelinating polyneuropathy" ("CIDP").[5] Joint Sub. at 1. The parties also dispute whether Petitioner has "preponderantly proven that she suffered from [TM]." Id. at 2.

Lastly, causation is in dispute, specifically all three Althen prongs: (1) "[w]hether [P]etitioner has preponderantly proven a medical or scientific theory establishing that administration of [a] [flu] vaccine can cause [TM];" (2) "[w]hether [P]etitioner has preponderantly proven a logical sequence of cause and effect between her October 11, 2021 [flu] vaccination and her condition;" and (3) "[w]hether [P]etitioner has preponderantly proven that her condition occurred within a medically appropriate timeframe relative to her October 11, 2021 [flu] vaccination and consistent with her proposed causal theory." Joint Sub. at 2.

II. BACKGROUND

A. Procedural History

Petitioner filed her petition, a declaration, and medical records on June 16, 2023.[6] Petition; Pet. Exs. 1-9. On April 10, 2024, Respondent filed his Rule 4(c) report, arguing against

[4] While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision."); see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[5] Petitioner reported a history of CIDP, however, records pertaining to this diagnosis and treatment were not filed. For more information, see infra Section II.C.

[6] Medical records were filed throughout litigation.

compensation. Resp. Rept. at 1. From July 2024 to October 2024, Petitioner filed expert reports from Dr. Joseph Jeret and Respondent filed expert reports from Dr. Peter Kang. Pet. Exs. 14, 34; Resp. Exs. A, C.

On November 25, 2024, the parties filed a joint status report indicating that they "would prefer to move forward with briefing to resolve the issue of entitlement." Joint Status Rept., filed Nov. 25, 2024 (ECF No. 48). Thereafter, a briefing schedule was set. Ruling on the Record Order dated Nov. 25, 2024 (ECF No. 49).

Petitioner filed a motion for a ruling on the record on January 24, 2025. Pet. Motion for a Ruling on the Record ("Pet. Mot."), filed Jan. 24, 2025 (ECF No. 51). Respondent filed a response on March 20, 2025, and Petitioner filed a reply on April 24, 2025. Resp. Brief in Response to Pet. Mot. ("Resp. Response"), filed Mar. 20, 2025 (ECF No. 52); Pet. Reply to Resp. Response ("Pet. Reply"), filed Apr. 24, 2025 (ECF No. 53).

This matter is now ripe for adjudication.

B. Transverse Myelitis

TM is an "inflammatory disorder of the spinal cord[] resulting in motor, sensory, and autonomic dysfunction."[7] Pet. Ex. 32 at 1; see also Resp. Ex. A at 11 (explaining TM is an "acquired disorder affecting the spinal cord that presents with weakness (typically paraparesis or quadriparesis), sensory changes (numbness, tingling, pain)[,] and bowel/bladder dysfunction").

In 2002, the TM Consortium Working Group proposed diagnostic criteria for idiopathic TM:

Table 1 *Criteria for idiopathic acute transverse myelitis*

Inclusion criteria	Exclusion criteria
Development of sensory, motor, or autonomic dysfunction attributable to the spinal cord	History of previous radiation to the spine within the last 10 y
Bilateral signs and/or symptoms (though not necessarily symmetric)	Clear arterial distribution clinical deficit consistent with thrombosis of the anterior spinal artery
Clearly defined sensory level	Abnormal flow voids on the surface of the spinal cord c/w AVM
Exclusion of extra-axial compressive etiology by neuroimaging (MRI or myelography; CT of spine not adequate)	Serologic or clinical evidence of connective tissue disease (sarcoidosis, Behçet's disease, Sjögren's syndrome, SLE, mixed connective tissue disorder, etc.)*
Inflammation within the spinal cord demonstrated by CSF pleocytosis *or* elevated IgG index *or* gadolinium enhancement. If none of the inflammatory criteria is met at symptom onset, repeat MRI and lumbar puncture evaluation between 2 and 7 d following symptom onset meet criteria	CNS manifestations of syphilis, Lyme disease, HIV, HTLV-1, *Mycoplasma*, other viral infection (e.g. HSV-1, HSV-2, VZV, EBV, CMV, HHV-6, enteroviruses)*
Progression to nadir between 4 h and 21 d following the onset of symptoms (if patient awakens with symptoms, symptoms must become more pronounced from point of awakening)	Brain MRI abnormalities suggestive of MS*
	History of clinically apparent optic neuritis*

*Do not exclude disease-associated acute transverse myelitis.

AVM = arteriovenous malformation; SLE = systemic lupus erythematosus; HTLV-1 = human T-cell lymphotropic virus-1; HSV = herpes simplex virus; VZV = varicella zoster virus; EBV = Epstein–Barr virus; CMV = cytomegalovirus; HHV = human herpes virus.

[7] "Autonomic symptoms consist variably of increased urinary urgency, bowel or bladder incontinence, difficulty or inability to void, incomplete evacuation, or bowel constipation." Pet. Ex. 32 at 1 (Transverse Myelitis Consortium Working Group, Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis, 59 Neurology 499 (2002) (also filed as Resp. Ex. A-3)).

Pet. Ex. 32 at 2 tbl.1. "A diagnosis of idiopathic [acute TM] should require that all of the inclusion criteria and none of the exclusion criteria are fulfilled." Id. at 2. Additionally, diagnosis "requires evidence of inflammation within the spinal cord" via magnetic resonance imaging ("MRI") or lumbar puncture. Id.

C. Factual History

1. Relevant Medical History[8]

Petitioner's pre-vaccination medical history was significant for hypertension, hyperlipidemia, morbid obesity, uncontrolled type II diabetes with hyperglycemia, chronic kidney disease, renal cysts, urinary urgency and incontinence, and incompletely distended urinary bladder. See, e.g., Pet. Ex. 2 at 129-33, 170-71, 174, 219, 222, 229-30, 252-53, 256, 288, 291, 331, 334-35, 362, 365, 375-79, 387-88, 420-23, 494, 506, 509, 524-26, 535-36. Petitioner also reported a history of CIDP that was treated with intravenous immunoglobulin ("IVIG") "years"[9] prior and had resolved. Id. at 133, 253, 256, 553; Pet. Ex. 3 at 255 (Petitioner reporting in October 2021 her CIDP "ha[d] been in remission for quite some time"). From 2019 through 2021, she periodically reported numbness and tingling in her arms and legs, though an electromyography ("EMG")/ nerve conduction study ("NCS") of the upper extremities done in September 2020 was reportedly normal. Pet. Ex. 2 at 170, 276, 288-91, 508. In April 2021, Petitioner reported "[s]he still ha[d] a little bit of numbness in both legs" following CIDP but she was "[m]uch improved." Id. at 170, 174. In July 2021, Petitioner reported leg stiffness that made it difficult to walk and made her fear falling; she was advised to do home exercises and, if that did not help, to return to physical therapy ("PT"). Id. at 133.

On October 11, 2021, at the age of 72, Petitioner received a flu vaccination[10] and a Covid-19 vaccination. Pet. Ex. 1 at 2-4.

On October 29, 2021, 18 days after vaccination, at 12:25 a.m., Petitioner arrived at the emergency department ("ED") via ambulance, reporting weakness and numbness in both arms, worse on the right, that began the previous day at 3:00 p.m. Pet. Ex. 3 at 116. Petitioner also reported "some difficulty signing her name." Id. at 128. She denied leg weakness. Id. at 116. Petitioner reported a history of diabetes and neuropathy, but that she had previously been told by her primary care provider ("PCP") that the numbness in her arms was not a neurological issue. Id. A physical and neurological examination noted weakness in bilateral upper extremities, no

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[8] This summary of medical records is largely taken from the parties' briefs, as the undersigned finds the parties provided an accurate representation of the records. See Pet. Mot. at 2-4; Resp. Response at 1-9. The undersigned has edited the summary.

[9] The exact timeframe of Petitioner's CIDP diagnosis is unclear as records document diagnosis in 2006 and 2013. See Pet. Ex. 2 at 553 (March 5, 2013); Pet. Ex. 3 at 249, 255 (2006); Pet. Ex. 6 at 5 (2006).

[10] Petitioner received the 2021-2022 FLUAD Quadrivalent vaccine. Pet. Ex. 1 at 2. The package insert was not filed but can be found at https://share.google/XSREkEP8QNeuv3Faa.

sensory deficits, and equal and symmetric strength in bilateral lower extremities. Id. at 119. Preliminary bloodwork and urinalysis showed several abnormalities, including elevated blood glucose, hemoglobin A1c, blood urea nitrogen ("BUN"), and creatinine, as well as bacteria in the urine. Id. at 120-23. An electrocardiogram ("EKG") was normal, a head computed tomography ("CT") showed mild chronic microvascular ischemic disease, and a CT angiogram of the head and neck showed thyroid nodules and multilevel degenerative disc and facet disease throughout the cervical spine. Id. at 123-27. ED staff consulted with neurologist Dr. Ajaz Qhavi regarding Petitioner's presentation, and Dr. Qhavi noted that "CIDP does not cause these symptoms" and recommended a cervical MRI. Id. at 128. A cervical spine MRI without contrast showed (1) intramedullary edema from C2/3 to C5, which was noted to "represent intramedullary edema or [TM]," with a contrast-enhanced MRI recommended for further evaluation and (2) multilevel degenerative disc disease causing mild to moderate multilevel central spinal canal narrowing from C4 to C7. Id. at 124-25. Dr. Qhavi recommended a lumbar puncture, which Petitioner underwent later that day. Id. at 128, 133-34. While the lumber puncture results were pending, Petitioner was admitted for "bilateral upper extremity tingling/mild weakness/numbness" of "[u]nclear etiology," though "possible [TM]/acute exacerbation of [CIDP]" was noted. Id. at 138-39, 144. If no infection was found on Petitioner's pending tests, Dr. Qhavi recommended starting steroids and obtaining a cervical spine MRI with contrast. Id. at 138-39.

Later that day, October 29, 2021, following admission, a cervical spine MRI with contrast was performed. Pet. Ex. 3 at 405. The MRI "[was] significantly degraded by motion" but showed "enhancement within the central aspect of the cord at the C4-5 disc space level corresponding to an area of T2 signal abnormality," and "[i]n light of the provided history," this was noted to be potentially "compatible with an active demyelinating plaque." Id. However, "there [was] no expansion of the cord[,] which is commonly seen in the setting of neoplasm or acute [TM]." Id. Brain MRI was recommended. Id. The lumbar puncture and cerebrospinal fluid ("CSF") testing and culture showed elevated glucose (117; reference range 40-70 mg/dL) and elevated protein (109; reference range 15-45 mg/dL), but were otherwise unremarkable, and lab tests for certain infectious organisms and markers of autoimmunity were negative. Id. at 286-307. A urine culture showed a urinary tract infection ("UTI"). Id. at 281-84.

At a neurology consult with Dr. Qhavi and nurse practitioner ("NP") Jamie Schoknect the same day (October 29), Petitioner reported a history of diabetes, diabetic neuropathy and polyneuropathy, "chronic paresthesias from the knee[s] down," CIDP that was "in remission for quite some time," and several other conditions. Pet. Ex. 3 at 249, 255. She reported that she "received [a] Covid booster and flu vaccine at the same time about [two] weeks ago," and she began noticing weakness in her arms the previous afternoon (October 28), followed in the evening by worsening arm weakness and mild weakness in her legs. Id. at 249.

Neurologic examination showed bilateral pronator drift; increased muscle tone in the upper extremities; decreased strength in bilateral arms (4/5), hand grasps (4/5), hip flexion (3/5), and ankle dorsiflexion (2/5); impaired temperature sensation from T2-T3 down to the feet; and deep tendon reflexes of 1+ in the upper extremities, 2+ in the knees, and absent in the ankles. Pet. Ex. 3 at 254. Dr. Qhavi also documented "[v]ibration perception [] impaired below knees," in contrast to the "vibration perception intact in feet" noted on examination, as well as "increased tone in both lower extremities," which was not noted on examination. Id. at 254-55. Dr. Qhavi

reviewed the cervical spine MRIs, noting they showed "faint enhancement" of a "long hyperintensity in [the] cervical spinal cord," as well as the lumbar puncture/CSF results, noting no significant abnormalities were seen. Id. at 255.

Dr. Qhavi opined that "[b]ased on history and neurologic examination, [Petitioner] [was] suffering with acute [TM]." Pet. Ex. 3 at 255. He further wrote, "In my opinion[,] [Petitioner] [is] suffering with post vaccination acute demyelinating syndrome." Id. NP Schoknecht's assessment likewise documented Petitioner's condition "[was] likely attributable to a post vaccination demyelination/[TM]." Id. Further testing was ordered to "rule out other causes of [TM]." Id. Petitioner was started on five days of high-dose IV methylprednisolone (Solu-Medrol). Id.

The following day, October 30, Petitioner underwent a brain MRI, with and without contrast, that showed "[m]oderately extensive nonspecific T2-FLAIR changes in the cerebral white matter and pons," which were noted to be "fairly typical of chronic microvascular ischemic changes." Pet. Ex. 3 at 414-15. There was "[n]o convincing evidence of active phase demyelination/pathologic enhancement." Id. at 415. Petitioner also underwent a thoracic spine MRI, with and without contrast, that same day, which showed mild to moderate multilevel degenerative thoracic spondylosis and neuroforaminal stenosis. Id. at 409-10. No cord signal or contrast enhancement was seen. Id.

During her hospital stay, Petitioner continued to see neurology, as well as internal medicine, endocrinology, rehabilitation medicine, PT, and occupational therapy ("OT"), and she both reported and was noted to be improving over time. See, e.g., Pet. Ex. 3 at 155, 157, 160, 163, 167, 171, 181, 187, 196, 206, 210, 231, 243.

On November 4, 2021, Petitioner was discharged from the hospital to inpatient rehabilitation. Pet. Ex. 3 at 145-46. Her discharge diagnoses included post-vaccination TM and chronic active health issues, including diabetes, diabetic neuropathy, chronic kidney disease, hypertension, hyperlipidemia, morbid obesity, and CIDP. Id. Discharge summary noted Petitioner "was admitted due to bilateral upper extremity weakness/generalized weakness likely caused by post vaccination [TM]." Id. at 146. Her symptoms improved on five days of IV steroids. Id. During her hospitalization, she developed severe hyperglycemia, was placed on an IV insulin drip, and was now stable. Id. Physical examination on discharge documented "[m]ildly decreased strength/weakness/numbness [in] bilateral upper extremities," but sensation was intact and all other findings were normal. Id.

From November 4 to December 9, 2021, Petitioner was in inpatient rehabilitation, where she continued with PT/OT, experienced urinary retention and incontinence, for which she had a Foley catheter placed and then removed, and ambulated independently with a walker by the time of discharge. See Pet. Ex. 3 at 447, 455, 459-60. At discharge on December 9, she refused a discharge home visit from PT and refused to begin home PT the next day, even though she was unable to ambulate on stairs on her own or without a device. Id. at 459-60. She was also noted to not be taking her blood pressure medication and was "not very convinced about [the] importance of the bowel program" despite her incontinence issues. Id. at 460.

On December 11, 2021, two days later, Petitioner returned to the ED via ambulance. Pet. Ex. 3 at 9. Petitioner reported bilateral lower extremity weakness that made her unable to get out of bed and off the floor. Id. She also reported urinary and bowel incontinence. Id. She was admitted, treated with IV antibiotics for an acute UTI and fluids for mild dehydration, and then discharged on December 14, 2021 to a skilled nursing facility. Id. at 26-27.

From December 14 to 30, 2021, Petitioner was in a skilled nursing facility for issues including neuromuscular deconditioning and gait dysfunction, and she completed a course of antibiotics, continued with PT/OT, and received insulin for elevated blood sugar. Pet. Ex. 4 at 25-29. She was discharged home on December 30, but "resist[ed]" medical advice to refrain from driving and refused to check her blood sugar or use insulin at home. Id. at 26, 73.

On January 28, 2022, Petitioner followed up with her PCP, Dr. Raymond Ballecer, for several issues, including "[a]cute [TM] secondary to post vaccine." Pet. Ex. 2 at 88. Petitioner reported some bowel and bladder incontinence. Id. She ambulated with a walker and cane and was attending PT. Id. Her acute TM was "[i]mproving." Id. at 91.

Petitioner was discharged from in-home PT on March 1, 2022. Pet. Ex. 5 at 5-9. She reported that she could "do everything but it just takes her a really long time" and that she "continue[d] to 'feel more normal every[]day.'" Id. at 8. She was assessed as having met the goal of independence with all basic gross motor skills. Id. at 9.

On May 3, 2022, Petitioner saw NP Jeremiah Parve at her PCP's office for various issues. Pet. Ex. 2 at 46-47. Petitioner complained of weakness with an onset of October 13, 2021 "after receiving COVID-19 vaccine and developing vaccine [TM]." Id. at 47. Petitioner reported "[g]radual[] improv[ment] since." Id. Petitioner also reported associated symptoms of anxiety, paresthesia, leg pain, tremors, intolerance to cold, and urinary incontinence. Id. Petitioner used a walker to ambulate. Id. On examination, she had sensory deficits in her bilateral upper and lower extremities and edema and weakness in her bilateral lower extremities. Id. at 51. NP Parve referred Petitioner to neurology for her TM. Id. at 53-54.

On June 20, 2022, Petitioner saw neurologist Dr. Assad Ullah for her TM. Pet. Ex. 6 at 4. Under history, Dr. Ullah noted that Petitioner "reported getting COVID and flu vaccination[s] on October 11, 2021" and "[a] few days later had sudden onset of weakness in the hands, arms, [and] legs, numbness and tingling in the arms and legs, [and was] unable to walk," which led to "[c]oncern [] for post vaccination [TM]" that was treated with IV steroids and led to an improvement of symptoms. Id. Petitioner reported "gradual improvement of symptoms although she [was] not back to her normal baseline." Id. She further reported some hand and finger weakness, using a walker to ambulate, a "couple of falls since discharge from rehab[ilitation]," and ongoing urinary incontinence. Id. On examination, Petitioner had an abnormal Romberg test, reduced pinprick in the distal left leg, reduced left ankle vibration sensation, increased (3+) reflexes in the bilateral knees, decreased (+1) reflexes in the bilateral ankles, and slightly decreased (5-/5) strength in the bilateral hands. Id. at 9-11. Dr. Ullah also reviewed some of Petitioner's imaging and tests. Id. at 11-13. His assessment was TM and he noted that the "[c]oncern ha[d] been for post vaccination myelitis for which she received IV Solu-Medrol." Id. at 13. He stated that "[s]he [did] not want to get the COVID booster or flu

vaccination in the future which under the circumstances [was] [a] reasonable decision." Id. He advised her to follow up with her PCP regarding urinary incontinence. Id.

On September 19, 2022, Petitioner saw urologist Dr. Richard Otto, reporting that since her Foley catheter was removed, she could not sense the need to urinate. Pet. Ex. 7 at 20. She reported that she had "[TM] post flu and covid booster vaccine[s] in the fall of 2021." Id. at 21. Assessment was neurogenic bladder. Id. at 25. A renal ultrasound was ordered and timed voiding was advised. Id. at 25-26. Renal ultrasound on October 5, 2022 showed an interval decrease in the size of a cyst in the right kidney and was otherwise unremarkable. Id. at 9, 13.

On October 7, 2022, Petitioner returned to Dr. Ullah. Pet. Ex. 8 at 8. Since her last appointment, she was "stable," reporting stable strength and sensation, although she had "some mild improvement of the feeling in the hands" and a cold feeling in her legs. Id. She also reported her bladder issues were "slightly better," and she was ambulating with a walker. Id. On examination, reflexes were increased (3+) in the bilateral biceps, triceps, and knees and strength was slightly reduced (4/5) in the bilateral hips and very slightly reduced (5-/5) in the bilateral ankles. Id. at 10-11. Petitioner also had positive bilateral Hoffman and cross-adductors signs and decreased pinprick in her legs. Id. at 11. Under assessment, Dr. Ullah noted that "[s]ubjectively [Petitioner] fe[lt] some improvement" and that "things [were] slowly getting better." Id. at 13. Petitioner was advised to continue at-home exercises and using her walker to minimize the risk of falls. Id.

Petitioner returned to Dr. Ullah on May 4, 2023, reporting improvement since her last visit. Pet. Ex. 12 at 47. She walked with her walker, had no falls, had improvement in her endurance and strength, stating that she did not feel as tired, but that she had a cold feeling in her hands, some numbness in her hands and feet, and continuing incontinence. Id. On examination, reflexes were increased (3+) in the bilateral biceps, triceps, and knees and decreased (1+) in the bilateral ankles; strength was slightly decreased (4/5) in the bilateral hips; and pinprick was decreased in the legs. Id. at 49-50. Dr. Ullah's assessment was unchanged, noting her stable physical examination. Id. at 52. He also noted that he had been "[u]nable to find any records" regarding Petitioner's reported "[h]istory of CIDP," and that her 2020 EMG on her upper extremities "did not show anything suggestive of CIDP." Id. He ordered a lower extremity EMG/NCS. Id.

An EMG/NCS of the bilateral legs conducted by Dr. Ullah on September 24, 2023 showed sensory motor axonal polyneuropathy. Pet. Ex. 12 at 34. "There were no findings to support predominantly demyelinating neuropathy." Id.

On November 9, 2023, Petitioner returned to Dr. Ullah, reporting persistent difficulties with balance and weakness, intermittent left upper extremity tingling, stable ambulation with a walker, and difficulty picking up objects with her fingers. Pet. Ex. 12 at 7. Regarding Petitioner's reported history of CIDP, Dr. Ullah's noted that the September 2023 EMG/NCS did not show any demyelination. Id. Physical examination showed slightly decreased (4/5) bilateral hip strength and decreased pinprick in legs, but was otherwise normal. Id. at 9-10.

No additional relevant records were filed.

2. Petitioner's Declarations

Petitioner's first declaration, which was undated, was filed with her petition on June 16, 2023. Pet. Ex. 9. Petitioner noted that she received a flu vaccine in her left deltoid on October 11, 2021, and on October 29, 2021, she "developed weakness and numbness in [her] bilateral arms." Id. at ¶¶ 2-3. "As a result of [her] vaccination, [she] suffered from [TM]." Id. at ¶ 4. She further indicated "[she] suffered no other injuries or accidents that would explain [her] [TM] diagnosis." Id. at ¶ 5.

In her second declaration, dated April 16, 2024, Petitioner acknowledged that she also received a Covid-19 vaccination on October 11, 2021. Pet. Ex. 13 at ¶ 1. She had not filed a claim with the Countermeasures Injury Compensation Program for alleged injuries from the Covid-19 vaccination. Id. at ¶ 2.

D. Expert Reports[11]

1. Petitioner's Expert, Dr. Joseph Jeret[12]

a. Background and Qualifications

Dr. Jeret is a board-certified neurologist. Pet. Ex. 14 at 1; Pet. Ex. 15 at 1. He received his M.D. from SUNY Downstate Medical Center. Pet. Ex. 14 at 1. He did a general internal medicine internship at Maimonides Medical Center followed by a residency in neurology and a fellowship in clinical neurophysiology at SUNY Downstate. Id. at 1; Pet. Ex. 15 at 1. Dr. Jeret is a practicing neurologist. Pet. Ex. 14 at 1-2. He works as a physician in the department of neurology at Optum, holds multiple hospital affiliations in New York, and maintains an active neurology practice in Long Island, NY. Id. at 1. He routinely cares for and diagnoses patients with various neurological illness including TM, multiple sclerosis, neuromyelitis optica, and CIDP. Id. at 1-2. Dr. Jeret has authored or co-authored publications in many areas of neurology reflecting his general neurology practice. Id. at 1; Pet. Ex. 15 at 2-7.

b. Opinion

i. Diagnosis

Dr. Jeret opined Petitioner's diagnosis is TM. Pet. Ex. 14 at 8, 11; Pet. Ex. 34 at 1, 3. For support, he cited the TM Consortium Working Group diagnostic criteria, noting she met all inclusionary criteria and no exclusionary criteria. Pet. Ex. 14 at 8-9, 11 (citing Pet. Ex. 32 at 2 tbl.1). Specifically, Petitioner had bilateral motor and sensory signs, a defined spinal sensory

[11] Although the undersigned has reviewed all the expert reports and medical literature, for the sake of brevity this Ruling does not include all details of the experts' opinions. Instead, the undersigned focuses on the experts' material opinions, as they relate to the relevant issues.

[12] Dr. Jeret provided two expert reports. Pet. Exs. 14, 34.

level, and urinary retention and bowel dysfunction due to autonomic involvement. Id. at 9. He also noted Petitioner's MRI showed an enhancing cervical cord lesion and she reached her nadir within 21 days of onset. Id. at 5, 9.

Additionally, Dr. Jeret opined Petitioner's records do not show evidence of "infection, inflammation, radiation, spinal cord infarction, connective tissue disorders, [] [multiple sclerosis]," or other diseases that could cause Petitioner's symptoms. Pet. Ex. 34 at 1. Her EMG excluded CIDP, and any pre-existing leg symptoms Petitioner may have had were "poorly[ ]described in the medical records." Id. at 2; see also Pet. Ex. 14 at 5, 8. Petitioner did not meet criteria for multiple sclerosis due to her lack of multiple lesions and multiple attacks. Pet. Ex. 14 at 5, 8. Nor did Petitioner have evidence of TM prior to vaccination; the records do not document any prior myelitis and the October 29, 2021 MRI showed enhancement, indicating an acute lesion. Pet. Ex. 34 at 2.

Further, Dr. Jeret explained that EMGs typically do not show abnormalities with central nervous system diseases like TM. Pet. Ex. 14 at 2. He was unable to review Petitioner's September 2020 upper extremity EMG/NCS because the report was not provided. Id. at 3. However, Petitioner's September 2023 lower extremity EMG/NCS report was available for his review. Id. at 7-8. Dr. Jeret interpreted the September 2023 EMG/NCS to show "sensorimotor mixed axonal and demyelinating polyneuropathy . . . most commonly seen with diabetes," which in Petitioner's case, was present and "poorly controlled." Id. at 8. Thus, he opined "[h]er EMG was most consistent with diabetic polyneuropathy." Id. Although Dr. Jeret did not agree with all of Dr. Ullah's findings related to this EMG, he "definitely agree[d]" the EMG was not consistent with CIDP. Id.

ii. Althen Prong One

Dr. Jeret proposed molecular mimicry[13] as his medical theory causally connecting the flu vaccine and TM. Pet. Ex. 14 at 9-12. Molecular mimicry, as explained by Karussis and Petrou,[14] is "the molecular similarity between the proteins of the viruses used for the vaccination and self antigens (for instance, CNS myelin components)." Pet. Ex. 25 at 7. The authors wrote that TM "may be idiopathic [], post-infectious[,] or post-vaccination." Id. at 6.

[13] Dr. Jeret also mentioned "epitope spreading, up-regulation of cytokines, and polyclonal activation of B and T cells" as mechanisms by which vaccines can cause TM. Pet. Ex. 14 at 9. However, because neither he nor Petitioner discussed these theories any further, the undersigned will not address them. See Pet. Mot. at 14 (noting Petitioner's theory as molecular mimicry and making no mention of any other theory).

[14] Dimitrios Karussis & Panayiota Petrou, The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes, 13 Autoimmun. Revs. 215 (2014). Dr. Jeret cited Karussis and Petrou, stating they "found a causal link 'very logical.'" Pet. Ex. 14 at 9 (quoting Pet. Ex. 25 at 6). The authors wrote, "for some vaccines such a causal link seems very logical," which was followed by a discussion of these "causal relationships," including GBS post-flu vaccine and TM post-oral polio vaccine, among others. Pet. Ex. 25 at 6. TM post-flu vaccine, however, was not mentioned. Id.

Citing a National Institute of Neurological Disorders and Stroke ("NINDS") TM fact sheet,[15] Dr. Jeret explained "post-vaccine autoimmune phenomena are due to the body's immune system mistakenly attacking its own tissue." Pet. Ex. 14 at 9; see Resp. Ex. D-4 at 2. The NINDS fact sheet also stated TM can occur, albeit rarely, after vaccination. Resp. Ex. D-4 at 2.

Agmon-Levin et al.[16] studied TM in the context of vaccines. Pet. Ex. 16. Regarding a causal mechanism, they noted "[t]he pathogenesis of TM is probably of an autoimmune nature." Id. at 1. "The etiology of most autoimmune processes is of a multi-factorial nature, combining genetic, immunological, hormonal[,] and environmental factors that form the 'mosaic of autoimmunity.'" Id. at 2. Infectious antigens, including the flu infection, were associated with up to 40% of TM cases. Id. Vaccines were also reported to precede TM. Id. at 1-2.

To investigate vaccine causation of TM, Agmon-Levin et al. conducted a literature search for cases of post-vaccination TM from 1970 and 2009 and found 43 cases, though six were excluded for insufficient data. Pet. Ex. 16 at 2. Of the 37 remaining cases, two followed a flu vaccination. Id. at 2, 3 tbl.1 (citing Pet. Ex. 27;[17] Pet. Ex. 28).[18] The authors described mechanisms by which vaccines may induce TM, including molecular mimicry, explaining it was the most common mechanism to explain how "infectious antigens and self antigens" could induce TM. Id. at 4.

Similarly, Karussis and Petrou conducted a PubMed search[19] for literature from 1979 to 2013 discussing vaccinations and central nervous system inflammatory diseases. Pet. Ex. 25 at 1-2. In the 71 cases found, the flu vaccine was the most commonly reported vaccine (21 cases).

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[15] Petitioner did not file this fact sheet. For a later version of this fact sheet, see Resp. Ex. D-4 (Transverse Myelitis, Nat'l Inst. Neurological Disorders & Stroke, https://www.ninds.nih.gov/health-information/disorders/transverse-myelitis (last reviewed Jan. 31, 2025)).

[16] N. Agmon-Levin et al., Transverse Myelitis and Vaccines: A Multi-Analysis, 18 Lupus 1198 (2009).

[17] A.J. Larner & S.F. Farmer, Myelopathy Following Influenza Vaccination in Inflammatory CNS Disorder Treated with Chronic Immunosuppression, 7 Eur. J. Neurol. 731 (2000).

[18] Naoko Nakamura et al., Neurologic Complications Associated with Influenza Vaccination: Two Adult Cases, 42 Intern. Med. 191 (2003).

[19] "PubMed is a free resource supporting the search and retrieval of biomedical and life sciences literature . . . . The PubMed database contains more than 39 million citations and abstracts of biomedical literature." About PubMed, Nat'l Libr. Med., Nat'l Ctr. for Biotechnology Info., https://pubmed.ncbi.nlm.nih.gov/about/ (last visited Feb. 4, 2026).

Id. at 2. Myelitis was reported in 24 of the 71 cases, nine[20] of which were following flu vaccination with onset period between four to 16 days. Id. at 2, 4 tbl.2.

Karussis and Petrou noted that "[m]olecular mimicry . . . represents one of the main immunopathogenetic mechanisms in post-vaccination [central nervous system] demyelination." Pet. Ex. 25 at 7. Though they acknowledged "[t]here is no absolute way to definitely link the onset or exacerbation of demyelination with the vaccine," Karussis and Petrou opined "the close temporal association with the time of vaccination strongly argues in favor of such pathogenetic correlation." Id.

Dr. Jeret also cited to Schattner,[21] who examined articles from 1966 to June 2004 and found TM "among the autoimmune manifestations reported after [flu] vaccination." Pet. Ex. 14 at 9 (citing Pet. Ex. 30 at 4 tbl.4).[22] Schattner noted molecular mimicry as a "[p]otential mechanism[] of virus-induced autoimmunity" under "[d]eleterious effects of antiviral antibodies." Pet. Ex. 30 at 6 tbl.7.

Shah et al.[23] investigated a correlation between TM and vaccinations using data from Vaccine Adverse Event Reporting System ("VAERS")[24] from 1985 to 2017. Pet. Ex. 31 at 2.

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[20] This may be based on incorrect data. Karussis and Petrou included both Nakamura et al. patients under the "myelitis" category; however, Nakamura et al. described two patients, one with acute disseminated encephalomyelitis ("ADEM") and a second with symptoms suggestive of myelitis and a GBS-like form of polyneuropathy (or acute myeloneuropathy). See Pet. Ex. 25 at 4 tbl.2; Pet. Ex. 28 at 1, 3. Thus, the patient with ADEM may have been mischaracterized.

[21] Ami Schattner, Consequence or Coincidence? The Occurrence, Pathogenesis and Significance of Autoimmune Manifestations After Viral Vaccines, 23 Vaccine 3876 (2005).

[22] Dr. Kang indicated the Schattner references concern GBS or are not specific to the flu vaccine or TM. Resp. Ex. A at 17. As these references were not filed, the undersigned cannot determine the accuracy of Dr. Kang's statement or Schattner. Moreover, Schattner examined studies published before the seasonal flu vaccine was universally recommended; thus, this study may not be as relevant as others cited. See Key Facts About Seasonal Flu Vaccine, Ctrs. for Disease Control & Prevention, Sept. 3, 2025, https://www.cdc.gov/flu/vaccines/keyfacts.html. However, the reference to molecular mimicry remains relevant.

[23] Shreya Shah et al., Development of Transverse Myelitis After Vaccination, A CDC/FDA Vaccine Adverse Event Reporting System (VAERS) Study, 1985-2007, 90 Neurology P5.099 (2018).

[24] The Vaccine Adverse Event Reporting System, or VAERS, is "a national early warning system to detect possible safety problems in U.S.-licensed vaccines. . . . VAERS is a passive reporting system . . . [and] is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." About VAERS, U.S. Dep't Health & Hum. Servs., https://vaers.hhs.gov/about.html (last visited Feb. 4, 2026).

Shah et al. concluded that "[a]lthough the reporting rate of post vaccination TM is in the range expected in the general population, the unbalanced distribution of these cases in the first [six] weeks after vaccination suggests that the association between vaccination and some cases may not be coincidental." Id. The full article was not provided, and thus, the undersigned cannot examine the data in it.

Dr. Jeret next cited Frohman and Wingerchuk.[25] Pet. Ex. 23. Frohman and Wingerchuk acknowledged the cause of TM is not known is many circumstances, but they identified vaccination is a common precipitator. Pet. Ex. 23 at 1, 8. Further, they observed that "mechanisms such as molecular mimicry and the development of autoantibodies may play roles in the pathogenesis of the syndrome." Id. at 1-2.

In his supplemental expert report, Dr. Jeret addressed literature cited by Respondent's expert Dr. Kang and concluded "there is no relevant literature that has demonstrated lack of association." Pet. Ex. 34 at 2-3. For example, the 2012 Institute of Medicine ("IOM") report,[26] according to Dr. Jeret, is "outdated" and the IOM "found no evidence to refute an association." Id. at 2. Thus, Dr. Jeret opined the report "proffers no opinion on causation." Id. He also criticized other literature from Dr. Kang as not being relevant to Petitioner. Id.

Lastly, Dr. Jeret cited case reports of TM following flu vaccinations in support of his opinion that the flu vaccine can cause TM.[27] Pet. Ex. 14 at 9.

Akkad et al.[28] discussed a patient who developed longitudinally extensive TM four days after a flu H1N1 vaccination. Pet. Ex. 17 at 1. The authors "effectively eliminated the most probable causes" before attributing their patient's TM as post-vaccination following H1N1 vaccination. Id. at 2. Ambrose et al.[29] commented on the case report from Akkad et al. Pet. Ex. 18 (citing Pet. Ex. 17). Ambrose et al. explained that the patient in Akkad et al. was treated for *Mycoplasma pneumoniae*, a well-established cause of TM, 20 days prior to onset and received a seasonal flu vaccine 27 days prior to onset, and these should also have been considered as

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[25] Elliot M. Frohman & Dean M. Wingerchuck, Transverse Myelitis, 363 New Eng. J. Med. 564 (2010).

[26] Inst. of Med., Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2012). Portions of this text were filed as Resp. Ex. A-7 and Resp. Ex. D-2.

[27] Petitioner filed numerous case reports of post-vaccination TM. The undersigned does not discuss all these articles as they are incomplete, in another language, the facts are different than those presented here, or the reports are not relevant to the vaccine and/or injury in this matter. See Pet. Exs. 19, 22, 27-29, 33, 35-37.

[28] Wafa Akkad et al., Longitudinally Extensive Transverse Myelitis Following Vaccination with Nasal Attenuated Novel Influenza A(H1N1) Vaccine, 67 Arch. Neurol. 1018 (2010).

[29] Christopher S. Ambrose et al., A Case Report of Transverse Myelitis Following Influenza Vaccination, 68 Arch. Neurol. 1085 (2011).

potential etiologies. Id. at 1. In a reply, Akkad et al. noted they investigated the claims of *Mycoplasma pneumoniae* and found no evidence to support such a diagnosis. Id. at 1-2.

Austin et al.[30] described a case of TM two months post-flu (H1N1) vaccination. Pet. Ex. 20 at 1. Although a "direct etiology" was not found, symptoms began two months post-vaccination which "suggest[ed] an immune mediated reaction to the immunization, or [autoimmune syndrome induced by adjuvants]." Id. at 2. The authors suggested there was an increase in the frequency of case reports of TM and growing body of "biological evidence of a postvaccination autoimmune pathogenesis." Id. at 1, 3.

Bakshi and Mazziotta[31] reported a case of acute TM four weeks following a flu vaccination. Pet. Ex. 21 at 1. Gui et al[32] described a patient who developed TM six days after H1N1 vaccination. Pet. Ex. 24 at 1. Lastly, Korn-Lubetzki et al.[33] described a case of TM with onset one month after H1N1 vaccination. Pet. Ex. 26 at 1. They noted a complete etiological workup was negative. Id. at 2. The authors indicated that "[t]he fact that the symptoms and signs had occurred a month after the H1N1 vaccination suggest[ed] the pathogenesis of post-vaccinal myelitis due to an immunological reaction to the vaccine." Id.

iii. Althen Prongs Two and Three

Dr. Jeret opined "it is very likely/certain that [Petitioner's] flu vaccine caused TM." Pet. Ex. 14 at 12.

First, as described above in his diagnosis section, he opined Petitioner met the criteria for a diagnosis of TM. Pet. Ex. 14 at 8-9, 11; Pet. Ex. 34 at 1, 3. Next, he reiterated that "[f]lu vaccines are known to cause TM" and "[t]he temporal relationship and exclusion of other causative factors satisfies this prong." Pet. Ex. 14 at 12.

Further, he cited to treating physician statements that offered support of Petitioner's flu vaccination as the cause of her TM. Pet. Ex. 14 at 11. He first noted Petitioner's treating neurologist, Dr. Qhavi, diagnosed Petitioner with post-vaccination TM. Id.; see Pet. Ex. 3 at 255 (Dr. Qhavi stating "[b]ased on history and neurologic examination, [Petitioner] [was] suffering with acute [TM]," and "[i]n [his] opinion[,] [Petitioner] [was] suffering with post vaccination

[30] Adam Austin et al., Transverse Myelitis Activation Post-H1N1 Immunization: A Case of Adjuvant Induction?, 17 IMAJ 120 (2005).

[31] Rohit Bakshi & John C. Mazziotta, Acute Transverse Myelitis After Influenza Vaccination: Magnetic Resonance Imaging Findings, 6 J. Neuroimaging 248 (1996).

[32] Li Gui et al., Acute Transverse Myelitis Following Vaccination Against H1N1 Influenza: A Case Report, 4 Int'l J. Clin. & Exp. Pathol. 312 (2011).

[33] Isabelle Korn-Lubetzki et al., H1N1 Vaccine-Related Acute Transverse Myelitis, 13 IMAJ 249 (2011).

acute demyelinating syndrome"). And this note, according to Dr. Jeret, "ascribed causation—not just association—to the vaccine." Pet. Ex. 14 at 11.

Dr. Jeret also cited to a note from Dr. Ullah that "implied causation." Pet. Ex. 14 at 11. Dr. Ullah's note stated Petitioner "[did] not want to get the COVID booster or flu vaccination in the future which under the circumstances [was] [a] reasonable decision." Pet. Ex. 6 at 13. Dr. Jeret opined this note showed Dr. Ullah "agree[d] that it was reasonable that [Petitioner] not get future flu vaccines." Pet. Ex. 14 at 11 (citing Pet. Ex. 6 at 13).

Second, Dr. Jeret opined there was "no concomitant disease or drug that can explain her development of TM." Pet. Ex. 14 at 12. He agreed with Dr. Kang that "infection, inflammation, radiation, spinal cord infarction, connective tissue disorders, [multiple sclerosis], ADEM, [myelin oligodendrocyte glycoprotein antibody-associated disease], and [neuromyelitis optica spectrum disorder]" can cause TM. Pet. Ex. 34 at 1. However, Dr. Jeret noted there was no evidence any of these other causes in Petitioner's record. Id.

Regarding timing, Dr. Jeret stated Petitioner's TM occurred within an appropriate time frame after vaccination. Pet. Ex. 14 at 12. Petitioner received her flu vaccine on October 11, 2021, noted difficulty writing on October 27, had bilateral upper extremity weakness and numbness on October 28, and presented to the ED on October 29. Id. Thus, Dr. Jeret opined the contemporaneous medical records document onset between 16-18 days post-flu vaccination, which "is consistent with the typical 5-42 day delay for other vaccine-triggered autoimmune responses." Id. at 4, 12.

An examination of the case reports cited by Dr. Jeret shows an onset period ranging from four days to two months. Agmon-Levin et al. included two cases of TM following flu vaccination, with an onset of seven days (Nakamura et al.) and nine days (Larner and Farmer). Pet. Ex. 16 at 3 tbl.1 (citing Pet. Exs. 27-28). Karussis and Petrou found nine cases, including Nakamura et al., of myelitis post-flu vaccination and onset ranged from four days to 16 days. Pet. Ex. 25 at 4 tbl.2. Akkad et al. discussed a patient who developed longitudinally extensive TM four days after a H1N1 vaccination. Pet. Ex. 17 at 1. Austin et al. described a case of TM two months after H1N1 vaccination. Pet. Ex. 20 at 1. Bakshi and Mazziotta reported a case of TM four weeks after a flu vaccination. Pet. Ex. 21 at 1. The patient in Gui et al. developed TM on the sixth day after H1N1 vaccination. Pet. Ex. 24 at 1. And Korn-Lubetzki et al. described a case of partial TM one month after H1N1 vaccination. Pet. Ex. 26 at 1.

2. Respondent's Expert, Dr. Peter Kang[34]

a. Background and Qualifications

Dr. Kang is Associate Professor of Neurology and the Director of the Neurology Residency Training Program at the Washington University School of Medicine in St. Louis, Missouri. Resp. Ex. A at 1. He obtained his M.D. in 2012 from the University of Pittsburgh School of Medicine, after which he completed an internal medicine internship, neurology

[34] Dr. Kang provided two expert reports. Resp. Exs. A, C.

residency, and neurocritical care fellowship at Washington University School of Medicine. Resp. Ex. B at 1. He is board certified in neurology and neurocritical care. Resp. Ex. A at 1; Resp. Ex. B at 3. His "clinical practice at Barnes-Jewish Hospital at the Washington University Medical Center focuses primarily on the care of patients suffering from a myriad of neurologic conditions . . . , including, but not limited to, cognitive impairment, disorders of consciousness, motor and sensory deficits, gait and balance disorders, and pain syndromes." Resp. Ex. A at 1. He "regularly treat[s] patients with autoimmune and inflammatory conditions affecting the central and peripheral nervous systems." Id. He has authored or co-authored over 50 publications. Resp. Ex. B at 8-11.

b. Opinion

i. Diagnosis

Dr. Kang had "considerable doubt that [P]etitioner was correctly diagnosed with [TM]." Resp. Ex. A at 19. Dr. Kang provided background on TM and explained that TM can occur "on its own" or can "present as a manifestation of several systemic inflammatory conditions or a set of neuroinflammatory conditions that lie on a spectrum." Id. at 11.

He acknowledged Petitioner's treating physicians diagnosed Petitioner with TM, yet he stressed "[i]t is important to recognize that just because a diagnosis is given by [P]etitioner's medical team, that this does not mean that the diagnosis is, without any doubt, the underlying true pathology causing [P]etitioner's symptoms and loss of function." Resp. Ex. C at 1. Because he did not think a complete workup to rule out other causes was performed in Petitioner's case, he questioned the diagnosis. Resp. Ex. A at 11-13. Dr. Kang explained that an inadequate workup may lead to an incorrect diagnosis, and he stressed the need for additional workup to rule out alternative diagnoses. Resp. Ex. C at 1-2.

Using the TM Consortium Working Group criteria cited by Dr. Jeret, Dr. Kang opined Petitioner does not meet the criteria "because alternative causes of myelopathy [were] not [] ruled out." Resp. Ex. A at 13. He asserted that exclusion of causative underlying disorders[35] must occur prior to diagnosing idiopathic TM. Id. at 11-12.

Dr. Kang reviewed Petitioner's October 29, 2021 cervical spine MRI and opined "[t]he intramedullary cervical spine lesion that likely represents [TM] spans 3-4 levels," which is "known as a Longitudinally Extensive [TM]" and "has implications for the underlying etiology." Resp. Ex. A at 5. Dr. Kang did not discuss these "implications." He also opined that Petitioner's findings on imaging (T2 signal hyperintensity and contrast enhancement over several levels in the cervical spine) "are nonspecific and can certainly be seen in a spinal cord infarction." Id. at 13. However, he did not opine that more likely than not Petitioner had a spinal cord infarction.

[35] For the full list of disorders Dr. Kang asserted should have been ruled out prior to diagnosis, see Resp. Ex. A at 11-13; Resp. Ex. C at 3. Dr. Kang maintained that the lack of medical record support for some of these disorders is due to the lack of testing, and as such, these disorders cannot be ruled out. Resp. Ex. C at 2.

Dr. Kang also took issue with the diagnosis here because he opined it is atypical for someone of Petitioner's age (72) to develop TM. Resp. Ex. A at 13; Resp. Ex. C at 2. Overall, he opined "[P]etitioner [was] in an atypical demographic for any inflammatory cause of [TM]." Resp. Ex. C at 3.

In his second expert report, Dr. Kang clarified that he "do[es] not claim any specific alternative diagnosis is certain or even likely; rather [he] simply suggest[ed] that there should be some doubt and a healthy level of skepticism in the purported diagnosis of vaccine-related [TM] in this case." Resp. Ex. C at 2.

ii. Althen Prong One

Dr. Kang opined that "there is no credible evidence that supports the notion that the [flu] vaccine causes or is even associated in an any way with the development of [TM]." Resp. Ex. A at 14; see also Resp. Ex. C at 3-4.

With regard to Dr. Jeret's proposed mechanisms by which the flu vaccine can cause TM, Dr. Kang opined Dr. Jeret did not provide any evidence to show these mechanisms—"molecular mimicry, epitope spreading, up-regulation of cytokines, and polyclonal activation of B and T cells"—occur with flu vaccination and TM. Resp. Ex. A at 17 (quoting Pet. Ex. 14 at 9-10). Dr. Kang explained that these "categories of exaggerated immunologic response in autoimmunity" are taken from Agmon-Levin et al. Id. And Agmon-Levin et al. along with Dr. Jeret's other literature provided "generalize[d] principles" shown in other disease processes without providing evidence equating these disease processes to the flu vaccine and TM specifically. Id. Thus, Dr. Kang asserted, "[t]hese are generic descriptions of overarching biologic principles of immune mechanisms that may link antigenic triggers, such as infectious agents, to inflammatory and autoimmune conditions in theory. These are not sufficient or relevant to the specific issue at hand here." Id.

Regarding molecular mimicry specifically, Dr. Kang does not appear to dispute this theory generally or as it relates to well-known associations (e.g., GBS and *Campylobacter jejuni*). Resp. Ex. A at 17-18. However, Dr. Kang maintained there is no evidence provided to support a finding that the flu vaccine can cause TM via molecular mimicry. Id. Although Dr. Kang acknowledged the antigenic targets in TM are unknown, he asserted "Dr. Jeret [did] not identify specific shared epitopes between the [flu] vaccine and components of the spinal cord, nor [did] he specify the autoantibodies that may be generated from an exaggerated immune response to the [flu] vaccine." Id. at 18. And thus, Dr. Kang concluded Dr. Jeret did not provide evidence to suggest molecular mimicry is the mechanism at play. Id.

Dr. Kang also reviewed and criticized Dr. Jeret's literature, noting no support for Dr. Jeret's contention that "[f]lu vaccines are known to cause TM." Resp. Ex. A at 14-16. He took issue with the fact that Dr. Jeret's literature consisted of case reports or articles grouping case reports, both of which he asserted are "not sufficient evidence to draw conclusions from." Id. at 14.

Dr. Kang also cited literature in support of his opinions. Resp. Ex. A at 16-17. First was the 2012 IOM report, which he stated "did not find sufficient epidemiological evidence to support the association between [flu] vaccine and [TM] or lack thereof." Id. at 16 (citing Resp. Ex. A-7 at 32-33). The IOM only reviewed one paper, Vellozzi et al., published in 2009, to evaluate the epidemiologic evidence. See Resp. Ex. A-7 at 32-33. Respondent did not file this paper, so it is not possible to address the evidence reviewed.

Dr. Kang next discussed two studies from Nordin et al. The goal of these studies was to evaluate the safety of the flu vaccine in pregnant women. The first, published in 2013,[36] examined the risk of flu vaccination (up to 42 days after vaccination) in pregnant women in the first trimester. Resp. Ex. A-8 at 1. Their cohort consisted of 75,906 vaccinated pregnant women matched by age, Vaccine Safety Datalink ("VSD")[37] location, and estimated pregnancy start date with 147,992 unvaccinated women. Id. at 3. No cases of TM were reported among the women vaccinated. Id. at 5. The second study from Nordin et al. was published in 2014[38] and similarly assessed the risk of adverse events and pregnancy complications in pregnant women following the 2009 H1N1 flu vaccination. Resp. Ex. A-9 at 1. Again, they found no cases of TM in those vaccinated within 42 days following vaccination. Id. at 4.

Dr. Kang also cited to Baxter et al.,[39] a study investigating the association between vaccination with acute demyelinating events (TM and ADEM) after vaccinations using VSD data. Resp. Ex. A-10 at 1. Using the TM Consortium Working Group definition for TM, 81 cases were identified as new, acute-onset idiopathic TM, and 67 of those had received a vaccination within the nine months prior to onset. Id. at 4-5. During their primary exposure window of 5-28 days, there were seven cases of TM. Id. at 1. Regarding TM, the authors found "no statistically significant increased risk of immunization in either the 5- to 28-day or the 2- to 42-day risk interval prior to onset," and thus, "no evidence of a safety concern" for TM. Id. at 5-6. However, the authors stated "[i]f there is any association, it is <1 per million doses." Id. at 6. They concluded that TM is "rarely, if ever, associated with vaccines." Id.

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[36] James D. Nordin et al., Maternal Safety of Trivalent Inactivated Influenza Vaccine in Pregnant Women, 121 Obstet. & Gynecol. 519 (2013).

[37] "The Vaccine Safety Datalink (VSD) is a collaborative project between [Centers for Disease Control and Prevention] and healthcare organizations across the United States . . . monitor[ing] the safety of vaccines and conduct[ing] studies about rare and serious adverse events following immunization." About the Vaccine Safety Datalink (VSD), Ctrs. for Disease Control & Prevention, Sept. 12, 2025, https://www.cdc.gov/vaccine-safety-systems/vsd/index.html.

[38] James D. Nordin et al., Monovalent H1N1 Influenza Vaccine Safety in Pregnant Women, Risks for Acute Adverse Events, 32 Vaccine 4985 (2014).

[39] Roger Baxter et al., Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis, 63 Clin. Infect. Dis. 1456 (2016).

iii. Althen Prongs Two and Three

Dr. Kang opined that even if Petitioner had TM, there is no evidence to support an association with her flu vaccination. Resp. Ex. A at 19; Resp. Ex. C at 4. Additionally, "her disease course [was] not attributable to the administration of the [flu] vaccine." Resp. Ex. A at 19.

Dr. Kang noted that prior to the flu vaccination in question, Petitioner received various flu vaccinations over the years without any adverse effects. Resp. Ex. A at 2 (citing Pet. Ex. 2 at 293, 380, 424, 558). He did not explain the relevance of Petitioner's history of vaccination or why her history made her less likely to adverse effects after the vaccination at issue here.

He discussed Petitioner's prior medical history, including her chronic conditions and functional deficits, as well as her non-compliance in aspects of her own care, noting Petitioner's pre-existing conditions (e.g., urinary incontinence) were likely exacerbated by her injury. Resp. Ex. A at 4, 19.

With regard to Petitioner's prior CIDP diagnosis, Dr. Kang opined the diagnosis was not confirmed from the records provided and the details surrounding this diagnosis are unknown. Resp. Ex. A at 3. He agreed Petitioner's EMG/NCS testing in 2020 and 2023 did not show evidence of CIDP. Id. Overall, he questioned whether she ever had CIDP, noting that some of Petitioner's prior complains "may have resulted from a previous lesion to the brain or spinal cord." Id. at 4. He acknowledged, however, that pre-existing leg symptoms as they relate to a CIDP diagnosis "is not a crucial aspect of the case." Resp. Ex. C at 3.

In response to Petitioner's treating physicians referring to Petitioner's TM as "post-vaccination," Dr. Kang maintained that the association between Petitioner's flu vaccination and TM "[was] not established and an adequate workup to rule out other entities did not take place." Resp. Ex. A at 6. Thus, this diagnosis of "post-vaccination" TM was "based only on [P]etitioner's report of a vaccination." Id.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health

& Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, Petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & 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, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance."

(quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded to medical records, special masters are not rigidly bound by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (noting Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In

determining whether a petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. DIAGNOSIS ANALYSIS

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury[,]" determining facts relating to the claimed injury can be significant in a case where diagnosis is not clear. Id. Here, the parties dispute diagnosis, and so it is appropriate to first resolve that issue.

For the reasons discussed below, the undersigned finds Petitioner's diagnosis is TM.

Petitioner's expert, Dr. Jeret, opined Petitioner's diagnosis is TM. He cited the TM Consortium Working Group diagnostic criteria, noting she met all inclusionary criteria: Petitioner had bilateral motor and sensory signs, a defined spinal sensory level, urinary retention and bowel dysfunction due to autonomic involvement, enhancement on cervical spine MRI, and reached her nadir within 21 days of onset. Dr. Jeret also opined none of the exclusionary criteria were present.

Respondent's expert, Dr. Kang, does not dispute Petitioner met the TM Consortium Working Group inclusionary criteria for TM; however, he took issue with the exclusionary criteria. More specifically, he expressed concerns that a complete workup was not completed and thus, not all exclusionary criteria could have been ruled out. Yet, he conceded that no alternative diagnosis was likely. See Resp. Ex. C at 2.

The undersigned finds a lack of testing for certain antibodies or diseases does not negate Petitioner's TM diagnosis. See Shapiro, 101 Fed. Cl. at 538 ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.").

Additionally, Petitioner's treating physicians consistently diagnosed Petitioner with TM. The undersigned gives weight to the statements of Petitioner's treating physicians as they are "in the best position" to determine Petitioner's injury. See Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326; Cucuras, 993 F.2d at 1528 (noting contemporaneous medical records, "in general, warrant consideration as trustworthy evidence").

In their joint submission, the parties stated they disputed whether Petitioner had pre-existing CIDP. Joint Sub. at 1. Dr. Jeret opined that Petitioner's EMG did not support a diagnosis of CIDP. Dr. Kang agreed Petitioner's EMG testing in 2020 and 2023 did not show evidence of CIDP. Dr. Kang questioned whether Petitioner ever had CIDP. He also acknowledged that any pre-existing leg symptoms they related to a prior CIDP diagnosis was not "a crucial aspect of the case." Resp. Ex. C at 3. Thus, the undersigned finds that to the extent that Petitioner may have had a prior diagnosis of CIDP, such diagnosis is not relevant to her post-vaccination diagnosis of TM here or relevant to the question of vaccine causation in this matter.

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

For the following reasons, the undersigned finds Petitioner provided preponderant evidence that molecular mimicry is a sound and reliable theory by which the flu vaccine can cause TM, and therefore, Petitioner satisfied Althen prong one.

The experts do not dispute the theory of molecular mimicry generally, or that it is sound and reliable under certain circumstances. In dispute is whether the flu vaccine specifically can cause TM via molecular mimicry.

First, medical literature filed by both parties supports vaccine causation of TM. See, e.g., Pet. Ex. 16 at 1 ("The pathogenesis of [TM] is mostly of an autoimmune nature, triggered by various environmental factors, including vaccination."); Pet. Ex. 23 at 1 (noting TM "most often occurs as an autoimmune phenomenon after an infection or vaccination"); Pet. Ex. 25 at 6 ("Immune mediated myelitis propagated by autoimmune mechanisms attacking mainly the white matter of the spinal cord is usually presented as acute [TM], which may be . . . post-vaccination."); Pet. Ex. 29 at 1 (noting "[a]cute [TM] has been described as an uncommon complication of vaccinations");[40] Resp. Ex. A-2 at 3, 11 (documenting vaccines as "triggers" of "immune-mediated myelopathies" and "inflammatory myelitis");[41] Resp. Ex. D-4 at 2 (documenting vaccines as a cause of TM).

Second, molecular mimicry as a casual mechanism in central nervous system disorders, including TM, is supported by the medical literature. See, e.g., Pet. Ex. 16 at 5 (noting molecular mimicry "is the most common mechanism" "by which vaccines may induce TM"); Pet. Ex. 23 at 1-2 ("The observation that systemic infection or immunization precedes many cases of [TM] suggests that mechanisms such as molecular mimicry and the development of autoantibodies represents one of the main immunopathogenetic mechanisms in post-vaccination [central nervous system] demyelination."); Resp. Ex. A-2 at 3 ("[T]here may be an element of molecular mimicry to many different antigens that all lead to a common downstream clinical presentation of myelopathy."); Resp. Ex. A-7 at 21 (indicating "molecular mimicry may contribute to the symptoms of [TM]"); Resp. Ex. D-4 at 2 (describing post-vaccination TM as a "phenomenon[] in which the body's immune system mistakenly attacks its own tissue while responding to . . . a vaccine").

Respondent's expert, Dr. Kang, maintained there is no evidence to support a finding that the flu vaccine can cause TM via molecular mimicry. Dr. Kang acknowledged the antigenic targets in TM are unknown, but then asserted Dr. Jeret failed to provide evidence of molecular mimicry between the flu vaccine and TM because he "[did] not identify specific shared epitopes between the [flu] vaccine and components of the spinal cord, nor [did] he specify the autoantibodies that may be generated from an exaggerated immune response to the [flu] vaccine." Resp. Ex. A at 18. Since the antigenic targets in TM are not known, it is not reasonable to require Petitioner to provide evidence of the specific epitopes that induce disease.

Further, Petitioner need not make a specific type of evidentiary showing or require identification of homology to prove that molecular mimicry is a sound and reliable theory by preponderant evidence. Given the state of current scientific knowledge, there is no way that a

[40] Nozomu Sato et al., Acute Transverse Myelitis and Acute Motor Axonal Neuropathy Developed After Vaccinations Against Seasonal and 2009 A/H1N1 Influenza, 50 Intern. Med. 503 (2011).

[41] Michael Levy, Immune-Mediated Myelopathies, 30 Continuum 180 (2024).

petitioner could satisfy such a requirement. Further, requiring proof of specific homology or proof of identical protein sequences between the flu vaccine and TM to prove causation would require scientific certainty, which is a bar too high. See Knudsen, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program"). Nor is Petitioner obligated to provide statistical or epidemiological evidence. See, e.g., Capizzano, 440 F.3d at 1325-26; see also Andreu, 569 F.3d at 1378 ("Requiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act.").

Third, molecular mimicry has been acknowledged as a sound and reliable theory in the Vaccine Program for vaccine-related central nervous system demyelinating diseases, including TM, following various vaccines, including the flu vaccine. See, e.g., Reinhardt v. Sec'y of Health & Hum. Servs., No. 17-1257V, 2021 WL 1851491, at *16 (Fed. Cl. Spec. Mstr. Apr. 2, 2021) (noting "that the Vaccine Program generally recognizes that the flu vaccine is capable of causing a demyelinating condition"); Palattao v. Sec'y of Health & Hum. Servs., No. 13-591V, 2019 WL 989380, at *35-37 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (explaining "many of the existing Program decisions in which TM has been found to be caused by a vaccine rely on a mechanism [of] []molecular mimicry"); J.S. v. Sec'y of Health & Hum. Servs., No. 14-851V, 2018 WL 11731139, at *13 (Fed. Cl. Spec. Mstr. Apr. 9, 2018) ("In the Program, petitioners have successfully established that a number of different vaccines (including the flu vaccine) were causally connected to their subsequent development of TM.").

And, as Petitioner indicated in her brief, Petitioners have prevailed on Althen prong one with a theory of molecular mimicry when TM has been alleged as a vaccine-related injury. Pet. Mot. at 16 (citing Le v. Sec'y of Health & Hum. Servs., No. 16-1078V, 2023 WL 3049203, *28-31 (Spec. Mstr. Fed. Cl. Mar. 30, 2023) (finding the Tdap vaccine can cause TM through the mechanism of molecular mimicry); Roberts v. Sec'y of Health & Hum. Servs., No. 09-427V, 2013 WL 5314698, at *6-7 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (finding petitioner entitled to compensation in a Tdap/TM case with the theory of molecular mimicry); Introini v. Sec'y of Health & Hum. Servs., No. 20-176V, 2022 WL 16915818, at *24-26 (Fed. Cl. Spec. Mstr. Oct. 19, 2022) (finding the Tdap vaccine can cause TM via molecular mimicry); White v. Sec'y of Health & Hum. Servs., No. 15-1521V, 2019 WL 7563239, at *23-24 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (finding the human papillomavirus vaccine can cause TM via molecular mimicry)).

Furthermore, Petitioners have also prevailed in flu vaccine/TM cases with a theory of molecular mimicry. See, e.g., Songero v. Sec'y of Health & Hum. Servs., No. 18-300V, 2025 WL 3013090 (Fed. Cl. Spec. Mstr. Oct. 3, 2025); Hitt v. Sec'y of Health & Hum. Servs., No. 15-1283V, 2020 WL 831822 (Fed. Cl. Spec. Mstr. Jan. 24, 2020); J.S., 2018 WL 11731139; Land v. Sec'y of Health & Hum. Servs., No. 12-474V, 2014 WL 2488705 (Fed. Cl. Spec. Mstr. May 13, 2014); Hayes ex rel. Hayes v. Sec'y of Health & Hum. Servs., No. 06-738V, 2010 WL 2985632 (Fed. Cl. Spec. Mstr. July 12, 2010); Bruce v. Sec'y of Health & Hum. Servs., No. 08-640V, 2010 WL 1223151 (Fed. Cl. Spec. Mstr. Mar. 2, 2010).

In Songero, Petitioner's expert's theory of molecular mimicry in a flu/TM case was accepted by the special master and Petitioner was determined to have satisfied Althen prong one.

Songero, 2025 WL 3013090, at *16-18. Like Petitioner here, the petitioner in Songero submitted literature discussing the association between flu and/or H1N1 flu vaccines and TM. Id. at *16. And in Songero, the special master found the case reports provided "some evidence of causation" and concluded "where medical literature has reported TM associated with flu vaccines, the evidence weighs in favor of causation." Id.

The special master in Songero also relied on Hitt, where petitioner prevailed on Althen prong one largely due to Respondent's expert opinion that the flu vaccine can cause TM or multiple sclerosis. Songero, 2025 WL 3013090, at *16-17; Hitt, 2020 WL 831822, at *10. The special master in Hitt also considered Petitioner's expert's theories connecting the flu vaccine to TM and multiple sclerosis, which was supported by medical literature, when finding Petitioner prevailed on Althen prong one. Hitt, 2020 WL 831822, at *10.

The special master in J.S. noted Petitioner's theory that the flu vaccine can cause TM via molecular mimicry was "consistent with other successful causation theories frequently proposed in [Vaccine] Program cases [of TM]" and such mechanism has been found "scientifically reliable" in "autoimmune-mediated demyelinating illnesses." J.S., 2018 WL 11731139, at *14. Given the expert testimony, literature, and prior Vaccine Program cases, the special master found Petitioner met his burden as to Althen prong one. Id.

In Land, the undersigned found Petitioner provided preponderant evidence to support the flu vaccine can cause TM via molecular mimicry. Land, 2014 WL 2488705, at *5. The undersigned analyzed the record and found Petitioner's expert's molecular mimicry theory and supportive medical literature satisfied Petitioner's burden for Althen prong one. Id. at *1, *5.

Similarly, the special masters in Hayes and Bruce found Petitioner's molecular mimicry theories connecting the flu vaccine and TM reached the level of preponderance required under Althen prong one. Hayes, 2010 WL 2985632, at *2-3; Bruce, 2010 WL 1223151, at *2.

Although decisions of other special masters are not binding on the undersigned, the undersigned finds these decisions instructive and persuasive. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

For all these reasons, the undersigned finds that the weight of the evidence as to Althen prong one preponderates in Petitioner's favor.

B. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

The undersigned finds that Petitioner has proven Althen prong two by preponderant evidence.

First, Petitioner's clinical course is consistent with Petitioner's theory. On October 11, 2021, Petitioner received the subject flu vaccination. On October 29, 18 days later, she presented to the ED complaining of weakness and numbness. Neurologist Dr. Qhavi ordered MRIs and testing, which later confirmed her TM diagnosis. Testing during her hospitalization did not show any signs of infection or other etiology to explain her TM. Petitioner also did not report any recent history of infection or illness.

Second, Petitioner's treating physicians documented statements in the medical records supportive of a logical sequence of cause and effect.

The first statements occurred during Petitioner's hospitalization. On October 29, 2021, neurologist Dr. Qhavi opined that "[b]ased on history and neurologic examination, [Petitioner] [was] suffering with acute [TM]." Pet. Ex. 3 at 255. He further wrote, "In my opinion[,] [Petitioner] [is] suffering with post vaccination acute demyelinating syndrome." Id. NP Schoknecht's assessment likewise documented Petitioner's condition "[was] likely attributable to a post vaccination demyelination/[TM]." Id. At discharge on November 4, 2021, Petitioner's diagnosis was post-vaccination TM. Id. at 145-46. Similarly, the discharge summary noted Petitioner "was admitted due to bilateral upper extremity weakness/generalized weakness likely caused by post vaccination [TM]." Id. at 146.

After hospitalization, at a follow-up appointment on January 28, 2022, PCP Dr. Ballecer noted Petitioner's visit was for several issues, including "[a]cute [TM] secondary to post vaccine." Pet. Ex. 2 at 88.

Neurologist Dr. Ullah, on June 20, 2022, noted the "[c]oncern [] for post vaccination [TM]" when discussing her clinical course. Pet. Ex. 6 at 4. He also stated that "[s]he [did] not want to get the COVID booster or flu vaccination in the future which under the circumstances [was] [a] reasonable decision." Id. at 13.

Thus, four different health care providers, including two neurologists, a PCP, and a NP concluded that Petitioner had post-vaccination TM which the undersigned finds persuasive evidence of a logical sequence of cause and effect. See Capizzano, 440 F.3d at 1326 (favoring treating physician statements as evidence in support of Althen prong two). Although some of the statements do not amount to opinions on causation, they provide support for an association between Petitioner's vaccination and TM. See, e.g., Osso v. Sec'y of Health & Hum. Servs., No. 18-575V, 2023 WL 5016473, at *2 (Fed. Cl. Spec. Mstr. July 13, 2023) (explaining statements from treating physicians that "do not amount to [an] opinion[] on causation" may still provide "circumstantial evidence" in support of Althen prong two). Collectively, these statements constitute persuasive evidence that Petitioner's treating physicians causally associated her flu vaccine with the development of her TM.

Lastly, no alternative cause was found despite a diagnostic workup. Dr. Kang, Respondent's expert, expressed concerns that a complete workup was not completed and thus, all alternative causes were not ruled out. However, Petitioners are not required to eliminate all alternative causes, and the lack of alternative cause "may be included as part of evidence to satisfy" Althen prong two. Ramsey v. Sec'y of Health & Hum. Servs., No. 21-1486V, 2023 WL 2823403, at *6 (Fed. Cl. Spec. Mstr. Apr. 6, 2023); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007) (noting petitioners may use rely on "evidence eliminating other potential causes to help carry the burden on causation"). Here, Petitioner's evidence that no alternative cause was found for her illness provides additional support for her prong two showing.

Thus, the undersigned finds Petitioner has proven Althen prong two by preponderant evidence.

C. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." Id. The Petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also be consistent with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn, 773 F.3d at 1243; Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358.

Regarding the date of onset, Dr. Jeret opined Petitioner's onset was between 16-18 days post-vaccination. Respondent and his expert, Dr. Kang, did not dispute this timeframe as to onset.

The undersigned agrees Petitioner's onset was 16 or 17 days after vaccination. Petitioner received her flu vaccination on October 11, 2021. On October 29, 2021, 18 days after vaccination, Petitioner presented to the ED. She complained of weakness and numbness in her bilateral arms that began the previous day, October 28, as well as difficulty signing her name two

days prior, October 27. This would place onset on October 27 or 28, 2021, 16 or 17 days post-vaccination.

This timeframe, according to Dr. Jeret, is "consistent with the typical 5-42 day delay for other vaccine-triggered autoimmune responses." Pet. Ex. 14 at 12. Dr. Jeret cited numerous case reports of TM post-flu vaccination with onset periods ranging from four days to two months. See Pet. Exs. 16-17, 20-21, 24-28. Additionally, Petitioner, in her brief, cited to past Program cases where petitioners were found entitled to compensation in cases of TM that occurred between three days and four weeks following Tdap vaccinations. Pet. Mot. at 20.

Moreover, Dr. Kang does not refute Dr. Jeret's opinion that Petitioner's onset period is medically acceptable under Althen prong three.

Finally, prior Vaccine Program cases have found this timing appropriate for TM. See, e.g., I.J. v. Sec'y of Health & Hum. Servs., No. 16-864V, 2021 WL 1232733, at *34 (Fed. Cl. Spec. Mstr. Jan. 4, 2021) (finding an onset of TM two weeks after receipt of the Tdap vaccine "a medically acceptable timeframe" and "a timeframe which has consistently been deemed medically appropriate in cases involving demyelinating conditions, including TM, following vaccination"), mot. for rev. granted on other grounds, 155 Fed. Cl. 20 (2021); Schmidt v. Sec'y of Health & Hum. Servs., No. 07-020V, 2009 WL 5196169, at *14 (Fed. Cl. Spec. Mstr. Dec. 17, 2009) (finding onset of TM one month after receiving the flu vaccine falls within a medically acceptable timeframe).

Therefore, the undersigned finds the temporal association is appropriate given the mechanism of injury and Petitioner has satisfied the third Althen prong.

VI. CONCLUSION

Based on the record, and for the reasons discussed above, the undersigned finds there is preponderant evidence to satisfy all three Althen prongs and to establish that Petitioner's flu vaccination caused her to develop TM. Thus, the undersigned finds that Petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master